

Case ID	Suspect Product Names	Suspect Product Reason for Use	Active Ingredients	Outcomes	Sex
Source Date	Concomitant Product Names	Event Date	Latest FDA Received Date	Case Priority	
Patient Age	Patient Weight	Sender	Reporter Type	Report	
Initial FDA Received Date	Country where Event occurred	Reported to Manufacturer?	Manufacturer Control Number	Manufacturer	
Literature Reference	Compounded Flag				
26008750	Contrave	Bupropion Hydrochloride\Naltrexone Hydrochloride;Herbals\Mitragynine	Product Used For Unknown		
	Indication;Supplementation Therapy	Withdrawal			
	Syndrome;Contraindicated Product	Administered;Labelled Drug-Drug Interaction			
	Issue;Illness	Non-Serious	Non-Serious	Not Specified	
	-	06-NOV-2025	Non-Expedited	Not Specified	
	Not Specified	Currax Pharmaceuticals	Consumer	Not Specified	
	-	09-DEC-2024	06-NOV-2025	US	Not Specified
	Specified	US-CURRAX PHARMACEUTICALS LLC-US-2024CUR005153	-		
25755184	Skyrizi;Humira;Rinvoq;Tylenol Acetaminophen;Tramadol;Upadacitinib;Risankizumab-Rzaa;Adalimumab;Herbals\Mitragynine	Abdominal Pain			
	Upper;Anxiety;Crohn's Disease;Depression;Pain;Product Used For Unknown				
	Indication	Faecal Calprotectin Increased;Drug Ineffective;Drug Dependence;Proctalgia;Rectal Discharge;Depression;Anal Fistula;Suicidal Ideation;Abscess;Illness;Inflammatory Marker Increased;Anxiety;Feeling Of Despair;Hospitalisation;Pain;Fistula;Fistula Discharge;Hypersomnia;Mental Disorder;Crohn's Disease			
	Outcomes;Hospitalized	Male	NOV-2023	05-NOV-2025	Other
	Expedited	22 YR	79.378 KG	Abbvie	Consumer
	Specified	Bentyl;Zoloft;Gabapentin;Amjevit;Wellbutrin;Imodium	US	Not Specified	Not Specified
	-	27-OCT-2025	03-SEP-2025	US-	
ABBVIE-6443000	-	-			
25979240	-	Herbals\Mitragynine	Supplementation		
	Therapy Death	Serious Died	Male	25-OCT-2024	29-OCT-2025
	Direct	45 YR	87.75 KG	Fda-Ctu	Consumer
	Specified	-	-	29-OCT-2025	Not Specified
	Specified	-	-	-	Not Specified
25974042	-	Herbals\Mitragynine	Disturbance In		
	Attention	Adverse Event	Serious Life Threatening		Female
	12-OCT-2025	28-OCT-2025	Direct	29 YR	76.5 KG
Ctu	Consumer	Not Specified	-	-	28-OCT-2025
	Not Specified	Not Specified	-	-	Yes
25956875	-	Herbals\Mitragynine	-	Overdose	
	Serious Died;Required Intervention;Life Threatening				Male
	03-AUG-2025	23-OCT-2025	Direct	32 YR	63 KG
Ctu	Consumer	Not Specified	-	-	23-OCT-2025
	Not Specified	Not Specified	-	-	-
25952897	-	Herbals\Mitragynine	Drug Dependence		
	Physical Product Label Issue;Anxiety;Mood Altered;Product Use In				

Unapproved Indication;Drug Dependence;Substance Use;Withdrawal  
 Syndrome              Serious Required Intervention;Hospitalized;Life  
 Threatening            Male       23-OCT-2025       23-OCT-2025     Direct   33 YR  
                         72 KG      Fda-Ctu Consumer       Not Specified   -       -  
                         23-OCT-2025   Not Specified   Y       -       -       -  
 25938723              Alcohol (Alcohol);Librium;Flurazepam;Adderall  
 Oxycodone;Amphetamine Aspartate\Amphetamine Sulfate\Dextroamphetamine  
 Saccharate\Dextroamphetamine Sulfate;Pregabalin;Flurazepam  
 Hydrochloride;Dextromethorphan;Lorazepam;Chlordiazepoxide  
 Hydrochloride;Alprazolam;Alcohol;Tianeptine;Clonazepam;Methamphetamine  
 ;Lisdexamfetamine;4-Amino-3-Phenylbutyric  
 Acid;Gabapentin;Herbals\Mitragynine;Methylphenidate      Product Used  
 For Unknown Indication Drug Abuse;Hyperhidrosis;Anxiety;Withdrawal  
 Syndrome;Myopia;Tremor;Drug Withdrawal Convulsions;Abdominal  
 Tenderness;Pancreatitis Acute      Serious Other Outcomes;Hospitalized  
                         Male       -       19-OCT-2025       Expedited    3 DEC   Not  
 Specified              Lupin      Healthcare Professional Not Specified   -  
                         06-OCT-2025   19-OCT-2025       US       Not Specified   US-  
 LUPIN PHARMACEUTICALS INC.-2025-09403   "Butler M, Pirkle J,  
 Carmichael A, Carlson-Dexter P, Rosella T. Successful symptom-based  
 management of active withdrawal from multiple illicit benzodiazepines.  
 BMJ Case Reports. 2025;18 (8):1-3"       -  
 25934636              -       Herbals\Mitragynine       -       Pruritus;Nasal  
 Congestion;Dyspnoea;Epistaxis;Accidental Exposure To Product;Throat  
 Tightness;Product Residue Present;Cough;Pneumonia;Pharyngeal  
 Swelling;Muscular Weakness;Tremor;Insomnia      Serious  
 Hospitalized;Disabled;Other Outcomes      Female   01-MAR-2025       16-  
 OCT-2025              Direct   27 YR      108 KG      Fda-Ctu Consumer   Not  
 Specified              -       -       16-OCT-2025       Not Specified   Y  
                         -       -       -  
 25925322              -       Quetiapine;Herbals\Mitragynine      Product Used  
 For Unknown Indication Neuroleptic Malignant  
 Syndrome;Overdose;Accidental Death;Toxicity To Various Agents;Drug  
 Interaction;Herbal Interaction      Serious Died;Other Outcomes      Male  
                         -       15-OCT-2025       Expedited    27 YR   Not Specified  
                         Medicap Laboratories      Healthcare Professional Not Specified  
                         Valproic Acid    04-OCT-2025       15-OCT-2025    US   Not  
 Specified              US-Medicap-000078      Hughes RL. Fatal combination  
 of mitragynine and quetiapine - a case report with discussion of a  
 potential herb-drug interaction. Forensic Sci Med Pathol. 2019 Mar  
 15(1):110-113. doi: 10.1007/s12024-018-0049-9. -  
 25887222              -       Herbals\Mitragynine;Fentanyl;Oxycodone  
 Hydrochloride      Product Used For Unknown Indication      Homicide;Drug  
 Diversion;Product Counterfeit      Non-Serious      Non-Serious      Male  
                         FEB-2024       06-OCT-2025       Non-Expedited   30 YR   Not  
 Specified              Purdue      Consumer       Not Specified   -       03-  
 OCT-2025              06-OCT-2025       US       Not Specified   US-PURDUE  
 PHARMA-USA-2025-0321119 -       -  
 25886095              -       Oxycodone  
 Hydrochloride;Fentanyl;Herbals\Mitragynine      Product Used For

Unknown Indication Drug Abuse;Drug Screen  
Positive;Overdose;Victim Of Homicide;Counterfeit Product Administered  
Serious Other Outcomes;Died Male 2024 06-OCT-2025  
Expedited 28 YR Not Specified Purdue Consumer  
Not Specified - 03-OCT-2025 06-OCT-2025 US  
Not Specified US-PURDUE PHARMA-USA-2025-0321120 -  
-

25873438 Dulcolax (Bisacodyl);Suboxone Buprenorphine  
Hydrochloride\Naloxone Hydrochloride;Herbals\Mitragynine;Bisacodyl  
Product Used For Unknown Indication Insomnia;Rectal  
Haemorrhage;Asthenia;Haematochezia;Vomiting;Dizziness;Drug Effect Less  
Than Expected;Decreased Appetite;Constipation;Migraine Non-Serious  
Non-Serious Not Specified - 03-OCT-2025 Non-  
Expedited Not Specified Not Specified Reckitt Benckiser  
Healthcare Professional Not Specified - 19-JUL-2025  
02-OCT-2025 US Not Specified US-INDIVIOR US-  
INDV-166579-2025 - -

25863951 - Herbals\Mitragynine Product Used For  
Unknown Indication Hypoxia;Respiratory Failure;Liver Injury  
Serious Hospitalized;Life Threatening;Died Male 28-  
SEP-2025 29-SEP-2025 Direct 55 YR Not Specified Fda-  
Ctu Healthcare Professional Not Specified - - 29-  
SEP-2025 Not Specified Not Specified - - -

25847731 - Herbals\Mitragynine -  
Seizure;Toxicity To Various Agents Serious Died Male 28-  
JUL-2025 24-SEP-2025 Direct 31 YR 126 KG Fda-Ctu  
Consumer Not Specified - - 24-SEP-2025 Not  
Specified Not Specified - - -

25840946 - Herbals\Mitragynine - Drug  
Dependence;Substance Use;Family Stress;Seizure;Withdrawal Syndrome  
Serious Other Outcomes Male - 23-SEP-2025 Direct  
36 YR 300 LB Fda-Ctu Not Specified Not Specified -  
- 23-SEP-2025 Not Specified Not Specified -  
- -

25836193 - Herbals\Mitragynine;7-  
Hydroxymitragynine;Mitragynine Pseudoindoxyl - Unresponsive  
To Stimuli;Drug Abuse Serious Died Female 24-JUL-2025 22-  
SEP-2025 Direct 46 YR Not Specified Fda-Ctu Consumer  
Not Specified - - 22-SEP-2025 Not Specified  
Not Specified - - -

25832399 Heroin Diamorphine;Oxycodone  
Hydrochloride;Herbals\Mitragynine Product Used For Unknown  
Indication Euphoric Mood;Skin Disorder;Drug  
Dependence;Anisocoria;Alopecia;Panic Attack Serious Other Outcomes  
Male - 22-SEP-2025 Non-Expedited 28 YR Not  
Specified Purdue Consumer Not Specified - 19-  
SEP-2025 22-SEP-2025 US Not Specified US-PURDUE  
PHARMA-USA-2025-0320720 - -

25831069 - Herbals\Mitragynine;7-Hydroxymitragynine  
- Withdrawal Syndrome;Insomnia;Dependence;Impaired

Quality Of Life;Substance Use;Constipation;Dizziness;Anxiety;Illness;Emotional Disorder;Depression;Diarrhoea  
 Serious Life Threatening;Other Outcomes;Disabled Female 08-SEP-2025 20-SEP-2025 Direct  
 37 YR 71.1 KG Fda-Ctu Consumer Not Specified -  
 - 20-SEP-2025 Not Specified Not Specified -  
 - Yes  
 25825699 - Herbals\Mitragynine - Depressed  
 Level Of Consciousness;Somnolence;Incorrect Dose Administered  
 Serious Died Male 30-AUG-2025 19-SEP-2025 Direct 33 YR  
 Not Specified Fda-Ctu Consumer Not Specified -  
 - 19-SEP-2025 Not Specified Not Specified -  
 - -  
 25823764 - Herbals\Mitragynine -  
 Seizure;Substance Use;Dependence;Withdrawal Syndrome Serious Other  
 Outcomes Male 18-SEP-2025 18-SEP-2025 Direct 24 YR  
 54 KG Fda-Ctu Healthcare Professional Not Specified -  
 - 18-SEP-2025 Not Specified Not Specified -  
 - -  
 25818188 - Herbals\Mitragynine - Product Label  
 Issue Non-Serious Non-Serious Not Specified - 18-  
 SEP-2025 Direct Not Specified Not Specified Fda-Ctu  
 Consumer Not Specified - - 18-SEP-2025 Not  
 Specified Not Specified - - -  
 25811385 Bixadi Buprenorphine;Herbals\Mitragynine  
 Product Used For Unknown Indication Myoclonus;Drug Withdrawal  
 Syndrome;Nightmare Non-Serious Non-Serious Female 2025  
 17-SEP-2025 Non-Expedited Not Specified Not Specified  
 Braeburn Pharmaceuticals Consumer Not Specified  
 - 21-AUG-2025 17-SEP-2025 US Not Specified  
 US-BRAEBURN PHARMACEUTICALS-US-BRA-25-000741 - -  
 25809149 Heroin Diamorphine;Herbals\Mitragynine;Oxycodone  
 Hydrochloride;Methamphetamine Analgesic Therapy;Product Used For  
 Unknown Indication Substance Abuse;Drug  
 Dependence;Injury;Withdrawal Syndrome Serious Other Outcomes Female  
 - 16-SEP-2025 Expedited Not Specified Not  
 Specified Purdue Consumer Not Specified - 13-  
 SEP-2025 16-SEP-2025 US Not Specified US-PURDUE  
 PHARMA-USA-2025-0320554 - -  
 25809020 - Herbals\Mitragynine - Drug  
 Dependence;Substance Abuser;Product Advertising Issue Serious Died  
 Female 08-NOV-2024 16-SEP-2025 Direct 27 YR Not  
 Specified Fda-Ctu Consumer Not Specified - -  
 16-SEP-2025 Not Specified Not Specified - -  
 -  
 25798167 Suboxone;Vivitrol Naltrexone;Buprenorphine  
 Hydrochloride\Naloxone Hydrochloride;Herbals\Mitragynine Drug  
 Dependence;Product Used For Unknown Indication Drug Withdrawal  
 Syndrome;Pain In Extremity;Feeling Abnormal;Contraindicated Product  
 Administered;Restlessness;Malaise Non-Serious Non-Serious

Male 29-AUG-2025 12-SEP-2025 Non-Expedited Not  
 Specified 99.773 KG Alkermes Consumer Not  
 Specified - 29-AUG-2025 12-SEP-2025 Not Specified  
 Not Specified US-ALKERMES INC.-ALK-2025-002275 -

25766636 - Herbals\Mitragynine -  
 Dependence;Overdose Serious Required  
 Intervention;Died;Hospitalized;Life Threatening Male 01-JUL-2018  
 03-SEP-2025 Direct 23 YR 76.5 KG Fda-Ctu Consumer  
 Not Specified - - 03-SEP-2025 Not Specified  
 Not Specified - - -

25761592 - Herbals\Mitragynine Attention Deficit  
 Hyperactivity Disorder Dependence Serious Other Outcomes Male  
 - 03-SEP-2025 Direct 18 YR 72 KG Fda-Ctu  
 Consumer Not Specified - - 03-SEP-2025 Not  
 Specified Not Specified - - -

25761531 - Herbals\Mitragynine -  
 Dyspnoea;Accidental Exposure To Product Serious Other Outcomes Male  
 01-MAR-2022 03-SEP-2025 Direct 48 YR Not Specified  
 Fda-Ctu Consumer Not Specified - - 03-  
 SEP-2025 Not Specified Not Specified - - -

25485621 - Herbals\Mitragynine;Buprenorphine  
 Anxiety;Dependence;Depressed Mood;Obsessive-Compulsive Disorder  
 Suicidal Ideation;Dependence;Off Label Use;Wrong Technique In Product  
 Usage Process;Drug Withdrawal Syndrome Serious Other Outcomes Not  
 Specified NOV-2024 02-SEP-2025 Expedited Not  
 Specified Not Specified Reckitt Benckiser Healthcare  
 Professional Not Specified - 25-AUG-2025 26-JUN-2025  
 GB Not Specified GB-INDIVIOR UK LIMITED-  
 INDV-164864-2025 "Filipa Teixeira, Oluwatobi Ajewole, Mihai  
 Picior, Emmert Roberts. Treatment of obsessive compulsive disorder  
 and Kratom dependence with buprenorphine and supportive care. BMJ Case  
 Reports. 2025;18:e265834" -

25750030 - Herbals\Mitragynine Anxiety  
 Seizure;Impaired Work Ability Serious Hospitalized;Life Threatening  
 Male 21-AUG-2025 30-AUG-2025 Direct 40 YR 119.25  
 KG Fda-Ctu Consumer Not Specified - - 30-  
 AUG-2025 Not Specified Not Specified - - -

25743346 Venlafaxine Venlafaxine  
 Hydrochloride;Quetiapine;Herbals\Mitragynine Product Used For  
 Unknown Indication Herbal Interaction;Antidepressant Drug Level  
 Above Therapeutic;Electrocardiogram Qt Prolonged;Serotonin  
 Syndrome;Drug Interaction Serious Hospitalized;Other Outcomes  
 Male - 30-AUG-2025 Expedited 36 YR Not  
 Specified Medicap Laboratories Healthcare Professional Not  
 Specified - 18-AUG-2025 30-AUG-2025 US Not  
 Specified US-Medicap-000029 "Brogdon H D, McPhee M M,  
 Paine M F, Cox E J and Burns A G. A Case of Potential Pharmacokinetic  
 Kratom-drug Interactions Resulting in Toxicity and Subsequent  
 Treatment of Kratom Use Disorder With Buprenorphine/Naloxone. J Addict

Med. 2022 Sep-Oct;16(5):606–609. doi: 10.1097/ADM.0000000000000968.  
 Epub 2022 Feb 14."

25732022 - Herbals\Mitragynine Pain Toxicity To  
 Various Agents;Seizure Serious Died Female 12-MAR-2025 27-  
 AUG-2025 Direct 39 YR 58.5 KG Fda-Ctu Consumer Not  
 Specified Fluoxetine;Lorazepam;Norfluoxetine;Methylphenidate  
 - 27-AUG-2025 Not Specified Not Specified -  
 - -

25726787 - Herbals\Mitragynine Alcohol Problem  
 Insomnia;Abdominal Discomfort;Restlessness;Withdrawal  
 Syndrome;Irritability;Depression;Hyperhidrosis;Anxiety;Nausea;Fatigue;  
 Drug Dependence;Emotional Disorder;Diarrhoea;Myalgia;Product  
 Advertising Issue Serious Other Outcomes;Required  
 Intervention;Disabled;Life Threatening Male 20-AUG-2025 25-  
 AUG-2025 Direct 29 YR 54 KG Fda-Ctu Consumer Not  
 Specified - - 25-AUG-2025 Not Specified Not  
 Specified - - -

25721295 - Herbals\Mitragynine - Psychotic  
 Disorder;Drug Dependence;Aggression;Crying;Delusion Serious Other  
 Outcomes Male 22-AUG-2025 22-AUG-2025 Direct 40 YR  
 Not Specified Fda-Ctu Consumer Not Specified -  
 - 22-AUG-2025 Not Specified Y - -

25705804 - Herbals\Mitragynine Pain  
 Dependence;Vomiting;Insomnia;Loss Of Personal Independence In Daily  
 Activities;Hyperhidrosis;Psychotic Disorder;Tremor;Withdrawal  
 Syndrome;Delusion;Impaired Work Ability;Fatigue;General Physical  
 Health Deterioration Serious Required Intervention;Disabled Female  
 02-JUL-2024 19-AUG-2025 Direct 54 YR 54 KG Fda-  
 Ctu Consumer Not Specified Herbals\Mitragynine -  
 19-AUG-2025 Not Specified Not Specified - -

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25690201 - Herbals\Mitragynine - "Restless Legs  
 Syndrome;Insomnia;Nausea;Withdrawal Syndrome;Paranoia;Drug  
 Dependence;Pain;Depression;Anxiety;Hallucination, Auditory"  
 Serious Other Outcomes Male 21-JUN-2025 15-AUG-2025 Direct  
 35 YR Not Specified Fda-Ctu Healthcare Professional Not  
 Specified - - 15-AUG-2025 Not Specified Not  
 Specified - - -

25690199 - Herbals\Mitragynine - Delusion;Acute  
 Psychosis;Paranoia;Obsessive-Compulsive Personality Disorder  
 Serious Hospitalized Male 03-FEB-2022 15-AUG-2025 Direct  
 43 YR Not Specified Fda-Ctu Healthcare Professional Not  
 Specified - - 15-AUG-2025 Not Specified Not  
 Specified - - -

25690197 - Herbals\Mitragynine - Drug  
 Dependence;Therapy Cessation;Hallucination;Withdrawal Syndrome;Drug  
 Tolerance;Paranoia Serious Other Outcomes Male 05-JUN-2023  
 15-AUG-2025 Direct 30 YR Not Specified Fda-Ctu  
 Healthcare Professional Not Specified - - 15-AUG-2025

	Not Specified	Not Specified	-	-	-	-	
25682776	-	Herbals\Mitragynine	Weight Control	Drug Dependence;Near Death Experience;Anxiety;Feeling Abnormal			
Serious Disabled;Hospitalized	Male	24-JUL-2025	14-AUG-2025				
Direct	29 YR	112.5 KG	Fda-Ctu Consumer	Not Specified	Not Specified	Not Specified	Not Specified
Specified	-	-	14-AUG-2025	Not Specified	Not Specified	Not Specified	Not Specified
Specified	-	-	-	-	-	-	-
25681939	-	Herbals\Mitragynine	-	Withdrawal Syndrome;Drug Dependence	Serious Required Intervention	Not Specified	Not Specified
Specified	-	14-AUG-2025	Direct	Not Specified	Not Specified	Not Specified	Not Specified
Specified	Fda-Ctu Consumer	Not Specified	Not Specified	-	-	-	-
14-AUG-2025	Not Specified	Not Specified	Not Specified	-	-	-	-
-	-	-	-	-	-	-	-
25663995	-	Herbals\Mitragynine	-	Withdrawal Syndrome;Dependence;Drug Dependence;Loss Of Personal Independence In Daily Activities;Mental Disorder;Physical Deconditioning;Hepatic Pain;Depression;Anhedonia;Gastrointestinal Disorder	Serious Required Intervention	Not Specified	Not Specified
Required Intervention	Female	08-AUG-2025	08-AUG-2025	Direct	45 YR	Not Specified	Not Specified
Not Specified	Not Specified	Fda-Ctu Consumer	Not Specified	Not Specified	Not Specified	Not Specified	Not Specified
Specified	-	-	08-AUG-2025	Not Specified	Not Specified	Not Specified	Not Specified
Specified	-	-	-	-	-	-	-
25658986	-	Herbals\Mitragynine	Asthenia Headache;Product Complaint;Nausea;Product Advertising Issue;Drug Dependence;Nonspecific Reaction;Pain;Withdrawal Syndrome				
Serious Hospitalized	Female	-	07-AUG-2025	Direct	45 YR		
113.4 KG	Fda-Ctu Consumer	Not Specified	Not Specified	Not Specified	Not Specified	Not Specified	Not Specified
-	07-AUG-2025	Not Specified	Not Specified	Not Specified	Not Specified	Not Specified	Not Specified
-	-	-	-	-	-	-	-
25656033	-	Herbals\Mitragynine	Self-Medication Cardiac Arrest;Substance Use;Brain Injury;Depressed Level Of Consciousness;Therapeutic Product Effect Variable;Product Measured Potency Issue;Circulatory Collapse;Oral Discharge;Paralysis;Loss Of Personal Independence In Daily Activities	Serious Disabled			
Male	30-APR-2022	07-AUG-2025	Direct	32 YR	79.38		
KG	Fda-Ctu Not Specified	Not Specified	Not Specified	-	-	07-	
AUG-2025	Not Specified	Y	-	-	-	-	-
25649556	-	Herbals\Mitragynine	Asthenia Death;Coma				
Serious Died	Female	09-OCT-2022	05-AUG-2025				
Direct	36 YR	63 KG	Fda-Ctu Consumer	Not Specified	Not Specified	Not Specified	Not Specified
-	-	05-AUG-2025	Not Specified	Not Specified	Not Specified	Not Specified	Not Specified
-	-	-	-	-	-	-	-
25646131	-	Herbals\Mitragynine	Anxiety Drug Withdrawal Syndrome	Serious Other Outcomes	Female	05-AUG-2025	
05-AUG-2025	Direct	40 YR	81.9 KG	Fda-Ctu Consumer	Not Specified	Not Specified	Not Specified
Not Specified	-	-	05-AUG-2025	Not Specified	Not Specified	Not Specified	Not Specified
Not Specified	-	-	-	-	-	-	-
25645630	-	Fentanyl;Herbals\Mitragynine Anxiety;Depression;Pain	Euphoric Mood;Withdrawal Syndrome;Drug Dependence;Illness	Serious Other Outcomes	Male	01-NOV-2024	
04-AUG-2025	Direct	144 YR	90 KG	Fda-Ctu Consumer	Not Specified	Not Specified	Not Specified

	Not Specified	-	-	04-AUG-2025	Not Specified
	Not Specified	-	-	-	
25645556	-	Herbals\Mitragynine;Cocaine;Lorazepam	-		
	Substance Abuse;Seizure	Serious Life Threatening;Hospitalized			
	Male	03-AUG-2025	04-AUG-2025	Direct	34 YR 89.5
KG	Fda-Ctu	Healthcare Professional	Not Specified		
Alcohol;Lisinopril;Buspirone	-	04-AUG-2025	Not Specified		
	Not Specified	-	-	-	
25645540	-				
	Herbals\Mitragynine;Herbals\Tetrahydrocannabiphorol	Anxiety			
	Insomnia;Confusional State;Schizophrenia;Decreased				
	Appetite;Anxiety;Tremor	Serious Hospitalized;Required Intervention			
	Male	26-JUL-2025	04-AUG-2025	Direct	19 YR 56.7
KG	Fda-Ctu Consumer	Not Specified	-	-	04-
AUG-2025	Not Specified	Not Specified	-	-	-
25645341	-	Herbals\Mitragynine	-	Hordeolum;Skin	
	Injury;Dependence;Alopecia	Serious Required Intervention	Female		
	15-FEB-2023	04-AUG-2025	Direct	28 YR 58.5	KG Fda-
Ctu	Consumer	Not Specified	-	-	04-AUG-2025
	Not Specified	Not Specified	-	-	-
25643805	-	Herbals\Mitragynine	Anxiety Drug		
	Dependence	Serious Required Intervention;Other Outcomes	Female		
	24-JUL-2025	04-AUG-2025	Direct	14 YR 49.5	KG Fda-
Ctu	Consumer	Not Specified	-	-	04-AUG-2025
	Not Specified	Not Specified	-	-	-
25644082	-	Herbals\Mitragynine	Euphoric Mood;Feeling		
	Of Relaxation	Impaired Quality Of Life;Drug Dependence			
	Serious Hospitalized;Life Threatening;Other Outcomes;Required				
	Intervention	Male	28-DEC-2024	03-AUG-2025	Direct 49 YR
		92.25 KG	Fda-Ctu Consumer	Not Specified	
	Unspecified Ingredient;Xanax	-	03-AUG-2025	Not Specified	
	Not Specified	-	-	-	
25643652	-	Herbals\Mitragynine	Dependence		
	Dependence;Drug Withdrawal Syndrome	Serious Required Intervention			
	Male	02-AUG-2025	02-AUG-2025	Direct	65 YR 81 KG
	Fda-Ctu Consumer	Not Specified	-	-	02-
AUG-2025	Not Specified	Not Specified	-	-	-
25640731	-	Herbals\Mitragynine	-	Withdrawal	
	Syndrome;Dependence;Dry Skin;Skin Exfoliation	Serious Hospitalized			
	Female	04-NOV-2024	02-AUG-2025	Direct	27 YR Not
	Specified	Fda-Ctu Consumer	Not Specified	-	-
	02-AUG-2025	Not Specified	Not Specified	-	-
	-				
25627045	-	Herbals\Mitragynine	Drug Dependence		
	Substance Use;Job Dissatisfaction;Withdrawal Syndrome;General Physical				
	Health Deterioration	Serious Other Outcomes;Required Intervention			
	Male	24-JUL-2025	30-JUL-2025	Direct	28 YR 103.5
KG	Fda-Ctu Consumer	Not Specified	-	-	30-
JUL-2025	Not Specified	Not Specified	-	-	-
25623069	-	Herbals\Mitragynine	Anxiety		

Hypertension;Dyspnoea;Palpitations;Heart Rate Increased Serious Other  
 Outcomes Female 18-AUG-2024 30-JUL-2025 Direct 50 YR  
 74.25 KG Fda-Ctu Consumer Not Specified  
 Vitamins;Krill Oil - 30-JUL-2025 Not Specified Not  
 Specified - - -  
 25622686 - Herbals\Mitragynine Energy Increased  
     Arthralgia;Bone  
 Pain;Vomiting;Constipation;Asthenia;Nausea;Headache;Withdrawal  
 Syndrome;Confusional State;Hyperhidrosis;Substance Use Serious  
 Required Intervention;Hospitalized Male 30-JUN-2025 29-  
 JUL-2025 Direct 52 YR 78.75 KG Fda-Ctu Consumer  
     Not Specified - - 29-JUL-2025 Not Specified  
     Not Specified - - -  
 25618818 - Herbals\Mitragynine -  
 Dependence;Partner Stress;Blood Testosterone Decreased;Renal  
 Disorder;Alopecia;Self Esteem Decreased;Withdrawal  
 Syndrome;Gallbladder Disorder;Dyschezia;Loss Of Employment  
 Serious Required Intervention Male - 29-JUL-2025 Direct  
     Not Specified 83.25 KG Fda-Ctu Consumer Not  
 Specified - - 29-JUL-2025 Not Specified Not  
 Specified - - -  
 25617799 - Herbals\Mitragynine - Cardiac  
 Arrest;Seizure Serious Died Male 28-JUL-2025 29-JUL-2025  
     Direct 31 YR 136.08 KG Fda-Ctu Healthcare  
 Professional Not Specified - - 29-JUL-2025 Not  
 Specified Not Specified - - -  
 25617090 - Herbals\Mitragynine Sleep Disorder  
 Quality Of Life Decreased;Drug Dependence Serious Required  
 Intervention Male 21-JUL-2025 28-JUL-2025 Direct 44 YR  
     81 KG Fda-Ctu Consumer Not Specified - -  
     28-JUL-2025 Not Specified Not Specified - - -  
 -  
 25613316 - Herbals\Mitragynine -  
 Dependence;Nonspecific Reaction Serious Disabled;Hospitalized;Other  
 Outcomes;Life Threatening Male - 27-JUL-2025 Direct  
     Not Specified Not Specified Fda-Ctu Consumer Not  
 Specified - - 27-JUL-2025 Not Specified Not  
 Specified - - -  
 25612923 - Herbals\Mitragynine Asthenia  
 Dyspnoea;Abdominal Pain Upper;Confusional State;Heart Rate Increased  
     Serious Required Intervention;Life Threatening Male 03-  
 JUL-2025 26-JUL-2025 Direct 36 YR 83.25 KG Fda-  
 Ctu Consumer Not Specified - - 26-JUL-2025  
     Not Specified Y - - -  
 25596657 - Herbals\Mitragynine Drug Dependence;Drug  
 Use Disorder Detoxification Serious Required Intervention Male  
     09-OCT-2024 22-JUL-2025 Direct 41 YR Not Specified  
     Fda-Ctu Consumer Not Specified - - 22-  
     JUL-2025 Not Specified Not Specified - - -  
 25584861 - Herbals\Mitragynine Alcohol Withdrawal

Syndrome Myocardial Infarction;Cerebrovascular Accident;Blood Pressure Increased;Substance Use;Intentional Overdose;Pulmonary Embolism;Thrombosis Serious Died Male 24-SEP-1924 17- JUL-2025 Direct 37 YR 157.5 KG Fda-Ctu Consumer  
 Not Specified Benadryl;Losartan - 17-JUL-2025  
 Not Specified Not Specified - - -  
 25566138 - Herbals\Mitragynine - Product Formulation Issue;Ill-Defined Disorder;Withdrawal Syndrome;Drug Dependence;Product Advertising Issue;Emotional Disorder Serious Required Intervention;Life Threatening Male 08-JUL-2025 15- JUL-2025 Direct 43 YR 99 KG Fda-Ctu Consumer Not Specified - 15-JUL-2025 Not Specified Y  
 - - -  
 25551627 - Herbals\Mitragynine Drug Withdrawal Syndrome Anger;Psychotic Disorder Serious Other Outcomes Male 10-DEC-2023 13-JUL-2025 Direct 61 YR 72 KG Fda-Ctu Consumer Not Specified - - 13- JUL-2025 Not Specified Not Specified - - -  
 25548770 - Herbals\Mitragynine;7-Hydroxymitragynine Depression;Adulterated Product;Dependence Serious Required Intervention;Other Outcomes Male 29-AUG-2024 13-JUL-2025 Direct 28 YR 74.25 KG Fda-Ctu Consumer Not Specified - 13-JUL-2025 Not Specified Not Specified - -  
 25529119 - Herbals\Mitragynine Anxiety;Depression Toxicity To Various Agents Serious Died Male 20- APR-2021 07-JUL-2025 Direct 32 YR Not Specified Fda- Ctu Consumer Not Specified Celexa;Prozac;Benadryl - 07-JUL-2025 Not Specified Not Specified - -  
 -  
 25525749 "Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate And Amphetamine Sulfate;Xanax" Alprazolam;Herbals\Mitragynine;Dronabinol;Amphetamine Aspartate\Amphetamine Sulfate\Dextroamphetamine Saccharate\Dextroamphetamine Sulfate;Cannabis Sativa Subsp. Indica Top;Fentanyl;Alprazolam Product Used For Unknown Indication Balance Disorder;Drug Abuse;Dysarthria;Drug Diversion;Impaired Driving Ability Serious Other Outcomes Male - 07-JUL-2025 Expedited Not Specified Not Specified Purdue Consumer Not Specified - 03-JUL-2025 07-JUL-2025 US Not Specified US-PURDUE-USA-2025-0318677 - -  
 25509786 - Herbals\Mitragynine Asthenia Restless Legs Syndrome;Rebound Psychosis;Depression;Drug Dependence;Withdrawal Syndrome Serious Other Outcomes;Required Intervention Male 01-MAY-2024 02-JUL-2025 Direct 36 YR 99 KG Fda-Ctu Consumer Not Specified Vitamins - 02-JUL-2025 Not Specified Y - -  
 -  
 25504696 - Herbals\Mitragynine Pain Panic Attack;Withdrawal Syndrome;Insomnia;Hyperhidrosis;Suicidal

Ideation;Vomiting;Drug Dependence;Abnormal Behaviour;Quality Of Life  
Decreased Serious Hospitalized;Disabled;Other Outcomes;Required  
Intervention Male 29-JUN-2025 02-JUL-2025 Direct 49 YR  
90 KG Fda-Ctu Consumer Not Specified - -  
02-JUL-2025 Not Specified Not Specified - -  
-  
25504579 - Herbals\Mitragynine Anxiety Toxicity To  
Various Agents;Seizure Serious Died Male 21-DEC-2024 01-  
JUL-2025 Direct 27 YR 67.5 KG Fda-Ctu Consumer Not  
Specified Hydrocortisone;Escitalopram - 01-JUL-2025  
Not Specified Not Specified - - Yes  
25504578 - Herbals\Mitragynine Asthenia  
Withdrawal Syndrome;Emotional  
Disorder;Fatigue;Formication;Sneezing;Insomnia;Feeling Of Body  
Temperature Change Serious Disabled Male 30-JUN-2025  
01-JUL-2025 Direct 58 YR 87.75 KG Fda-Ctu Other  
Not Specified Losartan;Magnesium Citrate;Unspecified  
Ingredient - 01-JUL-2025 Not Specified Not Specified  
- - -  
25499470 - Herbals\Mitragynine - Drug  
Dependence;Substance Use Serious Life Threatening;Other  
Outcomes Not Specified 30-JUN-2025 30-JUN-2025 Direct  
32 YR 175 LB Fda-Ctu Healthcare Professional Not Specified  
- - 30-JUN-2025 Not Specified Not Specified  
- - -  
25496375 - Herbals\Mitragynine - Drug  
Dependence;Substance Use Serious Life Threatening Male  
26-JUN-2025 27-JUN-2025 Direct 30 YR 185 LB Fda-  
Ctu Healthcare Professional Not Specified - - 27-  
JUN-2025 Not Specified Not Specified - - -  
25493866 - Herbals\Mitragynine -  
Anxiety;Tachycardia;Product Advertising Issue;Drug Withdrawal  
Syndrome;Chest Pain Serious Other Outcomes Male 24-JUN-2025  
27-JUN-2025 Direct 35 YR 74.25 KG Fda-Ctu  
Healthcare Professional Not Specified - - 27-JUN-2025  
Not Specified Not Specified - - -  
25482688 - Herbals\Mitragynine Energy Increased  
Product Complaint Serious Life Threatening Not  
Specified - 25-JUN-2025 Direct Not Specified Not  
Specified Fda-Ctu Consumer Not Specified - -  
25-JUN-2025 Not Specified Not Specified - -  
-  
25469790 Lybalvi Olanzapine\Samidorphan L-  
Malate;Herbals\Mitragynine Pain;Product Used For Unknown  
Indication Pain;Contraindicated Product Administered Non-  
Serious Non-Serious Not Specified - 23-JUN-2025 Non-  
Expedited Not Specified Not Specified Alkermes  
Consumer Not Specified - 17-JUN-2025 23-JUN-2025  
US Not Specified US-ALKERMES INC.-ALK-2025-001665  
- -

25468427 Lybalvi Olanzapine\Samidorphan L-Malate;Herbals\Mitragynine Product Used For Unknown Indication Withdrawal Syndrome;Contraindicated Product Administered Non-Serious Non-Serious Female - 23-JUN-2025 Non-Expedited Not Specified Not Specified Alkermes Healthcare Professional Not Specified Olanzapine 17-JUN-2025 23-JUN-2025 US Not Specified US-ALKERMES INC.-ALK-2025-001658 - -

25170437 Promethazine Pipamperone;Promethazine Hydrochloride;Ketamine;Mirtazapine;Citalopram;Nordazepam;Herbals\Mitragynine;Codeine Product Used For Unknown Indication Death;Drug Abuse Serious Other Outcomes;Died Male - 23-JUN-2025 Expedited 19 YR Not Specified Aurobindo Healthcare Professional Not Specified - 10-JUN-2025 08-APR-2025 BE Not Specified BE-AUROBINDO-AUR- APL-2025-016637 "Breugelmans L, Boland A, Fernandez MDMR, Di Fazio V, Wille S. A lethal case involving purple drank and Kratom. Toxic-Analyt-Clinique. 2025;37 (Suppl)(1):S17" -

18451955 Sertraline Sertraline Hydrochloride;Bupropion Hydrochloride;Amitriptyline Hydrochloride;Perphenazine;Herbals\Mitragynine;Phenethylamine Anxiety;Mood Altered Serotonin Syndrome;Hypertransaminasaemia;Metabolic Acidosis;Rhabdomyolysis;Drug Ineffective Serious Hospitalized Male - 20-JUN-2025 Expedited 20 YR Not Specified Aurobindo Healthcare Professional Not Specified - 05-JUN-2025 02-NOV-2020 US Not Specified US-MYLANLABS-2020M1090641 "Mantilla B, Vega MV, Solis X, Makram J, Mallah H, Test V.. A DANGEROUS DRUG AND HERBAL MIXTURE.. Chest. 2020;158 (Suppl.)(4):A812 (plus poster)." -

25462679 - Cosmetics;.Delta.9-Tetrahydrocannabinol\Herbals;Herbals\Mitragynine;.Delta.8-Tetrahydrocannabinol\Herbals Weight Control Product Advertising Issue;Headache;Product Label Issue;Weight Increased Serious Disabled Not Specified - 19-JUN-2025 Direct 34 YR Not Specified Fda-Ctu Consumer Not Specified - - 19-JUN-2025 Not Specified Y - - -

25461736 - Herbals\Mitragynine Anxiety;Pain Management Withdrawal Syndrome;Hyperhidrosis;Drug Dependence;Tachycardia;Respiratory Depression;Diarrhoea;Depressed Level Of Consciousness Serious Other Outcomes Male 18-JUN-2025 19-JUN-2025 Direct 42 YR 108 KG Fda-Ctu Consumer Not Specified Herbals\Mitragynine;Klonopin;Ibuprofen - 19-JUN-2025 Not Specified Not Specified - - -

25460975 - Turpentine;Herbals\Mitragynine;Tianeptine - Drug Withdrawal Syndrome;Acetonaemic Vomiting;Drug Dependence Non-Serious Non-Serious Male 11-JUN-2025 18-JUN-2025 Direct 35 YR Not Specified Fda-Ctu

Healthcare Professional Not Specified - - 18-JUN-2025  
 Not Specified Not Specified - - -  
 25460702 - Herbals\Mitragynine - Death  
 Serious Died Male 18-FEB-2025 18-JUN-2025 Direct 38 YR  
 81 KG Fda-Ctu Consumer Not Specified - -  
 18-JUN-2025 Not Specified Not Specified - - -  
 -  
 25438994 - Herbals\Mitragynine Alcohol Withdrawal  
 Syndrome Drug Dependence;Substance Use;Overdose Serious  
 Disabled;Life Threatening;Required Intervention;Hospitalized;Other  
 Outcomes Male 01-JUN-2025 14-JUN-2025 Direct 35 YR  
 72 KG Fda-Ctu Consumer Not Specified - -  
 14-JUN-2025 Not Specified Not Specified - - -  
 -  
 25406123 - Herbals\Mitragynine;Nitroglycerin;Verapamil  
 Hydrochloride Product Used For Unknown Indication;Vasospasm Drug  
 Ineffective Serious Other Outcomes Male - 06-JUN-2025  
 Expedited 52 YR Not Specified Aurobindo  
 Healthcare Professional Not Specified - 22-MAY-2025 06-  
 JUN-2025 US Not Specified US-AUROBINDO-AUR-  
 APL-2022-047873 "Riggs A, Briggs J, Goodrich W, Gardner G..  
 Intravenous kratom use with peripheral vasospasm. Clin-Toxicol-  
 (Phila). 2022;60 (Suppl. 2):147-148" -  
 25386228 - Herbals\Mitragynine;7-Hydroxymitragynine  
 Back Pain;Pain;Pain In Extremity Vomiting;Feeling  
 Abnormal;Product Advertising Issue;Restless Legs Syndrome;Drug  
 Withdrawal Syndrome;Impaired Work Ability;Middle Insomnia;Diarrhoea  
 Serious Other Outcomes;Required Intervention;Disabled Male  
 04-JAN-2025 31-MAY-2025 Direct 45 YR 80.55 KG  
 Fda-Ctu Consumer Not Specified  
 Herbals\Mitragynine;Clonazepam - 31-MAY-2025 Not Specified  
 Not Specified - - -  
 25379995 - Herbals\Mitragynine -  
 Overdose;Vomiting;Withdrawal Syndrome;Tremor;Fall Serious  
 Died;Other Outcomes Male 21-APR-2025 30-MAY-2025 Direct  
 32 YR 72.57 KG Fda-Ctu Not Specified Not Specified  
 - - 30-MAY-2025 Not Specified Not Specified  
 - - -  
 25379785 -  
 Fentanyl;Herbals\Mitragynine;Diazepam;Gabapentin Product Used  
 For Unknown Indication Overdose;Toxicity To Various Agents  
 Serious Died Male - 30-MAY-2025 Expedited 33 YR  
 Not Specified Mylan Consumer Not Specified -  
 27-MAY-2025 30-MAY-2025 US Not Specified US-  
 MYLANLABS-2025M1045745 - -  
 25375148 - Herbals\Mitragynine Anxiety;Headache  
 Drug Dependence;Product Communication Issue;Suicidal  
 Ideation;Withdrawal Syndrome;Substance Use Serious Disabled;Other  
 Outcomes;Required Intervention Male 08-MAY-2025 29-MAY-2025  
 Direct 69 YR 99 KG Fda-Ctu Consumer Not Specified

Klonopin;Clonidine;Gabapentin;Vitamin D;Paxil;Atorvastatin;Ibuprofen;Herbals\Mitragynine;Xarelto -  
 29-MAY-2025 Not Specified Not Specified - -  
 -  
 25369370 Suboxone Buprenorphine Hydrochloride\Naloxone Hydrochloride;Oxycodone Hydrochloride;Herbals\Mitragynine;Hydrocodone Bitartrate Detoxification;Pain Hypoaesthesia;Hyperhidrosis;Drug Dependence;Anxiety;Chills;Inadequate Analgesia Serious Other Outcomes Male 2019 28-MAY-2025 Non-Expedited Not Specified Not Specified Purdue Consumer Not Specified - 24-MAY-2025 28-MAY-2025 US Not Specified US-PURDUE PHARMA-USA-2025-0317721  
 - -  
 25341878 - Herbals\Mitragynine Stress Feeling Abnormal;Sluggishness;Motor Dysfunction;Hypoaesthesia Oral;Tongue Pruritus;Headache;Heart Rate Decreased;Bedridden;Fatigue;Nausea Serious Other Outcomes Female 17-MAY-2025 21-MAY-2025 Direct 29 YR 46.8 KG Fda-Ctu Consumer Not Specified - - 21-MAY-2025 Not Specified Not Specified - -  
 - -  
 25323735 - 7-Hydroxymitragynine;Herbals\Mitragynine Depression;Pain;Plasminogen Activator Inhibitor Polymorphism Quality Of Life Decreased;Somnolence;Drug Dependence Serious Disabled Male 17-APR-2025 16-MAY-2025 Direct 66 YR Not Specified Fda-Ctu Healthcare Professional Not Specified - - 16-MAY-2025 Not Specified Not Specified - Specified - - -  
 25324294 - Herbals\Mitragynine Limb Injury Product Complaint;Mental Disorder;Communication Disorder Serious Hospitalized;Disabled;Other Outcomes;Life Threatening;Required Intervention Male 06-MAY-2025 15-MAY-2025 Direct 46 YR 90 KG Fda-Ctu Consumer Not Specified - - 15-MAY-2025 Not Specified Not Specified - -  
 -  
 25324201 - Herbals\Mitragynine Anxiety Hallucination;Product Complaint;Paranoia Serious Other Outcomes;Hospitalized;Life Threatening;Disabled;Required Intervention Male 06-MAY-2025 15-MAY-2025 Direct Not Specified Not Specified Fda-Ctu Consumer Not Specified - - 15-MAY-2025 Not Specified Not Specified - -  
 - -  
 25302762 Heroin Diamorphine;Hydrocodone Bitartrate;Herbals\Mitragynine;Diazepam;Fentanyl;Gabapentin Product Used For Unknown Indication Drug Abuse;Road Traffic Accident;Toxicity To Various Agents;Overdose;Impaired Driving Ability Serious Died;Other Outcomes Male 20-JUN-2024 12-MAY-2025 Expedited 33 YR Not Specified Purdue Consumer Not Specified - 09-MAY-2025 12-MAY-2025 US Not Specified US-PURDUE-USA-2025-0317374 -  
 -

23415519 Suboxone Buprenorphine Hydrochloride\Naloxone  
 Hydrochloride;Herbals\Mitragynine;Docusate Sodium Product Used  
 For Unknown Indication Anal Haemorrhage;Discomfort;Loss Of Personal  
 Independence In Daily Activities;Anal  
 Injury;Dizziness;Haematochezia;Drug Ineffective;Vomiting;Pain;Faeces  
 Hard;Migraine;Sleep Disorder Serious Disabled;Other Outcomes Not  
 Specified - 06-MAY-2025 Expedited Not Specified Not Specified  
 Not Specified Chattem Consumer Not Specified -  
 04-JAN-2024 18-JAN-2024 US Not Specified US-  
 CHATTEMPRD-20240HG000558 - -  
 25273355 - Herbals\Mitragynine Psoriatic Arthropathy  
 Herbal Toxicity Serious Died Male 12-SEP-2024 05-  
 MAY-2025 Direct 40 YR 69.3 KG Fda-Ctu Consumer Not  
 Specified Stool Softener (Docusate) - 05-MAY-2025  
 Not Specified Not Specified - - -  
 25263508 - Herbals\Mitragynine - Withdrawal  
 Syndrome;Fatigue;Chills;Restlessness;Irritability;Feeling  
 Abnormal;Paranoid Personality Disorder Serious Other Outcomes Male  
 - 01-MAY-2025 Direct 33 YR Not Specified Fda-  
 Ctu Consumer Not Specified - - 01-MAY-2025  
 Not Specified Not Specified - - -  
 24678645 Sertraline;Trazodone Trazodone  
 Hydrochloride;Risperidone;Quetiapine;Sertraline  
 Hydrochloride;Herbals\Mitragynine;Olanzapine Product Used For  
 Unknown Indication Toxicity To Various Agents Serious Died  
 Female - 29-APR-2025 Expedited Not Specified  
 Not Specified Aurobindo Healthcare Professional Not  
 Specified - 16-APR-2025 29-NOV-2024 CZ Not  
 Specified CZ-AUROBINDO-AUR-APL-2024-057757 "Bursová M,  
 Černá I, Horák V, Čupárek Z. ÚMRTÍ SPOJENÉ S U\_ITÍM KRATOMU. Military  
 medical science list.. 2024;1(93)" -  
 13059359 -  
 Quinidine;Herbals\Mitragynine;Loperamide;Quinine Sulfate  
 Product Used For Unknown Indication Drug Interaction;Drug  
 Abuse;Accidental Overdose;Toxicity To Various Agents Serious  
 Died;Other Outcomes Not Specified - 29-APR-2025  
 Expedited 33 YR Not Specified Aurobindo Healthcare  
 Professional Not Specified - 14-APR-2025 23-DEC-2016  
 US Not Specified US-  
 MYLANLABS-2016M1057187 "Bishop-Freeman SC, Feaster MS, Beal J, Miller  
 A, Hargrove RL, Brower JO, et al.. Loperamide-related deaths in North  
 Carolina.. J-Anal-Toxicol. 2016;40(8):677-686" -  
 25245489 - 7-Hydroxymitragynine;Herbals\Mitragynine  
 Alcohol Use;Feeling Of Relaxation;Substance Use  
 Dependence;Product Formulation Issue;Illness;Depression;Anxiety;Drug  
 Withdrawal Syndrome Serious Disabled;Other Outcomes;Required  
 Intervention Male - 27-APR-2025 Direct 23 YR 75.6  
 KG Fda-Ctu Consumer Not Specified - - 27-  
 APR-2025 Not Specified Not Specified - - -  
 25245476 - Herbals\Mitragynine

Anxiety;Depression;Pain Withdrawal Syndrome;Drug Dependence  
 Serious Other Outcomes Male 19-APR-2025 27-APR-2025 Direct  
   40 YR 54 KG Fda-Ctu Consumer Not Specified -  
   - 27-APR-2025 Not Specified Not Specified -  
   - -

25242427 - Herbals\Mitragynine;Loperamide;Tramadol  
 Product Used For Unknown Indication Accidental Overdose;Drug  
 Interaction;Loss Of Consciousness;Cardiomegaly;Toxicity To Various  
 Agents Serious Died;Other Outcomes Male - 27-APR-2025  
   Expedited 24 YR Not Specified Aurobindo  
 Healthcare Professional Not Specified - 14-APR-2025 27-  
 APR-2025 US Not Specified US-AUROBINDO-AUR-  
 APL-2019-077852 "Bishop-Freeman SC, Feaster MS, Beal J, Miller A,  
 Hargrove RL, Brower JO, Winecker RE.. Loperamide-Related Deaths in  
 North Carolina. .. Journal of Analytical Toxicology.  
 2016;40(8):677-686" -

23355812 Propranolol Propranolol  
 Hydrochloride;Loperamide;Quinidine;Herbals\Mitragynine;Quinine  
 Sulfate;Citalopram Hydrobromide Product Used For Unknown Indication  
 Drug Interaction;Accidental Overdose;Drug Abuse;Toxicity To  
 Various Agents Serious Died Not Specified - 27-APR-2025  
   Expedited 37 YR Not Specified Aurobindo  
 Healthcare Professional Not Specified - 14-APR-2025 02-  
 JAN-2024 US Not Specified US-AUROBINDO-AUR-  
 APL-2019-077560 "Bishop-Freeman SC, Feaster MS, Beal J, Miller A,  
 Hargrove RL, Brower JO, et,al.. Loperamide-Related Deaths in North  
 Carolina.. Journal of Analytical Toxicology.. 2016;40(8):677-686"  
 -

25245337 - Herbals\Mitragynine - Impaired  
 Quality Of Life;Cerebral Disorder Serious Other Outcomes Male  
   20-APR-2025 26-APR-2025 Direct 31 YR Not Specified  
   Fda-Ctu Consumer Not Specified - - 26-  
 APR-2025 Not Specified Not Specified - - -

25234603 - Herbals\Mitragynine - Psychotic  
 Disorder;Substance Use Disorder;Plasma Protein Metabolism Disorder  
 Serious Required Intervention;Hospitalized;Disabled Male  
   - 24-APR-2025 Direct Not Specified 83.25 KG  
   Fda-Ctu Consumer Not Specified - - 24-  
 APR-2025 Not Specified Not Specified - - -

25224362 - Herbals\Mitragynine Dependence Drug  
 Abuse;Drug Dependence;Malaise;Partner Stress;Liver Disorder  
 Serious Required Intervention;Life Threatening;Disabled;Other Outcomes  
   Male 19-APR-2025 21-APR-2025 Direct 47 YR 72 KG  
   Fda-Ctu Consumer Not Specified Viibryd;Lamictal  
   - 21-APR-2025 Not Specified Not Specified -  
   - -

25220629 - Herbals\Mitragynine Anxiety;Pain  
 Influenza Like Illness;Blood Pressure Increased;Withdrawal  
 Syndrome;Drug Dependence;Suicidal Ideation Serious Hospitalized  
   Female 15-APR-2025 19-APR-2025 Direct 46 YR 66.15

KG	Fda-Ctu	Consumer	Not Specified	-	-	-	19-
APR-2025		Not Specified	Not Specified	-	-	-	
25220129	-	Herbals\Mitragynine;7-Hydroxymitragynine					
		Depression;Pain;Substance Use	Fall;Decreased				
		Appetite;Emotional Disorder;Somnolence;Weight Decreased;Drug					
		Dependence;Muscle Spasms;Epistaxis;Dyskinesia;Orthostatic					
		Intolerance;Vomiting;Injury;Constipation;Retrograde Amnesia					
		Serious Disabled;Required Intervention	Male	17-APR-2025		19-	
APR-2025	Direct	66 YR	95.4 KG	Fda-Ctu	Consumer	Not	
Specified		Losartan;Clonidine;Nuvigil;Suboxone;Trintellix;Vitamin					
D Nos	-	19-APR-2025	Not Specified	Not Specified	-		
	-	-					
25209681		Promethazine Hydrochloride And Codeine					
		Phosphate;Promethazine	Promethazine				
		Hydrochloride;Citalopram;Pipamperone;Ketamine;Mirtazapine;Codeine					
		Phosphate\Promethazine Hydrochloride;Herbals\Mitragynine;Nordazepam					
		Product Used For Unknown Indication	Drug Abuse				
		Serious Died;Other Outcomes	Male	-	17-APR-2025		
Expedited	19 YR	Not Specified	Quagen Pharmaceuticals				
Healthcare Professional	Not Specified	Cannabis Sativa Subsp.	Indica				
Top;Prazepam;Morphine	04-APR-2025	17-APR-2025	BE	Not			
Specified	BE-QUAGEN-2025QUALIT00301	Laetitia Breugelmans.A					
lethal case involving purple drank and Kratom.	Toxicologie Analytique &						
Clinique.2025;37:S17	-						
25209438	-	Herbals\Mitragynine	-	Quality Of			
		Life Decreased;Product Use In Unapproved Indication;Substance Use					
		Serious Required Intervention;Other Outcomes	Male	22-			
MAR-2024	17-APR-2025	Direct	43 YR	78.75 KG	Fda-		
Ctu	Consumer	Not Specified	-	-	17-APR-2025		
	Not Specified	Y	-	-	-		
25202828	-	Herbals\Mitragynine	Anxiety;Depression				
		Drug Dependence;Compulsive Shopping;Quality Of Life					
		Decreased;Product Complaint	Serious Hospitalized;Life				
		Threatening;Required Intervention	Male	06-APR-2025	15-		
APR-2025	Direct	46 YR	98.1 KG	Fda-Ctu	Consumer	Not	
Specified	-	-	15-APR-2025	Not Specified	Not		
Specified	-	-	-				
25200492		Lybalvi Olanzapine\Samidorphan L-					
		Malate;Herbals\Mitragynine	Product Used For Unknown				
		Indication;Schizophrenia	Drug Screen Negative;Contraindicated				
		Product Administered;Withdrawal	Syndrome	Non-Serious	Non-		
		Serious Not Specified	-	15-APR-2025	Non-Expedited	Not	
Specified	Not Specified	Alkermes	Healthcare				
Professional	Not Specified	-	07-APR-2025	15-APR-2025			
US	Not Specified	US-ALKERMES INC.-ALK-2025-000941					
	-	-					
25189640		Promethazine	Mirtazapine;Promethazine				
		Hydrochloride;Nordazepam;Citalopram;Codeine;Ketamine;Pipamperone;Herba					
		ls\Mitragynine	-	Drug Abuse	Serious Other Outcomes;Died		
		Male	-	11-APR-2025	Expedited	19 YR	Not

Specified            Organon Healthcare Professional Not Specified    -  
                  07-APR-2025    11-APR-2025    BE    Not Specified    BE-  
ORGANON-02504BEL001065 "Breugelmans L, Boland A, Fernandez MDMR, Di  
Fazio V, Wille S.. A lethal case involving purple drank and Kratom..  
Toxic-Analyt-Clinique. 2025;37(1):S17" -  
25188348            -            Fentanyl;Herbals\Mitragynine;Gabapentin Drug  
Abuse    Drug Abuse;Prescription Drug Used Without A Prescription  
                  Serious Died;Other Outcomes    Male    -    11-APR-2025  
                  Expedited    49 YR    Not Specified    Alvogen Healthcare  
Professional    Not Specified    -    27-MAR-2025    11-APR-2025  
                  US    Not Specified    US-ALVOGEN-2025096648 "Gummin DD,  
Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Pham  
NPT, Bronstein AC, DesLauriers C. 2023 Annual Report of the National  
Poison Data System (NPDS) from America's Poison Centers: 41st Annual  
Report. Clinical Toxicology. 2024 Dec 17; doi:<https://doi.org/10.1080/15563650.2024.2412423>" -  
25186726            -            Herbals\Mitragynine;Olanzapine;Hydromorphone  
                  Abdominal Pain;Product Used For Unknown  
Indication;Schizoaffective Disorder Bipolar Type            Toxicity To  
Various Agents;Overdose;Renal Impairment            Serious Died    Male  
                  -    11-APR-2025    Expedited    44 YR    Not Specified  
                  Teva    Healthcare Professional Not Specified  
Zopiclone;Escitalopram    03-APR-2025    11-APR-2025    CA    Not  
Specified            CA-TEVA-VS-3320544    -    -  
25184025            Promethazine            Promethazine  
Hydrochloride;Citalopram;Mirtazapine;Pipamperone;Nordazepam;Ketamine  
Hydrochloride;Herbals\Mitragynine;Codeine            -            Drug  
Abuse;Toxicity To Various Agents;Overdose            Serious Died    Male  
                  -    10-APR-2025    Expedited    19 YR    Not Specified  
                  Pfizer    Healthcare Professional Not Specified    -    04-  
APR-2025            10-APR-2025    BE    Not Specified    BE-PFIZER  
INC-202500072887            "Breugelmans, L.. A lethal case involving  
purple drank and Kratom.. Toxicologie Analytique & Clinique. 2025;37  
(1):S17" -  
25183604            -            Oxycodone;Herbals\Mitragynine;Gabapentin  
                  Drug Abuse    Drug Abuse    Serious Died;Other Outcomes  
                  Female    -    10-APR-2025    Expedited    64 YR    Not  
Specified            Alvogen Healthcare Professional Not Specified    -  
                  27-MAR-2025    10-APR-2025    US    Not Specified    US-  
ALVOGEN-2025096994            "Gummin DD, Mowry JB, Beuhler MC, Spyker DA,  
Rivers LJ, Feldman R, Brown K, Pham NPT, Bronstein AC, DesLauriers C.  
2023 Annual Report of the National Poison Data System (NPDS) from  
America's Poison Centers: 41st Annual Report. Clinical Toxicology.  
2024 Dec 17; doi:<https://doi.org/10.1080/15563650.2024.2412423>" -  
25179701            -            Herbals\Mitragynine;Hydromorphone  
Hydrochloride;Olanzapine            Abdominal Pain;Product Used For  
Unknown Indication;Schizoaffective Disorder Bipolar Type            Renal  
Impairment;Overdose;Toxicity To Various Agents    Serious Died    Male  
                  -    09-APR-2025    Expedited    44 YR    Not Specified  
                  Purdue    Healthcare Professional Not Specified

Escitalopram;Zopiclone 07-APR-2025 09-APR-2025 CA Not  
 Specified CA-PURDUE-USA-2025-0316666 - -  
 23819072 Sertraline Sertraline  
 Hydrochloride;Herbals\Mitragynine Anxiety;Depression  
 Electrocardiogram Qt Prolonged;Drug Interaction Serious Other  
 Outcomes;Hospitalized Female - 08-APR-2025 Expedited  
 17 YR Not Specified Aurobindo Healthcare  
 Professional Not Specified - 31-MAR-2025 06-MAY-2024  
 US Not Specified US-AUROBINDO-AUR-APL-2024-021444  
 "Truesdale N, Kaliki V, Fuller KE, Nathani Y. QTc prolongation  
 related to kratom ingestion with underlying SSRI usage. Am J Med Sci.  
 2024;367 (Suppl. 1):S284" -

25167106 - Herbals\Mitragynine;Herbals Pain Drug  
 Dependence Serious Disabled Male 04-APR-2025 04-  
 APR-2025 Direct 33 YR 74.25 KG Fda-Ctu Consumer  
 Not Specified - - 04-APR-2025 Not Specified  
 Y - - -

25147746 Promethazine Promethazine  
 Hydrochloride;Citalopram;Herbals\Mitragynine;Codeine;Nordazepam;Pipamp  
 erone;Mirtazapine;Ketamine Product Used For Unknown Indication  
 Drug Abuse Serious Other Outcomes;Died Male -  
 02-APR-2025 Expedited 19 YR Not Specified Natco  
 Pharma Healthcare Professional Not Specified Prazepam;Cannabis  
 Sativa Subsp. Indica Top;Morphine 24-MAR-2025 02-APR-2025  
 Not Specified Not Specified BE-NATCOUSA-2025-

NATCOUSA-000273 "Breugelmans L, Boland A, Fernandez MD, Di Fazio V,  
 Wille S. A lethal case involving purple drank and Kratom. Toxicologie  
 Analytique et Clinique Volume 37, Issue 1, Supplement, March 2025,  
 Page S17." -

25143321 -  
 Ketamine;Herbals\Mitragynine;Codeine;Pipamperone;Nordazepam;Promethazi  
 ne Hydrochloride;Citalopram;Mirtazapine Product Used For Unknown  
 Indication Drug Abuse Serious Died;Other Outcomes Male  
 - 01-APR-2025 Expedited 19 YR Not Specified  
 Strides Healthcare Professional Not Specified - 18-  
 MAR-2025 01-APR-2025 BE Not Specified BE-STRIDES

ARCOLAB LIMITED-2025SP003986 "Breugelmans L, Boland A, Fernandez  
 MDMR, Di Fazio V, Wille S.. A lethal case involving purple drank and  
 Kratom. Toxic-Analyt-Clinique. 2025;37 (Suppl.) (1):S17" -

25141084 - Herbals\Mitragynine Pain  
 Management;Substance Use Withdrawal Syndrome;Drug  
 Dependence;Product Use In Unapproved Indication;Product Communication  
 Issue Non-Serious Non-Serious Male 19-DEC-2024 30-  
 MAR-2025 Direct 38 YR 83.7 KG Fda-Ctu Consumer Not  
 Specified Suboxone;Herbals\Mitragynine - 30-MAR-2025  
 Not Specified Not Specified - - -

24591508 - Tramadol Hydrochloride;Herbals\Mitragynine  
 Pain Seizure;Toxicity To Various Agents;Drug  
 Interaction;Hypokalaemia;Electrocardiogram Qt Prolonged;Cognitive  
 Disorder Serious Hospitalized;Other Outcomes Male -

29-MAR-2025 Expedited Not Specified Not Specified  
 Graviti Pharmaceuticals Healthcare Professional Not Specified  
 - 20-MAR-2025 08-NOV-2024 US Not Specified  
 US-GRAVITIPHARMA-GRA-2410-US-LIT-0570 "Beresford T, Keffler  
 C, Wasserstein M, Ronan P.(P0-152) Kratom Tramadol Toxicity With  
 Seizure, Hypokalemia, Marked Q-T Prolongation, and Cognitive  
 Impairment: A Case Report.J-Acad-Consult-Liaison-Psychiatry.2022;63  
 (Suppl.):S69-S70" -

25135250 - Herbals\Mitragynine - Drug  
 Dependence;Mental Impairment;Completed Suicide Serious Died;Other  
 Outcomes Male - 27-MAR-2025 Direct 41 YR 76.5  
 KG Fda-Ctu Consumer Not Specified  
 Albuterol;Trazodone;Tramadol - 27-MAR-2025 Not Specified  
 Not Specified - - -

25122925 Promethazine Citalopram;Codeine;Promethazine  
 Hydrochloride;Pipamperone;Ketamine;Mirtazapine;Herbals\Mitragynine;Nor  
 dazepam Product Used For Unknown Indication Drug Abuse  
 Serious Died Male - 26-MAR-2025 Expedited 19 YR  
 Not Specified Mylan Healthcare Professional Not Specified  
 - 18-MAR-2025 26-MAR-2025 BE Not Specified  
 BE-MYLANLABS-2025M1024926 "Breugelmans L, Boland A,  
 Fernandez MDMR, Di Fazio V, Wille S. A lethal case involving purple  
 drank and Kratom. Toxic-Analyt-Clinique 2025; 37 (Suppl.) (1): S17."

23455182 Fluoxetine Fluoxetine  
 Hydrochloride;Herbals\Mitragynine;Bupropion;Fentanyl Pain Drug  
 Interaction;Serotonin Syndrome Serious Hospitalized Male -  
 26-MAR-2025 Expedited 68 YR Not Specified Teva  
 Healthcare Professional Not Specified - 19-MAR-2025  
 30-JAN-2024 US Not Specified US-TEVA-VS-3149311  
 "Grundmann O, Hendrickson RG, Greenberg MI. Kratom: History,  
 pharmacology, current user trends, adverse health effects and  
 potential benefits. Dis-Mon 2023; 69 (6)::; Grundmann O, Hendrickson  
 RG, Greenberg MI. Kratom: History, pharmacology, current user trends,  
 adverse health effects and potential benefits. Dis-Mon 2023; 69 (6)::"

25113550 - Herbals\Mitragynine - Mental Status  
 Changes;Hypoxia;Pallor Serious Hospitalized;Life Threatening Male  
 22-MAR-2025 22-MAR-2025 Direct 2 YR 13.3 KG Fda-  
 Ctu Healthcare Professional Not Specified - - 22-  
 MAR-2025 Not Specified Not Specified - - -

25104994 Zoloft Sertraline  
 Hydrochloride;Herbals\Mitragynine;Cyclobenzaprine;Cannabis Sativa  
 Subsp. Indica Top Pain Serotonin Syndrome Serious Life  
 Threatening;Hospitalized Male 06-MAR-2025 21-MAR-2025  
 Direct 28 YR 103.5 KG Fda-Ctu Healthcare  
 Professional Not Specified Unspecified Ingredient;Adderall Xr  
 - 21-MAR-2025 Not Specified Not Specified -

24989322 - Olanzapine;Herbals\Mitragynine;Hydromorphone

Abdominal Pain;Product Used For Unknown  
 Indication;Schizoaffective Disorder Bipolar Type Overdose;Renal  
 Impairment;Toxicity To Various Agents Serious Died Male -  
 21-MAR-2025 Expedited 44 YR Not Specified Sandoz  
 Healthcare Professional Not Specified Escitalopram;Zopiclone  
 20-MAR-2025 20-FEB-2025 CA Not Specified CA-  
 SANDOZ INC.-SDZ2025CA010384 - -  
 24829679 Buspirone;Trazodone Trazodone  
 Hydrochloride;Ziprasidone;Buspirone  
 Hydrochloride;Desvenlafaxine;Bupropion  
 Hydrochloride;Herbals\Mitragynine Depression;Product Used For  
 Unknown Indication Drug Interaction;Serotonin Syndrome  
 Serious Hospitalized;Other Outcomes Male - 21-MAR-2025  
 Expedited 63 YR 102.5 KG Graviti  
 Pharmaceuticals Healthcare Professional Not Specified  
 Diclofenac;Tizanidine;Glimepiride;Hydrochlorothiazide;Gabapentin;Metfo  
 rmin;Omeprazole;Amlodipine 11-MAR-2025 10-JAN-2025 US  
 Not Specified US-GRAVITIPHARMA-GRA-2501-US-  
 LIT-0007 "Eudaley ST, Brooks SP, Hamilton LA..Case Report:  
 Possible Serotonin Syndrome in a Patient Taking Kratom and Multiple  
 Serotonergic Agents..J-Pharm-Pract.2022;NA:NA" -  
 25094604 - Herbals\Mitragynine -  
 Vomiting;Nausea;Hypoesthesia Oral;Dizziness;Product Formulation  
 Issue;Vertigo Serious Other Outcomes;Disabled Female 12-MAR-2025  
 18-MAR-2025 Direct 30 YR 58.97 KG Fda-Ctu  
 Consumer Not Specified - - 18-MAR-2025 Not  
 Specified Not Specified - - -  
 25094332 - Herbals\Mitragynine Pain Quality Of  
 Life Decreased;Product Formulation Issue;Withdrawal Syndrome  
 Serious Life Threatening;Other Outcomes;Disabled;Required Intervention  
 Female 01-MAR-2025 18-MAR-2025 Direct 42 YR 58.5  
 KG Fda-Ctu Consumer Not Specified  
 Hydroxyzine;Magnesium;Methocarbamol;Lisinopril;Vitamin  
 B1;Minerals\Vitamins - 18-MAR-2025 Not Specified Not  
 Specified - - -  
 25079224 - Herbals\Mitragynine - Death  
 Serious Died Male 11-DEC-2021 14-MAR-2025 Direct 30 YR  
 101.25 KG Fda-Ctu Consumer Not Specified -  
 - 14-MAR-2025 Not Specified Y - -  
 -  
 25051391 Lybalvi Olanzapine\Samidorphan L-  
 Malate;Herbals\Mitragynine Product Used For Unknown Indication  
 Substance Use;Psychotic Disorder Non-Serious Non-  
 Serious Female - 07-MAR-2025 Non-Expedited Not Specified  
 Not Specified Alkermes Healthcare Professional Not  
 Specified Zyprexa 26-FEB-2025 07-MAR-2025 US Not  
 Specified US-ALKERMES INC.-ALK-2025-000501 - -  
 25021741 - Hydromorphone  
 Hydrochloride;Herbals\Mitragynine;Olanzapine Pain;Product Used For  
 Unknown Indication Toxicity To Various Agents;Renal

Impairment;Completed Suicide;Intentional Overdose      Serious Other  
 Outcomes;Died    Male    -    28-FEB-2025    Expedited    44 YR  
                     Not Specified    Sandoz    Healthcare Professional Not Specified  
                     Escitalopram;Zopiclone    26-FEB-2025    28-FEB-2025    CA  
                     Not Specified    CA-SANDOZ INC.-SDZ2025CA012346    -    -  
 25023423      -    Herbals\Mitragynine    Depression;Drug  
                     Dependence    Tremor;Thyroxine Decreased;Blood Thyroid Stimulating  
                     Hormone Increased;Fall;Incorrect Dose  
                     Administered;Seizure;Hypothyroidism;Euphoric Mood    Serious Other  
                     Outcomes;Required Intervention;Disabled;Life Threatening;Hospitalized  
                     Male    15-NOV-2022    27-FEB-2025    Direct    34 YR    83.25  
 KG    Fda-Ctu Consumer    Not Specified    -    -    27-  
                     Not Specified    Not Specified    -    -    -  
 25011290      -    Hydromorphone;Herbals\Mitragynine;Olanzapine  
                     Abdominal Pain;Product Used For Unknown  
                     Indication;Schizoaffective Disorder Bipolar Type  
                     Overdose;Toxicity To Various Agents;Renal Impairment    Serious Died  
                     Male    -    26-FEB-2025    Expedited    44 YR    Not  
                     Specified    Teva    Healthcare Professional Not Specified  
                     Escitalopram;Zopiclone    20-FEB-2025    26-FEB-2025    CA    Not  
                     Specified    CA-TEVA-VS-3303447    -    -  
 25014510      -    Herbals\Mitragynine    -    Drug  
                     Dependence    Serious Other Outcomes;Hospitalized;Required  
                     Intervention    Male    25-FEB-2025    25-FEB-2025    Direct    30 YR  
                     72.57 KG    Fda-Ctu Consumer    Not Specified    -  
                     -    25-FEB-2025    Not Specified    Not Specified    -  
                     -    -  
 25007716      -    Hydromorphone  
                     Hydrochloride;Olanzapine;Herbals\Mitragynine    Pain;Product Used For  
                     Unknown Indication    Toxicity To Various Agents;Completed  
                     Suicide;Intentional Overdose;Renal Impairment    Serious Died;Other  
                     Outcomes    Male    -    25-FEB-2025    Expedited    44 YR  
                     Not Specified    Teva    Healthcare Professional Not Specified  
                     Zopiclone;Escitalopram    20-FEB-2025    25-FEB-2025    CA  
                     Not Specified    CA-TEVA-VS-3303137    -    -  
 25004799      -    Herbals\Mitragynine    Disturbance In Social  
                     Behaviour    Overdose    Serious Died    Female    03-AUG-2023  
                     23-FEB-2025    Direct    26 YR    45 KG    Fda-Ctu Consumer  
                     Not Specified    Cortisone    -    23-FEB-2025    Not  
                     Specified    Not Specified    -    -    -  
 24988534      -    Olanzapine;Hydromorphone;Herbals\Mitragynine  
                     Abdominal Pain;Product Used For Unknown  
                     Indication;Schizoaffective Disorder Bipolar Type    Toxicity To  
                     Various Agents;Overdose;Renal Impairment    Serious Died    Male  
                     -    20-FEB-2025    Expedited    44 YR    Not Specified  
                     Sandoz    Healthcare Professional Not Specified  
                     Zopiclone;Escitalopram    18-FEB-2025    20-FEB-2025    CA    Not  
                     Specified    CA-SANDOZ INC.-SDZ2025CA010306    -    -  
 23690471      -    Herbals\Mitragynine;Olanzapine;Hydromorphone  
                     Hydrochloride    Pain;Product Used For Unknown Indication

Suspected Suicide;Overdose;Renal Impairment;Herbal Interaction;Renal Failure;Toxicity To Various Agents;Intentional Overdose;Completed Suicide Serious Died;Other Outcomes Male - 19-FEB-2025  
 Expedited 44 YR Not Specified Sandoz Healthcare Professional Not Specified Zopiclone;Olanzapine;Escitalopram 18-FEB-2025 01-APR-2024 CA Not Specified CA-SANDOZ INC.-SDZ2024CA034056 - -

24979676 Valium;Suboxone Buprenorphine Hydrochloride\Naloxone Hydrochloride;Meprobamate;Caffeine;Diazepam;Carisoprodol;Herbals\Mitragynine;Etizolam Product Used For Unknown Indication Toxicity To Various Agents;Impaired Driving Ability;Drug Dependence Serious Other Outcomes Male - 18-FEB-2025 Expedited 26 YR Not Specified Ranbaxy Healthcare Professional Not Specified - 04-FEB-2025 18-FEB-2025 US Not Specified US-SUN PHARMACEUTICAL INDUSTRIES

LTD-2025R1-494502 "Papsun DM, Chan-Hosokawa A, Lamb ME, Logan B. Increasing prevalence of designer benzodiazepines in impaired driving: A 5-year analysis from 2017 to 2021. J Anal Toxicol. 2023;47(8):668-679" -

24985527 - Herbals\Mitragynine Pain;Weight Decreased Product Use In Unapproved Indication;Euphoric Mood;Disturbance In Attention;Vomiting;Self-Medication Non-Serious Non-Serious Female 14-FEB-2025 17-FEB-2025 Direct 39 YR 101.25 KG Fda-Ctu Consumer Not Specified - - 17- FEB-2025 Not Specified Not Specified - - Yes

24973746 Percocet;Alcohol (Alcohol) Alcohol;Acetaminophen\Oxycodone Hydrochloride;Clonazepam;Herbals\Mitragynine Product Used For Unknown Indication Completed Suicide Serious Died Female 2023 17-FEB-2025 Expedited 38 YR Not Specified Endo Healthcare Professional Not Specified - 21- JAN-2025 17-FEB-2025 US Not Specified "US-ENDO USA, INC.-2025-000402" "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R, et al.. 2023 Annual Report of the National Poison Data System (NPDS) from America's Poison Centers: 41st Annual Report. Clinical Toxicology. 2024;1-235" -

24903738 - Lorazepam;Quetiapine;Lithium;Herbals\Mitragynine Bipolar Disorder;Mania;Toothache Sedation;Psychotic Symptom;Treatment Noncompliance;Intentional Product Misuse;Mania Serious Hospitalized Female - 13-FEB-2025 Expedited 69 YR Not Specified Teva Healthcare Professional Not Specified - 04-FEB-2025 30-JAN-2025 UA Not Specified UA-

TEVA-VS-3290374 "Bachu AK, Singal P, Griffin B, Harbaugh L, Prasad S, Jain L, et al. Kratom use and mental health: A systematic literature review and case example. [Review]. J-Addict-Dis 2024; 42 (4): 301-312.; Bachu AK, Singal P, Griffin B, Harbaugh L, Prasad S, Jain L, et al. Kratom use and mental health: A systematic literature review and case example. [Review]. J-Addict-Dis 2024; 42 (4): 301-312.; Bachu AK, Singal P, Griffin B, Harbaugh L, Prasad S, Jain L, et al. Kratom

use and mental health: A systematic review and meta-analysis." -

24900535 - Herbals\Mitragynine Anxiety Toxicity To  
 Various Agents Serious Died Female 26-AUG-2024 29-JAN-2025  
 Direct 41 YR 48.15 KG Fda-Ctu Consumer Not  
 Specified - - 29-JAN-2025 Not Specified Not  
 Specified - - -  
 24889954 - Herbals\Mitragynine - Substance  
 Use;Mouth Haemorrhage Serious Died Male 12-APR-2024 24-  
 JAN-2025 Direct 27 YR Not Specified Fda-Ctu Consumer  
 Not Specified - - 24-JAN-2025 Not Specified  
 Not Specified - - -  
 24869696 - Herbals\Mitragynine - Toxicity To  
 Various Agents Serious Died Male - 20-JAN-2025 Direct  
 25 YR 74.7 KG Fda-Ctu Consumer Not Specified -  
 - 20-JAN-2025 Not Specified Not Specified -  
 - -  
 24868050 - Herbals\Mitragynine Anxiety;Depression  
 Seizure Serious Other Outcomes Male 18-NOV-2024 20-  
 JAN-2025 Direct 29 YR 72 KG Fda-Ctu Consumer Not  
 Specified Lexapro;Wellbutrin - 20-JAN-2025 Not  
 Specified Not Specified - - -  
 24853253 - Oxycodone;Herbals\Mitragynine;Gabapentin  
 Product Used For Unknown Indication Drug Abuse  
 Serious Died;Other Outcomes Female - 17-JAN-2025  
 Expedited 64 YR Not Specified Apotex Healthcare  
 Professional Not Specified - 06-JAN-2025 17-JAN-2025  
 US Not Specified US-APOTEX-2025AP000914 "Gummin DD,  
 Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Pham  
 NPT, Bronstein AC, DesLauriers C.. 2023 Annual Report of the National  
 Poison Data System (NPDS) from America's Poison Centers: 41st Annual  
 Report. Clinical Toxicology. 2024;62 (12):793-1027" -  
 24856780 - Herbals\Mitragynine Pain Near Death  
 Experience;Substance Use Serious Life Threatening;Disabled  
 Female 28-DEC-2024 16-JAN-2025 Direct 36 YR Not  
 Specified Fda-Ctu Consumer Not Specified - -  
 16-JAN-2025 Not Specified Y - - -  
 24850249 - Herbals\Mitragynine Product Used For  
 Unknown Indication Incoherent;Vomiting;Skin Fissures;Memory  
 Impairment;Withdrawal Syndrome;Dry Skin;Drug Dependence;Eating  
 Disorder;Loss Of Personal Independence In Daily Activities;Insomnia  
 Serious Life Threatening;Disabled;Other Outcomes;Required  
 Intervention;Hospitalized Male 13-JAN-2025 16-JAN-2025  
 Direct 42 YR Not Specified Fda-Ctu Consumer Not  
 Specified - - 16-JAN-2025 Not Specified Not  
 Specified - - -  
 24850096 - Olanzapine;Herbals\Mitragynine;Hydromorphone  
 Hydrochloride Pain;Product Used For Unknown Indication Renal  
 Impairment;Overdose;Toxicity To Various Agents;Completed Suicide  
 Serious Other Outcomes;Died Male - 16-JAN-2025  
 Expedited 44 YR Not Specified Fresenius Kabi

Healthcare Professional Not Specified Zopiclone;Escitalopram 06-  
 JAN-2025 16-JAN-2025 CA Not Specified CA-  
 FreseniusKabi-FK202500275 - -  
 24848465 Salicylates Nos Unspecified  
 Ingredient;Acetaminophen;Herbals\Mitragynine Product Used For  
 Unknown Indication Drug Abuse Serious Died;Other Outcomes  
 Female - 16-JAN-2025 Expedited 65 YR Not  
 Specified Apotex Healthcare Professional Not Specified -  
 06-JAN-2025 16-JAN-2025 US Not Specified US-  
 APOTEX-2025AP000444 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA,  
 Rivers LJ, Feldman R, Brown K, Pham NPT, Bronstein AC, DesLauriers C..  
 2023 Annual Report of the National Poison Data System (NPDS) from  
 America's Poison Centers: 41st Annual Report. Clinical Toxicology.  
 2024;62 (12):793-1027" -  
 24849694 - Herbals\Mitragynine Insomnia;Pain  
 Suspected Product Contamination;Illness Serious Hospitalized Not  
 Specified 15-JAN-2025 15-JAN-2025 Direct 25 YR 54 KG  
 Fda-Ctu Consumer Not Specified - - 15-  
 JAN-2025 Not Specified Not Specified - - -  
 24845662 - Herbals\Mitragynine - Illness  
 Serious Disabled;Other Outcomes Female 14-JAN-2025 15-JAN-2025  
 Direct 36 YR Not Specified Fda-Ctu Consumer Not  
 Specified - - 15-JAN-2025 Not Specified Y  
 - - -  
 24840161 - Herbals\Mitragynine;Gabapentin;Fentanyl  
 Product Used For Unknown Indication Drug Abuse Serious  
 Died;Other Outcomes Male - 14-JAN-2025 Expedited  
 49 YR Not Specified Apotex Healthcare Professional Not  
 Specified - 06-JAN-2025 14-JAN-2025 US Not  
 Specified US-APOTEX-2025AP000336 "Gummin DD, Mowry JB, Beuhler  
 MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Pham NPT, Bronstein AC,  
 DesLauriers C.. 2023 Annual Report of the National Poison Data System  
 (NPDS) from America's Poison Centers: 41st Annual Report. Clinical  
 Toxicology. 2024;62 (12):793-1027" -  
 24836753 - Acetaminophen;Aspirin;Herbals\Mitragynine  
 - Toxicity To Various Agents;Drug Abuse Serious Other  
 Outcomes;Died Female - 13-JAN-2025 Expedited 65 YR  
 Not Specified Bayer Healthcare Professional Not Specified  
 - 06-JAN-2025 13-JAN-2025 US Not Specified  
 US-BAYER-2025A003194 "Gummin D D, Mowry J B, Beuhler M C,  
 Spyker D A, Rivers L J, Feldman R, Brown K, Pham N P T, Bronstein A C,  
 DesLauriers C.. 2023 Annual Report of the National Poison Data System®  
 (NPDS) from America's Poison Centers®: 41st Annual Report. Clinical  
 Toxicology. 2024;62:793-1027" -  
 24830903 Salicylates Nos Unspecified  
 Ingredient;Acetaminophen;Herbals\Mitragynine Drug Abuse;Product  
 Used For Unknown Indication Exposure To Toxic Agent Serious Died  
 Female 2023 10-JAN-2025 Expedited 65 YR Not  
 Specified Galpharm International Healthcare Professional Not  
 Specified - 06-JAN-2025 10-JAN-2025 US Not

Specified US-PERRIGO-25US000416 - -  
24828533 - Fentanyl;Herbals\Mitragynine;Cyclobenzaprine  
Product Used For Unknown Indication Drug Abuse  
Serious Died;Other Outcomes Female - 10-JAN-2025  
Expedited 37 YR Not Specified Apotex Healthcare  
Professional Not Specified - 06-JAN-2025 10-JAN-2025  
US Not Specified US-APOTEX-2025AP000265 "Gummin DD,  
Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Pham  
NPT, Bronstein AC, DesLauriers C.. 2023 Annual Report of the National  
Poison Data System (NPDS) from America's Poison Centers: 41st Annual  
Report. Clinical Toxicology. 2024;62 (12):793-1027"  
24827139 - Herbals\Mitragynine Depression;Stress  
Drug Dependence;Toxicity To Various Agents Serious Died  
Male 20-APR-2020 09-JAN-2025 Direct 32 YR 74.25  
KG Fda-Ctu Consumer Not Specified - - 09-  
JAN-2025 Not Specified Not Specified - - -  
24810286 - Fentanyl;Herbals\Mitragynine;Gabapentin  
Product Used For Unknown Indication Drug Abuse Serious  
Died;Other Outcomes Male - 06-JAN-2025 Expedited  
49 YR Not Specified Aveva Healthcare Professional Not  
Specified - 24-DEC-2024 06-JAN-2025 US Not  
Specified US-AVEVA-001308 "Gummin DD, Mowry JB, Beuhler MC,  
Spyker DA, Rivers LJ, Feldman R, Brown K, Pham NPT, Bronstein AC,  
DesLauriers C. 2023 Annual Report of the National Poison Data System  
(NPDS) from Americas Poison Centers 41st Annual Report. Clin Toxicol  
(Phila). 2024 Dec 17:1-35. doi: 10.1080/15563650.2024.2412423. Epub  
ahead of print."  
24807438 - Herbals\Mitragynine;Fentanyl;Methamphetamine  
Product Used For Unknown Indication Drug Abuse  
Serious Other Outcomes;Died Male - 05-JAN-2025  
Expedited 40 YR Not Specified Aveva Healthcare  
Professional Not Specified - 24-DEC-2024 05-JAN-2025  
US Not Specified US-AVEVA-001197 "Gummin DD, Mowry JB,  
Beuhler MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Pham NPT,  
Bronstein AC, DesLauriers C. 2023 Annual Report of the National Poison  
Data System (NPDS) from Americas Poison Centers 41st Annual Report.  
Clin Toxicol (Phila). 2024 Dec 17:1-35. doi:  
10.1080/15563650.2024.2412423. Epub ahead of print."  
24807325 - Herbals\Mitragynine;Fentanyl;Cyclobenzaprine  
Product Used For Unknown Indication Drug Abuse  
Serious Other Outcomes;Died Female - 05-JAN-2025  
Expedited 37 YR Not Specified Aveva Healthcare  
Professional Not Specified - 24-DEC-2024 05-JAN-2025  
US Not Specified US-AVEVA-001150 "Gummin DD, Mowry JB,  
Beuhler MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Pham NPT,  
Bronstein AC, DesLauriers C. 2023 Annual Report of the National Poison  
Data System (NPDS) from Americas Poison Centers 41st Annual Report.  
Clin Toxicol (Phila). 2024 Dec 17:1-35. doi:  
10.1080/15563650.2024.2412423. Epub ahead of print."  
24807204 - Fentanyl;Herbals\Mitragynine Product Used

For Unknown Indication Drug Abuse Serious Died;Other Outcomes  
Male - 05-JAN-2025 Expedited 35 YR Not Specified Aveva Healthcare Professional Not Specified -  
24-DEC-2024 05-JAN-2025 US Not Specified US-AVEVA-001078 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Pham NPT, Bronstein AC, DesLauriers C. 2023 Annual Report of the National Poison Data System (NPDS) from Americas Poison Centers 41st Annual Report. Clin Toxicol (Phila). 2024 Dec 17:1-35. doi: 10.1080/15563650.2024.2412423. Epub ahead of print."

-  
24801330 - Methamphetamine;Fentanyl;Herbals\Mitragynine Product Used For Unknown Indication Drug Abuse  
Serious Died;Other Outcomes Male - 02-JAN-2025 Expedited 31 YR Not Specified Aveva Healthcare Professional Not Specified - 24-DEC-2024 02-JAN-2025 US Not Specified US-AVEVA-000984 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Pham NPT, Bronstein AC, DesLauriers C. 2023 Annual Report of the National Poison Data System (NPDS) from Americas Poison Centers 41st Annual Report. Clin Toxicol (Phila). 2024 Dec 17:1-35. doi:  
10.1080/15563650.2024.2412423. Epub ahead of print."

-  
24789166 - Olanzapine;Herbals\Mitragynine;Hydromorphone Hydrochloride Pain;Product Used For Unknown Indication Completed Suicide;Toxicity To Various Agents;Renal Impairment;Overdose Serious Other Outcomes;Died Male - 30-DEC-2024 Expedited 44 YR Not Specified Teva Healthcare Professional Not Specified Zopiclone;Escitalopram 23-DEC-2024 30-DEC-2024 CA Not Specified CA-TEVA-VS-3280979

-  
24789696 - Herbals\Mitragynine - Diarrhoea;Drug Dependence;Withdrawal Syndrome;Insomnia;Vision Blurred;Chills;Pyrexia;Hyperhidrosis Serious Other Outcomes Male 25-DEC-2024 29-DEC-2024 Direct 49 YR 121.5 KG Fda-Ctu Consumer Not Specified - - 29- DEC-2024 Not Specified Not Specified - - -

24785048 Klonopin Lithium;Clonazepam;Cannabidiol\Herbals\Tetrahydrocannabinol Unspecified;Herbals\Mitragynine - Lethargy;Drug Interaction;Mental Status Changes Serious Required Intervention Female 03-DEC-2024 26-DEC-2024 Direct Not Specified Not Specified Fda-Ctu Consumer Not Specified - - 26-DEC-2024 Not Specified Not Specified -

-  
24782778 - Herbals\Mitragynine - Road Traffic Accident;Personality Change;Seizure;Drug Dependence Hospitalized;Other Outcomes Male 18-NOV-2024 26-DEC-2024 Direct 29 YR 67.5 KG Fda-Ctu Consumer Not Specified Wellbutrin;Lexapro;Melatonin - 26-DEC-2024 Not Specified Not Specified - - -  
24770968 - Herbals\Mitragynine;Gabapentin;Fentanyl

Product Used For Unknown Indication      Drug Abuse      Serious  
 Died;Other Outcomes      Not Specified      -      24-DEC-2024  
 Expedited      Not Specified      Not Specified      Glenmark  
 Healthcare Professional Not Specified      -      18-DEC-2024      24-  
 DEC-2024      US      Not Specified      US-GLENMARK  
 PHARMACEUTICALS-2024GMK096557      "Gummin DD, Mowry JB, Beuhler MC,  
 Spyker DA, Rivers LJ, Feldman R et al. 2023 Annual Report of the  
 National Poison Data System (NPDS) from America's Poison Centers: 41st  
 Annual Report. Clinical Toxicology. 2024;2-235" -  
 24668900      Trazodone;Risperdal;Sertraline      Sertraline  
 Hydrochloride;Quetiapine;Risperidone;Trazodone  
 Hydrochloride;Olanzapine;Herbals\Mitragynine      Product Used For  
 Unknown Indication;Psychotic Disorder      Toxicity To Various Agents  
 Serious Died      Female -      18-DEC-2024      Expedited  
 Not Specified      Not Specified      Aurobindo      Healthcare  
 Professional      Not Specified      -      03-DEC-2024      27-NOV-2024  
 CZ      Not Specified      CZ-AUROBINDO-AUR-APL-2024-057051  
 "Bursova M, Horak V, Syuparek Z, Yerna I.. Deaths associated  
 with Kratom use. Proceedings. 2024; 93(Military Medicine Science  
 Letters, Suppl. 1, 22nd conference of the military medicine society  
 CLS JEP, - 6 November 2024):5. 2024;SUPPL.. UVN Prague 5. 2024;1:5-6."  
 -  
 21711740      Hydroxyzine      Hydroxyzine  
 Hydrochloride;Benzoyllecgonine;Herbals\Tetrahydrocannabinol  
 Unspecified;Gabapentin;Herbals\Mitragynine;Cyclobenzaprine      -  
 Dyspnoea;Overdose      Serious Died      Not Specified      2020  
 17-DEC-2024      Expedited      Not Specified      Not Specified  
 Cipla      Healthcare Professional Not Specified      -      05-  
 DEC-2024      12-DEC-2022      US      Not Specified      US-CIPLA  
 LTD.-2022US07066      "Papsun DM, Krotulski AJ, Homan J, Temporal  
 KDH, Logan BK. Flualprazolam Blood Concentrations in 197 Forensic  
 Investigation Cases. Journal of Analytical Toxicology. 2021;45:226 to  
 232" -  
 24667039      Sertraline;Trazodone      Quetiapine;Trazodone  
 Hydrochloride;Risperidone;Olanzapine;Sertraline  
 Hydrochloride;Herbals\Mitragynine      Psychotic Disorder  
 Toxicity To Various Agents      Serious Died      Female -      13-  
 DEC-2024      Expedited      Not Specified      Not Specified      Mylan  
 Healthcare Professional Not Specified      -      09-DEC-2024  
 26-NOV-2024      CZ      Not Specified      CZ-  
 MYLANLABS-2024M1105271      "Bursova M, Horak V, Syuparek Z, Yerna I..  
 Deaths associated with Kratom use. Proceedings. 22nd conference of the  
 military medicine society CLS JEP. 2024;1 (93):5-6" -  
 24726792      -      Herbals\Mitragynine      Arthritis;Asthenia  
                   Nightmare;Product Complaint;Hot  
 Flush;Pain;Fatigue;Asthenia;Withdrawal Syndrome;General Physical  
 Health Deterioration;Insomnia;Flushing;Vomiting;Gastroenteritis  
 Salmonella;Depression;Diarrhoea      Serious Hospitalized      Female 04-  
 DEC-2024      11-DEC-2024      Direct      58 YR      96.75 KG      Fda-  
 Ct      Consumer      Not Specified      -      -      11-DEC-2024

Not Specified Not Specified - - -  
 24703335 Trazodone;Risperdal;Sertraline Sertraline  
 Hydrochloride;Trazodone  
 Hydrochloride;Risperidone;Herbals\Mitragynine;Quetiapine;Olanzapine  
 Product Used For Unknown Indication Toxicity To Various  
 Agents Serious Died Female - 05-DEC-2024 Expedited  
 Not Specified Not Specified Johnson And Johnson  
 Healthcare Professional Not Specified - 05-DEC-2024 05-  
 DEC-2024 CZ Not Specified CZ-  
 JNJFOC-20241212275 "Bursova M, Cerna I, Horak V, et al. Umrti  
 spojene s uzitim Kratomu. Sbornik. 2024; 93(Military Medicine Science  
 Letters, Suppl. 1, 22. konference spolecnosti vojenske mediciny CLS  
 JEP, UVN Praha 5.-6.11.2024):5." -

24695994 Alcohol (Alcohol)  
 Alcohol;Lidocaine;Alprazolam;Cocaine;Etizolam;Fentanyl;Herbals\Mitragynine;Cannabinol;Methamphetamine Product Used For Unknown Indication  
 Toxicity To Various Agents Serious Died Not Specified  
 - 04-DEC-2024 Expedited Not Specified Not  
 Specified Alembic Healthcare Professional Not Specified -  
 22-NOV-2024 04-DEC-2024 US Not Specified US-  
 ALEMBIC PHARMACEUTICALS LIMITED-2024SCAL001756 "Yu J, Diekhans K,  
 Tsang A, Rodda L.N. Fluorofentanyl and novel synthetic opioids in  
 accidental overdose deaths. Journal of Analytical Toxicology.  
 2024;48(8):573-581" -

24695059 - Herbals\Mitragynine Depression Drug  
 Dependence Serious Required Intervention;Other Outcomes Female  
 01-MAR-2024 04-DEC-2024 Direct 40 YR 58.5 KG Fda-  
 Ct Consumer Not Specified Clonidine - 04-  
 DEC-2024 Not Specified Not Specified - - -  
 24006620 Lybalvi Olanzapine\Samidorphan L-  
 Malate;Herbals\Mitragynine Product Used For Unknown Indication  
 Substance Use;Drug Withdrawal Syndrome Non-Serious Non-  
 Serious Female - 04-DEC-2024 Non-Expedited Not Specified  
 Not Specified Alkermes Healthcare Professional Not  
 Specified - 09-JUN-2024 24-JUN-2024 US Not  
 Specified US-ALKERMES INC.-ALK-2024-001590 - -  
 24530494 -

Nefopam;Aripiprazole;Cannabidiol;Tramadol;Trimeprazine;Loxapine;Diazepam;Herbals\Mitragynine;Tropatepine Hydrochloride Product Used  
 For Unknown Indication Death Serious Died Male AUG-2024  
 03-DEC-2024 Expedited 27 YR Not Specified Mylan  
 Healthcare Professional Not Specified - 26-NOV-2024  
 21-OCT-2024 FR Not Specified FR-

MYLANLABS-2024M1094207 - -

24538022 -  
 Cannabidiol;Diazepam;Tramadol;Herbals\Mitragynine;Loxapine;Trimeprazine;Tropatepine Hydrochloride;Nefopam;Aripiprazole Product Used  
 For Unknown Indication Death Serious Other Outcomes;Died Male  
 AUG-2024 29-NOV-2024 Expedited 27 YR Not  
 Specified Aurobindo Healthcare Professional Not Specified

- 16-NOV-2024 23-OCT-2024 FR Not Specified  
 FR-AUROBINDO-AUR-APL-2024-051027 - -  
 24670817 - Herbals\Mitragynine - Impaired  
 Driving Ability;Pruritus;Initial Insomnia;Poisoning;Ear Discomfort;Dizziness;Nausea;Gait Inability;Vision Blurred;Euphoric Mood;Abdominal Pain Upper Non-Serious Non-Serious Female  
 23-NOV-2024 27-NOV-2024 Direct 41 YR 96.75 KG  
 Fda-Ctu Consumer Not Specified Iron - 27-  
 NOV-2024 Not Specified Not Specified - - -  
 24543384 -  
 Loxapine;Herbals\Mitragynine;Trimeprazine;Nefopam Hydrochloride;Cannabidiol;Aripiprazole;Diazepam;Tramadol;Tropatepine Hydrochloride Product Used For Unknown Indication Death  
 Serious Died Not Specified AUG-2024 25-NOV-2024  
 Expedited Not Specified Not Specified Zydus Pharm Healthcare Professional Not Specified - 18-NOV-2024 24-  
 OCT-2024 FR Not Specified FR-CADILA HEALTHCARE LIMITED-  
 FR-ZYDUS-113782 - -  
 24660433 - Herbals\Mitragynine Pain  
 Asthenia;Weight Decreased;Withdrawal Syndrome Serious Other Outcomes  
 Male 18-NOV-2024 24-NOV-2024 Direct 53 YR 87.75  
 KG Fda-Ctu Consumer Not Specified  
 Metoprolol;Levothyroxine - 24-NOV-2024 Not Specified  
 Not Specified - - -  
 24450876 -  
 Cannabidiol;Diazepam;Trimeprazine;Loxapine;Aripiprazole;Tropatepine Hydrochloride;Nefopam;Tramadol;Herbals\Mitragynine Product Used For Unknown Indication Death Serious Died;Other Outcomes Male  
 AUG-2024 22-NOV-2024 Expedited 27 YR Not  
 Specified Otsuka Healthcare Professional Not Specified -  
 19-NOV-2024 17-OCT-2024 FR Not Specified FR-  
 OTSUKA-2024\_028211 - -  
 24654444 - Herbals\Mitragynine Drug Abuse Drug  
 Dependence Serious Other Outcomes;Required Intervention Male  
 21-NOV-2024 21-NOV-2024 Direct 16 YR 76.5 KG Fda-  
 Ctu Consumer Not Specified - - 21-NOV-2024  
 Not Specified Not Specified - - -  
 24611478 Risperdal;Trazodone;Sertraline Sertraline  
 Hydrochloride;Trazodone  
 Hydrochloride;Risperidone;Quetiapine;Olanzapine;Herbals\Mitragynine Psychotic Disorder Toxicity To Various Agents  
 Serious Died Female - 13-NOV-2024 Expedited Not  
 Specified Not Specified Johnson And Johnson Healthcare  
 Professional Not Specified - 07-NOV-2024 13-NOV-2024  
 CZ Not Specified CZ-JNJFOC-20241127742 - -  
 24613402 - Herbals\Mitragynine Anxiety Restless Legs  
 Syndrome Serious Disabled Male 01-JAN-2023 12-  
 NOV-2024 Direct 34 YR 58.5 KG Fda-Ctu Consumer Not  
 Specified Sertraline;Strattera - 12-NOV-2024 Not  
 Specified Not Specified - - -

24608517 - Herbals\Mitragynine Arthritis  
 Vomiting;Abdominal Pain Upper;Influenza Like Illness;Asthenia;Feeling  
 Cold Serious Hospitalized Female 10-JUN-2023 12-NOV-2024  
 Direct 57 YR 94.5 KG Fda-Ctu Consumer Not Specified  
 - - 12-NOV-2024 Not Specified Not Specified  
 - - -

24608643 - Herbals\Mitragynine -  
 Tremor;Constipation;Dependence;Nausea;Drug Withdrawal  
 Syndrome;Irritability;Vomiting;Cognitive Disorder;Substance  
 Use;Abdominal Distension;Night Sweats Serious Other Outcomes Male  
 10-NOV-2024 11-NOV-2024 Direct 48 YR 220 LB Fda-  
 Ctu Healthcare Professional Not Specified - - 11-  
 NOV-2024 Not Specified Not Specified - - -

24423784 - Herbals\Mitragynine;Olanzapine;Hydromorphone  
 Abdominal Pain;Product Used For Unknown  
 Indication;Schizoaffective Disorder Bipolar Type Renal  
 Impairment;Toxicity To Various Agents;Overdose Serious Died Male  
 2022 05-NOV-2024 Expedited 44 YR Not Specified  
 Teva Healthcare Professional Not Specified  
 Zopiclone;Escitalopram 30-SEP-2024 10-OCT-2024 CA Not  
 Specified CA-TEVA-VS-3251357 "Shi T, Shea JL. A case of  
 fatal overdose involving both hydromorphone and kratom. J-Forensic-Sci  
 2023; 69 355-358.; Shi T, Shea JL. A case of fatal overdose involving  
 both hydromorphone and kratom. J-Forensic-Sci 2023; 69 355-358.; Shi  
 T, Shea JL. A case of fatal overdose involving both hydromorphone and  
 kratom. J-Forensic-Sci 2023; 69 355-358." -

24576225 - Herbals\Mitragynine - Therapy Non-  
 Responder;Nonspecific Reaction;Physical Product Label  
 Issue;Lethargy;Feeling Abnormal;Dizziness Serious Other Outcomes  
 Male 03-NOV-2024 03-NOV-2024 Direct 79 YR 111.6  
 KG Fda-Ctu Consumer Not Specified - - 03-  
 NOV-2024 Not Specified Y - -

24570228 - Herbals\Mitragynine Product Use Issue  
 Generalised Tonic-Clonic Seizure;Substance Use Serious Other  
 Outcomes;Hospitalized Male - 30-OCT-2024 Direct 24 YR  
 67.5 KG Fda-Ctu Consumer Not Specified

Suboxone;Creatine - 30-OCT-2024 Not Specified Not  
 Specified - - -

24563829 -  
 Herbals\Mitragynine;Cannabidiol;Nefopam;Aripiprazole;Benzodiazepine;Tr  
 opatepine Hydrochloride;Tramadol;Loxapine;Diazepam;Trimeprazine  
 Product Used For Unknown Indication Death Serious Died Male  
 AUG-2024 30-OCT-2024 Expedited 27 YR Not  
 Specified Teva Healthcare Professional Not Specified -

21-OCT-2024 30-OCT-2024 FR Not Specified FR-  
 TEVA-VS-3256806 -

24544430 - Herbals\Mitragynine;Hydromorphone  
 Hydrochloride;Olanzapine Pain;Product Used For Unknown  
 Indication Completed Suicide;Renal Impairment;Toxicity To Various  
 Agents;Intentional Overdose Serious Died Male - 24-

OCT-2024 Expedited 44 YR Not Specified Cheplapharm  
 Healthcare Professional Not Specified Zopiclone; Escitalopram  
 17-OCT-2024 24-OCT-2024 CA Not Specified CA-  
 CHEPLA-2024013332 Unknown. Unknown. Unknown -  
 24535031 - Herbals\Mitragynine - Withdrawal  
 Syndrome; Product Advertising Issue Serious Required Intervention  
 Female 14-SEP-2024 21-OCT-2024 Direct 33 YR 81 KG  
 Fda-Ctu Consumer Not Specified - - 21-  
 OCT-2024 Not Specified Not Specified - - -  
 24446899 -  
 Herbals\Mitragynine; Diazepam; Loxapine; Trimeprazine; Aripiprazole; Tropat  
 epine Hydrochloride; Cannabidiol; Tramadol; Nefopam Hydrochloride  
 Product Used For Unknown Indication Death Serious Died Male  
 AUG-2024 16-OCT-2024 Expedited 27 YR Not  
 Specified Bausch And Lomb Healthcare Professional Not Specified  
 - 13-OCT-2024 16-OCT-2024 FR Not Specified  
 FR-BAUSCH-BL-2024-015269 - -  
 24446418 Sublocade; Suboxone Buprenorphine  
 Hydrochloride\Naloxone Hydrochloride; Herbals\Mitragynine; Buprenorphine  
 Drug Dependence Drug Half-Life Increased; Drug Screen  
 Positive; Withdrawal Syndrome; Panic  
 Attack; Dependence; Depression; Anhedonia; Rebound Effect Serious  
 Hospitalized Male 30-AUG-2023 15-OCT-2024 Direct 36 YR  
 81 KG Fda-Ctu Consumer Not Specified - -  
 15-OCT-2024 Not Specified Y - - Yes  
 24437297 - Herbals\Mitragynine Drug Abuse  
 Headache; Loss Of Personal Independence In Daily  
 Activities; Diarrhoea; Tachycardia; Vomiting Serious Other Outcomes  
 Male 10-OCT-2024 11-OCT-2024 Direct 28 YR 76.5  
 KG Fda-Ctu Healthcare Professional Not Specified - -  
 11-OCT-2024 Not Specified Not Specified - -  
 -  
 24428948 - Herbals\Mitragynine; Propranolol Hydrochloride  
 Product Used For Unknown Indication Cardio-Respiratory  
 Arrest; Completed Suicide; Toxicity To Various Agents Serious Died  
 Female 2022 11-OCT-2024 Expedited 25 YR Not  
 Specified Northstar Healthcare Professional Not Specified  
 - 30-SEP-2024 11-OCT-2024 US Not Specified  
 US-NORTHSTAR RX LLC-US-2024NSR000084 "Gummin DD, Mowry JB,  
 Beuhler MC, Spyker DA, Bronstein AC, Rivers LJ, et al.. 2022 Annual  
 Report of the National Poison Data System© (NPDS) from America's  
 Poison Centers: 40th Annual Report. Clinical Toxicology.  
 2022;61(10):717-939" -  
 24417459 - Herbals\Mitragynine; Inulin  
 Gastrointestinal Disorder Agitation; Laboratory Test  
 Abnormal; Nausea; Nightmare; Fatigue; Depression Serious Disabled  
 Female 24-JUN-2024 08-OCT-2024 Direct 70 YR 101.25  
 KG Fda-Ctu Consumer Not Specified Azo - 08-  
 OCT-2024 Not Specified Not Specified - - -  
 24409547 - Methylphenidate

Hydrochloride;Etizolam;Cannabidiol;Herbals\Mitragynine;Diazepam  
 Product Used For Unknown Indication      Accidental Overdose;Toxicity  
 To Various Agents      Serious Died      Male      25-MAR-2024      08-  
 OCT-2024      Expedited      28 YR      Not Specified      Sandoz  
 Consumer      Not Specified      –      19-JUL-2024      08-OCT-2024  
 AU      Not Specified      AU-SANDOZ INC.-SDZ2024AU085433      –  
 –  
 24340583      Sertraline      Sertraline  
 Hydrochloride;Levothyroxine;Buprenorphine;Herbals\Mitragynine  
 Anxiety;Hypothyroidism;Opioid Sparing Treatment;Relaxation Therapy  
 Drug Withdrawal Syndrome  
 Neonatal;Hypernatraemia;Ichthyosis;Generalised Tonic-Clonic  
 Seizure;Drug Withdrawal Syndrome;Foetal Exposure During Pregnancy  
 Serious Life Threatening;Congenital Anomaly;Hospitalized  
 Male      –      04-OCT-2024      Expedited      Not Specified  
 Not Specified      Teva      Healthcare Professional Not Specified  
 –      26-SEP-2024      19-SEP-2024      US      Not Specified  
 US-TEVA-VS-3243128      "Spungen HH, Mody K, Micetic B, Wade  
 C, Kang AM. Neonatal and Maternal Ichthyosiform Dermopathy in  
 Association with Kava Use during Pregnancy. J-Med-Toxicol 2024;;;  
 Spungen HH, Mody K, Micetic B, Wade C, Kang AM. Neonatal and Maternal  
 Ichthyosiform Dermopathy in Association with Kava Use during  
 Pregnancy. J-Med-Toxicol 2024;;; Spungen HH, Mody K, Micetic B, Wade  
 C, Kang AM. Neonatal and Maternal Ichthyosiform Dermopathy in  
 Association with Kava Use during Pregnancy. J-Med-Toxicol 2024;."  
 –  
 23055792      –      Olanzapine;Herbals\Mitragynine;Hydromorphone  
 Pain;Product Used For Unknown Indication      Toxicity To  
 Various Agents;Overdose      Serious Died      Male      –      04-OCT-2024  
 Expedited      44 YR      Not Specified      Ranbaxy Healthcare  
 Professional      Not Specified      Escitalopram;Zopiclone      20-SEP-2024  
 11-OCT-2023      CA      Not Specified      CA-SUN PHARMACEUTICAL  
 INDUSTRIES LTD-2023R1-411979      "Shi T, Shea LJ. A case of fatal  
 overdose involving both hydromorphone and kratom. J Forensic Sci.  
 2023;Sep 27; 69:355-358"  
 –  
 24397937      –      Herbals\Mitragynine      Pain      Substance  
 Use;Overdose      Serious Died      Male      21-AUG-2024      03-OCT-2024  
 Direct      32 YR      98.55 KG      Fda-Ctu Consumer      Not  
 Specified      –      –      03-OCT-2024      Not Specified      Not  
 Specified      –      –      –  
 24377559      –      Herbals\Mitragynine      Insomnia      Cold  
 Sweat;Tremor;Impaired Driving Ability;Nausea;Coordination  
 Abnormal;Vision Blurred      Serious Other Outcomes;Life Threatening      Male  
 28-SEP-2024      28-SEP-2024      Direct      27 YR      81 KG      Fda-  
 Ctu      Consumer      Not Specified      –      –      28-SEP-2024  
 Not Specified      Not Specified      –      –      –  
 24377255      –      Herbals\Mitragynine      Anxiety      Toxicity To  
 Various Agents      Serious Died      Female      16-DEC-2023      28-SEP-2024  
 Direct      34 YR      56.25 KG      Fda-Ctu Consumer      Not  
 Specified      –      –      28-SEP-2024      Not Specified      Not

Specified - - -  
 24344910 - Herbals\Mitragynine -  
 Nausea;Diarrhoea;Vomiting Serious Other Outcomes;Required  
 Intervention Male 14-SEP-2024 20-SEP-2024 Direct 47 YR  
     90 KG Fda-Ctu Consumer Not Specified - -  
     20-SEP-2024 Not Specified Y - - -  
 24333729 - Herbals\Mitragynine Fatigue  
 Hyperhidrosis;Diarrhoea;Substance Use;Anxiety;Restlessness;Pain  
 Serious Other Outcomes Female 17-SEP-2024 17-SEP-2024 Direct  
     37 YR 69.3 KG Fda-Ctu Healthcare Professional Not Specified  
     - - 17-SEP-2024 Not Specified Not Specified  
     - - -  
 24289708 -  
 Pregabalin;Herbals\Mitragynine;Tapentadol;Clonazepam;Carisoprodol  
     Product Used For Unknown Indication Toxicity To Various  
 Agents Non-Serious Non-Serious Female - 06-SEP-2024  
     Expedited 44 YR Not Specified Alkem Healthcare  
 Professional Not Specified Citalopram Hydrobromide 15-MAY-2024  
     06-SEP-2024 AU Not Specified AU-ALKEM LABORATORIES  
 LIMITED-AU-ALKEM-2024-10488 - -  
 24290864 - Herbals\Mitragynine Drug Dependence Dry  
 Skin;Skin Exfoliation;Pallor;Weight Decreased;Photophobia;Vision  
 Blurred;Drug Dependence Serious Other Outcomes;Disabled;Life  
 Threatening;Required Intervention Male 02-SEP-2024 05-  
 SEP-2024 Direct 46 YR 87.75 KG Fda-Ctu Consumer  
     Not Specified - - 05-SEP-2024 Not Specified  
     Not Specified - - -  
 24272154 Alcohol (Alcohol) Alcohol;.Delta.8-  
 Tetrahydrocannabinol\Herbals;Herbals\Mitragynine;Aripiprazole;Methylph  
 enidate Hydrochloride Product Used For Unknown Indication  
 Binocular Eye Movement  
 Disorder;Imprisonment;Nystagmus;Blepharospasm;Heart Rate  
 Increased;Impaired Driving Ability;Toxicity To Various Agents  
 Serious Other Outcomes;Disabled Male - 02-SEP-2024  
     Expedited 21 YR Not Specified Specgx Healthcare  
 Professional Not Specified - 21-AUG-2024 02-SEP-2024  
     US Not Specified US-SPECGX-T202401782 "Kedzierski N,  
 Mata D. Mitragynine in the Orange County DUID population. Journal of  
 Analytical Toxicology. 2023;47(8):770-85"  
 24272150 Alcohol (Alcohol)  
 Alcohol;Oxycodone;Oxymorphone;Herbals\Mitragynine Product Used  
 For Unknown Indication Balance Disorder;Impaired Driving  
 Ability;Nystagmus;Imprisonment;Toxicity To Various Agents  
 Serious Disabled;Other Outcomes Male - 02-SEP-2024  
     Expedited 51 YR Not Specified Specgx Healthcare  
 Professional Not Specified - 21-AUG-2024 02-SEP-2024  
     US Not Specified US-SPECGX-T202401781 "Kedzierski N,  
 Mata D. Mitragynine in the Orange County DUID population. Journal of  
 Analytical Toxicology. 2023;47(8):770-85"  
 24272141 -

Hydromorphone;Methamphetamine;Acetaminophen;Dihydrocodeine;Benzoylco  
nine;Herbals\Mitragynine;Hydrocodone;Amphetamine;Cocaine  
Product Used For Unknown Indication Extremity  
Contracture;Bruxism;Paranoia;Anxiety;Toxicity To Various Agents;Speech  
Disorder;Impaired Driving Ability;Imprisonment;Hyperhidrosis  
Serious Other Outcomes;Disabled Male - 02-SEP-2024  
Expedited 38 YR Not Specified Specgx Healthcare  
Professional Not Specified - 21-AUG-2024 02-SEP-2024  
US Not Specified US-SPECGX-T202401780 "Kedzierski N,  
Mata D. Mitragynine in the Orange County DUID population. Journal of  
Analytical Toxicology. 2023;47(8):770-85"  
24272140 Alcohol (Alcohol)  
Alcohol;Herbals\Mitragynine;Acetaminophen\Hydrocodone Product Used  
For Unknown Indication Eye Movement Disorder;Heart Rate  
Increased;Imprisonment;Balance Disorder;Impaired Driving  
Ability;Toxicity To Various Agents;Tremor;Nystagmus;Road Traffic  
Accident Serious Disabled;Other Outcomes Female - 02-  
SEP-2024 Expedited 42 YR Not Specified Specgx  
Healthcare Professional Not Specified - 21-AUG-2024 02-  
SEP-2024 US Not Specified US-SPECGX-  
T202401779 "Kedzierski N, Mata D. Mitragynine in the Orange  
County DUID population. Journal of Analytical Toxicology.  
2023;47(8):770-85"  
24272020 Pamelor;Zolpidem Zolpidem  
Tartrate;Oxycodone;Herbals\Mitragynine;Amitriptyline;Methocarbamol;Nor  
triptyline Hydrochloride;Oxymorphone;Gabapentin;Morphine  
Product Used For Unknown Indication Restlessness;Lacrimation  
Increased;Toxicity To Various Agents;Abnormal Behaviour;Impaired  
Driving Ability;Nystagmus;Balance Disorder;Imprisonment;Ocular  
Hyperaemia Serious Other Outcomes;Disabled Male - 02-  
SEP-2024 Expedited 31 YR Not Specified Specgx  
Healthcare Professional Not Specified - 21-AUG-2024 02-  
SEP-2024 US Not Specified US-SPECGX-  
T202401778 "Kedzierski N, Mata D. Mitragynine in the Orange  
County DUID population. Journal of Analytical Toxicology.  
2023;47(8):770-85"  
24278790 - Herbals\Mitragynine Anxiety Road Traffic  
Accident Serious Life Threatening;Required  
Intervention;Hospitalized;Other Outcomes Male 08-JUN-2024  
31-AUG-2024 Direct 25 YR 69.75 KG Fda-Ctu  
Consumer Not Specified - - 31-AUG-2024 Not  
Specified Not Specified - - -  
24263168 Buspirone Buspirone  
Hydrochloride;Alprazolam;Clonidine;Cyclobenzaprine;Herbals\Mitragynine  
;Gabapentin Product Used For Unknown Indication Toxicity To  
Various Agents;Accidental Overdose Serious Died Female -  
29-AUG-2024 Expedited Not Specified Not Specified  
Apotex Healthcare Professional Not Specified - 19-  
AUG-2024 29-AUG-2024 US Not Specified US-  
APOTEX-2024AP009652 "Torrico T, Patel K, Nikolov N, Salam MT,

Padhy R, Weinstein D.. Presence of kratom in opioid overdose deaths: findings from coroner postmortem toxicological report.. Frontiers in Psychiatry. 2024;14:1332999 (01-04)" -

24261090 Methadone Methadone  
 Hydrochloride;Herbals\Mitragynine;Morphine Product Used For  
 Unknown Indication Impaired Driving Ability;Pupillary Reflex  
 Impaired;Eye Movement Disorder;Miosis;Imprisonment;Lacrimation  
 Increased;Toxicity To Various Agents Serious Disabled;Other  
 Outcomes Male - 29-AUG-2024 Expedited 52 YR  
 Not Specified Specgx Healthcare Professional Not Specified  
 - 21-AUG-2024 29-AUG-2024 US Not Specified  
 US-SPECGX-T202401766 "Kedzierski N, Mata D. Mitragynine in  
 the Orange County DUID population. Journal of Analytical Toxicology.  
 2023;47(8):770-85" -

24253585 - Herbals\Mitragynine;Hydromorphone;Olanzapine  
 Product Used For Unknown Indication Completed  
 Suicide;Toxicity To Various Agents;Overdose;Renal Impairment  
 Serious Other Outcomes;Died Male - 27-AUG-2024  
 Expedited 44 YR Not Specified Aurobindo Healthcare  
 Professional Not Specified Escitalopram 15-AUG-2024 27-  
 AUG-2024 CA Not Specified CA-AUROBINDO-AUR-  
 APL-2024-042002 "Shi T, Shea LJ.. A case of fatal overdose involving  
 both hydromorphone and kratom. J Forensic Sci. 2023" -

24250943 - Herbals\Mitragynine Anxiety Mood  
 Swings;Pain In Extremity;Hyperhidrosis;Nausea;Chills;Thinking  
 Abnormal;Cold Sweat;Abdominal Pain Upper;Tremor;Abnormal  
 Behaviour;Diarrhoea Serious Disabled;Required  
 Intervention;Hospitalized Female 15-MAY-2024 25-AUG-2024  
 Direct 22 YR 54 KG Fda-Ctu Consumer Not Specified  
 Albuterol;Unspecified Ingredient - 25-AUG-2024  
 Not Specified Not Specified - - -

24250203 - Herbals\Mitragynine Substance Use Drug  
 Dependence;Hepatic Failure;Alcohol Use Serious Died Male 05-  
 AUG-2024 24-AUG-2024 Direct 32 YR Not Specified Fda-  
 Ctu Consumer Not Specified - - 24-AUG-2024  
 Not Specified Not Specified - - -

24020185 Alcohol (Alcohol);Spravato  
 Alcohol;Esketamine;Fentanyl;Cocaine;Herbals\Mitragynine Blood Pressure  
 Measurement;Depression;Product Used For Unknown Indication;Sleep  
 Disorder Depressed Mood;Poisoning Serious Died Male  
 MAY-2024 23-AUG-2024 Expedited 33 YR 90.8  
 KG Johnson And Johnson Healthcare Professional Not Specified  
 Trazodone;Lisinopril;Rexulti;Synthroid;Auvelity;Prozac 12-  
 AUG-2024 27-JUN-2024 US Not Specified US-  
 JNJFOC-20240660098 - -

24214283 - Herbals\Mitragynine - High-Pitched  
 Crying;Irritability;Drug Screen Positive;Agitation Neonatal;Suck-  
 Swallow Breathing Coordination Disturbance Serious Other Outcomes  
 Female 08-JUN-2024 14-AUG-2024 Direct 1 DAY 3.54  
 KG Fda-Ctu Healthcare Professional Not Specified - -

14-AUG-2024 Not Specified Not Specified - -  
 -  
 24214282 - Herbals\Mitragynine - Hypertonia  
 Neonatal;Blood Cannabinoids;Agitation Neonatal;Maternal Exposure  
 During Pregnancy;Drug Withdrawal Syndrome;Maternal Drugs Affecting  
 Foetus Serious Other Outcomes Female 01-AUG-2024 14-AUG-2024  
 Direct 1 DAY 3.6 KG Fda-Ctu Healthcare Professional Not  
 Specified Herbals\Tetrahydrocannabinol Unspecified -  
 14-AUG-2024 Not Specified Not Specified - -  
 -  
 24204569 Lybalvi Olanzapine\Samidorphan L-  
 Malate;Herbals\Mitragynine Blood Pressure  
 Abnormal;Contraception;Product Used For Unknown Indication  
 Burning Sensation;Genital Burning Sensation;Hyperhidrosis;Panic  
 Reaction;Substance Use;Dyskinesia;Abdominal Discomfort Non-Serious  
 Non-Serious Female AUG-2024 13-AUG-2024 Non-  
 Expedited Not Specified Not Specified Alkermes  
 Consumer Not Specified Unspecified Ingredient 03-AUG-2024  
 13-AUG-2024 US Not Specified US-ALKERMES INC.-  
 ALK-2024-002046 - -  
 24200495 - Herbals\Mitragynine - Substance  
 Use;Hypophagia;Impaired Work Ability;Insomnia Serious Died Male  
 07-JUL-2024 10-AUG-2024 Direct 32 YR 63 KG Fda-  
 Ctu Consumer Not Specified - - 10-AUG-2024  
 Not Specified Not Specified - - Yes  
 24200438 - Herbals\Mitragynine Product Used For  
 Unknown Indication Gait Inability;Toxicity To Various  
 Agents;Paralysis;Irregular  
 Breathing;Diarrhoea;Vomiting;Poisoning;Hallucination;Fear;Product  
 Label Issue;Blindness;Chills Serious Hospitalized Female 04-  
 AUG-2024 09-AUG-2024 Direct 48 YR 58.5 KG Fda-Ctu  
 Consumer Not Specified - - 09-AUG-2024 Not  
 Specified Y - - -  
 24200338 Paxlovid  
 Nirmatrelvir\Ritonavir;Herbals\Mitragynine;Methocarbamol  
 Covid-19 Abnormal Dreams;Dyspnoea;Crying;Head  
 Discomfort;Screaming;Feeling Abnormal;Vulvovaginal Pruritus;Visual  
 Impairment;Headache;Dizziness;Fear Non-Serious Non-Serious  
 Female 01-AUG-2024 09-AUG-2024 Direct 32 YR 59.4  
 KG Fda-Ctu Consumer Not Specified  
 Metoprolol;Bupropion;Estrogens;Tylenol;Buspirone;Zofran;Herbals\Mitragynine;Amitriptyline;Ibuprofen - 09-AUG-2024 Not Specified  
 Not Specified - - Yes  
 24167027 Adderall Amphetamine Aspartate\Amphetamine  
 Sulfate\Dextroamphetamine Saccharate\Dextroamphetamine  
 Sulfate;Herbals\Mitragynine Bone Pain;Humerus Fracture  
 Product Complaint;Drug Dependence;Cardiac Arrest;Toxicity To Various  
 Agents;Substance Use Serious Disabled;Died Male 23-JUN-2023  
 01-AUG-2024 Direct 33 YR Not Specified Fda-Ctu  
 Consumer Not Specified - - 01-AUG-2024 Not

Specified Not Specified - - -  
 24144944 - Lamotrigine;Zopiclone;7-Hydroxymitragynine;Citalopram;Herbals\Mitragynine Product Used  
 For Unknown Indication Pulmonary Congestion;Drug Interaction;Accidental Poisoning;Respiratory Depression;Toxicity To Various Agents Serious Other Outcomes;Died Male - 31-JUL-2024 Expedited Not Specified Not Specified  
 Ranbaxy Healthcare Professional Not Specified - 16-JUL-2024 29-JUL-2024 NO Not Specified NO-SUN PHARMACEUTICAL INDUSTRIES LTD-2014R1-90322 "Karin R, Fosen JT, Rogde S, Vindenes V. An accidental poisoning with mitragynine. Forensic Sci Int. 2014;245:e29-32" -

24152665 - Herbals\Mitragynine Post-Traumatic Stress Disorder Seizure;Substance Use;Post-Traumatic Stress Disorder Serious Died;Required Intervention;Hospitalized;Life Threatening;Disabled Male 18-APR-2024 29-JUL-2024 Direct 27 YR 99 KG Fda-Ctu Consumer Not Specified Benadryl;Gabapentin;Valium - 29-JUL-2024 Not Specified Not Specified - - Yes

23595917 - Hydromorphone Hydrochloride;Olanzapine;Herbals\Mitragynine Pain Overdose;Toxicity To Various Agents;Completed Suicide;Renal Impairment Serious Other Outcomes;Died Male - 25-JUL-2024 Expedited 44 YR Not Specified Pfizer Healthcare Professional Not Specified Zopiclone;Escitalopram 24-JUL-2024 05-MAR-2024 CA Not Specified CA-PFIZER INC-202400056465 - -

24129297 - Herbals\Mitragynine - Dysarthria;Eye Movement Disorder;Immobile;Drug Dependence;Tremor;Cluster Headache Serious Disabled;Other Outcomes Female 21-JUL-2024 23-JUL-2024 Direct 32 YR 71.21 KG Fda-Ctu Not Specified Not Specified - - 23-JUL-2024 Not Specified Not Specified - -

23806599 - Hydromorphone Hydrochloride;Olanzapine;Herbals\Mitragynine Pain;Product Used For Unknown Indication Completed Suicide;Toxicity To Various Agents;Renal Impairment;Renal Failure;Intentional Overdose;Overdose;Herbal Interaction Serious Died;Other Outcomes Male - 19-JUL-2024 Expedited 44 YR Not Specified Teva Healthcare Professional Not Specified Zopiclone;Escitalopram;Olanzapine 11-JUL-2024 02-MAY-2024 CA Not Specified CA-TEVA-VS-3191473 - -

24105852 - Diazepam;Herbals\Mitragynine;Cannabidiol;Etizolam;Methylphenidate Hydrochloride Product Used For Unknown Indication Toxicity To Various Agents;Accidental Overdose Serious Died Male 25-MAR-2024 17-JUL-2024 Expedited 28 YR Not Specified Johnson And Johnson Consumer Not Specified - 15-JUL-2024 17-JUL-2024 AU Not Specified AU- JNJFOC-20240737587 - -

24096419 - Herbals\Mitragynine Drug Dependence  
 Seizure Serious Other Outcomes;Hospitalized Male 26-SEP-2023  
 15-JUL-2024 Direct 49 YR 92.25 KG Fda-Ctu  
 Consumer Not Specified  
 Alprazolam;Trazodone;Ambien;Clonazepam;Tylenol;Olanzapine -  
 15-JUL-2024 Not Specified Y - - -  
 24088337 - Herbals\Mitragynine;Methamphetamine  
 Product Used For Unknown Indication Psychotic Disorder;Toxicity To  
 Various Agents;Drug Abuse Serious Other Outcomes;Hospitalized  
 Male - 15-JUL-2024 Non-Expedited 44 YR Not  
 Specified Dr Reddys Healthcare Professional Not Specified  
 - 02-JUL-2024 15-JUL-2024 US Not Specified  
 US-RDY-LIT/USA/24/0009991 "Sablaban IM, Gautam M. Kratom  
 and Stimulant Co-Addiction: A Case Series and Brief Review. Journal of  
 Addictive Diseases: The Official Journal of the ASAM, American Society  
 of Addiction Medicine. 2023 Jan;41(2): 181-184.  
 doi:10.1080/10550887.2022.2066459." -

24080776 Buspirone Buspirone  
 Hydrochloride;Herbals\Mitragynine - Death Serious Died  
 Male 18-MAR-2024 11-JUL-2024 Direct 27 YR Not  
 Specified Fda-Ctu Consumer Not Specified - -  
 11-JUL-2024 Not Specified Not Specified - - -

24064507 - Gabapentin;Herbals\Mitragynine Product Used  
 For Unknown Indication Treatment Noncompliance;Intentional Product  
 Misuse Serious Hospitalized Male - 09-JUL-2024  
 Expedited 44 YR Not Specified Mylan Healthcare  
 Professional Not Specified Methamphetamine 02-JUL-2024 09-  
 JUL-2024 US Not Specified US-MYLANLABS-2024M1063114  
 "Sablaban IM, Gautam M. Kratom & Stimulant Co-Addiction: A  
 Case Series and Brief Review. [Review]. J-Addict-Dis 2023; 41 (2):  
 181-184." -

24058768 - Buprenorphine;Herbals\Mitragynine  
 Product Used For Unknown Indication Drug Withdrawal Syndrome  
 Neonatal;Foetal Exposure During Pregnancy Serious Other Outcomes  
 Male - 08-JUL-2024 Non-Expedited Not Specified  
 Not Specified Aveva Healthcare Professional Not Specified  
 - 11-JUN-2024 08-JUL-2024 US Not Specified  
 US-AVEVA-000680 "Spungen HH, Mody K, Micetic B, Wade C, Kang  
 AM. Neonatal and Maternal Ichthyosiform Dermopathy in Association with  
 Kava Use during Pregnancy. J Med Toxicol. 2024, doi: 10.1007/  
 s13181-024-01016-x. PMID: 38839731." -

24062150 - Herbals\Mitragynine Substance Use Drug  
 Dependence Serious Other Outcomes Male 07-JUL-2024 07-  
 JUL-2024 Direct 54 YR 117 KG Fda-Ctu Consumer Not  
 Specified - - 07-JUL-2024 Not Specified Not  
 Specified - - -

22645484 - Clonazepam;Herbals\Mitragynine Product Used  
 For Unknown Indication Lethargy;Unresponsive To Stimuli  
 Serious Other Outcomes Male - 04-JUL-2024 Expedited

60 YR Not Specified Ranbaxy Healthcare Professional Not Specified - 19-JUN-2024 27-JUN-2023 US Not Specified US-SUN PHARMACEUTICAL INDUSTRIES LTD-2023R1-396275 "Palungwachira P, Yeh M, Whitworth B, Rushton W, Kazzi Z. Clinical Characteristics of Kratom Exposures Reported to the Georgia and Alabama Poison Control Centers from 2016–2020: A Retrospective Review. J Drug Alcohol Res. 2022;11(2):236162" -

24046897 - Herbals\Mitragynine Pain Malaise Serious Other Outcomes Female 20-JUN-2024 01-JUL-2024 Direct 21 YR 54 KG Fda-Ctu Consumer Not Specified - - 01-JUL-2024 Not Specified Y - - -

-

24010094 - Buprenorphine;Herbals\Mitragynine - Maternal Exposure During Pregnancy;Ichthyosis Acquired Serious Other Outcomes Female - 27-JUN-2024 Expedited 41 YR Not Specified Pfizer Healthcare Professional Not Specified - 19-JUN-2024 25-JUN-2024 US Not Specified US-PFIZER INC-PV202400080758 "Spungen, H.. Neonatal and Maternal Ichthyosiform Dermopathy in Association with Kava Use during Pregnancy.. Journal of Medical Toxicology. 2024;1-6" -

23999116 - Herbals\Mitragynine;Buprenorphine Ichthyosis Maternal Exposure During Pregnancy;Neonatal Seizure;Drug Withdrawal Syndrome Neonatal;Exposure Via Breast Milk Serious Hospitalized;Other Outcomes Male - 26-JUN-2024 Expedited Not Specified Not Specified Pfizer Healthcare Professional Not Specified - 19-JUN-2024 21-JUN-2024 US Not Specified US-PFIZER INC-202400196811 "Spungen, H.. Neonatal and Maternal Ichthyosiform Dermopathy in Association with Kava Use during Pregnancy. Journal of Medical Toxicology. 2024;1-6" -

23995850 - Herbals\Mitragynine Analgesic Therapy Hallucination;Blood Thyroid Stimulating Hormone Abnormal;Anger;Psychotic Disorder Serious Other Outcomes Female - 19-JUN-2024 Direct 40 YR 47.7 KG Fda-Ctu Consumer Not Specified - - 19-JUN-2024 Not Specified Not Specified - -

23984408 Suboxone;Valium Diazepam;Herbals\Mitragynine;Etizolam;Buprenorphine Hydrochloride\Naloxone Hydrochloride;Carisoprodol;Meprobamate;Caffeine Product Used For Unknown Indication Dysphonia;Disorientation;Slow Speech;Road Traffic Accident;Fall;Toxicity To Various Agents;Balance Disorder;Nystagmus Serious Other Outcomes Male - 18-JUN-2024 Expedited 26 YR Not Specified Arbor Healthcare Professional Not Specified - 06-JUN-2024 18-JUN-2024 US Not Specified "US-AZURITY PHARMACEUTICALS, INC.-US-2024AZR000722" "Papsun D.M., Chan-Hosokawa A., Lamb M.E., Logan B.. Increasing prevalence of designer benzodiazepines in impaired driving: a 5-year analysis from 2017 to 2021. J. Anal. Toxicol.. 2023;47:8:668 - 679" -

23982168 Sertraline Sertraline Hydrochloride;Bupropion Hydrochloride;Herbals\Mitragynine Antidepressant Therapy;Product Used For Unknown Indication Drug Interaction;Serotonin Syndrome Serious Other Outcomes;Hospitalized;Life Threatening Male - 17-JUN-2024 Expedited 28 YR Not Specified Epic Pharm Healthcare Professional Not Specified - 03-JUN-2024 17-JUN-2024 US Not Specified US-EPICPHARMA-US-2024EPCLIT00717 Marissa Saber.SEROTONIN SYNDROME DUE TO KRATOM AND ANTIDEPRESSANT INTERACTION: A CASE STUDY.Critical Care Medicine.JAN-2024;52:S642 -

23967333 - Bupropion;Sertraline Hydrochloride;Herbals\Mitragynine Antidepressant Therapy Serotonin Syndrome;Drug Interaction Serious Other Outcomes;Hospitalized;Life Threatening Male - 12-JUN-2024 Expedited 28 YR Not Specified Aci Healthcare Healthcare Professional Not Specified - 31-MAY-2024 12-JUN-2024 US Not Specified US-ACI HealthCare Limited-2158055 Source document (Full text) -

23964527 - Bupropion Hydrochloride;Herbals\Mitragynine;Sertraline Hydrochloride Antidepressant Therapy;Product Used For Unknown Indication Drug Interaction;Serotonin Syndrome Serious Life Threatening;Hospitalized;Other Outcomes Male - 12-JUN-2024 Expedited 28 YR Not Specified Granules India Healthcare Professional Not Specified - 29-MAY-2024 12-JUN-2024 US Not Specified US-GRANULES-US-2024GRALIT00212 Marissa Saber.SEROTONIN SYNDROME DUE TO KRATOM AND ANTIDEPRESSANT INTERACTION: A CASE STUDY..Critical Care Medicine.JAN-2024;52:S642 -

23945485 - Herbals\Mitragynine - Toxicity To Various Agents;Palpitations;Accidental Death Serious Died Not Specified 06-FEB-2024 05-JUN-2024 Direct 25 YR 78.75 KG Fda-Ctu Consumer Not Specified Not Specified - - 05-JUN-2024 Not Specified Not Specified - - -

23931703 Sertraline Sertraline Hydrochloride;Bupropion;Herbals\Mitragynine Antidepressant Therapy;Product Used For Unknown Indication Drug Interaction;Serotonin Syndrome Serious Hospitalized;Other Outcomes Male - 03-JUN-2024 Expedited 28 YR Not Specified Unknown Manufacturer Healthcare Professional Not Specified - 21-MAY-2024 03-JUN-2024 US Not Specified US-862174955-ML2024-03211 "Saber M, Zichichi A, Ammar M. SEROTONIN SYNDROME DUE TO KRATOM AND ANTIDEPRESSANT INTERACTION: A CASE STUDY. Critical Care Medicine. 2024 Jan; 52(Suppl 1): S642; abstract 1342." -

23931677 Sertraline Sertraline Hydrochloride;Bupropion Hydrochloride;Herbals\Mitragynine Product Used For Unknown Indication Seizure;Clonic Convulsion;Condition Aggravated;Tremor;Hyperreflexia;Vomiting;Headache;Agitation;Clonus;Drug Interaction;Serotonin Syndrome Serious Hospitalized;Other

Outcomes Not Specified - 03-JUN-2024 Expedited  
Not Specified Not Specified Alembic Healthcare  
Professional Not Specified - 20-MAY-2024 03-JUN-2024  
US Not Specified US-ALEMBIC PHARMACEUTICALS  
LIMITED-2024SCAL000709 "Saber M, Zichichi A, Ammar M. SEROTONIN  
SYNDROME DUE TO KRATOM AND ANTIDEPRESSANT INTERACTION: A CASE STUDY.  
Critical Care Medicine. 2024;52 (1):S642" -  
23926685 Sertraline Sertraline  
Hydrochloride;Herbals\Mitragynine;Bupropion Hydrochloride  
Antidepressant Therapy;Product Used For Unknown Indication  
Serotonin Syndrome;Herbal Interaction;Drug Interaction Serious Life  
Threatening;Hospitalized Male - 31-MAY-2024  
Expedited 28 YR Not Specified Hetero Healthcare  
Professional Not Specified - 20-MAY-2024 31-MAY-2024  
US Not Specified US-HETERO-HET2024US01561 "Saber  
M, Zichichi A, Ammar M.. SEROTONIN SYNDROME DUE TO KRATOM AND  
ANTIDEPRESSANT INTERACTION: A CASE STUDY. Critical Care Medicine.  
2024;52(1):S642" -  
23921757 Sertraline;Forfivo Xl Bupropion  
Hydrochloride;Sertraline Hydrochloride;Herbals\Mitragynine  
Product Used For Unknown Indication Drug Interaction;Serotonin  
Syndrome Serious Other Outcomes;Hospitalized;Life Threatening  
Not Specified - 30-MAY-2024 Expedited Not  
Specified Not Specified Twi Pharmaceuticals Healthcare  
Professional Not Specified - 20-MAY-2024 30-MAY-2024  
US Not Specified "US-TWI PHARMACEUTICAL,  
INC-2024SCTW000103" Saber M.; Zichichi A.; Ammar M.. SEROTONIN  
SYNDROME DUE TO KRATOM AND ANTIDEPRESSANT INTERACTION: A CASE STUDY.  
Crit. Care Med.. 2024;52:1 (S1):S642 -  
23919359 - Herbals\Mitragynine - Substance  
Use;Illness Serious Other Outcomes Male 12-MAY-2024 30-  
MAY-2024 Direct 50 YR 68.04 KG Fda-Ctu Not Specified  
Not Specified - - 30-MAY-2024 Not Specified  
Y - - -  
23918568 Sertraline Sertraline  
Hydrochloride;Herbals\Mitragynine;Bupropion Hydrochloride  
Antidepressant Therapy;Product Used For Unknown Indication  
Serotonin Syndrome;Drug Interaction;Herbal Interaction Serious Other  
Outcomes;Hospitalized Male - 30-MAY-2024 Expedited  
28 YR Not Specified Lupin Healthcare Professional Not  
Specified - 15-MAY-2024 30-MAY-2024 US Not  
Specified US-LUPIN HEALTHCARE (UK) LIMITED-2024-04254 "Saber  
M, Zichichi A, Ammar M. Serotonin syndrome due to kratom and  
antidepressant interaction: A case study. Critical care medicine.  
2024;52 (1):S642 abstr. 1342" -  
23906326 Nucynta Tapentadol  
Hydrochloride;Herbals\Mitragynine;Clonazepam;Carisoprodol;Pregabalin  
Product Used For Unknown Indication Toxicity To Various  
Agents Serious Died Female 23-APR-2021 28-MAY-2024  
Expedited 44 YR Not Specified Collegium Pharmaceutical

Healthcare Professional Not Specified Citalopram  
Hydrobromide 16-MAY-2024 28-MAY-2024 AU Not Specified  
"AU-COLLEGIUM PHARMACEUTICAL, INC.-20230900738" - -  
22636891 - Herbals\Mitragynine;Quetiapine Product Used  
For Unknown Indication Seizure Serious Other Outcomes Male -  
28-MAY-2024 Expedited 48 YR Not Specified  
Ranbaxy Healthcare Professional Not Specified - 13-MAY-2024  
26-JUN-2023 US Not Specified US-SUN PHARMACEUTICAL  
INDUSTRIES LTD-2023R1-396280 "Palungwachira P, Yeh M, Whitworth B,  
Rushton W, Kazzi Z. Clinical Characteristics of Kratom Exposures  
Reported to the Georgia and Alabama Poison Control Centers from  
2016-2020: A Retrospective Review. J Drug Alcohol Res.  
2022;11(2):236162" -  
23896959 - Herbals\Mitragynine -  
Colostomy;Diverticulitis;Product Residue Present;Pain Serious  
Disabled;Required Intervention;Other Outcomes;Hospitalized;Life  
Threatening Male 20-MAY-2024 24-MAY-2024 Direct 55 YR  
69.75 KG Fda-Ctu Consumer Not Specified -  
- 24-MAY-2024 Not Specified Not Specified -  
- -  
23896572 Sertraline Sertraline  
Hydrochloride;Bupropion;Herbals\Mitragynine Product Used For  
Unknown Indication Serotonin Syndrome;Drug Interaction  
Serious Other Outcomes;Hospitalized Male - 24-MAY-2024  
Expedited 28 YR Not Specified Apotex Healthcare  
Professional Not Specified - 15-MAY-2024 24-MAY-2024  
US Not Specified US-APOTEX-2024AP006141 "Saber M,  
Zichichi A, Ammar M. SEROTONIN SYNDROME DUE TO KRATOM AND  
ANTIDEPRESSANT INTERACTION: A CASE STUDY. Critical Care Medicine.  
2024;52 (Suppl 1):S642" -  
23890762 - Herbals\Mitragynine Substance Use Drug  
Abuse;Drug Dependence;Alcohol Abuse;Euphoric Mood Serious Other  
Outcomes;Hospitalized;Required Intervention Female - 23-  
MAY-2024 Direct Not Specified 60.75 KG Fda-Ctu  
Consumer Not Specified - - 23-MAY-2024 Not  
Specified Not Specified - - -  
23889816 - Sertraline Hydrochloride;Herbals\Mitragynine  
Anxiety;Depression Drug Interaction;Electrocardiogram Qt  
Prolonged Serious Other Outcomes;Hospitalized Female -  
23-MAY-2024 Expedited 17 YR Not Specified Aci  
Healthcare Healthcare Professional Not Specified - 10-  
MAY-2024 23-MAY-2024 US Not Specified US-ACI  
HealthCare Limited-2157339 Source document (Full text) -  
23886708 Sertraline Sertraline Hydrochloride;Bupropion  
Hydrochloride;Herbals\Mitragynine - Serotonin Syndrome  
Serious Hospitalized Male - 22-MAY-2024  
Expedited 28 YR Not Specified Princeton Pharmaceutical  
Healthcare Professional Not Specified - 15-MAY-2024 22-  
MAY-2024 US Not Specified US-PRINSTON PHARMACEUTICAL  
INC.-2024PRN00216 "Saber M, Zichichi A, Ammar M.. SEROTONIN

SYNDROME DUE TO KRATOM AND ANTIDEPRESSANT INTERACTION: A CASE STUDY.  
Critical Care Medicine. 2024;52(1):S642" -  
23861841 Sertraline Sertraline  
Hydrochloride;Bupropion;Herbals\Mitragynine Product Used For  
Unknown Indication;Tobacco User Serotonin Syndrome;Condition  
Aggravated;Clonus;Headache;Agitation;Sneezing;Seizure;Vomiting  
Serious Hospitalized;Other Outcomes Not Specified - 16-  
MAY-2024 Expedited Not Specified Not Specified  
Glaxosmithkline Healthcare Professional Not Specified - 13-  
MAY-2024 16-MAY-2024 US Not Specified US-GSK-  
US2024GSK060080 "Saber M, Zichichi A, Ammar M. Serotonin Syndrome Due  
To Kratom And Antidepressant Interaction: A Case Study. Critical Care  
Medicine. 2024;52 (1):S642" -  
23860811 Sertraline Sertraline  
Hydrochloride;Herbals\Mitragynine;Bupropion Agitation;Product Used  
For Unknown Indication Drug Interaction;Serotonin Syndrome  
Serious Life Threatening;Hospitalized;Other Outcomes Male -  
16-MAY-2024 Expedited 28 YR Not Specified Sandoz  
Healthcare Professional Not Specified  
Propofol;Ketamine;Droperidol 13-MAY-2024 16-MAY-2024 US  
Not Specified US-SANDOZ INC.-SDZ2024US048440 "Saber M.,  
Zichichi A., Ammar M. SEROTONIN SYNDROME DUE TO KRATOM AND  
ANTIDEPRESSANT. Y. Critical Care Medicine. 2024;52:1" -  
23858710 - Sertraline Hydrochloride;Herbals\Mitragynine  
Anxiety;Depression;Product Used For Unknown Indication Drug  
Interaction;Electrocardiogram Qt Prolonged Serious Other  
Outcomes;Hospitalized Female - 15-MAY-2024 Expedited  
17 YR Not Specified Granules India Healthcare  
Professional Not Specified - 02-MAY-2024 15-MAY-2024  
US Not Specified US-GRANULES-US-2024GRALIT00158 N  
Truesdale.QTc prolongation related to kratom ingestion with underlying  
SSRI usage.American Journal of the Medical Sciences.FEB-2024;367  
(Suppl. 1):S284 abstr -  
23851778 - Sertraline Hydrochloride;Herbals\Mitragynine  
Anxiety;Depression;Product Used For Unknown Indication Herbal  
Interaction;Electrocardiogram Qt Prolonged Serious Other  
Outcomes;Hospitalized Female - 14-MAY-2024 Expedited  
17 YR Not Specified Sciegen Healthcare Professional Not  
Specified - 02-MAY-2024 14-MAY-2024 US Not  
Specified US-SCIEGENP-2024SCLIT00279 "Truesdale N, et  
al.QTc prolongation related to kratom ingestion with underlying SSRI  
usage.American Journal of the Medical Sciences.feb-2024;367 (1):S284"  
-  
23853681 - Herbals\Mitragynine Anxiety;Insomnia  
Drug Withdrawal Syndrome;Substance Use Serious Other Outcomes  
Female 22-APR-2024 13-MAY-2024 Direct 68 YR 72 KG  
Fda-Ctu Consumer Not Specified Fish Oil -  
13-MAY-2024 Not Specified Not Specified - -  
-  
23847716 - Herbals\Mitragynine Product Used For

Unknown Indication Drug Withdrawal Syndrome;Stupor;Central  
 Nervous System Stimulation;Dizziness;Nausea Serious Other  
 Outcomes;Required Intervention;Disabled Male 01-MAY-2024 10-  
 MAY-2024 Direct 32 YR 60.75 KG Fda-Ctu Consumer  
 Not Specified - - 10-MAY-2024 Not Specified  
 Y - - -

23831491 - Herbals\Mitragynine Anxiety;Pain  
 Aggression;Drug Dependence;Diarrhoea;Pyrexia;Partner  
 Stress;Somnolence;Withdrawal  
 Syndrome;Vomiting;Myalgia;Pain;Irritability Serious Other Outcomes  
 Male 07-MAY-2024 07-MAY-2024 Direct 42 YR 78.75  
 KG Fda-Ctu Consumer Not Specified - - 07-  
 MAY-2024 Not Specified Not Specified - - Yes

23831162 - Herbals;Herbals\Mitragynine Depression  
 Temperature Regulation Disorder;Malaise;Weight  
 Decreased;Physical Product Label Issue;Skin Discolouration;Substance  
 Use;Depression;Dependence;Restlessness;Nausea;Therapy  
 Cessation;Alopecia;Insomnia;Drug Dependence;Withdrawal Syndrome  
 Serious Required Intervention;Other Outcomes Female 02-MAY-2024  
 07-MAY-2024 Direct 27 YR 58.5 KG Fda-Ctu Consumer  
 Not Specified Vitamin D;Magnesium Citrate;Melatonin;Vitamin  
 B12;Homeopathics;Tyrosine - 07-MAY-2024 Not Specified  
 Not Specified - - -

23821555 - Herbals\Mitragynine Anxiety;Insomnia  
 Drug-Induced Liver Injury Serious Hospitalized Male  
 24-APR-2024 05-MAY-2024 Direct 63 YR 74.25 KG  
 Fda-Ctu Consumer Not Specified Cannabis Sativa Subsp.  
 Indica Top - 05-MAY-2024 Not Specified Y -  
 - -

23820739 - Herbals\Mitragynine Depression Death  
 Serious Died Male - 04-MAY-2024 Direct 37 YR  
 Not Specified Fda-Ctu Consumer Not Specified -  
 - 04-MAY-2024 Not Specified Not Specified -  
 - -

23806729 Sertraline Sertraline  
 Hydrochloride;Herbals\Mitragynine  
 Anxiety;Depression;Phytotherapy Electrocardiogram Qt Prolonged;Drug  
 Interaction Serious Hospitalized;Other Outcomes Female -  
 02-MAY-2024 Expedited 17 YR Not Specified Lupin  
 Healthcare Professional Not Specified - 18-APR-2024  
 02-MAY-2024 US Not Specified US-LUPIN HEALTHCARE  
 (UK) LIMITED-2024-03502 "Truesdale N, Kaliki V, Fuller KE, Nathani Y.  
 QTc prolongation related to Kratom ingestion with underlying SSRI  
 usage. The American Journal of the Medical Sciences.  
 2024;367(S1):S284" -

23705204 Spravato  
 Esketamine;Herbals\Mitragynine;Hydrocodone;Baclofen  
 Depression;Product Used For Unknown Indication  
 Dizziness;Nausea;Vomiting Serious Other Outcomes Male 15-  
 MAR-2024 29-APR-2024 Expedited 30 YR 68.1 KG

Johnson And Johnson Healthcare Professional Not Specified -  
 18-APR-2024 04-APR-2024 US Not Specified US-  
 JNJFOC-20240382704 - -  
 23798731 - Herbals\Mitragynine Product Used For  
 Unknown Indication Therapy Cessation;Delirium;Mental Status  
 Changes;Sleep Deficit;Psychotic Disorder;Pain;Seizure Serious  
 Hospitalized;Life Threatening;Disabled;Other Outcomes Female 25-  
 JAN-2024 27-APR-2024 Direct 81 YR 48.15 KG Fda-  
 Ct Consumer Not Specified - - 27-APR-2024  
 tu Not Specified Not Specified - - -  
 23782989 Sertraline Sertraline  
 Hydrochloride;Herbals\Mitragynine  
 Anxiety;Depression;Phytotherapy Electrocardiogram Qt Prolonged;Drug  
 Interaction Serious Hospitalized Female - 25-APR-2024  
 Expedited 17 YR Not Specified Mylan Healthcare  
 Professional Not Specified - 18-APR-2024 25-APR-2024  
 US Not Specified US-  
 MYLANLABS-2024M1037072 "Truesdale N, Kaliki V, Fuller KE, Nathani Y.  
 QTc prolongation related to kratom ingestion with underlying SSRI  
 usage. Am-J-Med-Sci 2024; 367 (Suppl. 1) S284 abstr. 472." -  
 21146383 Buspirone;Trazodone Trazodone  
 Hydrochloride;Herbals\Mitragynine;Buspirone  
 Hydrochloride;Desvenlafaxine;Ziprasidone;Gabapentin;Bupropion  
 Depression;Neuropathy Peripheral;Product Used For Unknown Indication  
 Serotonin Syndrome Serious Other Outcomes;Hospitalized  
 Male 04-NOV-2018 25-APR-2024 Expedited 63 YR  
 102.5 KG Ranbaxy Healthcare Professional Not Specified  
 Hydrochlorothiazide;Amlodipine;Omeprazole;Glimepiride;Metformin;Diclof  
 enac;Tizanidine 10-APR-2024 29-JUL-2022 US Not Specified  
 US-SUN PHARMACEUTICAL INDUSTRIES  
 LTD-2022R1-346730 "Eudaley ST, Brooks SP, Hamilton LA. Case  
 Report: Possible Serotonin Syndrome in a Patient Taking Kratom and  
 Multiple Serotonergic Agents. J Pharm Pract. 2023;36(6):1523-1527"  
 -  
 23778259 Paxlovid  
 Nirmatrelvir\Ritonavir;Herbals\Mitragynine;Quetiapine Bipolar  
 Disorder;Covid-19;Hypertension;Menopausal Symptoms Drug  
 Interaction;Serotonin Syndrome Serious Hospitalized;Other Outcomes  
 Female - 24-APR-2024 Expedited 55 YR Not  
 Specified Sciegen Healthcare Professional Not Specified  
 Metoprolol 10-APR-2024 24-APR-2024 IL Not Specified  
 IL-SCIEGENP-2024SCLIT00244 "Albert R, et al. Serotonin  
 Syndrome in COVID-19: Polypharmacy with Paxlovid and Kratom. Journal of  
 the Academy of Consultation-Liaison Psychiatry .dec-2023;146:S72"  
 -  
 23768093 - Herbals\Mitragynine - Suicidal  
 Ideation;Product Advertising Issue;Dry Skin;Muscular Weakness;Drug  
 Dependence;Drug Tolerance;Alopecia Serious Other  
 Outcomes;Required Intervention Female 01-NOV-2023 19-APR-2024

Direct 37 YR 65.25 KG Fda-Ctu Consumer Not  
 Specified - - 19-APR-2024 Not Specified Not  
 Specified - - -  
 23768089 - Herbals\Mitragynine - Drug  
 Dependence;Withdrawal Syndrome;Product Advertising Issue  
 Serious Disabled;Other Outcomes Male 15-APR-2024 19-APR-2024  
 Direct 24 YR 67.5 KG Fda-Ctu Consumer Not Specified  
 - - 19-APR-2024 Not Specified Not Specified  
 - - -  
 23768069 - Herbals\Mitragynine Substance Use Drug  
 Dependence;Product Advertising Issue Serious Required Intervention  
 Female 01-APR-2024 19-APR-2024 Direct 30 YR 51.75  
 KG Fda-Ctu Consumer Not Specified - - 19-  
 APR-2024 Not Specified Not Specified - - -  
 23768067 - Herbals\Mitragynine Drug Dependence Weight  
 Decreased;Drug Dependence;Mental Impairment;Skin Disorder;Liver  
 Injury;Product Formulation Issue Serious Other Outcomes Female  
 16-APR-2024 19-APR-2024 Direct 37 YR 67.5 KG Fda-  
 Ctu Consumer Not Specified - - 19-APR-2024  
 Not Specified Not Specified - - -  
 23578072 Paxlovid  
 Quetiapine;Nirmatrelvir\Ritonavir;Herbals\Mitragynine  
 Covid-19;Menopausal Symptoms;Phytotherapy;Product Used For Unknown  
 Indication Herbal Interaction;Drug Interaction;Serotonin Syndrome  
 Serious Other Outcomes Female - 18-APR-2024  
 Expedited 55 YR Not Specified Aurobindo Healthcare  
 Professional Not Specified Metoprolol 03-APR-2024 29-  
 FEB-2024 US Not Specified US-AUROBINDO-AUR-  
 APL-2024-008192 "Albert R, Quraishi S, Ashley K.. Serotonin Syndrome  
 in COVID-19: Polypharmacy with Paxlovid and Kratom. Journal of the  
 Academy of Consultation-Liaison Psychiatry. 2024;64(Supplement):S72"  
 -  
 23523065 Paxlovid  
 Herbals\Mitragynine;Nirmatrelvir\Ritonavir;Quetiapine Bipolar  
 Disorder;Covid-19 Treatment;Hypertension;Menopausal Symptoms  
 Serotonin Syndrome;Drug Interaction Serious Other Outcomes Female  
 - 18-APR-2024 Expedited 55 YR Not Specified  
 Pfizer Healthcare Professional Not Specified Metoprolol  
 13-APR-2024 14-FEB-2024 US Not Specified US-  
 PFIZER INC-PV202400020037 "Albert, R.. Serotonin Syndrome in  
 COVID-19: Polypharmacy with Paxlovid and Kratom. Journal of the  
 Academy of Consultation-Liaison Psychiatry. 2023;64:S:S72" -  
 23744032 - Herbals\Mitragynine Product Used For  
 Unknown Indication Drug Dependence;Withdrawal Syndrome Non-  
 Serious Non-Serious Female 28-FEB-2024 14-APR-2024 Direct  
 24 YR 58.5 KG Fda-Ctu Healthcare Professional Not Specified  
 - - 14-APR-2024 Not Specified Not Specified  
 - - -  
 23731047 -  
 Parafluorofentanyl;Fentanyl;Herbals\Mitragynine;Despropionylfentanyl;Q

uinine Drug Abuse Cardiac Arrest;Drug Abuse;Prescription Drug Used Without A Prescription;Respiratory Arrest Serious Other Outcomes;Died Male - 11-APR-2024 Expedited 35 YR Not Specified Alvogen Healthcare Professional Not Specified - 27-MAR-2024 11-APR-2024 US Not Specified US-ALVOGEN-2024093540 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Pham NPT, Bronstein AC, DesLauriers C. 2022 Annual Report of the National Poison Data System (NPDS) from America's Poison Centers: 40th Annual Report. Clinical Toxicology. 2023 Dec 12;61 (10):717-939. doi:<https://doi.org/10.1080/15563650.2023.2268981>" -  
23730826 -  
Citalopram;Pseudoephedrine;Phenylpropanolamine;Herbals\Mitragynine;Dextromethorphan;Bupropion Suicide Attempt Completed Suicide;Respiratory Arrest;Cardiac Arrest Serious Died;Other Outcomes Male - 11-APR-2024 Expedited 39 YR Not Specified Alvogen Healthcare Professional Not Specified - 27-MAR-2024 11-APR-2024 US Not Specified US-ALVOGEN-2024093588 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Pham NPT, Bronstein AC, DesLauriers C. 2022 Annual Report of the National Poison Data System (NPDS) from America's Poison Centers: 40th Annual Report. Clinical Toxicology. 2023 Dec 12;61 (10):717-939. doi:<https://doi.org/10.1080/15563650.2023.2268981>" -  
23718715 - Herbals\Mitragynine - Emotional Distress;Nausea;Tremor;Vomiting;Tachycardia;Abdominal Pain Upper Non-Serious Non-Serious Female 05-APR-2024 07-APR-2024 Direct 21 YR 56.25 KG Fda-Ctu Consumer Not Specified Coenzyme Q10;Gabapentin;Fish Oil;Corlanor;Clarinex;Prozac - 07-APR-2024 Not Specified Not Specified - -  
23718104 Synthroid Levothyroxine Sodium;Herbals\Mitragynine Back Pain Substance Use;Chromaturia;Faeces Discoloured Non-Serious Non-Serious Female 24-APR-2023 06-APR-2024 Direct 46 YR 65.25 KG Fda-Ctu Consumer Not Specified Synthroid - 06-APR-2024 Not Specified Not Specified - -  
23699715 Vivitrol Naltrexone;Herbals\Mitragynine Alcoholism;Pain In Extremity;Product Used For Unknown Indication Substance Use Non-Serious Non-Serious Male - 03-APR-2024 Non-Expedited Not Specified Not Specified Alkermes Healthcare Professional Not Specified Trazodone;Fluoxetine 20-MAR-2024 03-APR-2024 US Not Specified US-ALKERMES INC.-ALK-2024-000792 - -  
23459072 Fluoxetine Fluoxetine Hydrochloride;Herbals\Mitragynine;Fentanyl;Bupropion Hydrochloride Pain;Product Used For Unknown Indication Serotonin Syndrome;Drug Interaction Serious Other Outcomes Male - 02-APR-2024 Non-Expedited 68 YR Not Specified

Graviti Pharmaceuticals Healthcare Professional Not Specified -  
21-MAR-2024 31-JAN-2024 US Not Specified US-  
GRAVITIPHARMA-GRA-2401-US-LIT-0008 "Grundmann O, Hendrickson RG,  
Greenberg MI.Kratom: History, pharmacology, current user trends,  
adverse health effects and potential benefits.Dis-Mon.2023;69:6"

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23693637 - Herbals\Mitragynine Anxiety "Mental  
Disorder;Legal Problem;Illogical Thinking;Hallucination, Auditory"  
Non-Serious Non-Serious Female 04-DEC-2023 31-  
MAR-2024 Direct 35 YR 74.25 KG Fda-Ctu Consumer  
Not Specified Herbals\Mitragynine - 31-MAR-2024  
Not Specified Not Specified - - -

23668375 - Herbals\Mitragynine Anxiety;Self-  
Medication;Stress Vomiting;Anger;Psychotic Disorder;Sleep  
Disorder;Drug Dependence;Adverse Event Serious Required  
Intervention;Other Outcomes Male 20-MAR-2024 23-MAR-2024  
Direct 22 YR 72 KG Fda-Ctu Consumer Not Specified  
- - 23-MAR-2024 Not Specified Not Specified  
- - -

23616995 Paxlovid  
Nirmatrelvir\Ritonavir;Herbals\Mitragynine;Quetiapine Bipolar  
Disorder;Covid-19;Hypertension;Menopausal Symptoms Drug  
Interaction;Serotonin Syndrome Serious Hospitalized Female -  
21-MAR-2024 Expedited 55 YR Not Specified Teva  
Healthcare Professional Not Specified Metoprolol 13-  
MAR-2024 11-MAR-2024 US Not Specified US-TEVA-  
VS-3164786 "Albert R, Quraishi S, Ashley K. (146) Serotonin  
Syndrome in COVID-19: Polypharmacy with Paxlovid and Kratom. J-Acad-  
Consult-Liaison-Psychiatry 2023; 64 (Suppl.) S72 abstr. 146.; Albert  
R, Quraishi S, Ashley K. (146) Serotonin Syndrome in COVID-19:  
Polypharmacy with Paxlovid and Kratom. J-Acad-Consult-Liaison-  
Psychiatry 2023; 64 (Suppl.) S72 abstr. 146." -

23647254 - Herbals\Mitragynine Asthenia  
Pyrexia;Pruritus;Skin Exfoliation;Flushing;Chills;Urticaria  
Serious Life Threatening;Other Outcomes Male 15-MAR-2024 18-  
MAR-2024 Direct 33 YR 104.85 KG Fda-Ctu Consumer  
Not Specified - - 18-MAR-2024 Not Specified  
Not Specified - - -

23637450 - Herbals\Mitragynine - Suspected  
Counterfeit Product;Manufacturing Product Shipping Issue;Manufacturing  
Facilities Issue Non-Serious Non-Serious Not Specified  
- 14-MAR-2024 Direct Not Specified Not Specified  
Fda-Ctu Not Specified Not Specified - - 14-  
MAR-2024 Not Specified Not Specified - - -

23617413 - Herbals\Mitragynine Spinal Fracture  
Tremor;Psychomotor Hyperactivity;Skin Burning  
Sensation;Headache;Insomnia;Drug Withdrawal Syndrome;Drug Dependence  
Serious Required Intervention;Other Outcomes;Hospitalized  
Female 20-NOV-2023 10-MAR-2024 Direct 33 YR 51.75  
KG Fda-Ctu Consumer Not Specified - - 10-

MAR-2024 Not Specified Not Specified - - -  
 23616935 - Herbals\Mitragynine - Muscle  
 Twitching;Anger;Drug Dependence;Mood Swings;Vomiting;Nausea Non-  
 Serious Non-Serious Male - 09-MAR-2024 Direct 47 YR  
 Not Specified Fda-Ctu Consumer Not Specified -  
 - 09-MAR-2024 Not Specified Not Specified -  
 - -  
 23415164 Methadone Methadone  
 Hydrochloride;Oxycodone;Buprenorphine\Naloxone;Herbals\Mitragynine  
 Anaesthesia;Anxiety;Pain;Procedural Pain  
 Palpitations;Intentional Product Misuse;Headache;Nausea;Chest  
 Discomfort;Drug Dependence Serious Hospitalized;Other Outcomes  
 Male - 07-MAR-2024 Expedited 42 YR Not  
 Specified Teva Healthcare Professional Not Specified  
 Bupivacaine;Alprazolam;Ketamine;Dexmedetomidine;Gabapentin;Hydromorphone;  
 Celecoxib;Ropivacaine;Ketorolac;Acetaminophen 23-FEB-2024  
 18-JAN-2024 US Not Specified US-TEVA-VS-3134597  
 Perez J. Kratom and opioid use disorder in the perioperative  
 period: A case report on the expanding role of buprenorphine. J-  
 Opioid-Manag 2023;19(1):91-93.; Perez J. Kratom and opioid use  
 disorder in the perioperative period: A case report on the expanding  
 role of buprenorphine. J-Opioid-Manag 2023;19(1):91-93. -  
 23600038 - Herbals\Mitragynine - Toxicity To  
 Various Agents;Vomiting;Diarrhoea;Abdominal Pain Upper Serious  
 Hospitalized Male 16-FEB-2024 05-MAR-2024 Direct 40 YR  
 90.72 KG Fda-Ctu Consumer Not Specified -  
 - 05-MAR-2024 Not Specified Not Specified -  
 - -  
 23595907 - Hydromorphone  
 Hydrochloride;Herbals\Mitragynine Pain Renal  
 Impairment;Overdose Serious Died;Other Outcomes Male -  
 05-MAR-2024 Expedited 44 YR Not Specified Pfizer  
 Healthcare Professional Not Specified  
 Olanzapine;Escitalopram Oxalate;Zopiclone 04-MAR-2024 05-  
 MAR-2024 CA Not Specified CA-PFIZER INC-202400056459  
 - -  
 23591918 - Herbals\Mitragynine - Seizure;Drug  
 Dependence;Toxicity To Various Agents;Overdose Serious Died Male  
 19-MAR-2022 02-MAR-2024 Direct 30 YR Not Specified  
 Fda-Ctu Consumer Not Specified - - 02-  
 MAR-2024 Not Specified Not Specified - - -  
 23586351 - Herbals\Mitragynine Pain  
 Hallucination;Psychotic Disorder;Seizure Serious  
 Hospitalized;Other Outcomes Male 09-FEB-2024 01-MAR-2024  
 Direct 48 YR 81 KG Fda-Ctu Consumer Not Specified  
 Suboxone;Keppra;Duloxetine;Prazosin - 01-MAR-2024  
 Not Specified Not Specified - - -  
 23585473 -  
 Nirmatrelvir;Herbals\Mitragynine;Ritonavir;Quetiapine  
 Covid-19;Menopausal Symptoms;Phytotherapy;Product Used For Unknown

Indication Serotonin Syndrome;Herbal Interaction;Drug Interaction  
Serious Other Outcomes Not Specified - 01-MAR-2024  
Expedited Not Specified Not Specified Hikma  
Healthcare Professional Not Specified Metoprolol 15-FEB-2024  
01-MAR-2024 US Not Specified US-HIKMA  
PHARMACEUTICALS USA INC.-US-H14001-24-01483 "Albert R, Quraishi S, Ashley K.. Albert R, Quraishi S, Ashley K. (146) Serotonin Syndrome in COVID-19: Polypharmacy with Paxlovid and Kratom.. Journal of the Academy of Consultation-Liaison Psychiatry.. 2024;64(Supplement):72"  
-  
23585410 - Herbals\Mitragynine - Toxicity To  
Various Agents Serious Died Male 29-NOV-2023 29-FEB-2024  
Direct 40 YR 77.4 KG Fda-Ctu Consumer Not Specified  
Benadryl;Zoloft - 29-FEB-2024 Not Specified Not  
Specified - - -  
23578412 - Quetiapine  
Fumarate;Herbals\Mitragynine;Ritonavir;Nirmatrelvir  
Covid-19;Menopausal Symptoms;Phytotherapy;Product Used For Unknown  
Indication Serotonin Syndrome;Herbal Interaction;Drug Interaction  
Serious Other Outcomes Female - 29-FEB-2024  
Expedited 55 YR Not Specified Jubilant Healthcare  
Professional Not Specified Metoprolol 15-FEB-2024 29-  
FEB-2024 US Not Specified US-JUBILANT CADISTA  
PHARMACEUTICALS-2024US000222 "Albert R, Quraishi S, Ashley K.  
Serotonin Syndrome in COVID-19: Polypharmacy with Paxlovid and  
Kratom.. Journal of the Academy of Consultation-Liaison Psychiatry..  
2024;64(Supplement):S72" -  
23543916 Paxlovid  
Nirmatrelvir\Ritonavir;Quetiapine;Metoprolol;Herbals\Mitragynine  
Covid-19;Menopausal Symptoms;Product Used For Unknown  
Indication Serotonin Syndrome Serious Other Outcomes Female  
- 29-FEB-2024 Expedited 55 YR Not Specified  
Sandoz Healthcare Professional Not Specified - 16-  
FEB-2024 20-FEB-2024 IL Not Specified IL-SANDOZ  
INC.-SDZ2024IL014961 "Albert R, Quraishi S, Ashley K.. Serotonin  
Syndrome in COVID-19: Polypharmacy with Paxlovid and Kratom. Journal  
of the Academy of Consultation- Liaison Psychiatry. 64:S72" -  
23569743 -  
Herbals\Mitragynine;Ritonavir;Nirmatrelvir;Quetiapine  
Covid-19;Menopausal Symptoms;Phytotherapy;Product Used For Unknown  
Indication Drug Interaction;Herbal Interaction;Serotonin Syndrome  
Serious Other Outcomes Not Specified - 27-FEB-2024  
Expedited Not Specified Not Specified Macleods  
Healthcare Professional Not Specified Metoprolol 15-  
FEB-2024 27-FEB-2024 US Not Specified US-MACLEODS  
PHARMACEUTICALS US LTD-MAC2024045997 "Albert R, Quraishi S, Ashley  
K.. (146) Serotonin Syndrome in COVID-19: Polypharmacy with Paxlovid  
and Kratom. Journal of the Academy of Consultation-Liaison Psychiatry.  
2024;64:S72." -  
23569619 -

Nirmatrelvir;Herbals\Mitragynine;Ritonavir;Quetiapine  
Covid-19;Menopausal Symptoms;Phytotherapy;Product Used For Unknown  
Indication Serotonin Syndrome;Herbal Interaction;Drug Interaction  
Serious Other Outcomes Female - 27-FEB-2024  
Expedited 55 YR Not Specified Accord Healthcare  
Professional Not Specified Metoprolol 15-FEB-2024 27-  
FEB-2024 US Not Specified US-  
Accord-408486 "Albert R, Quraishi S, Ashley K. (146) Serotonin  
Syndrome in COVID-19: Polypharmacy with Paxlovid and Kratom. Journal  
of the Academy of Consultation-Liaison Psychiatry.  
2024;64(Supplement):S72. DOI: 10.1016/j.jaclp.2023.11.616." -  
23566169 -

Nirmatrelvir;Herbals\Mitragynine;Ritonavir;Quetiapine  
Covid-19;Menopausal Symptoms;Phytotherapy;Product Used For Unknown  
Indication Drug Interaction;Herbal Interaction;Serotonin Syndrome  
Serious Other Outcomes Female - 26-FEB-2024  
Expedited 55 YR Not Specified Dr Reddys Healthcare  
Professional Not Specified Metoprolol 15-FEB-2024 26-  
FEB-2024 US Not Specified US-RDY-SP0/USA/24/0003104  
"Albert R, Quraishi S, Ashley K. (146) Serotonin Syndrome in  
COVID-19: Polypharmacy with Paxlovid and Kratom. Journal of the  
Academy of Consultation-Liaison Psychiatry. 2024;64(Supplement):S72.  
DOI: 10.1016/j.jaclp.2023.11.616." -

23563823 Paxlovid  
Nirmatrelvir\Ritonavir;Herbals\Mitragynine;Quetiapine Fumarate  
Covid-19;Menopausal Symptoms;Phytotherapy;Product Used For Unknown  
Indication Drug Interaction;Herbal Interaction;Serotonin Syndrome  
Serious Other Outcomes Female - 26-FEB-2024  
Expedited 55 YR Not Specified Lupin Healthcare  
Professional Not Specified Metoprolol 14-FEB-2024 26-  
FEB-2024 US Not Specified US-LUPIN PHARMACEUTICALS  
INC.-2024-01273 "Albert R, Quraishi S, Ashley K. Serotonin Syndrome in  
COVID-19: Polypharmacy with Paxlovid and Kratom. Journal of the  
Academy of Consultation-Liaison Psychiatry. 2023;64:S72" -  
23561779 Paxlovid

Nirmatrelvir\Ritonavir;Herbals\Mitragynine;Quetiapine  
Covid-19;Menopausal Symptoms Drug Interaction;Serotonin Syndrome  
Serious Other Outcomes Female - 25-FEB-2024  
Expedited 55 YR Not Specified Princeton Pharmaceutical  
Healthcare Professional Not Specified Metoprolol 14-FEB-2024  
25-FEB-2024 US Not Specified US-PRINSTON  
PHARMACEUTICAL INC.-2024PRN00081 "Albert R, Quraishi S, Ashley  
K. (146) Serotonin Syndrome in COVID-19: Polypharmacy with Paxlovid  
and Kratom. J. Acad. Consul. Liaison. Psychiatry. 2023;(64):S72"  
-

23557160 Paxlovid  
Nirmatrelvir\Ritonavir;Herbals\Mitragynine;Quetiapine Bipolar  
Disorder;Covid-19;Menopausal Symptoms;Product Used For Unknown  
Indication Drug Interaction;Serotonin Syndrome Serious  
Hospitalized;Other Outcomes Female - 23-FEB-2024

Expedited 55 YR Not Specified Unichem Healthcare  
 Professional Not Specified Metoprolol 09-FEB-2024 23-  
 FEB-2024 Not Specified Not Specified IL-Unichem  
 Pharmaceuticals (USA) Inc-UCM202402-000159 - -  
 23556123 - Quetiapine Fumarate;Herbals\Mitragynine  
 Bipolar Disorder;Menopausal Symptoms;Product Used For Unknown  
 Indication Serotonin Syndrome Serious Other Outcomes Female  
 - 22-FEB-2024 Expedited 55 YR Not Specified  
 Amneal Healthcare Professional Not Specified Metoprolol  
 13-FEB-2024 22-FEB-2024 IL Not Specified IL-  
 AMNEAL PHARMACEUTICALS-2024-AMRX-00591 "Albert R, Quraishi S, Ashley  
 K.. (146) Serotonin Syndrome in COVID-19: Polypharmacy with Paxlovid  
 and Kratom. J Acad Consult Liaison Psychiatry. 2023;64:S72" -  
 23552913 Paxlovid  
 Nirmatrelvir\Ritonavir;Quetiapine;Herbals\Mitragynine Bipolar  
 Disorder;Covid-19;Hypertension;Menopausal Symptoms Drug  
 Interaction;Serotonin Syndrome Serious Hospitalized Female -  
 22-FEB-2024 Expedited 55 YR Not Specified Mylan  
 Healthcare Professional Not Specified Metoprolol 14-  
 FEB-2024 22-FEB-2024 US Not Specified US-  
 MYLANLABS-2024M1016323 "Albert R, Quraishi S, Ashley K. (146)  
 Serotonin Syndrome in COVID-19: Polypharmacy with Paxlovid and Kratom.  
 J-Acad-Consult-Liaison-Psychiatry 2023; 64 (Suppl.) S72 abstr. 146."  
 -  
 23547485 - Herbals\Mitragynine;Fentanyl Product Used  
 For Unknown Indication Toxicity To Various Agents;Accidental Overdose  
 Serious Died Male - 21-FEB-2024 Expedited  
 Not Specified Not Specified Alvogen Healthcare  
 Professional Not Specified - 07-FEB-2024 21-FEB-2024  
 US Not Specified US-ALVOGEN-2024093073 "Torrico T,  
 Patel K, Nikolov N, Salam MT, Padhy R, Weinstein D. Presence of kratom  
 in opioid overdose deaths: findings from coroner postmortem  
 toxicological report. Front. Psychiatry. 2024 Jan 10;14:1332999:  
 doi:10.3389/fpsyg.2023.1332999" -  
 23547479 - Herbals\Mitragynine;Fentanyl Product Used  
 For Unknown Indication Toxicity To Various Agents;Accidental Overdose  
 Serious Died Male - 21-FEB-2024 Expedited  
 Not Specified Not Specified Alvogen Healthcare  
 Professional Not Specified Cannabis Sativa Subsp. Indica Top  
 07-FEB-2024 21-FEB-2024 US Not Specified US-  
 ALVOGEN-2024093074 "Torrico T, Patel K, Nikolov N, Salam MT,  
 Padhy R, Weinstein D. Presence of kratom in opioid overdose deaths:  
 findings from coroner postmortem toxicological report. Front.  
 Psychiatry. 2024 Jan 10;14:1332999: doi:doi: 10.3389/  
 fpsyg.2023.1332999" -  
 23547472 - Herbals\Mitragynine;Fentanyl Product Used  
 For Unknown Indication Accidental Overdose;Toxicity To Various Agents  
 Serious Died Male - 21-FEB-2024 Expedited  
 Not Specified Not Specified Alvogen Healthcare  
 Professional Not Specified - 07-FEB-2024 21-FEB-2024

US Not Specified US-ALVOGEN-2024093075 "Torrico T,  
Patel K, Nikolov N, Salam MT, Padhy R, Weinstein D. Presence of kratom  
in opioid overdose deaths: findings from coroner postmortem  
toxicological report. Frontiers in Psychiatry. 2024 Jan 10;14:  
1332999: doi:10.3389/fpsy.2023.1332999" -

23523373 Valtrex Valacyclovir Hydrochloride;Ranitidine  
Hydrochloride;Albuterol;Acetaminophen\Codeine  
Phosphate\Methocarbamol;Acetaminophen;Methocarbamol;Loratadine;Diphenh  
ydramine;Herbals\Mitragynine Product Used For Unknown Indication  
Foetal Exposure During Pregnancy;Drug Withdrawal Syndrome

Neonatal Serious Hospitalized;Other Outcomes Female -  
14-FEB-2024 Expedited Not Specified 3 KG

Fresenius Kabi Healthcare Professional Not Specified Citalopram  
05-FEB-2024 14-FEB-2024 CA Not Specified CA-  
FreseniusKabi-FK202401978 - -

23521867 Fluoxetine Fluoxetine  
Hydrochloride;Fentanyl;Herbals\Mitragynine;Bupropion - Drug  
Interaction;Serotonin Syndrome Serious Other Outcomes Male -  
14-FEB-2024 Expedited 68 YR Not Specified Appco  
Pharma Healthcare Professional Not Specified - 31-JAN-2024  
14-FEB-2024 US Not Specified US-Appco Pharma  
LLC-2153187 Initial -

23520936 Buspirone Buspirone Hydrochloride;Clonidine  
Hydrochloride;Alprazolam;Gabapentin;Cyclobenzaprine;Herbals\Mitragynin  
e Product Used For Unknown Indication Toxicity To Various  
Agents Serious Died Not Specified - 14-FEB-2024  
Expedited Not Specified Not Specified Alembic Healthcare  
Professional Not Specified - 02-FEB-2024 14-FEB-2024  
US Not Specified US-ALEMBIC PHARMACEUTICALS  
LIMITED-2024SCAL000076 "Torrico T, Patel K, Nikolov N, Salam M.T,  
Padhy R, Weinstein D. Presence of kratom in opioid overdose deaths:  
findings from coroner postmortem toxicological report. Frontiers in  
Psychiatry. 2023;14 (1332999):1-4" -

23478277 Fluoxetine Fluoxetine  
Hydrochloride;Bupropion;Fentanyl;Herbals\Mitragynine Product Used  
For Unknown Indication Serotonin Syndrome Serious Other Outcomes  
Male - 13-FEB-2024 Expedited 68 YR Not  
Specified Aurobindo Healthcare Professional Not Specified  
- 31-JAN-2024 04-FEB-2024 US Not Specified  
US-AUROBINDO-AUR-APL-2024-003927 "Grundmann O,  
Hendrickson RG, Greenberg MI. Kratom: History, pharmacology, current  
user trends, adverse health effects and potential benefits. Disease-a-  
Month. 2023;69:6" -

23511751 - Herbals\Mitragynine;Propranolol Hydrochloride  
Product Used For Unknown Indication Completed  
Suicide;Cardio-Respiratory Arrest Serious Died Female 2022  
12-FEB-2024 Expedited 25 YR Not Specified Endo  
Healthcare Professional Not Specified - 16-JAN-2024  
12-FEB-2024 US Not Specified US-ENDO  
PHARMACEUTICALS INC-2024-000757 "Gummin DD, Mowry JB, Beuhler MC,

Spyker DA, Rivers LJ, Feldman R, et al.. 2022 Annual Report of the National Poison Data System (NPDS) from America's Poison Centers: 40th Annual Report. Clinical Toxicology. 2023;61 (10):717-939" -

23510164 Buspirone Buspirone  
Hydrochloride;Alprazolam;Gabapentin;Cyclobenzaprine;Herbals\Mitragynine;Clonidine Product Used For Unknown Indication Toxicity To Various Agents;Accidental Overdose Serious Died Female -  
11-FEB-2024 Expedited Not Specified Not Specified Aveva Healthcare Professional Not Specified - 30-JAN-2024 11-FEB-2024 US Not Specified US-  
AVEVA-000590 "Torrico T, Patel K, Nikolov N, Salam MT, Padhy R, Weinstein D. Presence of kratom in opioid overdose deaths: findings from coroner postmortem toxicological report. Front Psychiatry, 2024 Jan 10;14:1332999. doi: 10.3389/fpsyg.2023.1332999." -

23510163 - Fentanyl;Herbals\Mitragynine Product Used For Unknown Indication Accidental Overdose;Toxicity To Various Agents Serious Died Male - 11-FEB-2024 Expedited Not Specified Not Specified Aveva Healthcare Professional Not Specified - 30-JAN-2024 11-FEB-2024 US Not Specified US-AVEVA-000591 "Torrico T, Patel K, Nikolov N, Salam MT, Padhy R, Weinstein D. Presence of kratom in opioid overdose deaths: findings from coroner postmortem toxicological report. Front Psychiatry, 2024 Jan 10;14:1332999. doi: 10.3389/fpsyg.2023.1332999." -

23510162 - Herbals\Mitragynine;Fentanyl Product Used For Unknown Indication Toxicity To Various Agents;Accidental Overdose Serious Died Male - 11-FEB-2024 Expedited Not Specified Not Specified Aveva Healthcare Professional Not Specified - 30-JAN-2024 11-FEB-2024 US Not Specified US-AVEVA-000593 "Torrico T, Patel K, Nikolov N, Salam MT, Padhy R, Weinstein D. Presence of kratom in opioid overdose deaths: findings from coroner postmortem toxicological report. Front Psychiatry, 2024 Jan 10;14:1332999. doi: 10.3389/fpsyg.2023.1332999." -

23510161 - Herbals\Mitragynine;Cannabis Sativa Subsp. Indica Top;Fentanyl Product Used For Unknown Indication Accidental Overdose;Toxicity To Various Agents Serious Died Male - 11-FEB-2024 Expedited Not Specified Not Specified Aveva Healthcare Professional Not Specified - 30-JAN-2024 11-FEB-2024 US Not Specified US-  
AVEVA-000592 "Torrico T, Patel K, Nikolov N, Salam MT, Padhy R, Weinstein D. Presence of kratom in opioid overdose deaths: findings from coroner postmortem toxicological report. Front Psychiatry, 2024 Jan 10;14:1332999. doi: 10.3389/fpsyg.2023.1332999." -

23509370 Fluoxetine Fluoxetine  
Hydrochloride;Herbals\Mitragynine;Bupropion Hydrochloride;Fentanyl Product Used For Unknown Indication Serotonin Syndrome Serious Other Outcomes Male - 10-FEB-2024 Expedited 68 YR Not Specified Granules India Healthcare Professional Not Specified - 31-JAN-2024 10-FEB-2024

US Not Specified US-GRANULES-

US-2024GRALIT00024 "Grundmann O.Kratom: History, pharmacology, current user trends, adverse health effects and potential benefits.DM Disease a Month .JAN-2023;69 (6)" -

23508595 - Acetaminophen\Codeine Phosphate\Methocarbamol;Ranitidine Hydrochloride;Acetaminophen\Methocarbamol;Albuterol;Herbals\Mitragynine;Loratadine;Citalopram;Diphenhydramine Product Used For Unknown Indication Maternal Exposure During Pregnancy;Caesarean Section;Live Birth Serious Other Outcomes Female - 09-FEB-2024 Expedited 37 YR Not Specified Fresenius Kabi Healthcare Professional Not Specified - 05-FEB-2024 09-FEB-2024 CA Not Specified CA-FreseniusKabi-

FK202401977 - -

23506278 Fluoxetine;Fentanyl Transdermal System Fentanyl;Fluoxetine Hydrochloride;Herbals\Mitragynine Pain;Product Used For Unknown Indication Drug Interaction;Serotonin Syndrome Serious Other Outcomes Male - 09-FEB-2024 Expedited 68 YR Not Specified Sciegen Healthcare Professional Not Specified Bupropion 01-FEB-2024 09-FEB-2024 US Not Specified US-SCIEGENP-2024SCLIT00039 "Grundmann O, et al..Kratom: History, pharmacology, current user trends, adverse health effects and potential benefits.DM Disease a Month.jun-2023;69 (6):1-13" -

23506205 Fluoxetine Fluoxetine Hydrochloride;Herbals\Mitragynine;Fentanyl;Bupropion Hydrochloride Product Used For Unknown Indication Serotonin Syndrome Serious Other Outcomes Male - 09-FEB-2024 Expedited 68 YR Not Specified Epic Pharm Healthcare Professional Not Specified - 29-JAN-2024 09-FEB-2024 US Not Specified US-EPICPHARMA-US-2024EPCLIT00240 "Grundmann O.Kratom: History, pharmacology, current user trends, adverse health effects and potential benefits.DM Disease a Month.JAN-2023;69" -

23496591 - Herbals\Mitragynine Substance Use Drug Dependence;Withdrawal Syndrome;Night Sweats;Restless Legs Syndrome;Product Advertising Issue;Insomnia Serious Other Outcomes Male 30-JAN-2024 08-FEB-2024 Direct 25 YR 63.5 KG Fda-Ctu Not Specified Not Specified - - 08-FEB-2024 Not Specified Not Specified - - -

23494001 - Herbals\Mitragynine Product Used For Unknown Indication Drug Dependence;Therapy Cessation;Withdrawal Syndrome Serious Required Intervention;Disabled Female 26-JAN-2024 06-FEB-2024 Direct 35 YR 58.5 KG Fda-Ctu Consumer Not Specified - - 06-FEB-2024 Not Specified Not Specified - - -

23493436 - Herbals\Mitragynine - Stress;Loss Of Personal Independence In Daily Activities;Drug Dependence Serious Other Outcomes;Disabled;Required Intervention Male 15-DEC-2023 06-FEB-2024 Direct 34 YR 76.5 KG Fda-Ctu

Consumer Not Specified - - 06-FEB-2024 Not  
Specified Y - - -  
23484289 Fluoxetine Fluoxetine  
Hydrochloride;Herbals\Mitragynine Pain Management;Product Used  
For Unknown Indication Serotonin Syndrome;Drug Interaction  
Serious Other Outcomes Male - 06-FEB-2024 Expedited  
68 YR Not Specified Sandoz Healthcare Professional Not  
Specified Bupropion;Fentanyl 01-FEB-2024 06-FEB-2024  
US Not Specified US-SANDOZ INC.-  
SDZ2024US011043 "Grundmann O,Hendrickson R G,Greenberg M I. Kratom:  
History, pharmacology, current user trends, adverse health effects and  
potential benefits. Disease-a-Month. 2023;69" -  
23482002 Fluoxetine Fluoxetine  
Hydrochloride;Bupropion;Fentanyl;Herbals\Mitragynine Pain  
Toxicity To Various Agents;Serotonin Syndrome;Drug Interaction  
Serious Life Threatening;Hospitalized;Other Outcomes Male -  
05-FEB-2024 Expedited 68 YR Not Specified  
Ranbaxy Healthcare Professional Not Specified - 23-JAN-2024  
05-FEB-2024 US Not Specified US-SUN PHARMACEUTICAL  
INDUSTRIES LTD-2024R1-429836 "Grundmann O,Hendrickson RG, Greenberg  
MI. Kratom: History, pharmacology, current user trends, adverse health  
effects and potential benefits. Dis Mon. 2023;69 (6):1-13" -  
23480743 Fluoxetine Fluoxetine  
Hydrochloride;Herbals\Mitragynine;Bupropion;Fentanyl Pain  
Prophylaxis Serotonin Syndrome;Drug Interaction Serious  
Hospitalized;Other Outcomes;Life Threatening Male - 05-  
FEB-2024 Expedited 68 YR Not Specified Micro Labs  
Healthcare Professional Not Specified - 23-JAN-2024  
05-FEB-2024 US Not Specified US-862174955-  
ML2024-00643 "Grundmann O, Hendrickson RG, Greenberg MI. Kratom:  
History, pharmacology, current user trends, adverse health effects and  
potential benefits. Disease-a-Month. 2023;(69(6)): 1-13. doi:<https://doi.org/10.1016/j.disamonth.2022.101442>." -  
23480553 Fluoxetine Fluoxetine  
Hydrochloride;Fentanyl;Herbals\Mitragynine;Bupropion Pain;Product  
Used For Unknown Indication Drug Interaction;Serotonin Syndrome  
Serious Other Outcomes Not Specified - 05-FEB-2024  
Expedited Not Specified Not Specified Zydus Pharm  
Healthcare Professional Not Specified - 23-JAN-2024  
05-FEB-2024 US Not Specified US-CADILA HEALTHCARE  
LIMITED-US-ZYDUS-102808 "Grundmann O, Hendrickson RG, Greenberg MI..  
Kratom: History, pharmacology, current user trends, adverse health  
effects and potential benefits.. Dis-Mon. 2023;69 No. 6." -  
23468572 - Herbals\Mitragynine Substance Use  
Product Complaint;Drug Dependence;Withdrawal Syndrome Serious  
Disabled;Other Outcomes Male 26-JAN-2024 01-FEB-2024 Direct  
36 YR 72 KG Fda-Ctu Consumer Not Specified  
Herbals\Mitragynine - 01-FEB-2024 Not Specified Not  
Specified - - -  
23466173 - Herbals\Mitragynine Osteoarthritis

Constipation;Insomnia;Anxiety;Drug Dependence;Euphoric Mood;Influenza Like Illness;Nasal Congestion;Rhinorrhea;Frustration Tolerance  
 Decreased Serious Other Outcomes Male 31-JAN-2024 31-  
 JAN-2024 Direct 62 YR 91 KG Fda-Ctu Healthcare  
 Professional Not Specified - - 31-JAN-2024 Not  
 Specified Not Specified - - -  
 23461854 Fluoxetine Fluoxetine  
 Hydrochloride;Fentanyl;Herbals\Mitragynine;Bupropion Pain Drug  
 Interaction;Serotonin Syndrome Serious Other Outcomes;Hospitalized  
 Male - 31-JAN-2024 Non-Expedited 68 YR Not  
 Specified Dr Reddys Healthcare Professional Not Specified  
 - 18-JAN-2024 31-JAN-2024 US Not Specified  
 US-RDY-LIT/USA/24/0001565 "Grundmann O, Hendrickson RG,  
 Greenberg MI. Kratom: History, pharmacology, current user trends,  
 adverse health effects and potential benefits. DM Disease a Month.  
 2023 Jan;69(6): doi:10.1016/j.disamonth.2022.101442." -

23453746 Vivitrol Naltrexone;Herbals\Mitragynine Drug  
 Dependence;Product Used For Unknown Indication Substance Use;Feeling  
 Abnormal Non-Serious Non-Serious Male - 29-  
 JAN-2024 Non-Expedited Not Specified Not Specified  
 Alkermes Consumer Not Specified Vitamins  
 Nos;Unspecified Ingredient 16-JAN-2024 29-JAN-2024 US  
 Not Specified US-ALKERMES INC.-ALK-2024-000103 -

23450118 Fluoxetine Fluoxetine  
 Hydrochloride;Herbals\Mitragynine;Bupropion;Fentanyl Pain;Product  
 Used For Unknown Indication Serotonin Syndrome;Drug Interaction  
 Serious Hospitalized;Other Outcomes Male - 29-  
 JAN-2024 Expedited 68 YR Not Specified Lupin  
 Healthcare Professional Not Specified - 18-JAN-2024 29-  
 JAN-2024 US Not Specified US-LUPIN PHARMACEUTICALS  
 INC.-2024-00461 "Grundmann O, Hendrickson RG, Greenberg MI. Kratom:  
 History, pharmacology, current user trends, adverse health effects and  
 potential benefits. Disease-a-Month. 2023;69 (6):1-13" -

23448431 - Pseudoephedrine Hydrochloride;Getacetetide  
 Acetate;Bupropion;Citalopram;Phenylpropanolamine;Herbals\Mitragynine  
 Product Used For Unknown Indication Toxicity To Various  
 Agents;Completed Suicide Serious Died Male - 27-  
 JAN-2024 Expedited 39 YR Not Specified Johnson And  
 Johnson Healthcare Professional Not Specified - 16-JAN-2024  
 27-JAN-2024 US Not Specified US-JNJFOC-20240152499 -

23447568 "Venlafaxine;Heroin;Zolpidem;Trazodone;Alcohol  
 (Alcohol);Hydroxyzine;Dextroamphetamine Saccharate, Amphetamine  
 Aspartate, Dextroamphetamine Sulfate And Amphetamine  
 Sulfate;Sertraline;Methadone;Restoril" Methadone  
 Hydrochloride;Temazepam;Olanzapine;Clonazepam;Carisoprodol;Valproic  
 Acid;Cannabis Sativa Subsp. Indica  
 Top;Lorazepam;Guaifenesin;Etizolam;Tapentadol;Herbals\Mitragynine;Morp  
 hine;Secobarbital;Buprenorphine;Benzoyllecgonine;Gabapentin;Diazepam;Co

caine;Oxazepam;Zopiclone;Phenylpropanolamine;Oxybate;Sertraline Hydrochloride;Topiramate;Methylphenidate Hydrochloride;Mirtazapine;Fentanyl Citrate;Meprobamate;Alprazolam;Phencyclidine;Amphetamine Aspartate\Amphetamine Sulfate\Dextroamphetamine Saccharate\Dextroamphetamine Sulfate;Pregabalin;Citalopram;Hydromorphone;Phenytoin;Hydroxyzine Hydrochloride;Chlordiazepoxide;Diphenhydramine;Carbamazepine;Alcohol;Cyclobenzaprine;Trazodone Hydrochloride;Midazolam;Dextromethorphan;Cathinone;Methamphetamine;Lamotrigine;Oxycodone;Pseudoephedrine;Doxylamine;Oxymorphone Hydrochloride;Hydrocodone;Diamorphine;Ketamine;Phentermine;Chlorpheniramine;Zolpidem Tartrate;Tramadol;Venlafaxine Hydrochloride;Codeine;Nordazepam Product Used For Unknown Indication Impaired Driving Ability;Road Traffic Accident Serious Died;Other Outcomes Not Specified - 26-JAN-2024 Expedited Not Specified Not Specified Specgx Healthcare Professional Not Specified - 18-JAN-2024 26-JAN-2024 US Not Specified US-SPECGX-T202400498 "D'Orazio AL, Mohr AL, Chan-Hosokawa A, Harper C, Huestis MA, Limoges JF et al. Recommendations for toxicological investigation of drug-impaired driving and motor vehicle fatalities-2021 update. Journal of Analytical Toxicology. 2021;45(6):529-36" -  
23444436 - Herbals\Mitragynine Pain Management Drug Dependence;Product Formulation Issue;Product Communication Issue;Product Advertising Issue;Victim Of Crime;Product Use In Unapproved Indication Serious Disabled;Life Threatening;Hospitalized Female 06-JAN-2024 25-JAN-2024 Direct 39 YR 178 LB Fda-Ctu Consumer Not Specified - - 25-JAN-2024 Not Specified Y - - -  
23442488 Fluoxetine Fluoxetine Hydrochloride;Bupropion;Fentanyl;Herbals\Mitragynine Pain;Product Used For Unknown Indication Serotonin Syndrome;Drug Interaction Serious Other Outcomes Male - 25-JAN-2024 Expedited 68 YR Not Specified Apotex Healthcare Professional Not Specified - 18-JAN-2024 25-JAN-2024 US Not Specified US-APOTEX-2024AP001528 "Grundmann O, Hendrickson RG, Greenberg MI. Kratom: History, pharmacology, current user trends, adverse health effects and potential benefits. Disease-a-Month. 2023;69 (6) 101442:1-13" -  
23440131 Fluoxetine Fluoxetine Hydrochloride;Herbals\Mitragynine;Fentanyl;Bupropion Pain Drug Interaction;Serotonin Syndrome Serious Hospitalized Male - 24-JAN-2024 Expedited 68 YR Not Specified Strides Healthcare Professional Not Specified - 18-JAN-2024 24-JAN-2024 US Not Specified US-STRIDES ARCOLAB LIMITED-2024SP000856 "Grundmann O, Hendrickson RG, Greenberg MI. Kratom: History, pharmacology, current user trends, adverse health effects and potential benefits.. Dis-Mon. 2023;69 (6)" -

23437711 Fluoxetine Fluoxetine  
Hydrochloride;Herbals\Mitragynine;Bupropion;Fentanyl Pain  
Serotonin Syndrome;Off Label Use;Drug Interaction Serious  
Hospitalized Male - 24-JAN-2024 Expedited 68 YR  
Not Specified Mylan Healthcare Professional Not Specified  
- 18-JAN-2024 24-JAN-2024 US Not Specified  
US-MYLANLABS-2024M1007022 "Grundmann O, Hendrickson RG,  
Greenberg MI. Kratom: History, pharmacology, current user trends,  
adverse health effects and potential benefits. Dis-Mon 2023; 69 (6):."  
-

23427626 - Herbals\Mitragynine Anxiety Sudden Death  
Serious Died Male - 20-JAN-2024 Direct 20 YR  
58.5 KG Fda-Ctu Consumer Not Specified Prozac -  
20-JAN-2024 Not Specified Not Specified - -

23410220 - Tramadol;Herbals\Mitragynine Product Used  
For Unknown Indication Drug Use Disorder;Substance Use Disorder  
Serious Other Outcomes Female - 17-JAN-2024  
Expedited Not Specified Not Specified Mylan Healthcare  
Professional Not Specified - 10-JAN-2024 17-JAN-2024  
FR Not Specified FR-MYLANLABS-2024M1004418 -

23403415 - Herbals\Mitragynine;Quinine;Fentanyl  
Product Used For Unknown Indication Drug Abuse;Cardio-Respiratory  
Arrest Serious Died;Other Outcomes Male - 16-JAN-2024  
Expedited 35 YR Not Specified Aveva Healthcare  
Professional Not Specified - 02-JAN-2024 16-JAN-2024  
US Not Specified US-AVEVA-000253 "David D. Gummin,  
James B. Mowry, Michael C. Beuhler, Daniel A. Spyker, Laura J. Rivers,  
Ryan Feldman, Kaitlyn Brown, Nathaniel P.T. Pham, Alvin C. Bronstein  
& Carol DesLauriers (2023) 2022 Annual Report of the National  
Poison Data System (NPDS) from America's Poison Centers : 40th Annual  
Report, Clinical Toxicology, 61:10, 717-939." -

23402314 - Herbals\Mitragynine;Fentanyl Product Used  
For Unknown Indication Drug Abuse Serious Died;Other Outcomes  
Male - 15-JAN-2024 Expedited 26 YR Not  
Specified Aveva Healthcare Professional Not Specified -  
02-JAN-2024 15-JAN-2024 US Not Specified US-  
AVEVA-000099 "David D. Gummin, James B. Mowry, Michael C. Beuhler,  
Daniel A. Spyker, Laura J. Rivers, Ryan Feldman, Kaitlyn Brown,  
Nathaniel P.T. Pham, Alvin C. Bronstein & Carol DesLauriers (2023)  
2022 Annual Report of the National Poison Data System (NPDS) from  
America's Poison Centers : 40th Annual Report, Clinical Toxicology,  
61:10, 717-939" -

23402305 - Cocaine;Herbals\Mitragynine;Fentanyl  
Product Used For Unknown Indication Drug Abuse Serious  
Died;Other Outcomes Male - 15-JAN-2024 Expedited  
26 YR Not Specified Aveva Healthcare Professional Not  
Specified - 02-JAN-2024 15-JAN-2024 US Not  
Specified US-AVEVA-000093 "David D. Gummin, James B. Mowry,

Michael C. Beuhler, Daniel A. Spyker, Laura J. Rivers, Ryan Feldman, Kaitlyn Brown, Nathaniel P.T. Pham, Alvin C. Bronstein & Carol DesLauriers (2023) 2022 Annual Report of the National Poison Data System (NPDS) from America's Poison Centers : 40th Annual Report, Clinical Toxicology, 61:10, 717-939" -

23401864 - Cannabis Sativa Subsp. Indica  
 Top;Fentanyl;Herbals\Mitragynine Product Used For Unknown  
 Indication Drug Abuse Serious Other Outcomes;Died Male  
 - 15-JAN-2024 Expedited 33 YR Not Specified  
 Aveva Healthcare Professional Not Specified - 02-  
 JAN-2024 15-JAN-2024 US Not Specified US-  
 AVEVA-000224 "David D. Gummin, James B. Mowry, Michael C. Beuhler, Daniel A. Spyker, Laura J. Rivers, Ryan Feldman, Kaitlyn Brown, Nathaniel P.T. Pham, Alvin C. Bronstein & Carol DesLauriers (2023) 2022 Annual Report of the National Poison Data System (NPDS) from America's Poison Centers : 40th Annual Report, Clinical Toxicology, 61:10, 717-939" -

23405969 - Herbals\Mitragynine Disturbance In  
 Attention Job Dissatisfaction;Fear;Tremor;Paranoia;Decreased Appetite;Dyspepsia;Weight Decreased;Depression;Anxiety;Drug Dependence Serious Other Outcomes;Hospitalized;Disabled;Required  
 Intervention Male 01-JAN-2024 14-JAN-2024 Direct 20 YR  
 63 KG Fda-Ctu Consumer Not Specified - -  
 14-JAN-2024 Not Specified Y - - -  
 23399922 - Herbals\Mitragynine;Fentanyl Product Used For Unknown Indication Drug Abuse Serious Died;Other Outcomes Male - 14-JAN-2024 Expedited 42 YR Not Specified  
 Aveva Healthcare Professional Not Specified -  
 02-JAN-2024 14-JAN-2024 US Not Specified US-  
 AVEVA-000354 "David D. Gummin, James B. Mowry, Michael C. Beuhler, Daniel A. Spyker, Laura J. Rivers, Ryan Feldman, Kaitlyn Brown, Nathaniel P.T. Pham, Alvin C. Bronstein & Carol DesLauriers (2023) 2022 Annual Report of the National Poison Data System (NPDS) from America's Poison Centers : 40th Annual Report, Clinical Toxicology, 61:10, 717-939" -

23405586 - Herbals\Mitragynine Depression  
 Product Advertising Issue;Product Measured Potency Issue;Product Formulation Issue;Drug Dependence;Dependence;Hallucination;Tremor;Psychotic Disorder Serious Disabled;Required Intervention;Other Outcomes Male 13-  
 JAN-2024 13-JAN-2024 Direct 40 YR 72 KG Fda-Ctu  
 Consumer Not Specified Valium;Lunesta - 13-JAN-2024  
 Not Specified Y - - -  
 23405515 Kava Piper Methysticum Root;Herbals\Mitragynine Product Used For Unknown Indication Disorientation;Feeling Abnormal;Lung Disorder;Product Contamination;Chest Pain;Taste Disorder;Poisoning;Diarrhoea;Product Complaint;Dyspnoea Non-Serious Non-Serious Male 01-DEC-2023 13-JAN-2024 Direct  
 54 YR 105.75 KG Fda-Ctu Consumer Not Specified  
 - - 13-JAN-2024 Not Specified Not Specified

- - -  
23396807 - Herbals\Mitragynine;Quinine;Fentanyl Citrate  
- Drug Abuse;Respiratory Arrest;Cardiac Arrest  
Serious Died;Other Outcomes Male 2022 12-JAN-2024  
Expedited 35 YR Not Specified Pfizer Healthcare  
Professional Not Specified - 05-JAN-2024 12-JAN-2024  
US Not Specified US-PFIZER  
INC-202400006919 "Gummin, D.. 2022 Annual Report of the  
National Poison Data System (NPDS) from America's Poison Centers: 40th  
Annual Report. Clinical Toxicology. 2023;61 (10):717-939" -  
23394684 - Tramadol;Herbals\Mitragynine Product Used  
For Unknown Indication Substance Use Disorder;Drug Use Disorder  
Serious Other Outcomes Female - 12-JAN-2024  
Expedited Not Specified Not Specified Aurobindo  
Healthcare Professional Not Specified - 03-JAN-2024 12-  
JAN-2024 FR Not Specified FR-AUROBINDO-AUR-  
APL-2024-000826 - -  
23392830 - Herbals\Mitragynine - Drug  
Dependence;Tremor;Chest Pain Serious Other Outcomes Male -  
11-JAN-2024 Direct Not Specified Not Specified Fda-  
Ctu Consumer Not Specified - - 11-JAN-2024  
Not Specified Not Specified - - -  
17904502 Trazodone;Amlodipine Amlodipine Besylate;Bupropion  
Hydrochloride;Trazodone  
Hydrochloride;Desvenlafaxine;Alteplase;Ziprasidone  
Hydrochloride;Buspirone Hydrochloride;Herbals\Mitragynine  
Depression;Hypertension;Product Used For Unknown Indication;Type 2  
Diabetes Mellitus Self-Medication;Drug Interaction;Serotonin  
Syndrome;Clonus;Confusional State;Hyperhidrosis Serious Other  
Outcomes;Hospitalized Male - 10-JAN-2024 Expedited  
63 YR 102.5 KG Aurobindo Healthcare  
Professional Not Specified  
Hydrochlorothiazide;Metformin;Omeprazole;Glimepiride;Gabapentin;Tizani  
dine;Diclofenac 04-JAN-2024 17-JUN-2020 US Not Specified  
US-AUROBINDO-AUR-APL-2020-029111 "Eudaley ST, Hamilton  
LA, Brooks S P.. Case report: Successful treatment of suspected  
kratominduced serotonin syndrome.. J-Am-Coll-Ciin-Pharm.  
2020;3(1):347" -  
23382096 -  
Bupropion;Citalopram;Dextromethorphan;Phenylpropanolamine;Herbals\Mitr  
agynine;Pseudoephedrine Product Used For Unknown Indication  
Cardio-Respiratory Arrest;Completed Suicide Serious  
Hospitalized;Died;Other Outcomes Male 2022 09-JAN-2024  
Expedited 39 YR Not Specified Apotex Healthcare  
Professional Not Specified - 02-JAN-2024 09-JAN-2024  
US Not Specified US-APOTEX-2024AP000426 "Gummin DD,  
Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Pham  
NPT, Bronstein AC, DesLauriers C.. 2022 Annual Report of the National  
Poison Data System (NPDS) from America's Poison Centers: 40th Annual  
Report. Clinical Toxicology. 2023;61(10):717-939" -

23380403 - Diphenhydramine;Acetaminophen;Herbals\Mitragynine Product Used  
 For Unknown Indication Completed Suicide Serious  
 Hospitalized;Other Outcomes;Died Female 2022 09-JAN-2024  
     Expedited 45 YR Not Specified Apotex Healthcare  
 Professional Not Specified - 02-JAN-2024 09-JAN-2024  
     US Not Specified US-APOTEX-2024AP000179 "Gummin DD,  
 Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Pham  
 NPT, Bronstein AC, DesLauriers C.. 2022 Annual Report of the National  
 Poison Data System (NPDS) from America's Poison Centers: 40th Annual  
 Report. Clinical Toxicology. 2023;61(10):717-939" -

23380153 - Herbals\Mitragynine;Fentanyl Product Used  
 For Unknown Indication Drug Abuse Serious Other Outcomes;Died  
     Male - 09-JAN-2024 Expedited 32 YR Not  
 Specified Aveva Healthcare Professional Not Specified -  
     02-JAN-2024 09-JAN-2024 US Not Specified US-  
 AVEVA-000208 "David D. Gummin, James B. Mowry, Michael C. Beuhler,  
 Daniel A. Spyker, Laura J. Rivers, Ryan Feldman, Kaitlyn Brown,  
 Nathaniel P.T. Pham, Alvin C. Bronstein & Carol DesLauriers (2023)  
 2022 Annual Report of the National Poison Data System (NPDS) from  
 America's Poison Centers : 40th Annual Report, Clinical Toxicology,  
 61:10, 717-939" -

21219859 Trazodone Ziprasidone Hydrochloride;Buspirone  
 Hydrochloride;Trazodone  
 Hydrochloride;Desvenlafaxine;Herbals\Mitragynine Product Used  
 For Unknown Indication Self-Medication;Serotonin Syndrome;Drug  
 Interaction Serious Hospitalized;Other Outcomes Male -  
     06-JAN-2024 Expedited 63 YR 102.5 KG  
 Aurobindo Healthcare Professional Not Specified  
 Bupropion;Gabapentin;Glimepiride;Amlodipine;Metformin;Tizanidine;Hydro  
 chlorothiazide;Diclofenac;Omeprazole 04-JAN-2024 17-AUG-2022  
     US Not Specified US-AUROBINDO-AUR-APL-2022-031927  
     "Eudaley ST, Brooks SP, Hamilton LA.. Case Report: Possible  
 Serotonin Syndrome in a Patient Taking Kratom and Multiple  
 Serotonergic Agents.. Journal of pharmacy practice. 2022;1-5" -

23369479 - Herbals\Mitragynine Product Used For  
 Unknown Indication Fall;Seizure;Loss Of Consciousness;Toxicity To  
 Various Agents Serious Died Male 24-JUL-2023 04-JAN-2024  
     Direct 25 YR 78.75 KG Fda-Ctu Consumer Not  
 Specified - - 04-JAN-2024 Not Specified Not  
 Specified - - -

23367047 - Herbals\Mitragynine - Drug  
 Ineffective Non-Serious Non-Serious Not Specified -  
     04-JAN-2024 Direct Not Specified Not Specified Fda-  
 Ctu Consumer Not Specified - - 04-JAN-2024  
     Not Specified Not Specified - - -

23351659 - Tapentadol;Pregabalin;Clonazepam;Herbals\Mitragynine;Carisoprodol  
 Product Used For Unknown Indication Toxicity To Various  
 Agents Serious Died Not Specified 23-APR-2021 29-DEC-2023

Expedited Not Specified Not Specified Cipla  
 Consumer Not Specified Citalopram Hydrobromide 18-DEC-2023  
 29-DEC-2023 AU Not Specified AU-CIPLA  
 LTD.-2023AU08519 - -  
 23348129 -  
 Phenylpropanolamine;Dextromethorphan;Pseudoephedrine;Herbals\Mitragynine;Citalopram;Bupropion Product Used For Unknown Indication  
 Suspected Suicide;Cardio-Respiratory Arrest Serious Died;Other Outcomes Not Specified - 28-DEC-2023 Expedited  
 Not Specified Not Specified Glaxosmithkline Healthcare  
 Professional Not Specified - 25-DEC-2023 28-DEC-2023  
 US Not Specified US-GSK-US2023GSK179976 "Gummin DD,  
 Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R, et al. 2022  
 Annual report of the national poison data system (NPDS) from america's poison Centers: 40th annual report. Clinical toxicology.  
 2023;61(10):717-939" -  
 23310675 -  
 Dextromethorphan;Bupropion;Phenylpropanolamine;Citalopram;Herbals\Mitr agynine;Pseudoephedrine Product Used For Unknown Indication  
 Cardiac Arrest;Respiratory Arrest;Completed Suicide Serious Died;Other Outcomes Male - 21-DEC-2023 Expedited  
 39 YR Not Specified Bausch And Lomb Healthcare  
 Professional Not Specified - 13-DEC-2023 18-DEC-2023  
 US Not Specified US-BAUSCH-  
 BL-2023-018557 "Gummin D, Mowry J, Beuhler M, Spyker D, Rivers L, Feldman R, Brown K, Pham N, Bronstein A, DesLauriers C. 2022 Annual Report of the National Poison Data System (NPDS) from America's Poison Centers: 40th Annual Report. Clinical Toxicology. 2023 DEC  
 12;61(10):717-939. doi:10.1080/15563650.2023.2268981" -  
 23301058 - Unspecified  
 Ingredient;Acetaminophen;Herbals\Mitragynine Suspected Suicide  
 Exposure To Toxic Agent;Completed Suicide Serious Died  
 Female 2022 15-DEC-2023 Expedited 45 YR Not  
 Specified Galpharm International Healthcare Professional Not  
 Specified - 13-DEC-2023 15-DEC-2023 US Not  
 Specified US-PERRIGO-23US014157 - -  
 23300559 - Morphine  
 Sulfate;Codeine;Naproxen;Herbals\Mitragynine Product Used For  
 Unknown Indication Toxicity To Various Agents;Drug Abuse  
 Serious Died;Hospitalized Male - 15-DEC-2023 Non-  
 Expedited 38 YR Not Specified Strides Healthcare  
 Professional Not Specified - 18-APR-2023 15-DEC-2023  
 US Not Specified US-STRIDES ARCOLAB  
 LIMITED-2023SP005907 "Rodriguez Salas J, Krotulski AJ, Newman R, Thogmartin JR, Mohr ALA, Logan BK.. Concentrations of para-Fluorofuranyl fentanyl in Paired Central and Peripheral Blood Collected during Postmortem Death Investigations.. J-Anal-Toxicol.  
 2022;46(4):358-373" -  
 23295786 Buspirone;Trazodone Trazodone  
 Hydrochloride;Buspirone

Hydrochloride;Herbals\Mitragynine;Desvenlafaxine;Ziprasidone;Bupropion Hydrochloride Antibiotic Therapy;Anxiety Disorder;Major Depression;Phytotherapy;Product Used For Unknown Indication Hyperreflexia;Drug Interaction;Aphasia;Pyrexia;Delirium;Confusional State;Flushing;Facial Paralysis;Dysarthria;Clonus;Serotonin Syndrome;Tremor Serious Hospitalized;Other Outcomes Male -  
14-DEC-2023 Expedited 63 YR 102.5 KG  
Jubilant Healthcare Professional Not Specified  
Diclofenac;Glimepiride;Tizanidine;Omeprazole;Hydrochlorothiazide;Gabapentin;Vancomycin;Metformin;Piperacillin Sodium\Tazobactam Sodium;Amlodipine;Acetaminophen 04-DEC-2023 14-DEC-2023 US  
Not Specified US-JUBILANT CADISTA  
PHARMACEUTICALS-2023US001597 "Eudaley ST, Brooks SP, Hamilton LA.. Case Report: Possible Serotonin Syndrome in a Patient Taking Kratom and Multiple Serotonergic Agents. Journal of Pharmacy Practice. 2023;36(6):1523-1527" -  
23257219 Trazodone;Buspirone Buspirone  
Hydrochloride;Trazodone  
Hydrochloride;Herbals\Mitragynine;Desvenlafaxine;Ziprasidone Product Used For Unknown Indication Drug Interaction;Serotonin Syndrome Serious Hospitalized Male - 04-DEC-2023  
Expedited 63 YR 102.5 KG Alvogen Healthcare  
Professional Not Specified  
Tizanidine;Bupropion;Hydrochlorothiazide;Omeprazole;Gabapentin;Diclofenac;Metformin;Amlodipine;Glimepiride 23-NOV-2023 04-DEC-2023  
US Not Specified US-ALVOGEN-2023092653 "Eudaley S T, Brooks S P, Hamilton L A. Case Report: Possible Serotonin Syndrome in a Patient Taking Serotonergic Agents. journal of Pharmacy Practice. 2023;36(6):1523?1527. doi:10.1177/08971900221116009" -  
17861180 Buspirone;Trazodone Trazodone  
Hydrochloride;Desvenlafaxine Succinate;Bupropion;Buspirone  
Hydrochloride;Herbals\Mitragynine;Ziprasidone Hydrochloride Depression Serotonin Syndrome;Drug Interaction;Off Label Use  
Serious Hospitalized;Life Threatening;Other Outcomes Male -  
28-NOV-2023 Expedited 63 YR 102 KG Pfizer  
Healthcare Professional Not Specified  
Tizanidine;Omeprazole;Gabapentin;Metformin;Glimepiride;Hydrochlorothiazide;Amlodipine Besylate;Diclofenac 20-NOV-2023 04-JUN-2020  
US Not Specified US-PFIZER  
INC-2020216505 "Eudaley, S.. Case report: Successful treatment of suspected kratom-induced serotonin syndrome. Journal of the American College of Clinical Pharmacy. 2020;3 (1):347" -  
23230891 - Herbals\Mitragynine - Substance Use;Toxicity To Various Agents Serious Died Female 09-JAN-2023  
24-NOV-2023 Direct 24 YR 54 KG Fda-Ctu Consumer  
Not Specified - - 24-NOV-2023 Not Specified  
Not Specified - - -  
23224916 Buspirone;Trazodone Trazodone  
Hydrochloride;Ziprasidone;Buspirone  
Hydrochloride;Desvenlafaxine;Herbals\Mitragynine;Bupropion

Anxiety Disorder;Major Depression;Product Used For Unknown Indication Drug Interaction;Serotonin Syndrome Serious Hospitalized Male - 24-NOV-2023 Expedited 63 YR 102.5  
KG Emcure Healthcare Professional Not Specified  
Glimepiride;Gabapentin;Diclofenac;Metformin;Tizanidine;Hydrochlorothiazide;Omeprazole;Amlodipine 14-NOV-2023 24-NOV-2023 US  
Not Specified US-AVET LIFESCIENCES LTD-2023-AVET-000342  
"Eudaley ST, Brooks SP, Hamilton LA.. Case Report: Possible Serotonin Syndrome in a Patient Taking Kratom and Multiple Serotonergic Agents. Journal of Pharmacy Practice. 2023;36(6):1523-1527" -

23182254 - Herbals\Mitragynine Pain Substance Use;Recalled Product Administered;Salmonellosis Serious Disabled;Required Intervention Male 13-NOV-2023 14-NOV-2023  
Direct 31 YR Not Specified Fda-Ctu Consumer Not Specified - - 14-NOV-2023 Not Specified Not Specified - - -

23164703 - Dietary Supplement\Herbals;Herbals\Mitragynine - Product Formulation Issue;Product Information Content Complaint Non-Serious Non-Serious Male - 08- NOV-2023 Direct Not Specified Not Specified Fda-Ctu Consumer Not Specified - - 08-NOV-2023 Not Specified - - -

23149661 - Herbals\Mitragynine;Sildenafil;Dietary Supplement Erectile Dysfunction Visual Impairment;Therapeutic Response Unexpected;Euphoric Mood;Mydriasis Serious Other Outcomes Male 28-OCT-2023 04-NOV-2023 Direct 37 YR 94.5  
KG Fda-Ctu Consumer Not Specified - - 04- NOV-2023 Not Specified Not Specified - - -

23124390 - Herbals\Mitragynine - Educational Problem;Dependence;Withdrawal Syndrome Serious Disabled;Other Outcomes Male 27-OCT-2023 28-OCT-2023 Direct Not Specified Not Specified Fda-Ctu Consumer Not Specified - 28-OCT-2023 Not Specified Not Specified - - -

23101045 - Mirtazapine;Herbals\Mitragynine Anxiety Toxicity To Various Agents;Cardiac Arrest Serious Died Male 20-DEC-2022 20-OCT-2023 Direct 24 YR Not Specified Fda-Ctu Not Specified Not Specified - - 20- OCT-2023 Not Specified Not Specified - - -

23090657 - Herbals\Mitragynine Pain Withdrawal Syndrome;Drug Dependence Serious Required Intervention;Disabled;Other Outcomes Female 20-OCT-2023 20- OCT-2023 Direct 50 YR 110.25 KG Fda-Ctu Consumer Not Specified - - 20-OCT-2023 Not Specified Not Specified - - -

23080351 - Herbals\Mitragynine - Circulatory Collapse;Tremor;Loss Of Consciousness;Legal Problem;Substance Use;Fall;Toxicity To Various Agents Serious Died Male 19- NOV-2020 18-OCT-2023 Direct 43 YR Not Specified Fda-

Ctu Healthcare Professional Not Specified - - 18-  
 OCT-2023 Not Specified Not Specified - - -  
 23070450 - Herbals\Mitragynine;Hydromorphone  
 Hydrochloride;Olanzapine Pain;Product Used For Unknown  
 Indication Renal Impairment;Completed Suicide;Overdose;Toxicity  
 To Various Agents Serious Died;Other Outcomes Male -  
 16-OCT-2023 Expedited 44 YR Not Specified Purdue  
 Healthcare Professional Not Specified  
 Escitalopram;Herbals\Mitragynine;Zopiclone 10-OCT-2023 16-  
 OCT-2023 CA Not Specified CA-PURDUE-USA-2023-0305318  
 "Shi T, Shea J.L. A case of fatal overdose involving both  
 hydromorphone and kratom. Journal of forensic sciences. 2023;00:1-4"  
 -  
 23065925 Hydromorphone Hcl Hydromorphone  
 Hydrochloride;Herbals\Mitragynine;Olanzapine Product Used For  
 Unknown Indication Renal Impairment;Toxicity To Various Agents  
 Serious Other Outcomes Male - 14-OCT-2023  
 Expedited 44 YR Not Specified Indoco Healthcare  
 Professional Not Specified - 01-OCT-2023 14-OCT-2023  
 CA Not Specified CA-Indoco-000464 "Shi T, Shea  
 JL. A case of fatal overdose involving both hydromorphone and kratom.  
 J Forensic Sci. 2023 Sep 27" -  
 23065827 Hydromorphone Hcl Hydromorphone  
 Hydrochloride;Herbals\Mitragynine;Olanzapine Product Used For  
 Unknown Indication Toxicity To Various Agents;Renal Impairment  
 Serious Other Outcomes Male - 14-OCT-2023  
 Expedited 44 YR Not Specified Cadila Healthcare  
 Professional Not Specified - 01-OCT-2023 14-OCT-2023  
 CA Not Specified CA-CPL-003703 "Shi T, Shea JL. A  
 case of fatal overdose involving both hydromorphone and kratom. J  
 Forensic Sci. 2023 Sep 27." -  
 23059601 - Herbals\Mitragynine -  
 Seizure;Intentional Product Use Issue Serious Other Outcomes;Life  
 Threatening Female 11-OCT-2023 12-OCT-2023 Direct 72 YR  
 69.8 KG Fda-Ctu Healthcare Professional Not Specified  
 Ibuprofen;Amlodipine  
 Besylate;Metformin;Levothyroxine;Doxycycline;Losartan;Duloxetine;Prega  
 balin - 12-OCT-2023 Not Specified Not Specified -  
 - -  
 23050243 - Herbals\Mitragynine Anxiety Adverse Drug  
 Reaction Serious Died Male 20-DEC-2022 09-OCT-2023  
 Direct 24 YR 85.5 KG Fda-Ctu Consumer Not Specified  
 - - 09-OCT-2023 Not Specified Not Specified  
 - - -  
 23037565 - Herbals\Mitragynine Disturbance In  
 Attention Dehydration;Retching;Malaise;Vomiting;Feeling  
 Abnormal;Hot Flush;Nausea Non-Serious Non-Serious Female  
 04-OCT-2023 05-OCT-2023 Direct 49 YR 70.2 KG Fda-  
 Ctu Consumer Not Specified  
 Ginkgo;Omeprazole;Glucosamine;Curcumin;Diclofenac - 05-

OCT-2023 Not Specified Y - - -  
 23020201 - Herbals\Mitragynine - Brain  
 Death;Fall Serious Died Male 09-FEB-2023 02-OCT-2023  
 Direct 40 YR 86.4 KG Fda-Ctu Consumer Not Specified  
 Device - 02-OCT-2023 Not Specified Not Specified  
 - - -

23015048 Methadone;Vivitrol  
 Naltrexone;Herbals\Mitragynine;Methadone Hydrochloride Drug  
 Dependence;Product Used For Unknown Indication Contraindicated  
 Product Administered Non-Serious Non-Serious Female 15-  
 AUG-2023 02-OCT-2023 Non-Expedited Not Specified Not  
 Specified Alkermes Healthcare Professional Not Specified  
 Remeron 21-SEP-2023 02-OCT-2023 US Not Specified  
 US-ALKERMES INC.-ALK-2023-003852 - -

22640937 - Nortriptyline;Herbals\Mitragynine;Baclofen  
 Product Used For Unknown Indication Unresponsive To  
 Stimuli;Lethargy;Electrocardiogram Qrs Complex Prolonged  
 Serious Other Outcomes Female - 30-SEP-2023 Expedited  
 57 YR Not Specified Ranbaxy Healthcare Professional Not  
 Specified - 17-SEP-2023 26-JUN-2023 US Not  
 Specified US-SUN PHARMACEUTICAL INDUSTRIES LTD-2023R1-396279  
 "Palungwachira P, Yeh M, Whitworth B, Rushton W, Kazzi Z.  
 Clinical Characteristics of Kratom Exposures Reported to the Georgia  
 and Alabama Poison Control Centers from 2016-2020: A Retrospective  
 Review. J Drug Alcohol Res. 2022;11(2):236162" -

21614526 -  
 Herbals\Mitragynine;Buprenorphine;Buprenorphine\Naloxone Drug  
 Use Disorder Exposure During Pregnancy;Drug Ineffective;Drug  
 Withdrawal Syndrome Serious Other Outcomes Female - 29-  
 SEP-2023 Expedited 27 YR Not Specified Ranbaxy  
 Healthcare Professional Not Specified - 26-SEP-2023 18-  
 NOV-2022 US Not Specified US-SUN PHARMACEUTICAL  
 INDUSTRIES LTD-2022R1-364360 "Zoucha K, Moore C. Kratom Use in  
 Pregnancy. J Addict Med. 2022;Sep/Oct; 16(5):e331-e332" -

22994000 - Herbals\Mitragynine Anxiety;Depression  
 Toxicity To Various Agents;Seizure;Overdose Serious Died  
 Male - 27-SEP-2023 Direct 36 YR Not Specified  
 Fda-Ctu Healthcare Professional Not Specified - -  
 27-SEP-2023 Not Specified Not Specified - - -

22993960 - Herbals\Mitragynine - Toxicity To  
 Various Agents;Loss Of Consciousness Serious Died Female -  
 27-SEP-2023 Direct 39 YR Not Specified Fda-Ctu  
 Healthcare Professional Not Specified - - 27-SEP-2023  
 Not Specified Not Specified - - -

22980079 - Herbals\Mitragynine Product Used For  
 Unknown Indication Suicidal Ideation;Withdrawal  
 Syndrome;Constipation;Depression;Restless Legs  
 Syndrome;Hyperhidrosis;Insomnia;Anxiety Serious Other Outcomes Not  
 Specified 23-JUN-2023 24-SEP-2023 Direct 40 YR 80.1

KG Fda-Ctu Consumer Not Specified - - 24-  
 SEP-2023 Not Specified Not Specified - - -  
 22910630 Spravato Esketamine;Herbals\Mitragynine  
 Anxiety;Attention Deficit Hyperactivity  
 Disorder;Depression;Generalised Anxiety Disorder;Insomnia;Major  
 Depression Sedation;Overdose;Loss Of Consciousness Serious Life  
 Threatening;Other Outcomes Female 2023 22-SEP-2023  
 Expedited 44 YR Not Specified Johnson And Johnson  
 Healthcare Professional Not Specified  
 Lunesta;Lexapro;Vyvanse;Klonopin 15-SEP-2023 06-SEP-2023  
 US Not Specified US-JNJFOC-20230868578 - -  
 22940434 - Herbals\Mitragynine -  
 Autopsy;Toxicity To Various Agents Serious Died Male -  
     13-SEP-2023 Direct 50 YR Not Specified Fda-Ctu  
 Healthcare Professional Not Specified - - 13-SEP-2023  
     Not Specified Not Specified - - -  
 16489116 Amlodipine;Fluoxetine Fluoxetine  
 Hydrochloride;Herbals\Mitragynine;Diphenhydramine;Amlodipine  
 Besylate;Sildenafil;Bentiamine\Bucetin\Caffeine\Ethenzamide;Trimiprami  
 ne Product Used For Unknown Indication Pulmonary  
 Oedema;Pneumonia;Toxicity To Various Agents Serious Other  
 Outcomes;Died Male - 12-SEP-2023 Expedited 56 YR  
     Not Specified Aurobindo Healthcare Professional Not  
 Specified - 02-SEP-2023 28-JUN-2019 DE Not  
     Specified DE-AUROBINDO-AUR-APL-2019-036700 "Fels H,  
 Lottner-Nau S, Sax T, Roider G, Graw M, Auwärter V, Musshoff F.  
 Postmortem concentrations of the synthetic opioid U-47700 in 26  
 fatalities associated with the drug. Forensic Science International.  
 2019;S0379-0738(19):30141-0" -  
 22925721 Buspirone;Paxlovid  
 Nirmatrelvir\Ritonavir;Herbals\Mitragynine;Buspirone  
 Hydrochloride;Quetiapine Covid-19 Treatment Serotonin  
 Syndrome;Drug Interaction Serious Other Outcomes;Hospitalized  
     Female - 08-SEP-2023 Expedited 5 DEC Not  
 Specified Pfizer Healthcare Professional Not Specified  
 Clonazepam;Lamotrigine 06-SEP-2023 08-SEP-2023 US Not  
 Specified US-PFIZER INC-PV202300151755 "Nasser, N.. Serotonin  
 Syndrome Precipitated by Paxlovid Initiation. Cureus. 2023" -  
 22923659 - Herbals\Mitragynine Drug Dependence Drug  
 Dependence Serious Hospitalized;Required Intervention Male  
     01-SEP-2023 07-SEP-2023 Direct 33 YR 67.5 KG Fda-  
 Ctu Consumer Not Specified Adderall - 07-  
 SEP-2023 Not Specified Not Specified - - -  
 22913233 -  
 Zopiclone;Citalopram;Lamotrigine;Herbals\Mitragynine Product Used  
 For Unknown Indication Drug Interaction;Pneumonia;Poisoning  
 Serious Died Male - 06-SEP-2023 Expedited Not  
 Specified Not Specified Mylan Healthcare Professional Not  
 Specified - 01-SEP-2023 06-SEP-2023 NO Not  
 Specified NO-MYLANLABS-2023M1092220 "Karinen R, Fosen J,

Rogde S, Vindenes V.. An accidental poisoning with mitragynine. Forensic Science International. 2014;245:E29–E32" -

22907600 - Herbals\Mitragynine Pain Abdominal Pain  
Upper;Vomiting;Drug Dependence;Myalgia;Diarrhoea;Withdrawal  
Syndrome;Nausea;Hyperhidrosis;Anxiety Non-Serious Non-Serious  
Male 31-AUG-2023 04-SEP-2023 Direct 36 YR 75.15  
KG Fda-Ctu Consumer Not Specified - - 04-  
SEP-2023 Not Specified Not Specified - - -

22882565 - Herbals\Mitragynine Substance Use  
Death;Psychotic Disorder;Bipolar Disorder Serious Died;Life  
Threatening Male 24-JUL-2023 29-AUG-2023 Direct 30 YR  
76.5 KG Fda-Ctu Consumer Not Specified Cannabis  
Sativa Subsp. Indica Top;Lyrica;Lithium - 29-AUG-2023 Not  
Specified Not Specified - - -

22868001 Lybalvi Olanzapine\Samidorphan L-  
Malate;Herbals\Mitragynine Bipolar I Disorder;Product Used For  
Unknown Indication;Substance Abuse;Thyroid Disorder Withdrawal  
Syndrome Non-Serious Non-Serious Female - 25-  
AUG-2023 Non-Expedited Not Specified 67.574 KG  
Alkermes Consumer Not Specified  
Levothyroxine;Lithium;Paxil;Latuda;Wellbutrin;Unspecified  
Ingredient;Lamictal 23-AUG-2023 25-AUG-2023 US Not  
Specified US-ALKERMES INC.-ALK-2023-003522 - -

22843148 - Herbals\Mitragynine Drug Dependence  
Arrhythmia;Taste Disorder;Drug Tolerance Increased;Gastrointestinal  
Disorder;Pruritus;Dependence;Vomiting;Erectile  
Dysfunction;Diarrhoea;Coordination Abnormal;Heart Rate  
Increased;Hyperhidrosis;Headache;Withdrawal Syndrome;Blood Pressure  
Increased Serious Disabled;Life Threatening;Required  
Intervention Male 01-AUG-2023 20-AUG-2023 Direct 38 YR  
76.5 KG Fda-Ctu Consumer Not Specified - -  
20-AUG-2023 Not Specified Not Specified - -

-

22843104 - Herbals\Mitragynine Alcohol Use Disorder  
Substance Use;Cardiac Arrest Serious Died Male 19-  
DEC-2021 19-AUG-2023 Direct 34 YR 90 KG Fda-Ctu  
Consumer Not Specified - - 19-AUG-2023 Not  
Specified Not Specified - - -

22839704 -  
Zopiclone;Lamotrigine;Citalopram;Herbals\Mitragynine Product Used  
For Unknown Indication Drug Interaction;Poisoning;Pneumonia  
Serious Died Male - 18-AUG-2023 Expedited Not  
Specified Not Specified Abbvie Healthcare Professional Not  
Specified - 14-AUG-2023 18-AUG-2023 NO Not  
Specified NO-ABBVIE-5372226 "Karin R, Fosen J, Rogde S,  
Vindenes V. An accidental poisoning with mitragynine. Forensic Sci  
Int. 2014;245:E29–E32." -

22820761 - Herbals\Mitragynine -  
Overdose;Seizure;Cardiac Arrest;Brain Death Serious Died Female  
04-AUG-2023 13-AUG-2023 Direct 30 YR 70 KG Fda-

Ctu Healthcare Professional Not Specified - - 13-  
 AUG-2023 Not Specified Not Specified - - -  
 22819308 - Herbals\Mitragynine Alcoholism;Anxiety  
     Generalised Tonic-Clonic Seizure Serious Other  
     Outcomes;Hospitalized;Life Threatening Male 04-JUL-2023 12-  
 AUG-2023 Direct 31 YR 85.5 KG Fda-Ctu Consumer Not  
     Specified - - 12-AUG-2023 Not Specified Not  
     Specified - - -  
 17889667 Buspirone;Trazodone Trazodone  
     Hydrochloride;Buspirone  
     Hydrochloride;Herbals\Mitragynine;Bupropion;Desvenlafaxine  
     Succinate;Ziprasidone Depression;Hypertension;Product Used For  
     Unknown Indication;Type 2 Diabetes Mellitus Drug  
     Interaction;Serotonin Syndrome Serious Hospitalized Male -  
     10-AUG-2023 Expedited 63 YR 102.5 KG Mylan  
     Healthcare Professional Not Specified  
     Glimepiride;Amlodipine;Gabapentin;Tizanidine;Omeprazole;Hydrochlorothiazide;Diclofenac;Metformin 01-AUG-2023 12-JUN-2020 US  
     Not Specified US-MYLANLABS-2020M1055177 "Eudaley ST,  
     Hamilton LA. Case report: Successful treatment of suspected  
     kratominduced serotonin syndrome. J-Am-Coll-Clin-Pharm 2020;3(1):347  
     abstr. 450." -  
 16314630 - Herbals\Mitragynine;Quetiapine Bipolar  
     Disorder;Product Used For Unknown Indication Toxicity To Various  
     Agents;Drug Interaction Serious Died Male - 09-AUG-2023  
     Expedited 27 YR Not Specified Teva Healthcare  
     Professional Not Specified - 31-JUL-2023 15-MAY-2019  
     US Not Specified US-TEVA-2019-US-1049610 - -  
 22802961 - Herbals\Mitragynine Anxiety;Insomnia  
     Drug Dependence;Quality Of Life Decreased Serious Other  
     Outcomes;Life Threatening;Required Intervention Male 08-AUG-2023  
     08-AUG-2023 Direct 31 YR 65.25 KG Fda-Ctu  
     Consumer Not Specified - - 08-AUG-2023 Not  
     Specified Not Specified - - -  
 22798057 Alcohol (Alcohol);Heroin  
     Oxycodone;Diamorphine;Clonazepam;Hydrocodone;Hydromorphone;Psilocin;Phencyclidine;Codeine;Flualprazolam;Morphine;Oxymorphone;Alcohol;Flubromazolam;Herbals\Mitragynine;Clonazolam;Fluoroketamine -  
     Nystagmus;Drug Abuse;Sinus Tachycardia;Sinus Bradycardia;Fall;Toxicity To Various Agents;Sinus Arrhythmia;Mental Status Changes  
     Serious Hospitalized;Other Outcomes Male - 08-AUG-2023  
     Expedited 28 YR Not Specified Cheplapharm  
     Healthcare Professional Not Specified - 01-AUG-2023 08-  
     AUG-2023 US Not Specified US-  
     CHEPLA-2023009702 "Domanski K, Fleming SW, Maag H, Raley EB,  
     DeBord J, Wright B, et al. A Psychonaut's Experience of Intoxication  
     with Multiple Classes of Drugs Including Novel Psychoactive Substance  
     2-fluorodeschloroketamine: Case Report and Urinary Analysis. Journal  
     of psychoactive drugs. 2022;54(4):319-323. DOI:  
     10.1080/02791072.2021.2006373." -

22798022 - Herbals\Mitragynine -  
Gastrointestinal Haemorrhage Serious Died Male 25-AUG-2018  
07-AUG-2023 Direct 30 YR Not Specified Fda-Ctu  
Consumer Not Specified - - 07-AUG-2023 Not  
Specified Not Specified - - -

22789411 - Quetiapine;Herbals\Mitragynine;Cannabis Sativa  
Flowering Top Back Pain;Depression Toxicity To Various  
Agents;Drug Interaction Serious Other Outcomes;Hospitalized Male  
- 04-AUG-2023 Expedited 33 YR Not Specified  
Astrazeneca Healthcare Professional Not Specified  
Methadone;Hydroxyzine 27-JUL-2023 04-AUG-2023 Not Specified  
Not Specified US-AstraZeneca-2023A174118 "Lefkovich E,  
Downing M, Zouridis S. Over-The-Counter Overdose: Toxicity Secondary  
to an Herbal Pain Supplement. 2023 RESIDENT AND MEDICAL STUDENT FORUM  
- NEW YORK CHAPTER OF THEAMERICAN COLLEGE OF PHYSICIANS (NYACP) 2023;"  
-

22787068 -  
Alprazolam;Morphine;Hydrocodone;Oxymorphone;Desmetramadol;Herbals\Mitr  
agynine;Clonazepam;Hydromorphone;Lorazepam;Phencyclidine;Codeine;Oxyco  
done;Ketamine Product Used For Unknown Indication  
Bradycardia;Nystagmus;Drug Abuse;Mental Status Changes;Fall;Sinus  
Tachycardia;Pupillary Reflex Impaired;Dissociative Disorder  
Serious Hospitalized;Other Outcomes Male - 04-AUG-2023  
Expedited 28 YR Not Specified Lupin Healthcare  
Professional Not Specified - 25-JUL-2023 04-AUG-2023  
US Not Specified US-LUPIN PHARMACEUTICALS  
INC.-2023-06389 "Domanski k, Fleming SW, Maag H, Raley E, Debord J,  
Wright B, et al. A Psychonaut's experience of intoxication with  
multiple classes of drugs including novel psychoactive substance 2-  
fluorodeschloroketamine: Case report and urinary analysis. Journal of  
Psychoactive Drugs. 2022;54(4):319-323" -

22780091 Heroin  
Diamorphine;Ketamine;Oxymorphone;Clonazepam;Oxycodone;Hydrocodone;Morp  
hine Sulfate;Herbals\Mitragynine;Hydromorphone Product Used For  
Unknown Indication Bradycardia;Drug Abuse;Mental Status  
Changes;Substance Use Serious Hospitalized Male - 03-  
AUG-2023 Expedited Not Specified Not Specified  
Strides Healthcare Professional Not Specified - 25-JUL-2023  
03-AUG-2023 US Not Specified US-STRIDES ARCOLAB  
LIMITED-2023SP012426 "Domanski k, Fleming SW, Maag H, Raley E,  
Debord J, Wright B, et al.. A Psychonaut's Experience of Intoxication  
with Multiple Classes of Drugs Including Novel Psychoactive Substance  
2-fluorodeschloroketamine: Case Report and Urinary Analysis.. J-  
Psychoactive-Drugs. 2022;54(4):319-323" -

22781580 - Herbals\Mitragynine Social Problem  
Palpitations;Adverse Drug Reaction;Depressed Mood;Drug  
Dependence;Alopecia Serious Life Threatening Male 01-  
AUG-2023 02-AUG-2023 Direct 36 YR 83.25 KG Fda-  
Ctu Consumer Not Specified - - 02-AUG-2023  
Not Specified Not Specified - - -

22772304 Escitalopram Escitalopram  
Oxalate;Herbals\Mitragynine Product Used For Unknown Indication  
Rhabdomyolysis;Agitation;Drug Abuse;Serotonin Syndrome  
Serious Other Outcomes Male - 01-AUG-2023 Expedited  
24 YR Not Specified Taro Healthcare Professional Not  
Specified - 18-JUL-2023 01-AUG-2023 US Not  
Specified US-TARO PHARMACEUTICALS USA  
INC.-2023TAR00806 "Palungwachira P, Yeh M, Whitworth B, Rushton  
W, Kazzi Z. Clinical Characteristics of Kratom Exposures Reported to  
the Georgia and Alabama Poison Control Centers from 2016–2020: A  
Retrospective Review. J Drug Alcohol Res. 2022;11(2):1-10" -

22772303 Escitalopram Escitalopram  
Oxalate;Aripiprazole;Herbals\Mitragynine Product Used For  
Unknown Indication Drug Abuse;Lethargy;Electrocardiogram Qt  
Prolonged;Torsade De Pointes Serious Other Outcomes Female -  
01-AUG-2023 Expedited 60 YR Not Specified Taro  
Healthcare Professional Not Specified - 18-JUL-2023  
01-AUG-2023 US Not Specified US-TARO  
PHARMACEUTICALS USA INC.-2023TAR00805 "Palungwachira P, Yeh M,  
Whitworth B, Rushton W, Kazzi Z. Clinical Characteristics of Kratom  
Exposures Reported to the Georgia and Alabama Poison Control Centers  
from 2016–2020: A Retrospective Review. J Drug Alcohol Res.  
2022;11(2):1-10" -

22768503 - Herbals\Mitragynine Depression  
Seizure;Accidental Overdose;Drug Dependence Serious Other  
Outcomes;Died Male 12-JUN-2022 31-JUL-2023 Direct 38 YR  
99 KG Fda-Ctu Consumer Not Specified  
Ritalin;Lexapro - 31-JUL-2023 Not Specified Not Specified  
- - -

22767666 - Baclofen;Herbals\Mitragynine;Nortriptyline  
Hydrochloride Product Used For Unknown Indication Therapy Non-  
Responder;Suicide Attempt;Lethargy;Electrocardiogram Qrs Complex  
Prolonged Serious Other Outcomes Female - 31-JUL-2023  
Expedited 57 YR Not Specified Taro Healthcare  
Professional Not Specified - 18-JUL-2023 31-JUL-2023  
US Not Specified US-TARO PHARMACEUTICALS USA  
INC.-2023TAR00804 "Palungwachira P, Yeh M, Whitworth B, Rushton  
W, Kazzi Z. Clinical Characteristics of Kratom Exposures Reported to  
the Georgia and Alabama Poison Control Centers from 2016–2020: A  
Retrospective Review. J Drug Alcohol Res. 2022;11(2):1-10" -

16017267 -  
Butyrfentanyl;Diphenhydramine;Oxycodone;Etizolam;Herbals\Mitragynine  
Product Used For Unknown Indication Drug Screen Positive  
Serious Died Not Specified - 31-JUL-2023  
Expedited Not Specified Not Specified Teva Healthcare  
Professional Not Specified - 21-JUL-2023 28-FEB-2019  
US Not Specified US-TEVA-2019-US-1017587 - -

22765730 - Herbals\Mitragynine Anxiety;Pain  
Product Advertising Issue;Anxiety;Drug Withdrawal Syndrome;Depression  
Serious Hospitalized Female 01-DEC-2020 30-JUL-2023

Direct 47 YR 54 KG Fda-Ctu Consumer Not Specified  
 - - 30-JUL-2023 Not Specified Not Specified  
 - - -  
 22755501 - Naltrexone Hydrochloride;Herbals\Mitragynine  
     Arthralgia;Weight Decreased "Off Label Use;Feeling  
     Cold;Hyperhidrosis;Restlessness;Mental Status Changes;Hallucination,  
     Visual;Agitation;Drug Interaction;Delirium;Heart Rate Increased"  
     Serious Other Outcomes;Hospitalized Male - 27-  
 JUL-2023 Expedited 56 YR Not Specified Accord  
 Healthcare Professional Not Specified Amlodipine;Metoprolol 16-  
 JUL-2023 27-JUL-2023 US Not Specified US-  
 Accord-369246 "Nunez T, Meyerson G, Alani M, Elahi S, Vargas E.  
     Supersensitivity Psychosis with Acute Dystonia. HCA Healthc J Med.  
     2023 Feb 28;4(1):57-60." -  
 22738090 Sertraline;Alcohol (Alcohol)  
     Alcohol;Olanzapine;Modafinil;3-  
     Fluorophenmetrazine;Benzoyllecgonine;Propylene  
     Glycol;Etonitazene;Gabapentin;Amphetamine;Sertraline  
     Hydrochloride;Desmethylsertraline;Melatonin;Herbals\Mitragynine;Etizol  
     am;.Alpha.-Hydroxyetizolam Product Used For Unknown Indication  
     Toxicity To Various Agents Serious Other Outcomes;Died  
     Male - 21-JUL-2023 Expedited 22 YR Not  
     Specified Ranbaxy Healthcare Professional Not Specified -  
     06-JUL-2023 21-JUL-2023 US Not Specified US-SUN  
 PHARMACEUTICAL INDUSTRIES LTD-2023R1-400611 "Papsun M D, Krotulski  
     A J, Logan B K. Proliferation of Novel Synthetic Opioids in Postmortem  
     Investigations After Core-Structure Scheduling for Fentanyl-Related  
     Substances. Am J Forensic Med Pathol. 2022;43:315-327" -  
 16026756 Escitalopram Escitalopram  
     Oxalate;Herbals\Mitragynine Anxiety;Back Pain;Hypertension;Major  
     Depression;Product Used For Unknown Indication Drug Interaction;Drug-  
     Induced Liver Injury Serious Other Outcomes Male - 20-  
     JUL-2023 Expedited 47 YR Not Specified Teva  
     Healthcare Professional Not Specified  
     Fexofenadine;Acetaminophen;Valsartan;Clonazepam;Metoprolol Tartrate  
     10-JUL-2023 03-MAR-2019 US Not Specified US-  
     TEVA-2019-US-1017222 - -  
 22704193 - Baclofen;Nortriptyline;Herbals\Mitragynine  
     Suspected Suicide Drug  
     Ineffective;Lethargy;Electrocardiogram Qrs Complex Prolonged  
     Serious Other Outcomes Female - 14-JUL-2023 Expedited  
     57 YR Not Specified Eurobindo Healthcare  
     Professional Not Specified - 29-JUN-2023 14-JUL-2023  
     US Not Specified US-AUROBINDO-AUR-APL-2023-047941  
     "Palungwachira P, Yeh M, Whitworth B, Rushton W, Kazzi Z..  
     ported to the Georgia and Alabama Poison Control Centers from 2016-  
     2020: A Retrospective Review. J-Drug-Alcohol-Res. 2022;11No. 2."  
     -  
 22704176 - Gabapentin;Herbals\Mitragynine;Lorazepam  
     Product Used For Unknown Indication Unresponsive To

Stimuli;Apnoeic Attack Serious Other Outcomes Male - 14-  
JUL-2023 Expedited 20 YR Not Specified Aurobindo  
Healthcare Professional Not Specified - 29-JUN-2023  
14-JUL-2023 US Not Specified US-AUROBINDO-AUR-  
APL-2023-047937 "P. Palungwachira, M. Yeh, B. Whitworth, W. Rushton  
and Z. Kazzi. Clinical Characteristics of Kratom Exposures Reported to  
the Georgia and Alabama Poison Control Centers from 2016–2020: A  
Retrospective Review. Journal of Drug and Alcohol Research. 2022;11:2"

-  
22704170 Escitalopram Escitalopram  
Oxalate;Herbals\Mitragynine;Aripiprazole Product Used For  
Unknown Indication Electrocardiogram Qt  
Prolonged;Lethargy;Torsade De Pointes Serious Other Outcomes Female  
- 14-JUL-2023 Expedited 60 YR Not Specified  
Aurobindo Healthcare Professional Not Specified -  
29-JUN-2023 14-JUL-2023 US Not Specified US-  
AUROBINDO-AUR-APL-2023-047934 "P. Palungwachira, M. Yeh, B.  
Whitworth, W. Rushton and Z. Kazzi. Clinical Characteristics of Kratom  
Exposures Reported to the Georgia and Alabama Poison Control Centers  
from 2016–2020: A Retrospective Review. Journal of Drug and Alcohol  
Research. 2022;11:2"

22703981 - Pregabalin;Clonazepam;Herbals\Mitragynine  
Product Used For Unknown Indication Apnoea;Drug  
Ineffective Serious Other Outcomes Male - 14-JUL-2023  
Expedited 20 YR Not Specified Aurobindo  
Healthcare Professional Not Specified - 29-JUN-2023 14-  
JUL-2023 US Not Specified US-AUROBINDO-AUR-  
APL-2023-047940 "Palungwachira P, Yeh M, Whitworth B, Rushton W, Kazzi  
Z. Clinical Characteristics of Kratom Exposures Reported to the  
Georgia and Alabama Poison Control Centers from 2016–2020: A  
Retrospective Review. J-Drug-Alcohol-Res. 2022;11No:2" -

22703746 Escitalopram Escitalopram  
Oxalate;Herbals\Mitragynine Product Used For Unknown Indication  
Serotonin Syndrome;Rhabdomyolysis;Agitation Serious Other  
Outcomes Male - 14-JUL-2023 Expedited 24 YR  
Not Specified Aurobindo Healthcare Professional Not  
Specified - 29-JUN-2023 14-JUL-2023 US Not  
Specified US-AUROBINDO-AUR-  
APL-2023-047936 "Palungwachira.P., Yeh.M, Whitworth.B, Rushton.W  
and Kazzi Z. Clinical Characteristics of Kratom Exposures Reported to  
the Georgia and Alabama Poison Control Centers from 2016–2020: A  
Retrospective Review. Journal of Drug and Alcohol Research. 2022;11:2"

-  
22621336 - Gabapentin;Lorazepam;Herbals\Mitragynine  
- Apnoea;Unresponsive To Stimuli Serious  
Hospitalized;Life Threatening Male - 14-JUL-2023  
Expedited 20 YR Not Specified Pfizer Healthcare  
Professional Not Specified - 12-JUL-2023 20-JUN-2023  
US Not Specified TH-PFIZER  
INC-202300226627 "Palungwachira, P.. Clinical Characteristics

of Kratom Exposures Reported to the Georgia and Alabama Poison Control Centers from 2016–2020: A Retrospective Review. Journal of Drug and Alcohol Research. 2022;11 (2):10.4303/jdar/236162" -

22705332 - Herbals\Mitragynine Depression;Pain  
Dependence;Drug Withdrawal Syndrome Non-Serious Non-Serious  
Female - 13-JUL-2023 Direct 27 YR 67.5 KG Fda-  
Ctu Consumer Not Specified - - 13-JUL-2023  
Not Specified Not Specified - - -  
22699975 - Herbals\Mitragynine Anxiety Intentional  
Overdose Serious Died Male 28-JUL-2022 12-JUL-2023  
Direct 50 YR 60.75 KG Fda-Ctu Consumer Not  
Specified Benazepril;Vitamin D - 12-JUL-2023 Not  
Specified Not Specified - - -  
22682730 - Herbals\Mitragynine Anxiety;Pain  
Seizure Serious Required Intervention;Life Threatening;Other  
Outcomes;Hospitalized Female 25-APR-2023 06-JUL-2023 Direct  
48 YR 69.75 KG Fda-Ctu Consumer Not Specified  
Vivitrol - 06-JUL-2023 Not Specified Not  
Specified - - -  
22666176 - Herbals\Mitragynine - Weight  
Decreased;Drug Dependence;Tremor Serious Died Male 10-  
NOV-2021 03-JUL-2023 Direct 40 YR Not Specified Fda-  
Ctu Consumer Not Specified - - 03-JUL-2023  
Not Specified Not Specified - - -  
22652454 - Pregabalin;Herbals\Mitragynine;Clonazepam  
Product Used For Unknown Indication;Suspected Suicide  
Unresponsive To Stimuli;Apnoea Serious Other Outcomes;Hospitalized  
Male - 29-JUN-2023 Expedited 20 YR Not  
Specified Hetero Healthcare Professional Not Specified -  
19-JUN-2023 29-JUN-2023 US Not Specified US-  
AMAROX PHARMA-HET2023US01810 "Palungwachira P, Yeh M, Whitworth B,  
Rushton W, Kazzi Z.. Clinical Characteristics of Kratom Exposures  
Reported to the Georgia and Alabama Poison Control Centers from 2016–  
2020: A Retrospective Review. Journal of Drug and Alcohol Research.  
2022;11(2):1-10" -  
22647695 - Lithium;Herbals\Mitragynine Product Used  
For Unknown Indication Lethargy;Unresponsive To Stimuli  
Serious Hospitalized Male - 28-JUN-2023 Expedited  
47 YR Not Specified Hetero Healthcare Professional Not  
Specified - 19-JUN-2023 28-JUN-2023 US Not  
Specified US-HETERO-HET2023US01806 "Palungwachira P, Yeh  
M, Whitworth B, Rushton W, Kazzi Z.. Clinical Characteristics of  
Kratom Exposures Reported to the Georgia and Alabama Poison Control  
Centers from 2016–2020: A Retrospective Review.. Journal of Drug and  
Alcohol Research.. 2022;11 (2):1-10" -  
22645480 - Herbals\Mitragynine;Pregabalin;Clonazepam  
Product Used For Unknown Indication Apnoeic  
Attack;Unresponsive To Stimuli Serious Other Outcomes Male -  
27-JUN-2023 Expedited 20 YR Not Specified  
Ranbaxy Healthcare Professional Not Specified - 12-JUN-2023

27-JUN-2023 US Not Specified US-SUN PHARMACEUTICAL INDUSTRIES LTD-2023R1-396278 "Palungwachira P, Yeh M, Whitworth B, Rushton W, Kazzi Z. Clinical Characteristics of Kratom Exposures Reported to the Georgia and Alabama Poison Control Centers from 2016-2020: A Retrospective Review. J Drug Alcohol Res. 2022;11(2):236162" -

22643781 Escitalopram Escitalopram Oxalate;Herbals\Mitragynine;Aripiprazole Product Used For Unknown Indication Lethargy;Electrocardiogram Qt Prolonged;Torsade De Pointes Serious Hospitalized Female -

27-JUN-2023 Expedited 60 YR Not Specified Hetero Healthcare Professional Not Specified - 19-JUN-2023

27-JUN-2023 US Not Specified US-AMAROX PHARMA-HET2023US01803 "Palungwachira P, Yeh M, Whitworth B, Rushton W, Kazzi Z.. Clinical Characteristics of Kratom Exposures Reported to the Georgia and Alabama Poison Control Centers from 2016-2020: A Retrospective Review.. Journal of Drug and Alcohol Research.. 2022;11(2):1-10" -

22642750 Vivitrol Naltrexone;Herbals\Mitragynine Product Used For Unknown Indication Unevaluable Event;Substance Use Non-Serious Non-Serious Not Specified - 27-JUN-2023 Non-Expedited Not Specified Not Specified Alkermes Consumer Not Specified - 20-JUN-2023

27-JUN-2023 US Not Specified US-ALKERMES INC.- ALK-2023-002437 - -

22633596 - Acetaminophen;Herbals\Mitragynine Product Used For Unknown Indication Unresponsive To Stimuli Serious Other Outcomes Female - 23-JUN-2023 Expedited 33 YR Not Specified Mylan Healthcare Professional Not Specified - 12-JUN-2023 23-JUN-2023 US Not Specified TH-MYLANLABS-2023M1065857 "Palungwachira P, Yeh M, Whitworth B, Rushton W, Kazzi Z. Clinical Characteristics of Kratom Exposures Reported to the Georgia and Alabama Poison Control Centers from 2016-2020: A Retrospective Review. J-Drug-Alcohol-Res 2022;11:No. 2." -

22628846 - Herbals\Mitragynine;Pregabalin;Clonazepam Product Used For Unknown Indication;Suspected Suicide Unresponsive To Stimuli;Drug Interaction;Suspected Suicide;Apnoea Serious Other Outcomes Male - 22-JUN-2023 Expedited 20 YR Not Specified Apotex Healthcare Professional Not Specified - 12-JUN-2023 22-JUN-2023 US Not Specified US-APOTEX-2023AP009169 "Palungwachira P, Yeh M, Whitworth B, Rushton W, Kazzi Z. Clinical Characteristics of Kratom Exposures Reported to the Georgia and Alabama Poison Control Centers from 2016-2020: A Retrospective Review. Journal of Drug and Alcohol Research. 2022;11 (2):1-10" -

22628738 - Acetaminophen;Herbals\Mitragynine Product Used For Unknown Indication;Suspected Suicide Drug Interaction;Suspected Suicide;Unresponsive To Stimuli Serious Other Outcomes Female - 22-JUN-2023 Expedited 33 YR

Not Specified Apotex Healthcare Professional Not Specified - 12-JUN-2023 22-JUN-2023 US Not Specified US-APOTEX-2023AP009170 "Palungwachira P, Yeh M, Whitworth B, Rushton W, Kazzi Z. Clinical Characteristics of Kratom Exposures Reported to the Georgia and Alabama Poison Control Centers from 2016–2020: A Retrospective Review. Journal of Drug and Alcohol Research. 2022;11 (2):1-10" -

22628423 Alcohol (Alcohol) Alcohol;Duloxetine;Herbals\Mitragynine;Aspirin Drug Abuse;Product Used For Unknown Indication Drug Interaction;Aggression;Drug Abuse;Myoclonus;Agitation Serious Other Outcomes Male - 22-JUN-2023 Expedited 57 YR Not Specified Apotex Healthcare Professional Not Specified - 12-JUN-2023 22-JUN-2023 US Not Specified US-APOTEX-2023AP009168 "Palungwachira P, Yeh M, Whitworth B, Rushton W, Kazzi Z. Clinical Characteristics of Kratom Exposures Reported to the Georgia and Alabama Poison Control Centers from 2016–2020: A Retrospective Review. Journal of Drug and Alcohol Research. 2022;11 (2):1-10" -

22628320 - Lithium;Herbals\Mitragynine Drug Abuse;Product Used For Unknown Indication Unresponsive To Stimuli;Drug Abuse;Drug Interaction;Lethargy Serious Other Outcomes Male - 22-JUN-2023 Expedited 47 YR Not Specified Apotex Healthcare Professional Not Specified - 12-JUN-2023 22-JUN-2023 US Not Specified US-APOTEX-2023AP009167 "Palungwachira P, Yeh M, Whitworth B, Rushton W, Kazzi Z. Clinical Characteristics of Kratom Exposures Reported to the Georgia and Alabama Poison Control Centers from 2016–2020: A Retrospective Review. Journal of Drug and Alcohol Research. 2022;11 (2):1-10" -

22627058 - Gabapentin;Lorazepam;Herbals\Mitragynine Product Used For Unknown Indication Unresponsive To Stimuli;Apnoea Serious Hospitalized;Life Threatening Male - 22-JUN-2023 Expedited 20 YR Not Specified Strides Healthcare Professional Not Specified - 12-JUN-2023 22-JUN-2023 TH Not Specified TH-STRIDES ARCOLAB LIMITED-2023SP009632 "Palungwachira P, Yeh M, Whitworth B, Rushton W, Kazzi Z.. Clinical Characteristics of Kratom Exposures Reported to the Georgia and Alabama Poison Control Centers from 2016–2020: A Retrospective Review.. J-Drug-Alcohol-Res. 2022;11 (2)." -

22624571 - Herbals\Mitragynine;Lorazepam;Gabapentin Product Used For Unknown Indication;Suspected Suicide Suspected Suicide;Drug Interaction;Unresponsive To Stimuli;Apnoea Serious Other Outcomes;Hospitalized Male - 21-JUN-2023 Expedited 20 YR Not Specified Apotex Healthcare Professional Not Specified - 12-JUN-2023 21-JUN-2023 US Not Specified US-APOTEX-2023AP009166 "Palungwachira P, Yeh M, Whitworth B, Rushton W, Kazzi Z. Clinical Characteristics of Kratom Exposures Reported to the Georgia and Alabama Poison Control Centers from 2016–2020: A Retrospective Review. Journal of Drug and Alcohol Research. 2022;11

(2):1-10" -  
22624423 Escitalopram Escitalopram  
Oxalate;Aripiprazole;Herbals\Mitragynine Drug Abuse;Product  
Used For Unknown Indication Drug Interaction;Electrocardiogram Qt  
Prolonged;Drug Abuse;Lethargy;Torsade De Pointes Serious  
Hospitalized;Other Outcomes Female - 21-JUN-2023  
Expedited 60 YR Not Specified Apotex Healthcare  
Professional Not Specified - 12-JUN-2023 21-JUN-2023  
US Not Specified US-APOTEX-2023AP009107 "Palungwachira  
P, Yeh M, Whitworth B, Rushton W, Kazzi Z. Clinical Characteristics of  
Kratom Exposures Reported to the Georgia and Alabama Poison Control  
Centers from 2016-2020: A Retrospective Review. Journal of Drug and  
Alcohol Research. 2022;11 (2):1-10" -  
22623753 Escitalopram Escitalopram  
Oxalate;Herbals\Mitragynine;Aripiprazole Product Used For  
Unknown Indication Lethargy;Electrocardiogram Qt  
Prolonged;Torsade De Pointes Serious Life Threatening;Hospitalized  
Female - 21-JUN-2023 Expedited 60 YR Not  
Specified Mylan Healthcare Professional Not Specified -  
12-JUN-2023 21-JUN-2023 US Not Specified TH-  
MYLANLABS-2023M1064786 "Palungwachira P, Yeh M, Whitworth B, Rushton  
W, Kazzi Z. Clinical Characteristics of Kratom Exposures Reported to  
the Georgia and Alabama Poison Control Centers from 2016-2020: A  
Retrospective Review. J-Drug-Alcohol-Res 2022;11:No. 2." -  
22623748 - Baclofen;Nortriptyline;Herbals\Mitragynine  
Product Used For Unknown Indication  
Lethargy;Electrocardiogram Qrs Complex Prolonged;Unresponsive To  
Stimuli Serious Hospitalized;Life Threatening Female - 21-  
JUN-2023 Expedited 57 YR Not Specified Mylan  
Healthcare Professional Not Specified - 12-JUN-2023 21-  
JUN-2023 US Not Specified TH-MYLANLABS-2023M1064814  
"Palungwachira P, Yeh M, Whitworth B, Rushton W, Kazzi Z.  
Clinical Characteristics of Kratom Exposures Reported to the Georgia  
and Alabama Poison Control Centers from 2016-2020: A Retrospective  
Review. J-Drug-Alcohol-Res 2022;11:No. 2." -  
22623742 - Lithium;Herbals\Mitragynine Drug  
Abuse;Product Used For Unknown Indication Unresponsive To  
Stimuli;Lethargy Serious Other Outcomes Male - 21-  
JUN-2023 Expedited 47 YR Not Specified Mylan  
Healthcare Professional Not Specified - 12-JUN-2023 21-  
JUN-2023 US Not Specified TH-MYLANLABS-2023M1064788  
"Palungwachira P, Yeh M, Whitworth B, Rushton W, Kazzi Z.  
Clinical Characteristics of Kratom Exposures Reported to the Georgia  
and Alabama Poison Control Centers from 2016-2020: A Retrospective  
Review. J-Drug-Alcohol-Res 2022;11:No. 2." -  
22621269 - Clonazepam;Herbals\Mitragynine Product Used  
For Unknown Indication Lethargy;Unresponsive To Stimuli  
Serious Other Outcomes Male - 20-JUN-2023 Expedited  
60 YR Not Specified Mylan Healthcare Professional Not  
Specified - 12-JUN-2023 20-JUN-2023 US Not

Specified TH-MYLANLABS-2023M1064800 "Palungwachira P, Yeh M, Whitworth B, Rushton W, Kazzi Z. Clinical Characteristics of Kratom Exposures Reported to the Georgia and Alabama Poison Control Centers from 2016–2020: A Retrospective Review. J–Drug–Alcohol–Res 2022;11:No. 2." -

22619735 - Gabapentin;Lorazepam;Herbals\Mitragynine Product Used For Unknown Indication Apnoea;Unresponsive To Stimuli Serious Life Threatening;Hospitalized Male - 20-JUN-2023 Expedited 20 YR Not Specified Mylan Healthcare Professional Not Specified - 12-JUN-2023 20-JUN-2023 US Not Specified TH-MYLANLABS-2023M1064789

"Palungwachira P, Yeh M, Whitworth B, Rushton W, Kazzi Z. Clinical Characteristics of Kratom Exposures Reported to the Georgia and Alabama Poison Control Centers from 2016–2020: A Retrospective Review. J–Drug–Alcohol–Res 2022;11:No. 2." -

22619365 - Herbals\Mitragynine Alcoholism Dependence Serious Required Intervention Male 05-JUN-2023 16-JUN-2023 Direct 41 YR 65.25 KG Fda-Ctu Consumer Not Specified Suboxone - - - Not Specified Not Specified - - -

22609062 - Herbals\Mitragynine Pain Alcoholism;Dependence;Drug Dependence Serious Disabled;Required Intervention;Hospitalized Female 01-JAN-2022 15-JUN-2023 Direct 33 YR Not Specified Fda-Ctu Consumer Not Specified - - 15-JUN-2023 Not Specified Not Specified - - -

22534982 - Herbals\Mitragynine Joint Injury Personality Change;Anxiety;Decreased Appetite;Drug Dependence;Drug Tolerance;Drug Effect Less Than Expected;Mood Swings;Withdrawal Syndrome;Aggression Serious Other Outcomes Male - 07-JUN-2023 Direct 31 YR 90 KG Fda-Ctu Consumer Not Specified - - 07-JUN-2023 Not Specified Not Specified - - -

22525830 Suboxone Buprenorphine Hydrochloride\Naloxone Hydrochloride;Herbals\Mitragynine Product Used For Unknown Indication Intentional Product Use Issue;Toxicity To Various Agents Serious Died;Other Outcomes Male - 06-JUN-2023 Expedited 52 YR Not Specified Reckitt Benckiser Healthcare Professional Not Specified - 01-JUN-2023 06-JUN-2023 US Not Specified US-INDIVIOR EUROPE

LIMITED-INDV-139608-2023 "Donna M. Papsun, Ayako Chan-Hosokawa, Laura Friederich, Justin Brower, Kristopher Graf and Barry Logan. The Trouble With Kratom: Analytical and Interpretative Issues Involving Mitragynine. Journal of Analytical Toxicology. 2019;43:615–629" -  
22518024 Trazodone Trazodone Hydrochloride;Herbals\Mitragynine;Ibuprofen Product Used For Unknown Indication Death Serious Died Male - 05-JUN-2023 Non-Expedited 52 YR Not Specified Alvogen Healthcare Professional Not Specified - 27-MAR-2023 05-JUN-2023 US Not Specified US-

ALVOGEN-2023091005 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Nathaniel PTP, Bronstein AC, Weber JA. 2021 Annual Report of the National Poison Data System (NPDS) from America's Poison Centers: 39th Annual Report. Clinical Toxicology. 2023Jan05;60(12):1381-1643. <https://doi:10.1080/15563650.2022.2132768>"

22400193 - Herbals\Mitragynine Anxiety  
Asthenia;Dependence;Irritability;Nausea;Diarrhoea;Pain;Judgement  
Impaired;Vomiting;Withdrawal Syndrome Serious Other Outcomes Male  
01-JUN-2023 01-JUN-2023 Direct 38 YR 99 KG Fda-  
Ctu Consumer Not Specified - - 01-JUN-2023  
Not Specified Not Specified - - -

22387618 - Herbals\Mitragynine Dependence;Substance  
Dependence Anger;Gallbladder Disorder;Loss Of Personal  
Independence In Daily Activities;Withdrawal Syndrome;Drug  
Dependence;Apathy;Headache;Restlessness;Abdominal  
Pain;Fatigue;Irritability;Delusion;Psychotic Disorder Non-Serious  
Non-Serious Male 15-MAR-2023 30-MAY-2023 Direct  
36 YR 200 LB Fda-Ctu Consumer Not Specified -  
- 30-MAY-2023 Not Specified Not Specified -

22384585 - Herbals\Mitragynine Analgesic Therapy  
Cardiac Arrest;Seizure;Brugada Syndrome;Clavicle  
Fracture;Product Use Issue;Fall Serious Other Outcomes;Life  
Threatening;Hospitalized Male 27-APR-2023 28-MAY-2023  
Direct 38 YR Not Specified Fda-Ctu Consumer Not  
Specified - - 28-MAY-2023 Not Specified Not  
Specified - - -

22384024 - Herbals\Mitragynine Product Used For  
Unknown Indication Delirium Tremens;Drug Withdrawal Syndrome;Drug  
Dependence Serious Disabled;Life Threatening;Required  
Intervention Male 01-MAR-2023 27-MAY-2023 Direct 36 YR  
85.5 KG Fda-Ctu Consumer Not Specified - -  
27-MAY-2023 Not Specified Not Specified - -

22366326 -  
Herbals\Mitragynine;Naproxen;Clonazepam;Cocaine;7-  
Aminoclonazepam;Levamisole;Naloxone;Benzoyllecgonine Product Used  
For Unknown Indication Toxicity To Various Agents Serious  
Died;Other Outcomes Female - 25-MAY-2023 Expedited  
28 YR Not Specified Ranbaxy Healthcare Professional Not  
Specified - 10-MAY-2023 25-MAY-2023 US Not  
Specified US-SUN PHARMACEUTICAL INDUSTRIES LTD-2023R1-390056  
"Salas JR, Krotulski AJ, Newman R, Thogmartin JR, Mohr ALA,  
Logan BK. Concentrations of para-Fluorofuranyl fentanyl in Paired  
Central and Peripheral Blood Collected during Postmortem Death  
Investigations. J Anal Toxicol. 2022;46:358-373" -

22366278 - 7-  
Hydroxymitragynine;Benzoyllecgonine;Herbals\Mitragynine;Codeine;Naproxene;Morphine Product Used For Unknown Indication Toxicity To

Various Agents Serious Died;Other Outcomes Male - 25-  
 MAY-2023 Expedited 38 YR Not Specified Ranbaxy  
 Healthcare Professional Not Specified - 10-MAY-2023 25-  
 MAY-2023 US Not Specified US-SUN PHARMACEUTICAL  
 INDUSTRIES LTD-2023R1-390054 "Salas JR, Krotulski AJ, Newman R,  
 Thogmartin JR, Mohr ALA, Logan BK. Concentrations of para-  
 Fluorofuranyl fentanyl in Paired Central and Peripheral Blood Collected  
 during Postmortem Death Investigations. J Anal Toxicol.  
 2022;46:358-373"  
 -  
 22366356 - Herbals\Mitragynine - "Substance  
 Use;Product Use Issue;Hallucination, Visual;Accidental  
 Death;Confusional State;Euphoric Mood;Hallucination, Auditory"  
 Serious Died;Hospitalized Male 11-AUG-2022 24-MAY-2023  
 Direct 30 YR 75.6 KG Fda-Ctu Consumer Not Specified  
 - - 24-MAY-2023 Not Specified Y -  
 -  
 21892904 Seroquel;Xywav Calcium Oxybate\Magnesium  
 Oxybate\Potassium Oxybate\Sodium Oxybate;Quetiapine  
 Fumarate;Olanzapine;Herbals\Mitragynine Hypersomnia;Product Used For  
 Unknown Indication;Restless Legs Syndrome;Somnolence Psychotic  
 Disorder;Personality Disorder;Product Administration  
 Interrupted;Adverse Drug Reaction;Suicidal Ideation;Drug  
 Interaction;Suicide Attempt;Exposure To Fungus Serious Other  
 Outcomes;Hospitalized Male 07-MAR-2023 18-MAY-2023 Non-  
 Expedited Not Specified Not Specified Jazz Healthcare  
 Professional Not Specified  
 Progesterone;Estradiol;Spironolactone;Requip;Atomoxetine 12-  
 APR-2023 20-JAN-2023 US Not Specified US-JAZZ-2022-  
 US-023024 - -  
 22309885 - Herbals\Mitragynine Product Used For  
 Unknown Indication Headache;Sneezing;Withdrawal  
 Syndrome;Dependence;Diarrhoea;Restless Legs Syndrome;Verbal  
 Abuse;Dyskinesia;Hyperhidrosis;Chills;Muscle  
 Atrophy;Anger;Irritability;Weight Decreased;Panic Attack Non-  
 Serious Non-Serious Male - 10-MAY-2023 Direct Not  
 Specified Not Specified Fda-Ctu Consumer Not Specified  
 Vitamin C;Dietary Supplement - 10-MAY-2023 Not  
 Specified Not Specified - - -  
 22304339 - Herbals\Mitragynine - Seizure  
 Serious Hospitalized;Died;Life Threatening Male - 09-  
 MAY-2023 Direct 24 YR 90 KG Fda-Ctu Consumer Not  
 Specified - - 09-MAY-2023 Not Specified Not  
 Specified - - -  
 22293916 Lybalvi Olanzapine\Samidorphan L-  
 Malate;Herbals\Mitragynine Product Used For Unknown Indication  
 Withdrawal Syndrome;Discomfort Non-Serious Non-Serious  
 Not Specified - 08-MAY-2023 Non-Expedited Not  
 Specified Not Specified Alkermes Healthcare  
 Professional Not Specified - 03-MAY-2023 08-MAY-2023  
 US Not Specified US-ALKERMES INC.-ALK-2023-001891

22291756 - Herbals;Herbals\Mitragynine Anxiety;Pain  
     Hot Flush;Drug Dependence;Pain;Withdrawal  
     Syndrome;Hyperhidrosis;Hallucination;Overdose;Respiratory  
     Distress;Chills;Pulmonary Fibrosis Serious  
     Disabled;Hospitalized;Life Threatening;Required Intervention Male  
     30-MAR-2023 05-MAY-2023 Direct 27 YR 66.6 KG Fda-  
     Ctu Consumer Not Specified Insulin Nos - 05-  
     MAY-2023 Not Specified Not Specified - - -  
 21414256 - Morphine;Herbals\Mitragynine;Hydrocodone  
     Headache;Product Used For Unknown Indication Acute Kidney  
     Injury;Drug Abuse Serious Other Outcomes Female - 05-  
     MAY-2023 Expedited 21 YR Not Specified Specgx  
     Healthcare Professional Not Specified - 24-APR-2023 06-  
     OCT-2022 US Not Specified US-SPECGX-  
 T202202113 "LeSaint KT, Yin S, Sharma A, Avery BA, McCurdy CR,  
     Waksman JC. Acute renal insufficiency associated with consumption of  
     hydrocodone- and morphine-adulterated Kratom (Mitragyna Speciosa).  
     Journal of Emergency Medicine. 2022;63(1):e28-30" -  
 22288662 - Herbals\Mitragynine Asthenia  
     Withdrawal Syndrome;Drug Dependence;Psychotic Disorder;Eye Disorder  
     Serious Disabled;Hospitalized Male 31-JUL-2022 04-  
     MAY-2023 Direct 24 YR 74.25 KG Fda-Ctu Consumer  
     Not Specified Vitamin D;Zoloft - 04-MAY-2023  
     Not Specified Not Specified - - -  
 22288643 - Herbals\Mitragynine Attention Deficit  
     Hyperactivity Disorder Agitation;Mental Disorder;Attention Deficit  
     Hyperactivity Disorder;Product Tampering;Nausea;Condition  
     Aggravated;Schizoaffective Disorder Bipolar Type;Withdrawal  
     Syndrome;Chest Pain;Product Taste Abnormal;Aggression Serious  
     Disabled;Required Intervention;Hospitalized Not Specified 04-  
     MAY-2023 04-MAY-2023 Direct 337 MTH 81.9 KG Fda-Ctu  
     Consumer Not Specified  
     Lamotrigine;Methylphenidate;Paliperidone - 04-MAY-2023  
     Not Specified Not Specified - - -  
 22285248 - Levamisole;Clonazepam;Herbals\Mitragynine  
     Drug Abuse;Product Used For Unknown Indication Toxicity To  
     Various Agents;Drug Abuse Serious Died;Hospitalized Female  
     - 04-MAY-2023 Expedited 28 YR Not Specified  
     Teva Healthcare Professional Not Specified Naproxen  
     24-APR-2023 04-MAY-2023 US Not Specified US-  
 TEVA-2023-US-2881991 - - -  
 22285035 - Herbals\Mitragynine Back Pain;Drug  
     Dependence Drug Withdrawal Syndrome Serious Other Outcomes  
     Male 06-NOV-2018 04-MAY-2023 Direct 39 YR 101.25  
     KG Fda-Ctu Consumer Not Specified - - 04-  
     MAY-2023 Not Specified Not Specified - - Yes  
 22283963 Naloxone Hcl Naloxone  
     Hydrochloride;Herbals\Mitragynine;Benzoyllecgonine;Clonazepam;Cocaine;N  
     aproxen;Levamisole - Toxicity To Various Agents

Serious Other Outcomes;Died;Hospitalized Female - 04-  
MAY-2023 Expedited 28 YR Not Specified Pfizer  
Healthcare Professional Not Specified - 25-APR-2023 04-  
MAY-2023 US Not Specified US-PFIZER INC-202300172008  
"Salas, J.. Concentrations of para-Fluorofuranyl fentanyl in  
Paired Central and Peripheral Blood Collected during Postmortem Death  
Investigations. Journal of Analytical Toxicology. 2022;46 (4):358-373"

-  
22284372 - Herbals\Mitragynine  
Anxiety;Depression;Lethargy;Post-Traumatic Stress Disorder;Stress  
Product Design Issue;Product Label Confusion;Drug Dependence  
Serious Disabled;Required Intervention Male 14-JUN-2015  
03-MAY-2023 Direct 34 YR 99 KG Fda-Ctu Consumer  
Not Specified - - 03-MAY-2023 Not Specified  
Y - - -

22284369 - Herbals\Mitragynine - Hepatic  
Failure;Toxicity To Various Agents;Renal Failure Serious  
Died;Hospitalized;Life Threatening Female 06-APR-2023 03-  
MAY-2023 Direct 23 YR Not Specified Fda-Ctu Consumer  
Not Specified Herbals\Mitragynine - 03-MAY-2023  
Not Specified Not Specified - - -

22283576 - Herbals\Mitragynine Substance Use  
Intentional Product Use Issue;Jaundice Serious Hospitalized;Required  
Intervention Male 09-JUL-2021 03-MAY-2023 Direct 2 DAY  
90 KG Fda-Ctu Consumer Not Specified - -  
03-MAY-2023 Not Specified Not Specified - - -

-  
22282385 - Herbals\Mitragynine Analgesic Therapy  
Death Serious Died Not Specified 14-AUG-2020 03-  
MAY-2023 Direct 32 YR Not Specified Fda-Ctu Consumer  
Not Specified - - 03-MAY-2023 Not Specified  
Y - - -

22259439 - Levamisole;Clonazepam;Herbals\Mitragynine  
Product Used For Unknown Indication Drug Abuse;Toxicity To  
Various Agents Serious Died;Hospitalized Female - 27-  
APR-2023 Expedited 28 YR Not Specified Mylan  
Healthcare Professional Not Specified Naproxen 18-APR-2023  
27-APR-2023 US Not Specified US-  
MYLANLABS-2023M1042993 "Rodriguez Salas J, Krotulski AJ, Newman R,  
Thogmartin JR, Mohr ALA, Logan BK. Concentrations of para-  
Fluorofuranyl fentanyl in Paired Central and Peripheral Blood Collected  
during Postmortem Death Investigations. J-Anal-Toxicol  
2022;46(4):358-373." -

22242539 - Herbals\Mitragynine Drug Dependence  
Withdrawal Syndrome;Feeling Abnormal Serious Other Outcomes Male  
16-APR-2023 23-APR-2023 Direct 39 YR Not Specified  
Fda-Ctu Consumer Not Specified - - 23-  
APR-2023 Not Specified Not Specified - - -

22234404 - Herbals\Mitragynine Disturbance In  
Attention Vomiting;Drug Withdrawal

Syndrome;Anxiety;Pain;Depression;Dehydration;Urine Amphetamine  
 Positive              Serious Required Intervention;Disabled Male    15-  
 APR-2023              19-APR-2023      Direct    29 YR    80.1 KG Fda-Ctu  
 Consumer              Not Specified    -        -        19-APR-2023      Not  
 Specified              Not Specified    -        -        -  
 21727410              Naloxone Hcl      Naloxone  
 Hydrochloride;Herbals\Mitragynine              -        Toxicity To Various  
 Agents              Serious Died      Male    -        12-APR-2023      Expedited  
                     33 YR    Not Specified      Pfizer      Healthcare Professional Not  
 Specified              -        11-APR-2023      14-DEC-2022      US        Not  
 Specified              US-PFIZER INC-PV202200118721      "Behonick, G.. Two  
 Single-Drug Fatal Intoxications by Mitragynine. Journal of Analytical  
 Toxicology. 2022;46(5):E110-E114"              -  
 22201307              -        Herbals\Mitragynine    -        Substance  
 Use;Resuscitation      Serious Required Intervention      Male    05-  
 APR-2023              11-APR-2023      Direct    33 YR    Not Specified Fda-  
 Ctu              Consumer              Not Specified    -        -        11-APR-2023  
                     Not Specified              Not Specified    -        -        -  
 22197048              -        Fentanyl;Cannabis Sativa Subsp. Indica  
 Top;Herbals\Mitragynine Drug Abuse      Drug Abuse;Incorrect Route Of  
 Product Administration;Cardiac Arrest;Respiratory Arrest  
 Serious Died      Male    -        11-APR-2023      Expedited      24 YR  
                     Not Specified              Alvogen Healthcare Professional Not Specified  
                     -        27-MAR-2023      11-APR-2023      US        Not Specified  
                     US-ALVOGEN-2023090497      "Gummin DD, Mowry JB, Beuhler MC,  
 Spyker DA, Rivers LJ, Feldman R, Brown K, Nathaniel PTP, Bronstein AC,  
 Weber JA.. 2021 Annual Report of the National Poison Data System  
 (NPDS) from America's Poison Centers: 39th Annual Report. Clinical  
 Toxicology. 05Jan2023;60(12):1381-1643 . doi:<https://doi.org/10.1080/15563650.2022.2132768>"      -  
 22196087              -        Herbals\Mitragynine;Fentanyl      Product Used  
 For Unknown Indication      Prescription Drug Used Without A  
 Prescription;Death      Serious Died      Male    -        11-APR-2023  
                     Expedited      42 YR    Not Specified      Alvogen Healthcare  
 Professional              Not Specified    -        27-MAR-2023      11-APR-2023  
                     US        Not Specified              US-ALVOGEN-2023089931      "Gummin DD,  
 Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R, Brown K,  
 Nathaniel PTP, Bronstein AC, Weber JA.. 2021 Annual Report of the  
 National Poison Data System© (NPDS) from America's Poison Centers:  
 39th Annual Report.. Clinical toxicology. 2023Jan05;60(12):1381-1643.  
 doi:[10.1080/15563650.2022.2132768](https://doi.org/10.1080/15563650.2022.2132768)"      -  
 22196048              Sertraline              Sertraline  
 Hydrochloride;Acetaminophen;Herbals\Mitragynine Suicide Attempt  
 Completed Suicide      Serious Died      Male    -        11-APR-2023  
                     Expedited      34 YR    Not Specified      Alvogen Healthcare  
 Professional              Not Specified    -        27-MAR-2023      11-APR-2023  
                     US        Not Specified              US-ALVOGEN-2023089806      "Gummin DD,  
 Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R, Brown K,  
 Nathaniel PTP, Bronstein AC, Weber JA. 2021 Annual Report of the  
 National Poison Data System (NPDS) from America's Poison Centers: 39th

Annual Report. Clinical Toxicology. 2023 Jan 05;60(12):1381-1643.  
doi:10.1080/15563650.2022.2132768" -

22195924            Sertraline            Sertraline  
Hydrochloride;Fentanyl;Herbals\Mitragynine            Drug Abuse            Drug  
Abuse;Prescription Drug Used Without A Prescription            Serious Died  
Male            -            11-APR-2023            Expedited            39 YR            Not  
Specified            Alvogen Healthcare Professional Not Specified            -  
27-MAR-2023            11-APR-2023            US            Not Specified            US-  
ALVOGEN-2023089863            "Gummin DD, Mowry JB, Beuhler MC, Spyker DA,  
Rivers LJ, Feldman R, Brown K, Nathaniel PTP, Bronstein AC, Weber JA.  
2021 Annual Report of the National Poison Data System© (NPDS) from  
America's Poison Centers: 39th Annual Report . Clinical Toxicology.  
2023-Jan-05;60 (12):1381-1643. doi:<https://doi.org/10.1080/15563650.2022.2132768>" -

22195915            -            Herbals\Mitragynine;Fentanyl            Product Used  
For Unknown Indication            Death            Serious Died            Male            -            11-  
APR-2023            Expedited            28 YR            Not Specified            Alvogen  
Healthcare Professional Not Specified            -            27-MAR-2023            11-  
APR-2023            US            Not Specified            US-  
ALVOGEN-2023089777            "Gummin DD, Mowry JB, Beuhler MC, Spyker DA,  
Rivers LJ, Feldman R, Brown K, Nathaniel PTP, Bronstein AC, Weber JA.  
2021 Annual Report of the National Poison Data System (NPDS) from  
America's Poison Centers: 39th Annual Report. Clinical Toxicology.  
2023 Jan 05;60(12):1381-1643. doi:10.1080/15563650.2022.2132768"

22195783            -            Fentanyl;Herbals\Mitragynine            Suicide  
Attempt Completed Suicide;Prescription Drug Used Without A  
Prescription            Serious Died            Female            -            11-APR-2023  
Expedited            54 YR            Not Specified            Alvogen Healthcare  
Professional            Not Specified            -            27-MAR-2023            11-APR-2023  
US            Not Specified            US-ALVOGEN-2023089887            "Gummin DD,  
Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R, Brown K,  
Nathaniel PTP, Bronstein AC, Weber JA.. 2021 Annual Report of the  
National Poison Data System© (NPDS) from America's Poison Centers:  
39th Annual Report.. Clinical toxicology. 2023Jan05;60(12):1381-1643.  
doi:10.1080/15563650.2022.2132768" -

22195671            -            Gabapentin;Valproic  
Acid;Herbals\Mitragynine;Alcohol;Butalbital            Suicide Attempt  
Respiratory Arrest;Cardiac Arrest;Completed Suicide            Serious Died  
Female            -            11-APR-2023            Expedited            45 YR            Not  
Specified            Alvogen Healthcare Professional Not Specified            -  
27-MAR-2023            11-APR-2023            US            Not Specified            US-  
ALVOGEN-2023090040            "Gummin DD, Mowry JB, Beuhler MC, Spyker DA,  
Rivers LJ, Feldman R, Brown K, Nathaniel PTP, Bronstein AC, Weber JA..  
2021 Annual Report of the National Poison Data System (NPDS) from  
America's Poison Centers: 39th Annual Report. Clinical Toxicology.  
2023 Jan 05;60(12):1381-1643. doi:10.1080/15563650.2022.2132768"

22195005            -            Gabapentin;Fentanyl;Etizolam;Oxycodone;Herbals\Mitragynine            Drug

Abuse Prescription Drug Used Without A Prescription;Drug Abuse  
Serious Died Male - 11-APR-2023 Expedited  
46 YR Not Specified Alvogen Healthcare Professional Not  
Specified - 27-MAR-2023 11-APR-2023 US Not  
Specified US-ALVOGEN-2023089886 "Gummin DD, Mowry JB, Beuhler  
MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Nathaniel PTP, Bronstein  
AC, Weber JA. 2021 Annual Report of the National Poison Data System  
(NPDS) from America's Poison Centers: 39th Annual Report. Clinical  
Toxicology. 2023 Jan 05;60(12):1381-1643.  
doi:10.1080/15563650.2022.2132768" -

22194175 - Alcohol;Herbals\Mitragynine;Fentanyl Drug  
Abuse Prescription Drug Used Without A Prescription;Cardiac  
Arrest;Drug Abuse;Respiratory Arrest Serious Died Male -  
11-APR-2023 Expedited 41 YR Not Specified  
Alvogen Healthcare Professional Not Specified - 27-MAR-2023  
11-APR-2023 US Not Specified US-ALVOGEN-2023090326  
"Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Rivers LJ,  
Feldman R, Brown K, Pham NP , Bronstein AC, Weber J.. 2021 Annual  
Report of the National Poison Data System© (NPDS) from America's  
Poison Centers: 39th Annual Report.. Clinical toxicity.  
2023Jan05;60(12):1381-1643. doi:10.1080/15563650.2021.1989785" -

22193454 Salicylate;Sertraline;Heroin Sertraline  
Hydrochloride;Diamorphine;Alprazolam;Salicylic Acid;Cannabis Sativa  
Subsp. Indica Top;Fentanyl;Herbals\Mitragynine;Cocaine;Aripiprazole  
Product Used For Unknown Indication Death Serious Died  
Male - 10-APR-2023 Expedited 17 YR Not  
Specified Alvogen Healthcare Professional Not Specified -  
27-MAR-2023 10-APR-2023 US Not Specified US-  
ALVOGEN-2023090164 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA,  
Rivers LJ, Feldman R, Brown K, Pham NP , Bronstein AC, Weber J. 2021  
Annual Report of the National Poison Data System© (NPDS) from America?  
s Poison Centers: 39th Annual Report. Clinical toxicity.  
2023Jan05;60:1381-1643. doi: <https://doi.org/10.1080/15563650.2022.2132768>" -

22189858 Venlafaxine Venlafaxine  
Hydrochloride;Herbals\Mitragynine;Amphetamine Drug Abuse Drug  
Abuse Serious Died Male - 10-APR-2023 Expedited  
31 YR Not Specified Alvogen Healthcare Professional Not  
Specified - 27-MAR-2023 10-APR-2023 US Not  
Specified US-ALVOGEN-2023091145 "Gummin DD, Mowry JB, Beuhler  
MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Pham NP , Bronstein AC,  
Weber J. 2021 Annual Report of the National Poison Data System© (NPDS)  
from America?s Poison Centers: 39th Annual Report. Clinical toxicity.  
2023Jan05;60:1381-1643. doi:10.1080/15563650.2021.1989785" -

22190944 - Herbals\Mitragynine Feeling Of Relaxation  
Somniphobia;Product  
Complaint;Hypopnoea;Hyperhidrosis;Anxiety;Dry Mouth;Dizziness;Feeling  
Hot;Hot Flush;Nausea Serious Other Outcomes Female 08-APR-2023  
09-APR-2023 Direct 36 YR 58.5 KG Fda-Ctu Consumer  
Not Specified - - 09-APR-2023 Not Specified

Y - - - -  
22188537 - Alcohol;Gabapentin;Herbals\Mitragynine Drug  
Abuse Drug Abuse Serious Died Male - 09-APR-2023  
Expedited 45 YR Not Specified Alvogen Healthcare  
Professional Not Specified - 27-MAR-2023 09-APR-2023  
US Not Specified US-ALVOGEN-2023090248 "Gummin DD,  
Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R, Brown K,  
Nathaniel PTP, Bronstein AC, Weber JA. 2021 Annual Report of the  
National Poison Data System (NPDS) from America's Poison Centers: 39th  
Annual Report. Clinical Toxicology. 2023-Jan-05;60 (12):1381-1643.  
doi: <https://doi.org/10.1080/15563650.2022.2132768>" -  
22188284 -  
Gabapentin;Lorazepam;Aripiprazole;Acetaminophen;Herbals\Mitragynine  
Intentional Product Misuse Intentional Product Misuse  
Serious Died Male - 08-APR-2023 Expedited  
22 YR Not Specified Alvogen Healthcare Professional Not  
Specified - 27-MAR-2023 08-APR-2023 US Not  
Specified US-ALVOGEN-2023089713 "Gummin DD, Mowry JB, Beuhler  
MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Nathaniel PTP, Bronstein  
AC, Weber JA.. 2021 Annual Report of the National Poison Data System©  
(NPDS) from America's Poison Centers: 39th Annual Report.. Clinical  
toxicity. 2023Jan05;60(12):1381-1643.  
doi:10.1080/15563650.2021.1989785" -  
22160856 - Herbals\Mitragynine -  
Nausea;Vomiting;Sensory Disturbance;Paraesthesia;Product  
Complaint;Headache;Paradoxical Drug Reaction Non-Serious Non-  
Serious Male 30-MAR-2023 31-MAR-2023 Direct 34 YR 90 KG  
Fda-Ctu Consumer Not Specified - - 31-  
MAR-2023 Not Specified Not Specified - - -  
20667448 Venlafaxine Venlafaxine  
Hydrochloride;Herbals\Mitragynine;Quetiapine Fumarate Product Used  
For Unknown Indication Electrocardiogram Qt Prolonged;Drug  
Interaction;Serotonin Syndrome Serious Other Outcomes;Hospitalized  
Male - 31-MAR-2023 Expedited 36 YR Not  
Specified Rising Pharmaceuticals Healthcare Professional Not  
Specified - 20-MAR-2023 04-APR-2022 US Not  
Specified US-RISINGPHARMA-US-2022RISLIT00319 Brogdon HD.A  
Case of Potential Pharmacokinetic Kratom-drug Interactions Resulting  
in Toxicity and Subsequent Treatment of Kratom Use Disorder With  
Buprenorphine/Naloxone.Journal of Addiction Medicine.14-FEB-2022  
-  
22140015 - Herbals\Mitragynine Substance Use  
Appetite Disorder;Weight Decreased;Depression;Apathy;Lethargy;Drug  
Dependence;Socioeconomic Precarity Serious Hospitalized;Required  
Intervention Male 25-FEB-2023 24-MAR-2023 Direct 31 YR  
67.5 KG Fda-Ctu Consumer Not Specified  
Lexapro;Vitamin C - 24-MAR-2023 Not Specified Not  
Specified - - -  
22134904 - Herbals\Mitragynine Anxiety;Pain In  
Extremity Toxicity To Various Agents;Drug Dependence;Substance

Use Serious Died Female 15-MAY-2022 23-MAR-2023 Direct  
 28 YR 64.8 KG Fda-Ctu Consumer Not Specified  
 Concerta - 23-MAR-2023 Not Specified Not Specified  
 - - -  
 22119202 - Herbals\Mitragynine Anxiety  
 Dependence;Aggression;Restless Legs Syndrome;Asthenia;Skin  
 Disorder;Disturbance In Attention;Dyspepsia;Anxiety Serious  
 Hospitalized;Required Intervention Male 31-OCT-2022 20-  
 MAR-2023 Direct 31 YR 54 KG Fda-Ctu Consumer Not  
 Specified - - 20-MAR-2023 Not Specified Not  
 Specified - - -  
 22103278 -  
 Herbals\Mitragynine;Gabapentin;Butalbital;Alcohol;Valproic Acid  
 Product Used For Unknown Indication Suspected Suicide  
 Serious Died;Other Outcomes Female - 16-MAR-2023  
 Expedited 45 YR Not Specified Catalent Pharma Healthcare  
 Professional Not Specified - 05-MAR-2023 16-MAR-2023  
 US Not Specified US-CATALENT PHARMA SOLUTIONS-  
 CAT-000011-2023 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Rivers  
 LJ, Feldman R, Brown K, Nathaniel PTP, Bronstein AC, Weber JA.2021  
 Annual Report of the National Poison Data System (NPDS) from America's  
 Poison Centers: 39th Annual Report.Clinical toxicology  
 (Philadelphia).DEC-2022;60(12):1381-1643" -  
 22090073 - Herbals\Mitragynine Product Used For  
 Unknown Indication Unevaluable Event Serious Died Male  
 - 13-MAR-2023 Direct 32 YR 94.5 KG Fda-Ctu  
 Consumer Not Specified - - 13-MAR-2023 Not  
 Specified Not Specified - - -  
 22073940 - Herbals\Mitragynine - Fall;Drug  
 Abuse;Confusional State;Fatigue;Loss Of Consciousness;Intentional  
 Overdose Serious Required Intervention Male 06-MAR-2023  
 07-MAR-2023 Direct 33 YR Not Specified Fda-Ctu  
 Consumer Not Specified - - 07-MAR-2023 Not  
 Specified Not Specified - - -  
 22066563 Vivitrol;Heroin  
 Naltrexone;Diamorphine;Herbals\Mitragynine Drug  
 Dependence;Product Used For Unknown Indication Contraindicated  
 Product Administered;Drug Ineffective;Substance Abuse Non-Serious  
 Non-Serious Not Specified - 06-MAR-2023 Non-  
 Expedited Not Specified Not Specified Alkermes  
 Consumer Not Specified - 03-MAR-2023 06-MAR-2023  
 US Not Specified US-ALKERMES INC.-ALK-2023-000931  
 - -  
 22035701 - Herbals\Mitragynine Anxiety  
 Contraindicated Product Administered;Disorientation;Pneumonia  
 Aspiration;Vomiting;Coma;Aspiration;Dyspnoea;Oxygen Saturation  
 Decreased;Product Label Issue;Cerebrovascular Accident;Serotonin  
 Syndrome Serious Life Threatening;Disabled;Hospitalized Male  
 29-JAN-2023 23-FEB-2023 Direct 50 YR 104.78 KG  
 Fda-Ctu Consumer Not Specified

Sertraline;Buspirone;Gabapentin;Remeron;Metoprolol - 23-  
 FEB-2023 Not Specified Not Specified - - -  
 22022197 - Herbals\Mitragynine Arthralgia;Back Pain  
     "Death;Delusional Disorder, Unspecified Type;Abnormal  
     Behaviour;Hallucination" Serious Died;Hospitalized Male  
     06-FEB-2023 20-FEB-2023 Direct 48 YR 67.5 KG Fda-  
 Ctu Consumer Not Specified  
 Ibuprofen;Seroquel;Herbals\Mitragynine - 20-FEB-2023 Not  
     Specified Not Specified - - -  
 22008425 Sertraline;Heroin Diamorphine;Sertraline  
     Hydrochloride;Cocaine;Fentanyl Citrate;Cannabis Sativa Subsp. Indica  
     Top;Alprazolam;Herbals\Mitragynine;Aripiprazole Product Used For  
     Unknown Indication Death Serious Died Male 2021 19-  
     FEB-2023 Expedited 17 YR Not Specified Specgx  
     Healthcare Professional Not Specified - 05-JAN-2023 19-  
     FEB-2023 US Not Specified US-SPECGX-  
 T202300403 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Rivers  
     LJ, Feldman R et al. 2021 Annual Report of the National Poison Data  
     System (NPDS) from America's Poison Centers: 39th Annual Report.  
     Clinical Toxicology. 2022;60(12):1381-643" -  
 22008414 - Fentanyl Citrate;Herbals\Mitragynine;Cannabis  
     Sativa Subsp. Indica Top Product Used For Unknown Indication  
     Drug Abuse;Incorrect Route Of Product Administration;Analgesic  
     Drug Level Increased Serious Died Male 2021 19-FEB-2023  
     Expedited 24 YR Not Specified Specgx Healthcare  
     Professional Not Specified - 05-JAN-2023 19-FEB-2023  
     US Not Specified US-SPECGX-T202300495 "Gummin DD,  
     Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R et al. 2021  
     Annual Report of the National Poison Data System (NPDS) from America's  
     Poison Centers: 39th Annual Report. Clinical Toxicology.  
     2022;60(12):1381-643" -  
 22008410 - Herbals\Mitragynine;Fentanyl Citrate  
     Product Used For Unknown Indication Death Serious Died Male  
     2021 19-FEB-2023 Expedited 28 YR Not Specified  
     Specgx Healthcare Professional Not Specified - 05-  
     JAN-2023 19-FEB-2023 US Not Specified US-SPECGX-  
 T202300518 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Rivers  
     LJ, Feldman R et al. 2021 Annual Report of the National Poison Data  
     System (NPDS) from America's Poison Centers: 39th Annual Report.  
     Clinical Toxicology. 2022;60(12):1381-643" -  
 22020899 Methadone Methadone  
     Hydrochloride;Herbals\Mitragynine - Analgesic Drug Level  
     Increased;Drug Dependence;Drug Abuse Serious Hospitalized Male  
     06-FEB-2023 17-FEB-2023 Direct 42 YR Not Specified  
     Fda-Ctu Consumer Not Specified - - 17-  
     FEB-2023 Not Specified Not Specified - - -  
 21999326 - Herbals\Mitragynine - Drug Screen  
     Positive Non-Serious Non-Serious Not Specified -  
     15-FEB-2023 Direct Not Specified Not Specified Fda-  
 Ctu Consumer Not Specified - - 15-FEB-2023

Not Specified Y - - -

21996460 Vivitrol Naltrexone;Herbals\Mitragynine Drug Dependence;Product Used For Unknown Indication Dyspnoea;Heart Rate Increased;Anxiety;Blood Pressure Increased;Substance Use Disorder;Drug Withdrawal Syndrome Non-Serious Non-Serious Female -

15-FEB-2023 Non-Expedited Not Specified Not Specified

Alkermes Consumer Not Specified - 14-

FEB-2023 15-FEB-2023 US Not Specified US-ALKERMES

INC.-ALK-2023-000609 - -

21992615 Sertraline;Salicylate;Heroin Aripiprazole;Diamorphine;Salicylic Acid;Cocaine;Fentanyl;Herbals\Mitragynine;Sertraline Hydrochloride;Alprazolam;Unspecified Ingredient;Cannabis Sativa Subsp. Indica Top Product Used For Unknown Indication Death

Serious Died Male 2021 15-FEB-2023 Expedited 17 YR

Not Specified Endo Healthcare Professional Not Specified

- 18-JAN-2023 15-FEB-2023 US Not Specified

US-ENDO PHARMACEUTICALS INC-2023-000543 -

21909633 Vivitrol Naltrexone;Herbals\Mitragynine Drug Use Disorder;Product Used For Unknown Indication Hyperhidrosis;Tremor;Substance Use Disorder;Nausea;Withdrawal Syndrome

Non-Serious Non-Serious Male 10-JAN-2023 15-

FEB-2023 Non-Expedited Not Specified Not Specified

Alkermes Healthcare Professional Not Specified - 14-

FEB-2023 25-JAN-2023 US Not Specified US-ALKERMES

INC.-ALK-2023-000288 -

21984130 - Herbals\Mitragynine - Tic;Overdose

Serious Hospitalized Male 10-FEB-2023 10-FEB-2023

Direct Not Specified Not Specified Fda-Ctu Not Specified

Not Specified - - 10-FEB-2023 Not Specified

Not Specified - - -

21979697 Venlafaxine Venlafaxine

Hydrochloride;Herbals\Mitragynine;Amphetamine Product Used For Unknown Indication Drug Abuse Serious Died Male -

10-FEB-2023 Expedited 31 YR Not Specified Bausch And Lomb Healthcare Professional Not Specified - 02-

FEB-2023 10-FEB-2023 US Not Specified US-BAUSCH-BL-2023-002262 "Gummin D, Mowry J, Beuhler M, Spyker D, Rivers L, Feldman R, Brown K, Pham N, Bronstein A, Weber J. 2021 Annual Report of the National Poison Data System (NPDS) from America's Poison Centers: 39th Annual Report. Clinical Toxicology. 2023 JAN 05;60(12):1381-1643. doi:10.1080/15563650.2022.2132768" -

21976393 Alcohol (Alcohol)

Alcohol;Clonazepam;Herbals\Mitragynine Product Used For Unknown Indication Cardio-Respiratory Arrest;Drug Abuse Serious Died

Male 2021 10-FEB-2023 Expedited 21 YR Not Specified

Endo Healthcare Professional Not Specified -

18-JAN-2023 10-FEB-2023 US Not Specified US-

ENDO PHARMACEUTICALS INC-2023-000710 - -

21974859 - Diazepam;Herbals\Mitragynine;Fentanyl

Product Used For Unknown Indication      Drug Abuse      Serious Died  
 Male      -      09-FEB-2023      Expedited      70 YR      Not  
 Specified      Bausch And Lomb Healthcare Professional Not Specified  
 -      02-FEB-2023      09-FEB-2023      US      Not Specified  
 US-BAUSCH-BL-2023-002101      "Gummin D, Mowry J, Beuhler M,  
 Spyker D, Rivers L, Feldman R, Brown K, Pham N, Bronstein A, Weber J.  
 2021 Annual Report of the National Poison Data System (NPDS) from  
 America's Poison Centers: 39th Annual Report. Clinical Toxicology.  
 2023 JAN 05;60 (12):1381-1643. doi:10.1080/15563650.2022.2132768"  
 -

21970341      -      Herbals\Mitragynine;Fentanyl;Diazepam  
 Product Used For Unknown Indication      Drug Abuse      Serious Died  
 Male      2021      09-FEB-2023      Expedited      70 YR      Not  
 Specified      Endo      Healthcare Professional Not Specified      -  
 18-JAN-2023      09-FEB-2023      US      Not Specified      US-  
 ENDO PHARMACEUTICALS INC-2023-000602      -      -

21970297      -      Getacatetide  
 Acetate;Ephedrine;Phenylpropanolamine;Herbals\Mitragynine  
 Product Used For Unknown Indication      Toxicity To Various Agents  
 Serious Died      Male      -      09-FEB-2023      Expedited  
 32 YR      Not Specified      Johnson And Johnson      Healthcare  
 Professional      Not Specified      -      27-JAN-2023      09-FEB-2023  
 US      Not Specified      US-JNJFOC-20230211671      -      -

21972776      -      Herbals\Mitragynine      -      Overdose  
 Serious Hospitalized;Life Threatening;Other Outcomes      Male  
 22-DEC-2022      08-FEB-2023      Direct      31 YR      67.5 KG Fda-  
 Ctu      Consumer      Not Specified      -      -      08-FEB-2023  
 Not Specified      Not Specified      -      -      -

21957665      -      Herbals\Mitragynine;Aripiprazole;Acetaminophen;Lorazepam;Gabapentin  
 -      Death;Intentional Product Misuse      Serious  
 Died;Other Outcomes      Male      2021      06-FEB-2023      Expedited  
 22 YR      Not Specified      Pfizer      Healthcare Professional Not  
 Specified      -      27-JAN-2023      06-FEB-2023      US      Not  
 Specified      US-PFIZER INC-202300053813      "Gummin, D.. 2021  
 Annual Report of the National Poison Data System (NPDS) from America's  
 Poison Centers: 39th Annual Report. Clinical Toxicology. 2022;60  
 (12):1381-1643" -

21961725      -      Herbals\Mitragynine      Dependence      Eye  
 Disorder;Skin Discolouration;Skin Exfoliation;Product  
 Complaint;Unevaluable Event;Withdrawal Syndrome;Drug Dependence  
 Serious Life Threatening;Required Intervention;Disabled Male      02-  
 FEB-2023      04-FEB-2023      Direct      27 YR      56.25 KG Fda-  
 Ctu      Consumer      Not Specified      -      -      04-FEB-2023  
 Not Specified      Not Specified      -      -      -

21952960      Methadone      Methadone  
 Hydrochloride;Herbals\Mitragynine      Product Used For Unknown  
 Indication      Completed Suicide;Analgesic Drug Level Increased  
 Serious Died      Male      2021      04-FEB-2023      Expedited  
 39 YR      Not Specified      Specgx      Healthcare Professional Not

Specified - 05-JAN-2023 04-FEB-2023 US Not  
Specified US-SPECGX-T202300115 "Gummin DD, Mowry JB, Beuhler  
MC, Spyker DA, Rivers LJ, Feldman R et al. 2021 Annual Report of the  
National Poison Data System (NPDS) from America's Poison Centers: 39th  
Annual Report. Clinical Toxicology. 2022;60(12):1381-643" -  
21946205 - Herbals\Mitragynine;Fentanyl Citrate -  
Drug Abuse;Cardiac Arrest;Respiratory Arrest Serious Other  
Outcomes;Hospitalized;Died Male 2021 02-FEB-2023  
Expedited 41 YR Not Specified Pfizer Healthcare  
Professional Not Specified - 27-JAN-2023 02-FEB-2023  
US Not Specified US-PFIZER  
INC-202300043123 "Gummin, D.. 2021 Annual Report of the  
National Poison Data System (NPDS) from America's Poison Centers: 39th  
Annual Report. Clinical Toxicology. 2022;60 (12):1381-1643" -  
21946143 - Herbals\Mitragynine;Fentanyl Citrate -  
Death Serious Other Outcomes;Died Male 2021 02-  
FEB-2023 Expedited 28 YR Not Specified Pfizer  
Healthcare Professional Not Specified - 27-JAN-2023 02-  
FEB-2023 US Not Specified US-PFIZER INC-202300042710  
"Gummin, D.. 2021 Annual Report of the National Poison Data  
System (NPDS) from America's Poison Centers: 39th Annual Report.  
Clinical Toxicology. 2022;60 (12):1381-1643" -  
21946136 - Fentanyl Citrate;Herbals\Mitragynine -  
Completed Suicide Serious Died;Other Outcomes Female  
2021 02-FEB-2023 Expedited 54 YR Not Specified  
Pfizer Healthcare Professional Not Specified - 27-  
JAN-2023 02-FEB-2023 US Not Specified US-PFIZER  
INC-202300042664 "Gummin, D.. 2021 Annual Report of the  
National Poison Data System (NPDS) from America's Poison Centers: 39th  
Annual Report. Clinical Toxicology. 2022;60 (12):1381-1643" -  
21945311 - Fentanyl Citrate;Herbals\Mitragynine -  
Death Serious Died;Other Outcomes Male 2021 02-  
FEB-2023 Expedited 42 YR Not Specified Pfizer  
Healthcare Professional Not Specified - 27-JAN-2023 02-  
FEB-2023 US Not Specified US-PFIZER INC-202300042762  
"Gummin, D.. 2021 Annual Report of the National Poison Data  
System (NPDS) from America's Poison Centers: 39th Annual Report.  
Clinical Toxicology. 2022;60 (12):1381-1643" -  
21945291 Sertraline;Heroin  
Diamorphine;Alprazolam;Cocaine;Aspirin;Sertraline  
Hydrochloride;Cannabis Sativa Subsp. Indica Top;Aripiprazole;Fentanyl  
Citrate;Herbals\Mitragynine - Death Serious  
Hospitalized;Other Outcomes;Died Male 2021 02-FEB-2023  
Expedited 17 YR Not Specified Pfizer Healthcare  
Professional Not Specified - 27-JAN-2023 02-FEB-2023  
US Not Specified US-PFIZER  
INC-202300042960 "Gummin, D.. 2021 Annual Report of the  
National Poison Data System (NPDS) from America's Poison Centers: 39th  
Annual Report. Clinical Toxicology. 2022;60 (12):1381-1643" -  
21937016 - Herbals\Mitragynine;Cocaine;Fentanyl

Citrate;Cannabis Sativa Subsp. Indica Top - Drug  
 Abuse;Respiratory Arrest;Cardiac Arrest Serious  
 Died;Hospitalized;Other Outcomes Male 2021 01-FEB-2023  
     Expedited 27 YR Not Specified Pfizer Healthcare  
 Professional Not Specified - 27-JAN-2023 01-FEB-2023  
     US Not Specified US-PFIZER

INC-202300042451 "Gummin, D.. 2021 Annual Report of the  
 National Poison Data System (NPDS) from America's Poison Centers: 39th  
 Annual Report. Clinical Toxicology. 2022;60 (12):1381-1643" -

21934729 Corpse Ephedrine  
 Sulfate;Herbals\Mitragynine;Phenylpropanolamine;Dextromethorphan  
     Product Used For Unknown Indication Death;Cardio-  
 Respiratory Arrest Serious Died Male 2021 01-FEB-2023  
     Expedited 32 YR Not Specified Endo Healthcare  
 Professional Not Specified - 18-JAN-2023 01-FEB-2023  
     US Not Specified US-ENDO PHARMACEUTICALS

INC-2023-000225 - -

21934056 Trazodone Trazodone  
 Hydrochloride;Ibuprofen;Herbals\Mitragynine Product Used For  
 Unknown Indication Death Serious Died Male 2021 01-  
     FEB-2023 Expedited 52 YR Not Specified Endo  
 Healthcare Professional Not Specified - 18-JAN-2023 01-  
     FEB-2023 US Not Specified US-ENDO PHARMACEUTICALS

INC-2023-000348 -

21935676 - Herbals\Mitragynine  
 Anxiety;Asthenia;Depression Dependence;Concussion;Head Injury;Loss  
 Of Consciousness Serious Other Outcomes Male 14-MAR-2022  
     31-JAN-2023 Direct 55 YR 92.25 KG Fda-Ctu  
 Consumer Not Specified Valium;Lisinopril;Motrin -  
     31-JAN-2023 Not Specified Not Specified -

21932948 - Flubromazolam;Fentanyl Citrate;Cannabis Sativa  
 Subsp. Indica Top;Herbals\Mitragynine - Drug Abuse;Cardiac  
 Arrest;Respiratory Arrest Serious Other Outcomes;Died Male  
     2021 31-JAN-2023 Expedited 24 YR Not Specified  
     Pfizer Healthcare Professional Not Specified - 27-  
     JAN-2023 31-JAN-2023 US Not Specified US-PFIZER

INC-202300041969 "Gummin, D.. 2021 Annual Report of the  
 National Poison Data System (NPDS) from America's Poison Centers: 39th  
 Annual Report. Clinical Toxicology. 2022;60 (12):1381-1643" -

21927733 Trazodone Trazodone  
 Hydrochloride;Herbals\Mitragynine;Ibuprofen Product Used For  
 Unknown Indication Exposure To Toxic Agent Serious Died Male  
     2021 30-JAN-2023 Expedited 52 YR Not Specified  
     Galpharm International Healthcare Professional Not Specified  
     - 23-JAN-2023 30-JAN-2023 US Not Specified  
     US-PERRIGO-23US000960 - -

21926051 - Herbals\Mitragynine Asthenia  
 Amnesia;Dysarthria;Delusion;Balance Disorder;Euphoric Mood  
 Serious Other Outcomes Female 21-JAN-2023 29-JAN-2023 Direct

63 YR 76.5 KG Fda-Ctu Consumer Not Specified  
 Vitamin C;Garlic;Vitamins - 29-JAN-2023 Not Specified  
 Not Specified - - -

21919380 - Doxylamine  
 Succinate;Cocaine;Herbals\Mitragynine Drug Abuse Exposure To  
 Toxic Agent Serious Died Male 2021 27-JAN-2023  
 Expedited 20 YR Not Specified Galpharm International  
 Healthcare Professional Not Specified - 23-JAN-2023 27-  
 JAN-2023 US Not Specified US-PERRIGO-23US001235 -  
 -

21917719 -  
 Aripiprazole;Acetaminophen;Herbals\Mitragynine;Lorazepam;Gabapentin  
 Product Used For Unknown Indication Intentional Product  
 Misuse Serious Died Male - 27-JAN-2023 Expedited  
 22 YR Not Specified Glenmark Healthcare  
 Professional Not Specified - 17-JAN-2023 27-JAN-2023  
 US Not Specified US-GLENMARK  
 PHARMACEUTICALS-2023GMK078006 "Gummin DD, Mowry JB, Beuhler MC,  
 Spyker DA, Rivers LJ, Feldman R, Brown K, Pham Nathaniel PT, Bronstein  
 AC, Weber JA.. 2021 Annual Report of the National Poison Data System  
 (NPDS) from America's Poison Centers: 39th Annual Report.. Clinical  
 Toxicology.. 2022;60 (12):1381-1643" -

21916131 -  
 Acetaminophen;Gabapentin;Aripiprazole;Lorazepam;Herbals\Mitragynine  
 Product Used For Unknown Indication Exposure To Toxic  
 Agent Serious Died Male 2021 26-JAN-2023 Expedited  
 22 YR Not Specified Galpharm International Healthcare  
 Professional Not Specified - 23-JAN-2023 26-JAN-2023  
 US Not Specified US-PERRIGO-23US000849 - -

21909724 Sertraline Sertraline  
 Hydrochloride;Herbals\Mitragynine;Acetaminophen Suspected Suicide  
 Exposure To Toxic Agent Serious Died Male 2021 25-  
 JAN-2023 Expedited 34 YR Not Specified Galpharm  
 International Healthcare Professional Not Specified - 23-  
 JAN-2023 25-JAN-2023 US Not Specified US-  
 PERRIGO-23US000857 - -

21908138 - Herbals\Mitragynine Substance Use  
 Product Complaint;Product Use Issue;Product Communication  
 Issue;Confusional State;Substance Use;Euphoric Mood;Impaired Driving  
 Ability;Therapeutic Drug Monitoring Analysis Not Performed  
 Serious Other Outcomes Female 20-JAN-2023 24-JAN-2023 Direct  
 30 YR 54 KG Fda-Ctu Consumer Not Specified -  
 - 24-JAN-2023 Not Specified Y - -

21894625 Trazodone Trazodone  
 Hydrochloride;Ibuprofen;Herbals\Mitragynine Product Used For  
 Unknown Indication Intentional Product Use Issue Serious  
 Hospitalized;Died Male - 22-JAN-2023 Expedited  
 52 YR Not Specified Apotex Healthcare Professional Not  
 Specified - 09-JAN-2023 22-JAN-2023 US Not

Specified US-APOTEX-2023AP001301 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Pham Nathaniel PT, Bronstein AC, Weber JA. 2021 Annual Report of the National Poison Data System (NPDS) from America's Poison Centers: 39th Annual Report. Clinical Toxicology. 2022;60:12:1381-1643" -

21891841 - Herbals\Mitragynine Product Used For Unknown Indication Hyperhidrosis;Withdrawal Syndrome;Tremor;Drug Dependence;Asthenia;Insomnia;Impulsive Behaviour;Vomiting;Depression;Memory Impairment;Thinking Abnormal;Emotional Disorder;Suicidal Ideation;Diarrhoea;Feeling Abnormal;Restless Legs Syndrome Non-Serious Non-Serious Male - 20-JAN-2023 Direct 39 YR 87.75 KG Fda-  
Ctu Consumer Not Specified - - 20-JAN-2023  
Not Specified Not Specified - - -

21888023 Alcohol (Alcohol)  
Alcohol;Fentanyl;Herbals\Mitragynine Product Used For Unknown Indication Drug Abuse;Cardio-Respiratory Arrest Serious Died;Other Outcomes;Hospitalized Male 2021 20-JAN-2023  
Expedited 41 YR Not Specified Apotex Healthcare Professional Not Specified - 09-JAN-2023 20-JAN-2023  
US Not Specified US-APOTEX-2023AP001014 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Pham Nathaniel PT, Bronstein AC, Weber JA. 2021 Annual Report of the National Poison Data System (NPDS) from America's Poison Centers: 39th Annual Report. Clinical Toxicology. 2022;60:12:1381-1643" -

21883867 - Herbals\Mitragynine;Fentanyl;Diazepam Product Used For Unknown Indication Drug Abuse Serious Other Outcomes;Died Male - 19-JAN-2023 Non-Expedited 70 YR  
Not Specified Apotex Healthcare Professional Not Specified - 09-JAN-2023 19-JAN-2023 US Not Specified US-APOTEX-2023AP001599 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Pham Nathaniel PT, Bronstein AC, Weber JA. 2021 Annual Report of the National Poison Data System (NPDS) from America's Poison Centers: 39th Annual Report. Clinical Toxicology. 2022;60:12:1381-1643" -

21883344 Sertraline Sertraline Hydrochloride;Herbals\Mitragynine;Acetaminophen Product Used For Unknown Indication Completed Suicide Serious Hospitalized;Other Outcomes;Died Male 2021 19-JAN-2023  
Expedited 34 YR Not Specified Apotex Healthcare Professional Not Specified - 09-JAN-2023 19-JAN-2023  
US Not Specified US-APOTEX-2023AP000800 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Pham Nathaniel PT, Bronstein AC, Weber JA. 2021 Annual Report of the National Poison Data System (NPDS) from America's Poison Centers: 39th Annual Report. Clinical Toxicology. 2022;60:12:1381-1643" -

21882849 - Fentanyl;Methamphetamine;Herbals\Mitragynine Product Used For Unknown Indication Drug Abuse Serious Other Outcomes;Died Male - 19-JAN-2023 Non-Expedited 57 YR Not Specified Apotex Healthcare

Professional Not Specified - 09-JAN-2023 19-JAN-2023  
US Not Specified US-APOTEX-2023AP001394 "Gummin DD,  
Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Pham  
Nathaniel PT, Bronstein AC, Weber JA. 2021 Annual Report of the  
National Poison Data System (NPDS) from America's Poison Centers: 39th  
Annual Report. Clinical Toxicology. 2022;60:12:1381-1643" -  
21882068 Heroin;Sertraline Sertraline  
Hydrochloride;Fentanyl;Cannabis Sativa Subsp. Indica  
Top;Herbals\Mitragynine;Diamorphine;Cocaine;Alprazolam;Aripiprazole  
Product Used For Unknown Indication Death Serious Other  
Outcomes;Died;Hospitalized Male 2021 19-JAN-2023  
Expedited 17 YR Not Specified Apotex Healthcare  
Professional Not Specified - 09-JAN-2023 19-JAN-2023  
US Not Specified US-APOTEX-2023AP002115 "Gummin DD,  
Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Pham  
Nathaniel PT, Bronstein AC, Weber JA. 2021 Annual Report of the  
National Poison Data System (NPDS) from America's Poison Centers: 39th  
Annual Report. Clinical Toxicology. 2022;60:12:1381-1643" -  
21878217 Alcohol (Alcohol)  
Alcohol;Gabapentin;Herbals\Mitragynine Product Used For Unknown  
Indication Drug Abuse Serious Died;Other Outcomes Male  
- 18-JAN-2023 Expedited 45 YR Not Specified  
Apotex Healthcare Professional Not Specified - 09-  
JAN-2023 18-JAN-2023 US Not Specified US-  
APOTEX-2023AP002156 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA,  
Rivers LJ, Feldman R, Brown K, Pham Nathaniel PT, Bronstein AC, Weber  
JA. 2021 Annual Report of the National Poison Data System (NPDS) from  
America's Poison Centers: 39th Annual Report. Clinical Toxicology.  
2022;60:12:1381-1643" -  
21877437 Alcohol (Alcohol) Alcohol;Valproic  
Acid;Gabapentin;Herbals\Mitragynine;Butalbital Product Used For  
Unknown Indication Cardio-Respiratory Arrest;Completed Suicide  
Serious Other Outcomes;Died;Hospitalized Female 2021  
18-JAN-2023 Expedited 45 YR Not Specified Apotex  
Healthcare Professional Not Specified - 09-JAN-2023  
18-JAN-2023 US Not Specified US-APOTEX-2023AP001683  
"Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Rivers LJ,  
Feldman R, Brown K, Pham Nathaniel PT, Bronstein AC, Weber JA. 2021  
Annual Report of the National Poison Data System (NPDS) from America's  
Poison Centers: 39th Annual Report. Clinical Toxicology.  
2022;60:12:1381-1643" -  
21876037 -  
Oxycodone;Etizolam;Fentanyl;Gabapentin;Herbals\Mitragynine  
Product Used For Unknown Indication Drug Abuse Serious Other  
Outcomes;Died Male - 18-JAN-2023 Expedited 46 YR  
Not Specified Apotex Healthcare Professional Not Specified  
- 09-JAN-2023 18-JAN-2023 US Not Specified  
US-APOTEX-2023AP001163 "Gummin DD, Mowry JB, Beuhler MC,  
Spyker DA, Rivers LJ, Feldman R, Brown K, Pham Nathaniel PT, Bronstein  
AC, Weber JA. 2021 Annual Report of the National Poison Data System

(NPDS) from America's Poison Centers: 39th Annual Report. Clinical Toxicology. 2022;60:12:1381-1643" -

21876005           Alcohol (Alcohol)  
Alcohol;Fentanyl;Herbals\Mitragynine     Product Used For Unknown  
Indication     Drug Abuse     Serious Other Outcomes;Died     Male  
-               18-JAN-2023     Non-Expedited     42 YR     Not Specified  
Apotex     Healthcare Professional Not Specified     -     09-  
JAN-2023     18-JAN-2023     US     Not Specified     US-  
APOTEX-2023AP001048     "Gummin DD, Mowry JB, Beuhler MC, Spyker DA,  
Rivers LJ, Feldman R, Brown K, Pham Nathaniel PT, Bronstein AC, Weber  
JA. 2021 Annual Report of the National Poison Data System (NPDS) from  
America's Poison Centers: 39th Annual Report. Clinical Toxicology.  
2022;60:12:1381-1643" -

21865359           Alcohol (Alcohol)  
Alcohol;Clonazepam;Herbals\Mitragynine;Fentanyl Product Used For  
Unknown Indication     Drug Abuse     Serious Other Outcomes;Died  
Male     -     18-JAN-2023     Non-Expedited     26 YR     Not  
Specified     Apotex     Healthcare Professional Not Specified     -  
09-JAN-2023     16-JAN-2023     US     Not Specified     US-  
APOTEX-2023AP000453     "Gummin DD, Mowry JB, Beuhler MC, Spyker DA,  
Rivers LJ, Feldman R, Brown K, Pham Nathaniel PT, Bronstein AC, Weber  
JA. 2021 Annual Report of the National Poison Data System (NPDS) from  
America's Poison Centers: 39th Annual Report. Clinical Toxicology.  
2022;60:12:1381-1643" -

21873010           -     Chlorpheniramine  
Maleate;Fentanyl;Herbals\Mitragynine     -     Toxicity To Various  
Agents;Drug Abuse     Serious Died     Female     -     17-JAN-2023  
Expedited     31 YR     Not Specified     Bayer     Healthcare  
Professional     Not Specified     -     09-JAN-2023     17-JAN-2023  
US     Not Specified     US-BAYER-2023A003690     Gummin D D;  
Mowry J B; Beuhler C; Spyker D A; Rivers L J; Feldman R; Brown K; Pham  
Nathanuek; Bronsteun A C; Weber J A. 2021 Annual Report of the  
National Poison Data System© (NPDS) from America's Poison Centers:  
39th Annual Repor. Clinical Toxicology. 2022;60:12:1381-1643 -

21872866           Alcohol (Alcohol)  
Alcohol;Fentanyl;Herbals\Mitragynine     Product Used For Unknown  
Indication     Drug Abuse     Serious Other Outcomes;Died     Male  
-     17-JAN-2023     Non-Expedited     38 YR     Not Specified  
Apotex     Healthcare Professional Not Specified     -     09-  
JAN-2023     17-JAN-2023     US     Not Specified     US-  
APOTEX-2023AP000932     "Gummin DD, Mowry JB, Beuhler MC, Spyker DA,  
Rivers LJ, Feldman R, Brown K, Pham Nathaniel PT, Bronstein AC, Weber  
JA. 2021 Annual Report of the National Poison Data System (NPDS) from  
America's Poison Centers: 39th Annual Report. Clinical Toxicology.  
2022;60:12:1381-1643" -

21872340           Sertraline;Heroin  
Diamorphine;Aripiprazole;Herbals\Mitragynine;Sertraline  
Hydrochloride;Fentanyl;Alprazolam;Cannabis Sativa Subsp. Indica  
Top;Cocaine;Aspirin     -     Toxicity To Various Agents;Product Use  
Issue     Serious Died;Hospitalized     Male     -     17-JAN-2023

Expedited 17 YR Not Specified Bayer Healthcare  
Professional Not Specified - 09-JAN-2023 17-JAN-2023  
US Not Specified US-BAYER-2023A002779 Gummin D D;  
Mowry J B; Beuhler C; Spyker D A; Rivers L J; Feldman R; Brown K; Pham  
Nathanuek; Bronsteun A C; Weber J A. 2021 Annual Report of the  
National Poison Data System© (NPDS) from America's Poison Centers:  
39th Annual Repor. Clinical Toxicology. 2022;60:12:1381-1643 -  
21871552 - Herbals\Mitragynine;Fentanyl Product Used  
For Unknown Indication Completed Suicide Serious Other  
Outcomes;Died Female 2021 17-JAN-2023 Expedited 54 YR  
Not Specified Apotex Healthcare Professional Not Specified  
- 09-JAN-2023 17-JAN-2023 US Not Specified  
US-APOTEX-2023AP001335 "Gummin DD, Mowry JB, Beuhler MC,  
Spyker DA, Rivers LJ, Feldman R, Brown K, Pham Nathaniel PT, Bronstein  
AC, Weber JA. 2021 Annual Report of the National Poison Data System  
(NPDS) from America's Poison Centers: 39th Annual Report. Clinical  
Toxicology. 2022;60:12:1381-1643" -  
21871276 -  
Lorazepam;Gabapentin;Herbals\Mitragynine;Acetaminophen;Aripiprazole  
Product Used For Unknown Indication Intentional Product  
Misuse Serious Died Male 2021 17-JAN-2023 Expedited  
22 YR Not Specified Apotex Healthcare Professional Not  
Specified - 09-JAN-2023 17-JAN-2023 US Not  
Specified US-APOTEX-2023AP000328 "Gummin DD, Mowry JB, Beuhler  
MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Pham Nathaniel PT,  
Bronstein AC, Weber JA. 2021 Annual Report of the National Poison Data  
System (NPDS) from America's Poison Centers: 39th Annual Report.  
Clinical Toxicology. 2022;60:12:1381-1643" -  
21870466 Alcohol (Alcohol)  
Alcohol;Fentanyl;Herbals\Mitragynine Product Used For Unknown  
Indication Drug Abuse Serious Other Outcomes;Died Male  
- 17-JAN-2023 Non-Expedited 57 YR Not Specified  
Apotex Healthcare Professional Not Specified - 09-  
JAN-2023 17-JAN-2023 US Not Specified US-  
APOTEX-2023AP001401 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA,  
Rivers LJ, Feldman R, Brown K, Pham Nathaniel PT, Bronstein AC, Weber  
JA. 2021 Annual Report of the National Poison Data System (NPDS) from  
America's Poison Centers: 39th Annual Report. Clinical Toxicology.  
2022;60:12:1381-1643" -  
21867698 - Chlorpheniramine;Herbals\Mitragynine;Fentanyl  
Product Used For Unknown Indication Drug Abuse  
Serious Died;Other Outcomes Female - 16-JAN-2023 Non-  
Expedited 31 YR Not Specified Apotex Healthcare  
Professional Not Specified - 09-JAN-2023 16-JAN-2023  
US Not Specified US-APOTEX-2023AP000645 "Gummin DD,  
Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Pham  
Nathaniel PT, Bronstein AC, Weber JA. 2021 Annual Report of the  
National Poison Data System (NPDS) from America's Poison Centers: 39th  
Annual Report. Clinical Toxicology. 2022;60:12:1381-1643" -  
21866057 - Fentanyl;Cocaine;Herbals\Mitragynine;Cannabis

Sativa Subsp. Indica Top Product Used For Unknown Indication  
Drug Abuse;Cardio-Respiratory Arrest Serious  
Hospitalized;Other Outcomes;Died Male 2021 16-JAN-2023  
Expedited 27 YR Not Specified Apotex Healthcare  
Professional Not Specified - 09-JAN-2023 16-JAN-2023  
US Not Specified US-APOTEX-2023AP000475 "Gummin DD,  
Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Pham  
Nathaniel PT, Bronstein AC, Weber JA. 2021 Annual Report of the  
National Poison Data System (NPDS) from America's Poison Centers: 39th  
Annual Report. Clinical Toxicology. 2022;60:12:1381-1643" -  
21865432 - Cannabis Sativa Subsp. Indica  
Top;Fentanyl;Herbals\Mitragynine Product Used For Unknown  
Indication Drug Abuse Serious Other Outcomes;Died Male  
- 16-JAN-2023 Non-Expedited 28 YR Not Specified  
Apotex Healthcare Professional Not Specified - 09-  
JAN-2023 16-JAN-2023 US Not Specified US-  
APOTEX-2023AP000529 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA,  
Rivers LJ, Feldman R, Brown K, Pham Nathaniel PT, Bronstein AC, Weber  
JA. 2021 Annual Report of the National Poison Data System (NPDS) from  
America's Poison Centers: 39th Annual Report. Clinical Toxicology.  
2022;60:12:1381-1643" -  
21865135 - Herbals\Mitragynine;Fentanyl Product Used  
For Unknown Indication Death Serious Died;Other Outcomes Male  
2021 16-JAN-2023 Expedited 28 YR Not Specified  
Apotex Healthcare Professional Not Specified - 09-  
JAN-2023 16-JAN-2023 US Not Specified US-  
APOTEX-2023AP000533 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA,  
Rivers LJ, Feldman R, Brown K, Pham Nathaniel PT, Bronstein AC, Weber  
JA. 2021 Annual Report of the National Poison Data System (NPDS) from  
America's Poison Centers: 39th Annual Report. Clinical Toxicology.  
2022;60:12:1381-1643" -  
21865069 Heroin Diamorphine;Fentanyl;Herbals\Mitragynine  
Product Used For Unknown Indication Drug Abuse  
Serious Died;Other Outcomes Male - 16-JAN-2023 Non-  
Expedited 26 YR Not Specified Apotex Healthcare  
Professional Not Specified - 09-JAN-2023 16-JAN-2023  
US Not Specified US-APOTEX-2023AP000425 "Gummin DD,  
Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Pham  
Nathaniel PT, Bronstein AC, Weber JA. 2021 Annual Report of the  
National Poison Data System (NPDS) from America's Poison Centers: 39th  
Annual Report. Clinical Toxicology. 2022;60:12:1381-1643" -  
21864247 - Herbals\Mitragynine;Fentanyl;Cannabis Sativa  
Subsp. Indica Top Product Used For Unknown Indication  
Cardio-Respiratory Arrest;Drug Abuse Serious  
Hospitalized;Died;Other Outcomes Male 2021 16-JAN-2023  
Expedited 24 YR Not Specified Apotex Healthcare  
Professional Not Specified - 09-JAN-2023 16-JAN-2023  
US Not Specified US-APOTEX-2023AP000371 "Gummin DD,  
Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Pham  
Nathaniel PT, Bronstein AC, Weber JA. 2021 Annual Report of the

National Poison Data System (NPDS) from America's Poison Centers: 39th Annual Report. Clinical Toxicology. 2022;60:12:1381-1643" -

21870942 - Herbals\Mitragynine Drug Dependence Drug Screen Positive;Legal Problem Non-Serious Non-Serious Male 30-DEC-2022 14-JAN-2023 Direct 51 YR 99 KG Fda-Ctu Consumer Not Specified Herbals\Mitragynine - 14-JAN-2023 Not Specified Not Specified - - -

21858301 Methadone Methadone Hydrochloride;Fentanyl;Herbals\Mitragynine Product Used For Unknown Indication Drug Abuse Serious Died;Other Outcomes Male - 13-JAN-2023 Non-Expedited 31 YR Not Specified Apotex Healthcare Professional Not Specified - 09-JAN-2023 13-JAN-2023 US Not Specified US-APOTEX-2023AP000658 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Pham Nathaniel PT, Bronstein AC, Weber JA. 2021 Annual Report of the National Poison Data System (NPDS) from America's Poison Centers: 39th Annual Report. Clinical Toxicology. 2022;60:12:1381-1643" -

21857327 - Herbals\Mitragynine;Fentanyl;Alprazolam Product Used For Unknown Indication Drug Abuse Serious Died;Other Outcomes Male - 13-JAN-2023 Expedited 24 YR Not Specified Apotex Healthcare Professional Not Specified - 09-JAN-2023 13-JAN-2023 US Not Specified US-APOTEX-2023AP000380 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Rivers LJ, Feldman R, Brown K, Pham Nathaniel PT, Bronstein AC, Weber JA. 2021 Annual Report of the National Poison Data System (NPDS) from America's Poison Centers: 39th Annual Report. Clinical Toxicology. 2022;60:12:1381-1643" -

21854881 - Herbals\Mitragynine Anxiety Death Serious Died Male 02-DEC-2021 12-JAN-2023 Direct 23 YR 83.25 KG Fda-Ctu Consumer Not Specified Not Specified Not Specified Hydroxyzine;Citalopram - - -

21850359 - Herbals\Mitragynine Drug Dependence Death Serious Died Female 01-APR-2020 11-JAN-2023 Direct 37 YR 72 KG Fda-Ctu Consumer Not Specified - - 11-JAN-2023 Not Specified Not Specified Not Specified -

21844334 - Herbals\Mitragynine Product Used For Unknown Indication Substance Use Serious Died Male 24- JUL-2022 10-JAN-2023 Direct 23 YR Not Specified Fda-Ctu Consumer Not Specified - - 10-JAN-2023 Not Specified Not Specified -

21835312 - Gabapentin;Acetaminophen;Herbals\Mitragynine Product Used For Unknown Indication Toxicity To Various Agents;Intentional Product Misuse Serious Died Male 2021 09-JAN-2023 Expedited 22 YR Not Specified Johnson And Johnson Healthcare Professional Not Specified - 01-JAN-2023 09-JAN-2023 US Not Specified US-

JNJFOC-20230106764 - - -

21810314 - Herbals\Mitragynine Anxiety;Disturbance In  
 Attention Impaired Work Ability;Movement  
 Disorder;Retching;Motion Sickness;Dizziness;Product Odour  
 Abnormal;Product Complaint;Vomiting Projectile;Malaise;Product Taste  
 Abnormal;Nervousness Serious Other Outcomes Female 30-AUG-2022  
 01-JAN-2023 Direct 50 YR 72 KG Fda-Ctu Consumer  
 Not Specified Unspecified Ingredient - 01-JAN-2023  
 Not Specified Y - - -

21801398 Kava Piper Methysticum Root;Herbals\Mitragynine  
 Asthenia Personality Change;Chest Pain;Drug  
 Dependence;Irritability;Sleep Disorder;Abnormal Behaviour;Road Traffic  
 Accident;Thinking Abnormal;Cardiac Arrest;Drug Tolerance;Incorrect  
 Dose Administered;Unevaluable Event;Weight Decreased Serious Died  
 Male 28-JUL-2021 30-DEC-2022 Direct 36 YR 90 KG  
 Fda-Ctu Consumer Not Specified - - 30-  
 DEC-2022 Not Specified Y - - -

21793690 - Herbals\Mitragynine - Product  
 Formulation Issue;Product Contamination;Drug Abuse;Withdrawal Syndrome  
 Serious Other Outcomes Male 23-DEC-2022 28-DEC-2022  
 Direct 39 YR 174 LB Fda-Ctu Not Specified Not Specified  
 - - 28-DEC-2022 Not Specified Not Specified  
 - - -

21793686 - Herbals\Mitragynine -  
 Diarrhoea;Panic Attack;Confusional State;Withdrawal Syndrome;Mood  
 Altered;Asthenia;Anhedonia;Irritability;Nausea;Brain Fog  
 Serious Other Outcomes Male 15-OCT-2018 28-DEC-2022 Direct  
 39 YR 70.2 KG Fda-Ctu Not Specified Not Specified -  
 - 28-DEC-2022 Not Specified Not Specified -  
 - -

21793677 - Herbals\Mitragynine - Seizure;Drug  
 Dependence Serious Died Not Specified 05-FEB-2021 28-  
 DEC-2022 Direct Not Specified Not Specified Fda-Ctu Not  
 Specified Not Specified - - 28-DEC-2022 Not  
 Specified Not Specified - - -

21773877 Mayzent Siponimod;Herbals\Mitragynine Multiple  
 Sclerosis Overdose Serious Hospitalized Female 10-  
 DEC-2022 22-DEC-2022 Direct 50 YR Not Specified Fda-  
 Ctu Not Specified Not Specified - - 22-DEC-2022  
 Not Specified Not Specified - - -

21767861 - Herbals\Mitragynine - Toxicity To  
 Various Agents Serious Died Male 20-OCT-2021 22-DEC-2022  
 Direct 22 YR 90 KG Fda-Ctu Consumer Not Specified  
 Not Specified Not Specified - - Not Specified  
 - - -

21767238 - Herbals\Mitragynine - Drug  
 Withdrawal Syndrome;Drug Dependence;Misleading Laboratory Test Result  
 Non-Serious Non-Serious Male - 22-DEC-2022  
 Direct 39 YR 174 LB Fda-Ctu Healthcare Professional Not  
 Specified - - 22-DEC-2022 Not Specified Not

Specified - - -  
21727524 -

Fentanyl;Oxymorphone;Oxycodone;Herbals\Mitragynine Drug Abuse  
Drug Abuse Serious Died;Other Outcomes Male -  
14-DEC-2022 Non-Expedited 29 YR Not Specified

Alvogen Healthcare Professional Not Specified - 04-MAR-2022  
14-DEC-2022 US Not Specified US-ALVOGEN-2022087411  
"Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Bronstein AC,  
Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the American  
Association of Poison Control Centers' National Poison Data System  
(NPDS): 38th Annual Report. Clin Toxicol (Phila). 2021  
Dec;59(12):1282-1501. doi: 10.1080/15563650.2021.1989785." -

21727491 - Alprazolam;Fentanyl;Herbals\Mitragynine Drug Abuse  
Serious Died;Other Outcomes Male -  
14-DEC-2022 Non-Expedited 35 YR Not Specified

Alvogen Healthcare Professional Not Specified - 04-MAR-2022  
14-DEC-2022 US Not Specified US-ALVOGEN-2022086808  
"Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Bronstein AC,  
Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the American  
Association of Poison Control Centers' National Poison Data System  
(NPDS): 38th Annual Report. Clin Toxicol (Phila). 2021  
Dec;59(12):1282-1501. doi: 10.1080/15563650.2021.1989785." -

21727084 - Alcohol;Fentanyl;Herbals\Mitragynine Drug Abuse  
Serious Other Outcomes;Died Female -  
14-DEC-2022 Non-Expedited 36 YR Not Specified

Alvogen Healthcare Professional Not Specified - 04-MAR-2022  
14-DEC-2022 US Not Specified US-ALVOGEN-2022087530  
"Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Bronstein AC,  
Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the American  
Association of Poison Control Centers' National Poison Data System  
(NPDS): 38th Annual Report. Clin Toxicol (Phila). 2021  
Dec;59(12):1282-1501. doi: 10.1080/15563650.2021.1989785." -

21726997 - Clobazam;Fentanyl;Herbals\Mitragynine Drug Abuse  
Serious Died;Other Outcomes Female -  
14-DEC-2022 Non-Expedited 29 YR Not Specified

Alvogen Healthcare Professional Not Specified - 04-MAR-2022  
14-DEC-2022 US Not Specified US-ALVOGEN-2022087123  
"Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Bronstein AC,  
Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the American  
Association of Poison Control Centers' National Poison Data System  
(NPDS): 38th Annual Report. Clin Toxicol (Phila). 2021  
Dec;59(12):1282-1501. doi: 10.1080/15563650.2021.1989785." -

21725394 - Herbals\Mitragynine;Diazepam;Fentanyl Drug Abuse  
Serious Other Outcomes;Died Male -  
14-DEC-2022 Non-Expedited 31 YR Not Specified

Alvogen Healthcare Professional Not Specified - 04-MAR-2022  
14-DEC-2022 US Not Specified US-ALVOGEN-2022087459  
"Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Bronstein AC,  
Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the American  
Association of Poison Control Centers' National Poison Data System

(NPDS): 38th Annual Report. Clin Toxicol (Phila). 2021 Dec;59(12):1282–1501. doi: 10.1080/15563650.2021.1989785." -

21725228 - Herbals\Mitragynine;Fentanyl;Methamphetamine Drug Abuse Drug Abuse Serious Other Outcomes;Died Male - 14-DEC-2022 Non-Expedited 24 YR Not Specified Alvogen Healthcare Professional Not Specified - 04-MAR-2022 14-DEC-2022 US Not Specified US-ALVOGEN-2022086184 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Bronstein AC, Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 38th Annual Report. Clin Toxicol (Phila). 2021 Dec;59(12):1282–1501. doi: 10.1080/15563650.2021.1989785." -

21725014 -

Methocarbamol;Herbals\Mitragynine;Fentanyl;Etizolam Drug Abuse Drug Abuse Serious Other Outcomes;Died Male - 14-DEC-2022 Non-Expedited 35 YR Not Specified Alvogen Healthcare Professional Not Specified - 04-MAR-2022 14-DEC-2022 US Not Specified US-ALVOGEN-2022087520 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Bronstein AC, Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 38th Annual Report. Clin Toxicol (Phila). 2021 Dec;59(12):1282–1501. doi: 10.1080/15563650.2021.1989785." -

21724976 - Herbals\Mitragynine;Fentanyl Drug Abuse Drug Abuse Serious Died;Other Outcomes Male - 14-DEC-2022 Non-Expedited 31 YR Not Specified Alvogen Healthcare Professional Not Specified - 04-MAR-2022 14-DEC-2022 US Not Specified US-ALVOGEN-2022087140 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Bronstein AC, Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 38th Annual Report. Clin Toxicol (Phila). 2021 Dec;59(12):1282–1501. doi: 10.1080/15563650.2021.1989785." -

21727879 - Herbals\Mitragynine - Product Information Content Complaint;Weight Decreased Non-Serious Non-Serious Not Specified - 13-DEC-2022 Direct Not Specified Not Specified - Not Specified Fda-Ctu Not Specified Not Specified - - 13-DEC-2022 Not Specified Not Specified - -

21722150 - Fentanyl;Herbals\Mitragynine Drug Abuse Drug Abuse Serious Other Outcomes;Died Male - 13-DEC-2022 Non-Expedited 59 YR Not Specified Alvogen Healthcare Professional Not Specified - 04-MAR-2022 13-DEC-2022 US Not Specified US-ALVOGEN-2022087308 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Bronstein AC, Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 38th Annual Report. Clin Toxicol (Phila). 2021 Dec;59(12):1282–1501. doi: 10.1080/15563650.2021.1989785." -

21722149 - Herbals\Mitragynine;Fentanyl Drug Abuse

Drug Abuse      Serious Other Outcomes;Died      Male      -  
13-DEC-2022      Non-Expedited      50 YR      Not Specified  
Alvogen Healthcare Professional Not Specified      -      04-MAR-2022  
13-DEC-2022      US      Not Specified      US-ALVOGEN-2022087302  
"Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Bronstein AC,  
Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the American  
Association of Poison Control Centers' National Poison Data System  
(NPDS): 38th Annual Report. Clin Toxicol (Phila). 2021  
Dec;59(12):1282-1501. doi: 10.1080/15563650.2021.1989785."      -  
21722147      -      Fentanyl;Herbals\Mitragynine      Drug Abuse  
Drug Abuse      Serious Other Outcomes;Died      Male      -  
13-DEC-2022      Non-Expedited      22 YR      Not Specified  
Alvogen Healthcare Professional Not Specified      -      04-MAR-2022  
13-DEC-2022      US      Not Specified      US-ALVOGEN-2022087293  
"Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Bronstein AC,  
Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the American  
Association of Poison Control Centers' National Poison Data System  
(NPDS): 38th Annual Report. Clin Toxicol (Phila). 2021  
Dec;59(12):1282-1501. doi: 10.1080/15563650.2021.1989785."      -  
21722110      -      Herbals\Mitragynine;Acetaminophen\Oxycodone  
Hydrochloride;Alcohol;Fentanyl      Drug Abuse      Drug Abuse  
Serious Hospitalized;Died      Male      -      13-DEC-2022      Non-  
Expedited      16 YR      Not Specified      Alvogen Healthcare  
Professional      Not Specified      -      04-MAR-2022      13-DEC-2022  
US      Not Specified      US-ALVOGEN-2022087020      "Gummin DD,  
Mowry JB, Beuhler MC, Spyker DA, Bronstein AC, Rivers LJ, Pham NPT,  
Weber J. 2020 Annual Report of the American Association of Poison  
Control Centers' National Poison Data System (NPDS): 38th Annual  
Report. Clin Toxicol (Phila). 2021 Dec;59(12):1282-1501. doi:  
10.1080/15563650.2021.1989785." -  
21721919      -      Herbals\Mitragynine;Fentanyl      Drug Abuse  
Drug Abuse      Serious Died;Other Outcomes      Male      -  
13-DEC-2022      Non-Expedited      34 YR      Not Specified  
Alvogen Healthcare Professional Not Specified      -      04-MAR-2022  
13-DEC-2022      US      Not Specified      US-ALVOGEN-2022087221  
"Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Bronstein AC,  
Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the American  
Association of Poison Control Centers' National Poison Data System  
(NPDS): 38th Annual Report. Clin Toxicol (Phila). 2021  
Dec;59(12):1282-1501. doi: 10.1080/15563650.2021.1989785." -  
21721876      -      Oxycodone;Herbals\Mitragynine;Fentanyl      Drug  
Abuse      Drug Abuse      Serious Died;Other Outcomes      Male      -  
13-DEC-2022      Non-Expedited      46 YR      Not Specified  
Alvogen Healthcare Professional Not Specified      -      04-MAR-2022  
13-DEC-2022      US      Not Specified      US-ALVOGEN-2022087651  
"Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Bronstein AC,  
Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the American  
Association of Poison Control Centers' National Poison Data System  
(NPDS): 38th Annual Report. Clin Toxicol (Phila). 2021  
Dec;59(12):1282-1501. doi: 10.1080/15563650.2021.1989785." -

21721743 - Fentanyl;Herbals\Mitragynine Drug Abuse  
 Drug Abuse Serious Died;Other Outcomes Male -  
 13-DEC-2022 Non-Expedited 26 YR Not Specified  
 Alvogen Healthcare Professional Not Specified - 04-MAR-2022  
 13-DEC-2022 US Not Specified US-ALVOGEN-2022087367  
 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Bronstein AC,  
 Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the American  
 Association of Poison Control Centers' National Poison Data System  
 (NPDS): 38th Annual Report. Clin Toxicol (Phila). 2021  
 Dec;59(12):1282-1501. doi: 10.1080/15563650.2021.1989785." -  
 21686144 Invega;Invega Sustenna;Haldol  
 Haloperidol;Paliperidone Palmitate;Herbals\Mitragynine;Paliperidone  
 Product Used For Unknown Indication;Schizoaffective Disorder  
 Schizoaffective Disorder;Product Dose Omission Issue;Drug  
 Ineffective Serious Hospitalized Female 26-NOV-2022 13-  
 DEC-2022 Non-Expedited 34 YR Not Specified Johnson And  
 Johnson Consumer Not Specified - 08-DEC-2022 06-  
 DEC-2022 US Not Specified US-JNJFOC-20221160650 -  
 -  
 21699300 - Herbals\Mitragynine - Drug  
 Abuser;Generalised Tonic-Clonic Seizure;Vomiting;Dependence;Weight  
 Decreased Serious Required Intervention;Life Threatening Male  
 26-SEP-2022 07-DEC-2022 Direct 25 YR 60.75 KG  
 Fda-Ctu Consumer Not Specified Lamictal;Prozac -  
 07-DEC-2022 Not Specified Not Specified - -  
 -  
 21682039 - Herbals\Mitragynine - Drug  
 Dependence;Withdrawal Syndrome Serious Required Intervention;Other  
 Outcomes Male 05-NOV-2022 03-DEC-2022 Direct Not  
 Specified Not Specified Fda-Ctu Consumer Not Specified  
 - - 03-DEC-2022 Not Specified Not Specified  
 - - -  
 21580186 -  
 Herbals\Mitragynine;Clonidine;Naltrexone;Ondansetron Alcohol  
 Abuse;Drug Withdrawal Syndrome;Product Used For Unknown Indication  
 Drug Ineffective;Drug Withdrawal Syndrome Serious  
 Hospitalized Male - 01-DEC-2022 Expedited 46 YR  
 Not Specified Teva Healthcare Professional Not Specified  
 Duloxetine 21-NOV-2022 10-NOV-2022 US Not  
 Specified US-TEVA-2022-US-2823519 - -  
 21656492 - Herbals\Mitragynine Substance Use Death  
 Serious Died Female 26-NOV-2022 28-NOV-2022 Direct  
 40 YR Not Specified Fda-Ctu Consumer Not Specified  
 Risperidone;Herbals\Mitragynine;Cephalexin;Benadryl;Famotidine;Melatonin;  
 Atorvastatin - 28-NOV-2022 Not Specified Not Specified  
 - - -  
 21210049 Buspirone;Trazodone Trazodone  
 Hydrochloride;Herbals\Mitragynine;Desvenlafaxine;Buspirone  
 Hydrochloride;Ziprasidone Product Used For Unknown Indication

Drug Interaction;Serotonin Syndrome;Self-Medication  
 Serious Hospitalized;Other Outcomes Male - 23-NOV-2022  
 Expedited 63 YR 102 KG Dr Reddys Healthcare  
 Professional Not Specified  
 Gabapentin;Metformin;Omeprazole;Hydrochlorothiazide;Tizanidine Hydrochloride;Amlodipine;Diclofenac;Bupropion;Glimepiride 11-NOV-2022 14-AUG-2022 US Not Specified US-drreddys-SP0/USA/22/0153193 "Hamilton L, Eudaley S, Brooks S. Case Report: Possible Serotonin Syndrome in a Patient Taking Kratom and Multiple Serotonergic Agents. J Pharm Pract. 2022;UNKNOWN:1-5.  
 doi:10.1177/08971900221116009" -

17874207 Trazodone;Buspirone Buspirone Hydrochloride;Bupropion Hydrochloride;Trazodone Hydrochloride;Desvenlafaxine;Herbals\Mitragynine;Ziprasidone Hydrochloride Depression;Hypertension;Product Used For Unknown Indication;Type 2 Diabetes Mellitus Serotonin Syndrome;Drug Interaction Serious Other Outcomes;Hospitalized Male - 23-NOV-2022 Expedited 63 YR 102.5 KG Lupin Healthcare Professional Not Specified  
 Gabapentin;Diclofenac;Hydrochlorothiazide;Amlodipine;Omeprazole;Tizanidine;Metformin;Glimepiride 11-NOV-2022 09-JUN-2020 US Not Specified US-LUPIN PHARMACEUTICALS INC.-2020-02668 "Eudaley ST, Hamilton LA. Case report: Successful treatment of suspected kratom induced serotonin syndrome. Journal of the American College of Clinical Pharmacy. 2020;3:347" -

21628069 - Herbals\Mitragynine Phytotherapy Somnolence;Heart Rate Increased Non-Serious Non-Serious Female 06-NOV-2022 21-NOV-2022 Direct 36 YR Not Specified Fda-Ctu Consumer Not Specified Fish Oil;Vitamins;Arginine;Flax Seed;Theanine;Valerian - 21-NOV-2022 Not Specified Y - - -

21621626 - Herbals\Mitragynine - Mental Disorder;Quality Of Life Decreased;Agitation;General Physical Condition Abnormal Serious Other Outcomes Female 14-AUG-2021 20-NOV-2022 Direct 31 YR 56.25 KG Fda-Ctu Consumer Not Specified - - 20-NOV-2022 Not Specified Not Specified - -

21614648 - Buprenorphine\Naloxone;Herbals\Mitragynine;Buprenorphine Drug Use Disorder Abdominal Pain;Drug Withdrawal Syndrome Neonatal;Breast Milk Substitute Intolerance;Foetal Exposure During Pregnancy Serious Other Outcomes Female - 18-NOV-2022 Expedited Not Specified Not Specified Ranbaxy Healthcare Professional Not Specified - 05-NOV-2022 18-NOV-2022 US Not Specified US-SUN PHARMACEUTICAL INDUSTRIES LTD-2022R1-364362 "Zoucha K, Moore C. Kratom Use in Pregnancy. J Addict Med. 2022;Sep-Oct;16(5):e331-e332" -

21614527 Methadone Methadone Hydrochloride;Buprenorphine\Naloxone;Herbals\Mitragynine Drug Use Disorder Drug Withdrawal Syndrome;Exposure During

Pregnancy;Drug Ineffective;Live Birth     Serious Other Outcomes     Female  
   -     18-NOV-2022     Expedited     34 YR     Not Specified  
     Ranbaxy Healthcare Professional Not Specified     -     05-  
 NOV-2022     18-NOV-2022     US     Not Specified     US-SUN  
 PHARMACEUTICAL INDUSTRIES LTD-2022R1-364356     "Zoucha K, Moore C.  
 Kratom Use in Pregnancy. J Addict Med. 2022;16(5):e331-e332"     -  
 21553105     Methadone     Methadone Hydrochloride;Buprenorphine  
 Hydrochloride\Naloxone Hydrochloride;Herbals\Mitragynine     Drug  
 Withdrawal Syndrome     Maternal Exposure During Pregnancy;Drug  
 Ineffective     Serious Other Outcomes     Female     -     04-NOV-2022  
     Expedited     34 YR     Not Specified     Mylan     Healthcare  
 Professional     Not Specified     -     26-OCT-2022     04-NOV-2022  
     US     Not Specified     US-  
 MYLANLABS-2022M1119984     "Zoucha K, Moore C. Kratom Use in Pregnancy.  
 J-Addict-Med 2022;16(5):e331-e332."     -  
 21548749     -     Herbals\Mitragynine;Buprenorphine  
 Hydrochloride\Naloxone Hydrochloride;Buprenorphine     Drug  
 Withdrawal Syndrome     Maternal Exposure During Pregnancy;Drug  
 Ineffective     Serious Other Outcomes     Female     -     03-NOV-2022  
     Expedited     27 YR     Not Specified     Mylan     Healthcare  
 Professional     Not Specified     -     26-OCT-2022     03-NOV-2022  
     US     Not Specified     US-  
 MYLANLABS-2022M1119985     "Zoucha K, Moore C. Kratom Use in Pregnancy.  
 J-Addict-Med 2022;16(5):e331-e332."     -  
 21530232     -     Herbals\Mitragynine     Anxiety Drug  
 Dependence;Withdrawal Syndrome     Serious Required Intervention     Male  
     11-SEP-2022     28-OCT-2022     Direct     Not Specified     Not  
 Specified     Fda-Ctu Consumer     Not Specified     -     -  
     28-OCT-2022     Not Specified     Not Specified     -     -  
     -  
 21515536     Venlafaxine     Venlafaxine  
 Hydrochloride;Quetiapine;Herbals\Mitragynine     Product Used For  
 Unknown Indication     Serotonin Syndrome;Drug  
 Interaction;Electrocardiogram Qt Prolonged     Serious Other Outcomes  
     Male     2022     27-OCT-2022     Expedited     36 YR     Not  
 Specified     Osmotica     Healthcare Professional Not Specified  
     -     18-OCT-2022     27-OCT-2022     US     Not Specified  
     US-Osmotica\_Pharmaceutical\_US\_LLC-POI0573202200110     Burns  
 A. A Case of Potential Pharmacokinetic Kratom-drug Interactions  
 Resulting in Toxicity and Subsequent Treatment of Kratom Use Disorder  
 With Buprenorphine Naloxone. Journal of Addiction Medicine. 2022  
 SEP;16(5):606-609.     -  
 21515323     -     Herbals\Mitragynine     -     Night  
 Sweats;Dyspnoea;Fatigue;Decreased Appetite;Tremor;Vomiting  
 Serious Other Outcomes     Female     -     27-OCT-2022     Direct     Not  
 Specified     Not Specified     Fda-Ctu Consumer     Not Specified  
     -     -     27-OCT-2022     Not Specified     Not Specified  
     -     -     -  
 21500652     "Dextroamphetamine Saccharate, Amphetamine Aspartate,  
 Dextroamphetamine Sulfate And Amphetamine Sulfate"     Amphetamine

Aspartate\Amphetamine Sulfate\Dextroamphetamine Saccharate\Dextroamphetamine Sulfate;Herbals\Mitragynine Product Used For Unknown Indication Metabolic Acidosis;Overdose;Hypotension;Substance Use;Syncope;Cardiac Arrest;Brain Oedema;Brain Death Serious Died;Other Outcomes Female - 25-OCT-2022 Expedited 38 YR Not Specified Specgx Healthcare Professional Not Specified - 11-OCT-2022 25-OCT-2022 US Not Specified US-SPECGX-T202202178 "Theegala V, Solanki KK, Grover BS. Cardiac arrest in a middle-aged woman from combined use of kratom and amphetamine. Chest. 2022;162(4):A776" -

21497197 Sertraline;Alcohol (Alcohol) Alcohol;Gabapentin Enacarbil;Atenolol;Sertraline Hydrochloride;Herbals\Mitragynine;Amphetamine Sulfate Product Used For Unknown Indication Cardio-Respiratory Arrest;Toxicity To Various Agents;Completed Suicide Serious Died Male 2020 23- OCT-2022 Expedited 29 YR Not Specified Arbor Healthcare Professional Not Specified - 10-OCT-2022 23-OCT-2022 US Not Specified "US-ARBOR PHARMACEUTICALS, LLC-US-2022ARB002515" "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Brinstein AC, Rivers LJ, et al.. 2020 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 38th Annual Report. Clinical Toxicology. 2021;59(12):1282-1501" -

21494480 Lybalvi Olanzapine\Samidorphan L-Malate;Herbals\Mitragynine Bipolar I Disorder;Product Used For Unknown Indication Withdrawal Syndrome;Diarrhoea Non-Serious Non-Serious Female - 21-OCT-2022 Non-Expedited 4 DEC Not Specified Alkermes Healthcare Professional Not Specified Olanzapine 11-OCT-2022 21-OCT-2022 US Not Specified US-ALKERMES INC.- ALK-2022-004981 - -

21493929 - Amphetamine Sulfate;Herbals\Mitragynine Product Used For Unknown Indication Cardiac Arrest;Overdose Serious Life Threatening;Hospitalized Female - 21-OCT-2022 Expedited 38 YR Not Specified Arbor Healthcare Professional Not Specified - 13-OCT-2022 21-OCT-2022 US Not Specified "US-ARBOR PHARMACEUTICALS, LLC-US-2022ARB002672" "Theegala V., K Solanki K., S Grover B.. Cardiac arrest in a middle-aged woman from combined use of kratom and amphetamine. Chest. 2022;162:4" -

21484966 - Gabapentin Enacarbil;Oxycodone;Herbals\Mitragynine Product Used For Unknown Indication Drug Abuse;Toxicity To Various Agents Serious Died Female 2020 20-OCT-2022 Expedited 47 YR Not Specified Arbor Healthcare Professional Not Specified - 10-OCT-2022 20-OCT-2022 US Not Specified "US-ARBOR PHARMACEUTICALS, LLC-US-2022ARB002347" "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Brinstein AC, Rivers LJ, et al.. 2020 Annual Report of the American Association of Poison Control Centers' National

Poison Data System (NPDS): 38th Annual Report. Clinical toxicology. 2021;59(12):1282-1501" -  
21484910 -  
Fentanyl;Morphine;Etizolam;Herbals\Mitragynine;Methamphetamine;Gabapentin Enacarbil Product Used For Unknown Indication Toxicity To Various Agents;Drug Abuse Serious Died Female 2020 20-OCT-2022 Expedited 32 YR Not Specified Arbor Healthcare Professional Not Specified - 10-OCT-2022 20-OCT-2022 US Not Specified "US-ARBOR PHARMACEUTICALS, LLC-US-2022ARB002327" "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Brinstein AC, Rivers LJ, et al.. 2020 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 38th Annual Report. Clinical toxicology. 2021;59(12):1282-1501" -  
21159410 Buspirone;Trazodone Trazodone Hydrochloride;Ziprasidone;Buspirone Hydrochloride;Herbals\Mitragynine;Bupropion;Desvenlafaxine Anxiety Disorder;Major Depression;Product Used For Unknown Indication Serotonin Syndrome;Drug Interaction Serious Other Outcomes;Hospitalized Male 2018 20-OCT-2022 Expedited 63 YR Not Specified Cipla Healthcare Professional Not Specified Diclofenac;Omeprazole;Metformin;Amlodipine;Hydrochlorothiazide;Gabapentin;Glimepiride;Tizanidine 10-OCT-2022 02-AUG-2022 US Not Specified US-CIPLA LTD.-2022US04708 "Eudaley ST, Hamilton LA, Brooks SP. Case Report: Possible Serotonin Syndrome in a Patient Taking Kratom and Multiple Serotonergic Agents. Journal of Pharmacy Practice. 2022;1 to 5" -  
21459528 - Herbals\Mitragynine Anxiety Dependence;Seizure Serious Other Outcomes Male 25-FEB-2022 14-OCT-2022 Direct 29 YR 60.75 KG Fda-Ctu Consumer Not Specified Zonisamide;Lamotrigine - 14-OCT-2022 Not Specified Not Specified - - -  
21450754 - Herbals\Mitragynine Product Used For Unknown Indication Drug Abuse Serious Other Outcomes;Required Intervention;Hospitalized Male 06-OCT-2022 12-OCT-2022 Direct 35 YR Not Specified Fda-Ctu Consumer Not Specified - - 12-OCT-2022 Not Specified Not Specified - -  
21184754 Trazodone;Buspirone Ziprasidone;Buspirone Hydrochloride;Trazodone Hydrochloride;Desvenlafaxine;Bupropion Hydrochloride;Herbals\Mitragynine Anxiety;Depression Tremor;Confusional State;Blood Creatine Phosphokinase Increased;Hyperthermia;Blood Lactic Acid Increased;Hyperreflexia;Drug Interaction;Dysarthria;Aphasia;Flushing;Clonus;Hyperhidrosis;Serotonin Syndrome;Facial Paralysis Serious Other Outcomes;Hospitalized Not Specified - 12-OCT-2022 Expedited Not Specified Not Specified Alembic Healthcare Professional Not Specified - 28-SEP-2022 08-AUG-2022 US Not Specified US-ALEMBIC PHARMACUETICALS LIMITED-2022SCAL000361

"Eudaley S, Brooks S, Hamilton L.. Case Report: Possible Serotonin Syndrome in a Patient Taking Kratom and Multiple Serotonergic Agents. Journal of Pharmacy Practice. 2022" -  
 21258987 Lybalvi Olanzapine\Samidorphan L-Malate;Herbals\Mitragynine Bipolar Disorder;Product Used For Unknown Indication;Restless Legs Syndrome;Sleep Disorder  
 Dystonia Non-Serious Non-Serious Male 11-AUG-2022  
 10-OCT-2022 Non-Expedited Not Specified Not Specified  
 Alkermes Healthcare Professional Not Specified  
 Zyprexa 26-SEP-2022 26-AUG-2022 US Not Specified US-  
 ALKERMES INC.-ALK-2022-004120 - -  
 21422042 - Herbals\Mitragynine - Death  
 Serious Died Male 15-MAY-2022 06-OCT-2022 Direct 32 YR  
 103.5 KG Fda-Ctu Consumer Not Specified -  
 - 06-OCT-2022 Not Specified Not Specified -  
 - -  
 21416543 - Herbals\Mitragynine Pain  
 Nervousness;Drug Withdrawal Syndrome;Restlessness;Dependence Non-Serious  
 Serious Non-Serious Female 30-SEP-2021 05-OCT-2022 Direct  
 57 YR 54 KG Fda-Ctu Consumer Not Specified  
 Vitamin D2;Whey;Gabapentin;Lipitor;Cannabidiol\Herbals;Cannabis Sativa  
 Subsp. Indica Top;Magnesium;Ativan;Duloxetine - 05-OCT-2022  
 Not Specified Not Specified - - -  
 21407552 - Herbals\Mitragynine - Withdrawal  
 Syndrome Serious Required Intervention Male 10-SEP-2022  
 04-OCT-2022 Direct 40 YR 99 KG Fda-Ctu Not Specified  
 Not Specified - - 04-OCT-2022 Not Specified  
 Not Specified - - -  
 21407421 - Herbals\Mitragynine - Ear  
 Infection;Aortic Valve Disease;Seizure;Pulmonary  
 Oedema;Vertigo;Coronary Artery Stenosis;Toxicity To Various  
 Agents;Substance Abuse;Tympanic Membrane Perforation Serious Died  
 Male - 04-OCT-2022 Direct 27 YR Not Specified  
 Fda-Ctu Healthcare Professional Not Specified - -  
 04-OCT-2022 Not Specified Not Specified - -  
 -  
 21327833 - Herbals\Mitragynine Anxiety;Depression  
 Dependence;Vomiting;Pain;Withdrawal Syndrome;Loss Of Personal  
 Independence In Daily Activities;Palpitations;Skin Burning  
 Sensation;Cold Sweat;Tremor;Appetite Disorder;Weight Decreased  
 Serious Other Outcomes Female 01-JAN-2018 12-SEP-2022 Direct  
 36 YR 63 KG Fda-Ctu Consumer Not Specified  
 Vitamin B12;Magnesium;Vitamin D3 - 12-SEP-2022 Not  
 Specified Y - - -  
 17926244 Buspirone;Trazodone Trazodone  
 Hydrochloride;Desvenlafaxine;Herbals\Mitragynine;Ziprasidone;Buspirone  
 Hydrochloride;Bupropion Depression Drug Interaction;Serotonin  
 Syndrome Serious Hospitalized;Other Outcomes Male -  
 07-SEP-2022 Expedited 63 YR Not Specified Micro  
 Labs Healthcare Professional Not Specified

Omeprazole;Metformin;Amlodipine;Tizanidine;Diclofenac Sodium 26–  
 AUG–2022 23–JUN–2020 US Not Specified US–MICRO LABS  
 LIMITED–ML2020–01798 – –

21255402 – Tramadol;Herbals\Mitragynine Pain  
 Toxicity To Various Agents;Cognitive Disorder;Electrocardiogram Qt  
 Prolonged;Seizure;Overdose;Drug Interaction;Hypokalaemia  
 Serious Hospitalized Male – 06–SEP–2022 Expedited  
 3 DEC Not Specified Teva Healthcare Professional Not  
 Specified – 01–SEP–2022 25–AUG–2022 US Not  
 Specified US–TEVA–2022–US–2066531 – –

17913888 Buspirone;Trazadone Trazodone  
 Hydrochloride;Herbals\Mitragynine;Ziprasidone;Bupropion;Desvenlafaxine  
 ;Buspirone Hydrochloride Depression Serotonin  
 Syndrome;Drug Interaction Serious Hospitalized Male –  
 06–SEP–2022 Expedited 63 YR Not Specified Teva  
 Healthcare Professional Not Specified – 01–SEP–2022  
 18–JUN–2020 US Not Specified US–TEVA–2020–  
 US–1510324 – –

21296835 – Herbals\Mitragynine Analgesic Therapy  
 Legal Problem;Imprisonment;Drug Dependence Serious Other  
 Outcomes Male 15–JUN–2019 03–SEP–2022 Direct 33 YR  
 76.5 KG Fda–Ctu Consumer Not Specified Suboxone  
 – 03–SEP–2022 Not Specified Not Specified –  
 – –

21296794 – Herbals\Mitragynine Dependence  
 Delusional Perception;Drug Dependence;Drug Abuse Serious Other  
 Outcomes Male 25–AUG–2022 03–SEP–2022 Direct 41 YR  
 85.5 KG Fda–Ctu Consumer Not Specified – –  
 03–SEP–2022 Not Specified Not Specified – –  
 –

21263276 –  
 Morphine;Herbals\Mitragynine;Acetaminophen\Hydrocodone Pain;Product  
 Used For Unknown Indication Flank Pain;Nausea;Acute Kidney  
 Injury;Vomiting Serious Hospitalized;Other Outcomes Female –  
 02–SEP–2022 Expedited 21 YR Not Specified  
 Vistapharm Healthcare Professional Not Specified Percocet  
 22–AUG–2022 29–AUG–2022 Not Specified Not Specified  
 "US–VistaPharm, Inc.–VER202208–000709" – –

21278982 – Herbals\Mitragynine;Tramadol Hydrochloride  
 Pain Hypokalaemia;Cognitive Disorder;Drug  
 Interaction;Generalised Tonic–Clonic Seizure;Electrocardiogram Qt  
 Prolonged;Toxicity To Various Agents Serious Hospitalized;Other  
 Outcomes Male – 01–SEP–2022 Expedited Not  
 Specified Not Specified Aci Healthcare Healthcare  
 Professional Not Specified – 19–AUG–2022 01–SEP–2022  
 US Not Specified US–ACI HealthCare Limited–2132444  
 "Beresford T, Keffler C, Wasserstein M, Ronan P. (P0–152)  
 Kratom Tramadol Toxicity With Seizure, Hypokalemia, Marked Q–T  
 Prolongation, and Cognitive Impairment: A Case Report. Journal of the  
 Academy of Consultation–Liaison Psychiatry 63 (Suppl.): S69–S70 abstr.

P0-152, May 2022. URL: <http://doi.org/10.1016/j.jaclp.2022.03.145>"

21255634 - Morphine  
Sulfate;Hydrocodone;Herbals\Mitragynine Headache  
Proteinuria;Acute Kidney Injury Serious Hospitalized;Other Outcomes  
Female - 25-AUG-2022 Expedited 21 YR Not  
Specified Pfizer Healthcare Professional Not Specified -  
15-AUG-2022 25-AUG-2022 US Not Specified US-  
PFIZER INC-PV202200043672 "LeSaint, K.. Acute Renal  
Insufficiency Associated With Consumption of Hydrocodone- and  
Morphine-Adulterated Kratom (Mitragyna Speciosa). Journal of Emergency  
Medicine. 2022;10.1016/j.jemermed.2022.02.004" -

21252250 - Herbals\Mitragynine;Tramadol Pain  
Electrocardiogram Qt Prolonged;Seizure;Cognitive Disorder;Drug  
Interaction;Hypokalaemia Serious Other Outcomes Not Specified  
- 25-AUG-2022 Expedited Not Specified Not  
Specified Zydus Pharm Healthcare Professional Not Specified  
- 12-AUG-2022 25-AUG-2022 US Not Specified  
US-CADILA HEALTHCARE LIMITED-US-ZYDUS-081624 "Beresford T,  
Keffler C, Wasserstein M, Ronan P. (P0-152) Kratom Tramadol Toxicity  
With Seizure, Hypokalemia, Marked Q-T Prolongation, and Cognitive  
Impairment: A Case Report. J-Acad-Consult-Liaison-Psychiatry. 2022;63  
(Suppl.:S69-S70 abstr. P0-152" -

17921208 Buspirone;Trazodone Trazodone  
Hydrochloride;Desvenlafaxine;Buspirone Hydrochloride;Ziprasidone  
Hydrochloride;Herbals\Mitragynine;Bupropion Depression;Product  
Used For Unknown Indication Drug Interaction;Serotonin Syndrome  
Serious Other Outcomes Not Specified - 24-AUG-2022  
Expedited Not Specified Not Specified Zydus Pharm  
Healthcare Professional Not Specified - 12-AUG-2022  
22-JUN-2020 US Not Specified US-CADILA HEALTHCARE  
LIMITED-US-ZYDUS-052052 "Eudaley ST, Hamilton LA. Case report:  
Successful treatment of suspected kratominduced serotonin syndrome. J-  
Am-Coll-Clin-Pharm. 2020;3(1)347:450" -

21205413 Buspirone;Trazodone Trazodone  
Hydrochloride;Desvenlafaxine;Buspirone  
Hydrochloride;Ziprasidone;Herbals\Mitragynine Product Used For  
Unknown Indication Self-Medication;Drug Interaction;Serotonin  
Syndrome Serious Other Outcomes;Hospitalized Not Specified  
- 20-AUG-2022 Expedited Not Specified Not  
Specified Macleods Healthcare Professional Not Specified

Amlodipine;Tizanidine;Metformin;Gabapentin;Omeprazole;Bupropion;Diclof  
enac;Glimepiride;Hydrochlorothiazide 09-AUG-2022 12-AUG-2022  
US Not Specified US-MACLEODS PHARMACEUTICALS US LTD-  
MAC2022036805 "Eudaley ST, Brooks SP, Hamilton LA.. Case Report:  
Possible Serotonin Syndrome in a Patient Taking Kratom and Multiple  
Serotonergic Agents. Journal of pharmacy practice. 2022;1-5" -

21225453 - Herbals\Mitragynine;Tramadol Pain  
Hypokalaemia;Cognitive Disorder;Toxicity To Various

Agents;Electrocardiogram Qt Prolonged;Generalised Tonic-Clonic Seizure  
Serious Hospitalized;Other Outcomes Male - 18-  
AUG-2022 Expedited 3 DEC Not Specified Ranbaxy  
Healthcare Professional Not Specified - 03-AUG-2022 18-  
AUG-2022 US Not Specified US-SUN PHARMACEUTICAL  
INDUSTRIES LTD-2022R1-348953 "Beresford T, Keffler C, Wasserstein  
M, Ronan P. Kratom Tramadol Toxicity With Seizure, Hypokalemia, Marked  
Q-T Prolongation, and Cognitive Impairment: A Case Report. J Acad  
Consult Liaison Psychiatry. 2022;63 (Suppl.):S69-70(Abstract  
ID:P0-152)" -  
21223322 - Tramadol;Herbals\Mitragynine Pain Mood  
Swings;Electrocardiogram Qt Prolonged;Delirium;Toxicity To Various  
Agents;Fall;Drug Interaction;Generalised Tonic-Clonic Seizure;Loss Of  
Consciousness;Cognitive Disorder;Hypokalaemia Serious Other  
Outcomes;Hospitalized Not Specified - 17-AUG-2022  
Expedited Not Specified Not Specified Macleods  
Healthcare Professional Not Specified - 05-AUG-2022 17-  
AUG-2022 US Not Specified US-MACLEODS PHARMACEUTICALS US  
LTD-MAC2022036828 "Beresford T, Keffler C, Wasserstein M, Ronan  
P. (P0-152) Kratom Tramadol Toxicity With Seizure, Hypokalemia, Marked  
Q-T Prolongation, and Cognitive Impairment: A Case Report. Journal of  
the Academy of Consultation-Liaison Psychiatry. 2022;63:S69-70" -  
21219739 - Herbals\Mitragynine;Tramadol Hydrochloride  
Pain Loss Of Consciousness;Fall;Drug  
Interaction;Hypokalaemia;Toxicity To Various Agents;Electrocardiogram  
Qt Prolonged;Generalised Tonic-Clonic Seizure;Affect  
Lability;Cognitive Disorder;Delirium Serious Hospitalized;Other  
Outcomes Not Specified - 17-AUG-2022 Expedited  
Not Specified Not Specified Ipcia Healthcare  
Professional Not Specified - 05-AUG-2022 17-AUG-2022  
US Not Specified US-IPCA LABORATORIES LIMITED-IPC-2022-  
US-001081 "Thomas Beresford, Carrie Keffler, Mitzi Wasserstein,  
et.al. Kratom tramadol toxicity with seizure, hypokalemia, marked Q-T  
prolongation, and cognitive impairment: A case report. Journal of the  
Academy of Consultation-Liaison Psychiatry. 2022;63:S69-S70" -  
21219728 - Tramadol;Herbals\Mitragynine Pain Loss  
Of Consciousness;Toxicity To Various Agents;Delirium;Hypokalaemia;Mood  
Swings;Fall;Cognitive Disorder;Generalised Tonic-Clonic  
Seizure;Electrocardiogram Qt Prolonged;Drug Interaction Serious Other  
Outcomes;Hospitalized Male - 17-AUG-2022 Expedited  
3 DEC Not Specified Aurobindo Healthcare  
Professional Not Specified - 05-AUG-2022 17-AUG-2022  
US Not Specified US-AUROBINDO-AUR-APL-2022-032197  
"Beresford T, Keffler C, Wasserstein M, Ronan P.. (P0-152)  
Kratom Tramadol Toxicity With Seizure, Hypokalemia, Marked Q-T  
Prolongation, and Cognitive Impairment: A Case Report.. Journal of the  
Academy of Consultation-Liaison Psychiatry. 2022;63Supplement:S69-70"  
-  
17893646 Trazodone;Buspirone Buspirone  
Hydrochloride;Ziprasidone;Trazodone

Hydrochloride;Herbals\Mitragynine;Bupropion;Desvenlafaxine  
Anxiety;Depression;Phytotherapy;Product Used For Unknown Indication  
Serotonin Syndrome;Herbal Interaction Serious Other  
Outcomes;Hospitalized Male 11-APR-2018 17-AUG-2022  
Expedited 63 YR 102.5 KG Apotex Healthcare  
Professional Not Specified  
Tizanidine;Amlodipine;Omeprazole;Hydrochlorothiazide;Gabapentin;Metformin;Diclofenac;Glimepiride 05-AUG-2022 15-JUN-2020 US  
Not Specified US-APOTEX-2020AP012002 "Eudaley ST, Hamilton  
LA. Case report: Successful treatment of suspected kratominduced serotonin syndrome.. JACCP Journal of the American College of Clinical Pharmacy. 2020;3 (1):347" -  
21216260 Buspirone;Trazodone Trazodone  
Hydrochloride;Desvenlafaxine;Buspirone  
Hydrochloride;Ziprasidone;Herbals\Mitragynine Product Used For Unknown Indication Drug Interaction;Serotonin Syndrome  
Serious Hospitalized;Other Outcomes Male - 16-AUG-2022  
Expedited 63 YR 102 KG Hikma Healthcare  
Professional Not Specified  
Tizanidine;Glimepiride;Metformin;Hydrochlorothiazide;Omeprazole;Diclofenac;Bupropion;Amlodipine;Gabapentin 03-AUG-2022 16-AUG-2022  
Not Specified Not Specified US-Hikma Pharmaceuticals USA  
Inc.-US-H14001-22-58394 - -  
21214315 - Tramadol Hydrochloride;Herbals\Mitragynine  
Pain Mood Swings;Hypokalaemia;Drug Interaction;Electrocardiogram Qt Prolonged;Cognitive Disorder;Delirium;Loss Of Consciousness;Fall;Generalised Tonic-Clonic Seizure;Toxicity To Various Agents Serious Hospitalized;Other  
Outcomes Male - 16-AUG-2022 Expedited 3 DEC  
Not Specified Lupin Healthcare Professional Not Specified  
- 03-AUG-2022 16-AUG-2022 US Not Specified  
US-LUPIN PHARMACEUTICALS INC.-2022-10203 "Beresford T, Keffler C, Wasserstein M, Ronan P. Kratom Tramadol toxicity with seizure, hypokalemia, marked q-t prolongation, and cognitive impairment: A case report. Journal of the Academy of Consultation-Liaison Psychiatry. 2022;63:S69-S70" -  
21213865 - Tramadol;Herbals\Mitragynine Pain  
Generalised Tonic-Clonic Seizure;Hypokalaemia;Electrocardiogram Qt Prolonged;Toxicity To Various Agents;Cognitive Disorder Serious Other  
Outcomes;Hospitalized Male - 16-AUG-2022 Expedited  
Not Specified Not Specified Apotex Healthcare  
Professional Not Specified - 03-AUG-2022 16-AUG-2022  
US Not Specified US-APOTEX-2022AP010924 "Beresford T, Keffler C, Wasserstein M, Ronan P.. (P0-152) Kratom Tramadol Toxicity With Seizure, Hypokalemia, Marked Q-T Prolongation, and Cognitive Impairment: A Case Report.. Journal of the Academy of Consultation-Liaison Psychiatry. 2022;63:S69-S70" -  
17872686 Buspirone;Trazodone Trazodone  
Hydrochloride;Desvenlafaxine;Ziprasidone;Buspirone  
Hydrochloride;Herbals\Mitragynine;Bupropion Bacteraemia;Major

Depression;Product Used For Unknown Indication Drug Interaction;Serotonin Syndrome;Product Use In Unapproved Indication Serious Other Outcomes;Hospitalized Male 04-NOV-2018  
15-AUG-2022 Expedited 63 YR 102.5 KG  
Novartis Healthcare Professional Not Specified  
Metformin;Gabapentin;Glimepiride;Omeprazole;Piperacillin And Tazobactam;Tizanidine;Vancomycin;Ampicillin;Hydrochlorothiazide;Amlodipine;Cefepime;Diclofenac 09-AUG-2022 08-JUN-2020 US  
Not Specified NVSC2020US158992 "Eudaley ST, Hamilton LA. Case report: Successful treatment of suspected kratom-induced serotonin syndrome. JOURNAL OF AMERICAN COLLEGE OF CLINICAL PHARMACY. 2020;3(1):347" -  
17883627 Buspirone;Trazodone Trazodone Hydrochloride;Herbals\Mitragynine;Buspirone Hydrochloride;Desvenlafaxine;Bupropion;Ziprasidone Depression Drug Interaction;Serotonin Syndrome Serious Hospitalized;Other Outcomes Male - 14-AUG-2022  
Expedited 63 YR Not Specified Dr Reddys Healthcare Professional Not Specified - 05-AUG-2022 11-JUN-2020 US Not Specified US-drreddys-USA/USA/ 20/0123997 "Eudaley S, Hamilton L. Case report: Successful treatment of suspected kratominduced serotonin syndrome. JACCP Journal of the American College of Clinical Pharmacy. 2020;3(1):347-347. doi:10.1002/jac5.1204" -  
21203414 - Herbals\Mitragynine;Tramadol Pain Drug Interaction;Overdose;Cognitive Disorder;Generalised Tonic-Clonic Seizure;Toxicity To Various Agents;Hypokalaemia;Electrocardiogram Qt Prolonged Serious Hospitalized Male - 11-AUG-2022  
Expedited 3 DEC Not Specified Mylan Healthcare Professional Not Specified - 03-AUG-2022 11-AUG-2022 US Not Specified US- MYLANLABS-2022M1085118 "Beresford T, Keffler C, Wasserstein M, Ronan P. (P0-152) Kratom Tramadol Toxicity With Seizure, Hypokalemia, Marked Q-T Prolongation, and Cognitive Impairment: A Case Report. J-Acad-Consult-Liaison-Psychiatry 2022;63 (Suppl.):S69-S70 abstr. P0-152."  
-  
21203367 Qdolo Tramadol Hydrochloride;Herbals\Mitragynine Pain Generalised Tonic-Clonic Seizure;Toxicity To Various Agents;Electrocardiogram Qt Prolonged;Cognitive Disorder;Hypokalaemia Serious Hospitalized Not Specified - 11-AUG-2022  
Expedited Not Specified Not Specified Athena Healthcare Professional Not Specified - 03-AUG-2022 11-AUG-2022 US Not Specified US-SABAL THERAPEUTICS LLC-2022-ATH-00014 "Beresford T., Keffler C., Wasserstein M., Ronan P.. Kratom Tramadol Toxicity With Seizure, Hypokalemia, Marked Q-T Prolongation, and Cognitive Impairment: A Case Report. Journal of the Academy of Consultation-Liaison Psychiatry. 2022;63:S:S69" -  
21199821 - Herbals\Mitragynine;Tramadol Pain Hypokalaemia;Seizure;Cognitive Disorder;Drug Interaction;Affective Disorder;Electrocardiogram Qt Prolonged;Toxicity To Various Agents

Serious Hospitalized Male - 11-AUG-2022  
 Expedited 3 DEC Not Specified Strides Healthcare  
 Professional Not Specified - 03-AUG-2022 11-AUG-2022  
 US Not Specified US-STRIDES ARCOLAB  
 LIMITED-2022SP010158 "Beresford T, Keffler C, Wasserstein M, Ronan P.. (P0-152) Kratom Tramadol Toxicity With Seizure, Hypokalemia, Marked Q-T Prolongation, and Cognitive Impairment: A Case Report.. J-Acad-Consult-Liaison-Psychiatry. 2022;63 (Suppl.):S69-S70 abstr.  
 P0-152." -

21199901 - Herbals\Mitragynine - Drug  
 Dependence Serious Other Outcomes Not Specified 12-NOV-2021  
 10-AUG-2022 Direct 30 YR Not Specified Fda-Ctu  
 Consumer Not Specified - - 10-AUG-2022 Not  
 Specified Not Specified - - -

21193544 Trazodone Herbals\Mitragynine;Trazodone  
 Hydrochloride;Ziprasidone;Desvenlafaxine;Buspirone Hydrochloride  
 Product Used For Unknown Indication;Tooth Abscess Drug  
 Interaction;Serotonin Syndrome Serious Hospitalized Male -  
 10-AUG-2022 Expedited 63 YR 102.5 KG  
 Unichem Healthcare Professional Not Specified  
 Hydrochlorothiazide;Tizanidine;Piperacillin Sodium\Tazobactam  
 Sodium;Ampicillin;Amlodipine;Vancomycin;Amoxicillin\Clavulanate  
 Potassium;Lorazepam;Diclofenac;Glimepiride;Gabapentin;Metformin;Cefepime;Bupropion;Omeprazole 29-JUL-2022 10-AUG-2022 Not Specified  
 Not Specified US-Unichem Pharmaceuticals (USA) Inc-UCM202208-000729 - - -

21193542 Tramadol Hcl Tramadol  
 Hydrochloride;Herbals\Mitragynine Pain;Product Used For Unknown  
 Indication Fall;Electrocardiogram Qt Prolonged;Drug  
 Interaction;Cognitive Disorder;Hypokalaemia;Seizure;Toxicity To  
 Various Agents Serious Hospitalized Male - 10-AUG-2022  
 Expedited Not Specified Not Specified Unichem  
 Healthcare Professional Not Specified - 29-JUL-2022 10-AUG-2022 Not Specified Not Specified US-Unichem  
 Pharmaceuticals (USA) Inc-UCM202208-000738 - - -

21192472 - Herbals\Mitragynine;Tramadol Hydrochloride  
 Pain Loss Of Consciousness;Electrocardiogram Qt  
 Prolonged;Generalised Tonic-Clonic Seizure;Mood Swings;Drug  
 Interaction;Fall;Cognitive Disorder;Toxicity To Various  
 Agents;Delirium;Hypokalaemia Serious Other Outcomes;Hospitalized  
 Male - 09-AUG-2022 Expedited 3 DEC Not  
 Specified Johnson And Johnson Healthcare Professional Not  
 Specified - 01-AUG-2022 09-AUG-2022 US Not  
 Specified US-JNIFOC-20220818641 - - -

21184115 - Herbals\Mitragynine Product Used For  
 Unknown Indication Respiratory Depression;Toxicity To Various  
 Agents Serious Died Male - 06-AUG-2022 Direct Not  
 Specified Not Specified Fda-Ctu Consumer Not Specified Not Specified  
 - - 06-AUG-2022 Not Specified Not Specified  
 - - -

21177773 - Herbals\Mitragynine - Death;Toxicity  
 To Various Agents Serious Died Male 31-MAY-2022 05-  
 AUG-2022 Direct 31 YR Not Specified Fda-Ctu Consumer  
     Not Specified Benadryl - 05-AUG-2022 Not  
     Specified Not Specified - - -

21176316 - Herbals\Mitragynine Analgesic Therapy  
     Withdrawal Syndrome Serious Required  
 Intervention;Hospitalized Male 15-APR-2020 04-AUG-2022  
     Direct 35 YR 76.5 KG Fda-Ctu Consumer Not Specified  
     - - 04-AUG-2022 Not Specified Not Specified  
     - -

21169852 - Herbals\Mitragynine;Desvenlafaxine;Trazodone  
     Hydrochloride;Bupropion;Buspirone Hydrochloride Product Used For  
     Unknown Indication Herbal Interaction;Drug Interaction;Serotonin  
     Syndrome Serious Hospitalized;Other Outcomes Male -  
     04-AUG-2022 Expedited 63 YR 102.5 KG Oxford  
     Pharmaceuticals Healthcare Professional Not Specified  
     Diclofenac;Omeprazole;Tizanidine;Glimepiride;Gabapentin;Amlodipine;Met  
     formin;Hydrochlorothiazide 20-JUL-2022 04-AUG-2022 US  
     Not Specified "US-Oxford Pharmaceuticals, LLC-2131507"  
     "Eudaley ST, Brooks SP, Hamilton LA. Case Report: Possible  
     Serotonin Syndrome in a Patient Taking Kratom and Multiple  
     Serotonergic Agents. Journal of Pharmacy Practice. 2022 Jul  
     15:08971900221116009." -

21160764 Trazodone;Buspirone Buspirone  
     Hydrochloride;Herbals\Mitragynine;Trazodone  
     Hydrochloride;Desvenlafaxine;Bupropion Product Used For Unknown  
     Indication Serotonin Syndrome;Herbal Interaction;Drug Interaction  
     Serious Hospitalized Male - 02-AUG-2022  
     Expedited 63 YR 102.5 KG Alvogen Healthcare  
     Professional Not Specified  
     Metformin;Gabapentin;Omeprazole;Diclofenac;Glimepiride;Amlodipine;Tiza  
     nidine;Hydrochlorothiazide 20-JUL-2022 02-AUG-2022 US  
     Not Specified US-ALVOGEN-2022-ALVOGEN-120686 "Eudaley ST,  
     Brooks SP, Hamilton LA. Case Report: Possible Serotonin Syndrome in a  
     Patient Taking Kratom and Multiple Serotonergic Agents. J Pharm Pract.  
     2022 Jul 15:8971900221116009. doi: 10.1177/08971900221116009. Epub  
     ahead of print. PMID: 35840540." -

21160134 - Herbals\Mitragynine - Restless Legs  
     Syndrome;Drug Withdrawal Syndrome;Depression;Drug Abuse Serious  
     Hospitalized;Required Intervention Male 15-JUL-2022 01-  
 AUG-2022 Direct 23 YR Not Specified Fda-Ctu Consumer  
     Not Specified - - 01-AUG-2022 Not Specified  
     Not Specified - - -

21154719 - Herbals\Mitragynine - Death  
 Serious Died Male 09-JUL-2022 29-JUL-2022 Direct 25 YR  
     72 KG Fda-Ctu Healthcare Professional Not Specified -  
     - 29-JUL-2022 Not Specified Not Specified -

21081195 - Ursodiol;Herbals\Mitragynine Attention

Deficit Hyperactivity Disorder;Cholestatic Liver Injury;Phytotherapy  
 Drug Ineffective;Multiple Organ Dysfunction Syndrome  
 Serious Hospitalized Female - 29-JUL-2022 Expedited  
 37 YR Not Specified Teva Healthcare Professional Not  
 Specified Amphetamine\Dextroamphetamine 20-JUL-2022 14-  
 JUL-2022 US Not Specified US-TEVA-2022-US-2053941 -  
 -

21138096 - Ziprasidone  
 Hydrochloride;Desvenlafaxine;Trazodone  
 Hydrochloride;Herbals\Mitragynine;Buspirone Hydrochloride  
 Anxiety Disorder;Hypertension;Major Depression;Product Used For  
 Unknown Indication;Type 2 Diabetes Mellitus Drug  
 Interaction;Serotonin Syndrome Serious Other Outcomes;Hospitalized  
 Male - 27-JUL-2022 Expedited 63 YR 102.5  
 KG Accord Healthcare Professional Not Specified  
 Omeprazole;Bupropion;Gabapentin;Amlodipine;Glimepiride;Metformin;Hydro  
 chlorothiazide;Diclofenac;Tizanidine 17-JUL-2022 27-JUL-2022  
 US Not Specified US-Accord-270588 "Eudaley ST,  
 Brooks SP, Hamilton LA. Case Report: Possible Serotonin Syndrome in a  
 Patient Taking Kratom and Multiple Serotonergic Agents. J Pharm Pract.  
 2022 Jul 15:8971900221116009." -

21133272 Paxlovid  
 Nirmatrelvir\Ritonavir;Herbals\Mitragynine Covid-19 Treatment  
 Withdrawal Syndrome;Drug Interaction Non-Serious Non-  
 Serious Female 22-JUL-2022 26-JUL-2022 Non-Expedited 36 YR  
 Not Specified Pfizer Consumer Not Specified  
 Propranolol;Gabapentin 23-JUL-2022 26-JUL-2022 US Not  
 Specified US-PFIZER INC-202201002065 - -  
 21094031 - Herbals\Mitragynine Substance Use Liver  
 Injury Serious Died;Hospitalized Male 05-AUG-2021 17-  
 JUL-2022 Direct 31 YR 83.25 KG Fda-Ctu Consumer  
 Not Specified - - 17-JUL-2022 Not Specified  
 Not Specified - - -

21093964 - Herbals\Mitragynine Nervousness;Pain  
 Sudden Death;Toxicity To Various Agents;Drug Dependence  
 Serious Died Female 15-MAY-2022 17-JUL-2022 Direct 28 YR  
 58.5 KG Fda-Ctu Consumer Not Specified - -  
 17-JUL-2022 Not Specified Not Specified - -

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21075223 - Herbals\Mitragynine Asthenia;Insomnia  
 Decreased Appetite;Constipation;Libido Decreased;Withdrawal  
 Syndrome;Urine Analysis Abnormal;Alopecia;Hepatic Failure  
 Serious Life Threatening;Other Outcomes;Disabled;Required  
 Intervention;Hospitalized Female 25-JUN-2021 12-JUL-2022  
 Direct 27 YR 56.25 KG Fda-Ctu Consumer Not  
 Specified - - 12-JUL-2022 Not Specified Not  
 Specified - - -

16717179 - Citalopram  
 Hydrobromide;Herbals\Mitragynine;Ranitidine;Loratadine;Albuterol;Aceta  
 minophen;Diphenhydramine;Valacyclovir Hydrochloride;Methocarbamol

Exposure During Pregnancy;Product Used For Unknown Indication						
Foetal Exposure During Pregnancy;Drug Withdrawal Syndrome						
Neonatal	Serious	Other Outcomes;Hospitalized	Female	-		
11-JUL-2022	Expedited	Not Specified	3.68	KG		
Allergan	Healthcare Professional	Not Specified	-		28-	
JUN-2022	19-AUG-2019	CA	Not Specified	CA-		
ALLERGAN-1933574US	-	-				
16717258	Valtrex Citalopram Hydrobromide;Valacyclovir Hydrochloride;Herbals\Mitragynine;Loratadine;Ranitidine;Albuterol;Acetaminophen\Methocarbamol;Diphenhydramine Product Used For Unknown Indication	Caesarean Section;Maternal Exposure During Pregnancy				
Serious	Other Outcomes	Female	-	05-JUL-2022		
Expedited	Not Specified	Not Specified	Allergan			
Healthcare Professional	Not Specified	-	28-JUN-2022	19-		
AUG-2019	CA	Not Specified	CA-ALLERGAN-1933436US	-		
21028472	-	Herbals\Mitragynine	Anxiety;Back Disorder Brain Fog;Road Traffic Accident;Euphoric Mood;Adverse Drug Reaction;Drug Dependence	Non-Serious	Non-Serious	Male
02-JUN-2022	30-JUN-2022	Direct	46	YR	86.18	KG
Fda-Ctu Consumer	Not Specified	-	-	-	30-	
JUN-2022	Not Specified	Not Specified	-	-	-	
21026779	-	Herbals\Mitragynine	Anxiety Vomiting;Nausea;Food Poisoning	Non-Serious	Non-Serious	Female
22-MAY-2022	29-JUN-2022	Direct	42	YR	Not Specified	
Fda-Ctu Consumer	Not Specified					
Glucosamine;Collagen;Calcium;Yaz;Famotidine;Vitamin D				-	29-	
JUN-2022	Not Specified	Y	-	-	-	
21008823	-	Herbals\Mitragynine	-		Drug Withdrawal Syndrome;Substance Use;Drug Dependence	Serious
Hospitalized;Disabled	Not Specified	24-JUN-2022	25-JUN-2022			
Direct	Not Specified	Not Specified	Fda-Ctu Consumer			
Not Specified	-	-	25-JUN-2022	Not Specified		
Not Specified	-	-				
21003944	-	Herbals\Mitragynine	Pain Overdose;Drug Dependence;Dependence	Serious	Life Threatening;Hospitalized	Male
-	24-JUN-2022	Direct	32	YR	67.5	KG Fda-Ctu
Consumer	Not Specified	-	-	24-JUN-2022	Not Specified	
Specified	Not Specified	-	-	-		
19826544	Hydrocodone Bitartrate And Acetaminophen					
Acetaminophen\Hydrocodone Bitartrate;Alprazolam;Oxycodone;Escitalopram Oxalate;Hydrocodone;Tramadol;Herbals\Mitragynine					Anxiety;Back Pain;Depression;Drug Withdrawal Syndrome;Intervertebral Disc Degeneration	
Drug Withdrawal Syndrome;Drug Tolerance;Drug Use Disorder;Drug Dependence;Intentional Product Misuse;Drug Ineffective;Intentional Overdose;Depression;Anxiety						Serious
Hospitalized;Other Outcomes	Male	-	20-JUN-2022			
Expedited	5 DEC	Not Specified	Lupin	Healthcare		
Professional	Not Specified	-	07-JUN-2022	14-SEP-2021		
US	Not Specified	US-LUPIN PHARMACEUTICALS				

INC.-2021-17175 "Bowe A, Kerr PL. A complex case of kratom dependence, depression, and chronic pain in opioid use disorder: effects of buprenorphine in clinical management. Journal of Psychoactive Drugs. 2020;52(5):447-452" -

20963498 - Herbals\Mitragynine - Intentional Product Misuse;Withdrawal Syndrome;Educational Problem;Dependence;Personal Relationship Issue;Overdose;Drug Tolerance;Drug Dependence;Loss Of Personal Independence In Daily Activities Serious Disabled;Hospitalized;Required Intervention;Life Threatening Female - 15-JUN-2022 Direct 19 YR Not Specified Fda-Ctu Healthcare Professional Not Specified - - 15-JUN-2022 Not Specified Not Specified - - -

20951894 Zoloft Sertraline Hydrochloride;Herbals\Mitragynine Anxiety Toxicity To Various Agents;Drug Abuser Serious Died Male 03-MAY-2022 11-JUN-2022 Direct 39 YR 81 KG Fda-Ctu Consumer Not Specified Aripiprazole;Bupropion Hydrochloride;Sertraline - 11-JUN-2022 Not Specified Not Specified - - -

20939015 - Herbals\Mitragynine Substance Use Alcohol Poisoning;Herbal Toxicity Serious Died Female 29-MAY-2019 09-JUN-2022 Direct 52 YR Not Specified Fda-Ctu Consumer Not Specified - - 09-JUN-2022 Not Specified Not Specified - - -

20909802 - Herbals\Mitragynine Seizure;Drug Dependence;Quality Of Life Decreased Serious Disabled;Other Outcomes;Life Threatening Male 13-SEP-2021 02-JUN-2022 Direct 29 YR Not Specified Fda-Ctu Consumer Not Specified - - 02-JUN-2022 Not Specified Not Specified - - -

20906527 - Herbals\Mitragynine Affective Disorder Seizure Serious Other Outcomes;Hospitalized;Life Threatening;Required Intervention Male 29-MAY-2022 02-JUN-2022 Direct 35 YR 81 KG Fda-Ctu Consumer Not Specified - - 02-JUN-2022 Not Specified Not Specified - - -

20906522 - Herbals\Mitragynine Rheumatoid Arthritis Toxicity To Various Agents;Hypertension;Unresponsive To Stimuli;Withdrawal Syndrome;Respiratory Depression Serious Hospitalized;Life Threatening;Other Outcomes Female 12-JAN-2022 02-JUN-2022 Direct 44 YR 63 KG Fda-Ctu Consumer Not Specified Buspirone;Nexium;Vitamins;Ambien;Clonidine;Seroquel - 02-JUN-2022 Not Specified Not Specified - - -

20863949 Venlafaxine Venlafaxine Hydrochloride;Herbals\Mitragynine;Quetiapine - Electrocardiogram Qt Prolonged;Serotonin Syndrome;Drug Interaction Serious Hospitalized Male - 23-MAY-2022 Expedited 36 YR Not Specified Astrazeneca Healthcare Professional Not Specified - 15-MAY-2022 23-MAY-2022

Not Specified Not Specified US-AstraZeneca-2022A187677  
Brogdon H.D.; McPhee M.M.; Paine M.F.; Cox E.J.; Burns  
A.G.. A Case of Potential Pharmacokinetic Kratom-drug Interactions  
Resulting in Toxicity and Subsequent Treatment of Kratom Use Disorder  
With Buprenorphine/Naloxone. Journal of addiction medicine 2022;

20587441 Venlafaxine Venlafaxine  
Hydrochloride;Quetiapine;Herbals\Mitragynine Product Used For  
Unknown Indication Electrocardiogram Qt Prolonged;Serotonin  
Syndrome;Drug Interaction;Drug Level Above Therapeutic Serious Other  
Outcomes Male - 18-MAY-2022 Expedited 36 YR  
Not Specified Hikma Healthcare Professional Not Specified  
- 04-MAY-2022 14-MAR-2022 Not Specified Not  
Specified US-Hikma Pharmaceuticals USA Inc.-US-H14001-22-56956

20531342 Venlafaxine Venlafaxine  
Hydrochloride;Herbals\Mitragynine;Quetiapine Drug Abuse;Drug Use  
Disorder;Product Used For Unknown Indication Antidepressant Drug  
Level Above Therapeutic;Electrocardiogram Abnormal;Herbal  
Interaction;Antipsychotic Drug Level Above Therapeutic;Serotonin  
Syndrome;Drug Interaction;Toxicity To Various Agents;Drug Use  
Disorder;Electrocardiogram Qt Prolonged Serious Other Outcomes Not  
Specified - 18-MAY-2022 Expedited Not Specified  
Not Specified Macleods Healthcare Professional Not  
Specified Buprenorphine\Naloxone 04-MAY-2022 01-MAR-2022  
US Not Specified US-MACLEODS PHARMACEUTICALS US LTD-  
MAC2022034574 "Brogdon HD, McPhee MM, Paine MF, Cox EJ, Burns AG. A  
Case of Potential Pharmacokinetic Kratom-drug Interactions Resulting  
in Toxicity and Subsequent Treatment of Kratom Use Disorder With  
Buprenorphine/Naloxone. American Society of Addiction Medicine.  
2022;00:00" -

20588988 Venlafaxine Quetiapine;Venlafaxine  
Hydrochloride;Herbals\Mitragynine Product Used For Unknown  
Indication Antidepressant Drug Level Above Therapeutic;Drug Level  
Above Therapeutic;Electrocardiogram Abnormal;Drug  
Interaction;Electrocardiogram Qt Prolonged;Herbal  
Interaction;Serotonin Syndrome;Antipsychotic Drug Level Above  
Therapeutic Serious Other Outcomes Male - 17-MAY-2022  
Expedited 36 YR Not Specified Aurobindo  
Healthcare Professional Not Specified Buprenorphine\Naloxone 04-  
MAY-2022 14-MAR-2022 US Not Specified US-AUROBINDO-  
AUR-APL-2022-007142 "Brogdon HD, McPhee MM, Paine MF, Cox EJ,  
Burns AG.. A Case of Potential Pharmacokinetic Kratom-drug  
Interactions Resulting in Toxicity and Subsequent Treatment of Kratom  
Use Disorder With Buprenorphine/Naloxone.. Journal of addiction  
medicine. 2022" -

20581439 Venlafaxine Venlafaxine Hydrochloride;Quetiapine  
Fumarate;Herbals\Mitragynine Product Used For Unknown Indication  
Herbal Interaction;Drug Interaction;Antipsychotic Drug Level  
Above Therapeutic;Electrocardiogram Qt Prolonged;Serotonin

Syndrome;Electrocardiogram Abnormal      Serious Other  
Outcomes;Hospitalized    Male    -    16-MAY-2022    Expedited  
                      36 YR    Not Specified    Lupin    Healthcare Professional Not  
Specified    -    04-MAY-2022    11-MAR-2022    US    Not  
Specified    US-LUPIN PHARMACEUTICALS  
INC.-2022-03085 "Brogdon HD, McPhee MM, Paine MF, Cox EJ, Burns AG. A case of potential pharmacokinetic kratom-drug interactions resulting in toxicity and subsequent treatment of kratom use disorder with buprenorphine/naloxone. American Society of Addiction Medicine. 2022"

-  
20832558      -    Herbals\Mitragynine    Anxiety  
Anxiety;Hypertension;Restless Legs Syndrome;Chest Pain    Serious  
Disabled    Female    13-MAY-2022    14-MAY-2022    Direct    45 YR  
                      55.8 KG Fda-Ctu Consumer    Not Specified    Prozac    -  
                      14-MAY-2022    Not Specified    Not Specified    -    -

-  
20552469      Venlafaxine    Venlafaxine  
Hydrochloride;Herbals\Mitragynine;Quetiapine    Product Used For  
Unknown Indication    Herbal Interaction;Electrocardiogram  
Abnormal;Serotonin Syndrome;Electrocardiogram Qt Prolonged;Toxicity To  
Various Agents;Antidepressant Drug Level Above  
Therapeutic;Antipsychotic Drug Level Above Therapeutic;Drug  
Interaction    Serious Other Outcomes    Male    -    13-MAY-2022  
                      Expedited    36 YR    Not Specified    Torrent Healthcare  
Professional    Not Specified    -    04-MAY-2022    04-MAR-2022  
                      US    Not Specified    US-TORRENT-00011765    -    -

20587236      -    Quetiapine  
Fumarate;Herbals\Mitragynine;Venlafaxine Hydrochloride    Product Used  
For Unknown Indication    Electrocardiogram Abnormal;Drug  
Interaction;Antidepressant Drug Level Above Therapeutic;Serotonin  
Syndrome;Drug Level Above Therapeutic;Herbal  
Interaction;Electrocardiogram Qt Prolonged;Antipsychotic Drug Level  
Above Therapeutic    Serious Other Outcomes    Male    -    12-  
MAY-2022    Expedited    36 YR    Not Specified    Dr Reddys  
Healthcare Professional Not Specified    -    04-MAY-2022  
                      14-MAR-2022    US    Not Specified    US-drreddys-SP0/USA/

22/0147506      "Burns A, Brogdon H, McPhee M, Paine M, Cox E. A Case  
of Potential Pharmacokinetic Kratom-drug Interactions Resulting in  
Toxicity and Subsequent Treatment of Kratom Use Disorder With  
Buprenorphine/Naloxone. J Addict Med. 2022;UNK:UNK-UNK. doi:10.1097/  
ADM.0000000000000968"    -

20584138      Venlafaxine    Venlafaxine  
Hydrochloride;Herbals\Mitragynine;Quetiapine    Product Used For  
Unknown Indication    Drug Level Above Therapeutic;Electrocardiogram  
Qt Prolonged;Drug Interaction;Serotonin Syndrome    Serious Other  
Outcomes    Male    -    10-MAY-2022    Expedited    36 YR  
                      Not Specified    Bausch And Lomb Healthcare Professional Not  
Specified    -    04-MAY-2022    11-MAR-2022    US    Not  
Specified    US-BAUSCH-BL-2022-006009    "Brogdon H, McPhee M,  
Paine M, Cox E, Burns A. A Case of Potential Pharmacokinetic Kratom-

drug Interactions Resulting in Toxicity and Subsequent Treatment of Kratom Use Disorder With Buprenorphine/Naloxone. Journal of Addiction Medicine. 2022;1-4. doi:1097/ADM.0000000000000968" -

20801307 - Herbals\Mitragynine - Death  
 Serious Died Male 04-APR-2022 07-MAY-2022 Direct 41 YR  
 Not Specified Fda-Ctu Consumer Not Specified -  
 - 07-MAY-2022 Not Specified Not Specified -  
 - -

20778443 - Herbals\Mitragynine Drug Dependence Blood Pressure Increased;Drug Dependence;Psychomotor Hyperactivity Non-Serious Non-Serious Male 18-MAR-2022 03-MAY-2022 Direct  
 Not Specified Not Specified Fda-Ctu Consumer Not Specified Not Specified - - -  
 Specified - - 03-MAY-2022 Not Specified Not Specified Not Specified

20778086 - Herbals\Mitragynine - Drug Dependence;Rhinorrhoea;Vomiting;Agitation;Sleep Disorder;Sleep Apnoea Syndrome;Withdrawal Syndrome;Influenza Like Illness Serious Hospitalized;Disabled Female 28-APR-2022 03-MAY-2022 Direct  
 50 YR Not Specified Fda-Ctu Not Specified Not Specified Not Specified - 03-MAY-2022 Not Specified Not Specified - -

20719274 - Herbals\Mitragynine - Cardiac Arrest;Seizure;Vertigo;Herbal Toxicity;Bell's Palsy Serious Died  
 Male 13-APR-2019 15-APR-2022 Direct 27 YR 81 KG  
 Fda-Ctu Consumer Not Specified - - 15-  
 APR-2022 Not Specified Not Specified - - -

20713303 - Herbals\Mitragynine Fatigue Blood Potassium Decreased;Adverse Drug Reaction;Product Complaint;Drug Dependence Serious Other Outcomes Female 18-OCT-2020 14-  
 APR-2022 Direct 52 YR 62.1 KG Fda-Ctu Consumer Not Specified Vitamin B;Vitamin C;Magnesium - 14-APR-2022  
 Not Specified Not Specified - - -

20706519 - Herbals\Mitragynine Alcohol Detoxification Seizure;Dependence Serious Hospitalized;Died Male  
 05-FEB-2021 11-APR-2022 Direct 21 YR 61.23 KG  
 Fda-Ctu Consumer Not Specified - - 11-  
 APR-2022 Not Specified Not Specified - - -

20701017 - Herbals\Mitragynine Anxiety;Insomnia Herbal Toxicity Serious Died Male 21-FEB-2021 11-  
 APR-2022 Direct 26 YR 78.75 KG Fda-Ctu Consumer  
 Not Specified - - 11-APR-2022 Not Specified  
 Not Specified - - -

20699441 - Herbals\Mitragynine Drug Dependence Accidental Overdose Serious Died Male - 10-APR-2022  
 Direct Not Specified 103.5 KG Fda-Ctu Consumer  
 Not Specified - - 10-APR-2022 Not Specified  
 Not Specified - - -

20631085 Venlafaxine Venlafaxine Hydrochloride;Quetiapine;Herbals\Mitragynine Drug Use Disorder;Product Used For Unknown Indication Serotonin

Syndrome;Intentional Product Misuse;Drug Interaction;Electrocardiogram  
 Qt Prolonged      Serious Hospitalized      Male      -      07-APR-2022  
                     Expedited      36 YR      Not Specified      Teva      Healthcare  
 Professional      Not Specified      -      30-MAR-2022      24-MAR-2022  
                     US      Not Specified      US-TEVA-2022-US-2018997 "Brogdon HD,  
 McPhee MM, Paine MF, Cox EJ, Burns AG. A Case of Potential  
 Pharmacokinetic Kratom-drug Interactions Resulting in Toxicity and  
 Subsequent Treatment of Kratom Use Disorder With Buprenorphine/  
 Naloxone. J-Addict-Med 2022;::." -  
 20679122      -      Herbals\Mitragynine      Product Used For  
 Unknown Indication      Drug Tolerance Increased;Product  
 Complaint;Drug Dependence;Dependence      Serious Other Outcomes      Male  
                     01-APR-2022      05-APR-2022      Direct      36 YR      Not Specified  
                     Fda-Ctu Consumer      Not Specified      -      -      05-  
                     APR-2022      Not Specified      Not Specified      -      -      -  
 20658365      -      Herbals\Mitragynine      Relaxation Therapy  
                     Drug Dependence;Withdrawal Syndrome      Serious Disabled;Other  
 Outcomes      Male      29-MAR-2022      30-MAR-2022      Direct      33 YR  
                     87.75 KG      Fda-Ctu Consumer      Not Specified      -  
                     -      30-MAR-2022      Not Specified      Not Specified      -  
                     -      -  
 20642682      -      Herbals\Mitragynine      Asthenia  
                     Euphoric Mood;Psychotic Disorder;Dependence      Serious Other Outcomes  
                     Male      01-MAR-2022      27-MAR-2022      Direct      47 YR      121.5  
 KG      Fda-Ctu Consumer      Not Specified      Buspar;Vasotec;Paxil  
                     -      27-MAR-2022      Not Specified      Not Specified      -  
                     -      -  
 20636132      -      Herbals\Mitragynine      Anxiety Marital  
                     Problem;Paranoia;Delusion;Product Complaint;Self-Medication  
                     Serious Hospitalized      Male      31-JUL-2021      24-MAR-2022      Direct  
                     38 YR      112.5 KG      Fda-Ctu Consumer      Not Specified  
                     -      -      24-MAR-2022      Not Specified      Not Specified  
                     -      -      -  
 20576068      Venlafaxine      Venlafaxine Hydrochloride;Quetiapine  
                     Fumarate;Herbals\Mitragynine      Product Used For Unknown Indication  
                     Serotonin Syndrome;Drug Interaction;Drug Level Above  
                     Therapeutic;Dizziness;Herbal Interaction;Electrocardiogram Abnormal  
                     Serious Other Outcomes      Male      -      24-MAR-2022  
                     Expedited      36 YR      Not Specified      Alembic Healthcare  
 Professional      Not Specified      -      11-MAR-2022      10-MAR-2022  
                     US      Not Specified      US-ALEMBIC PHARMACEUTICALS  
                     LIMITED-2022SCAL000070 "McPhee MM, Paine MF, Cox EJ, Burns AG.. A  
                     Case of Potential Pharmacokinetic Kratom-drug Interactions Resulting  
                     in Toxicity and Subsequent Treatment of Kratom Use Disorder With  
                     Buprenorphine/Naloxone.. Journal of addiction medicine. 2022" -  
 20570100      Venlafaxine      Venlafaxine  
                     Hydrochloride;Quetiapine;Herbals\Mitragynine      Opioid Sparing  
                     Treatment;Product Used For Unknown Indication      Serotonin  
                     Syndrome;Electrocardiogram Qt Prolonged;Drug Level Above  
                     Therapeutic;Drug Interaction      Serious Other Outcomes      Male      -

24-MAR-2022 Expedited 36 YR Not Specified  
Unichem Healthcare Professional Not Specified - 11-MAR-2022  
09-MAR-2022 Not Specified Not Specified US-Unichem  
Pharmaceuticals (USA) Inc-UCM202203-000202 - -  
20626838 - Herbals\Mitragynine Asthenia  
Feeling Abnormal;Illness;Dyspnoea;Withdrawal Syndrome Non-Serious  
Non-Serious Male - 22-MAR-2022 Direct Not  
Specified 81 KG Fda-Ctu Consumer Not Specified -  
- 22-MAR-2022 Not Specified Not Specified -  
- -  
20619042 - Diazepam;Fentanyl;Herbals\Mitragynine  
Product Used For Unknown Indication Drug Abuse Serious Died  
Male 2020 22-MAR-2022 Expedited 31 YR Not  
Specified Endo Healthcare Professional Not Specified -  
22-FEB-2022 22-MAR-2022 US Not Specified US-  
ENDO PHARMACEUTICALS INC-2022-001574 - -  
20622022 - Herbals\Mitragynine Anxiety;Insomnia  
Socioeconomic Precarity;Drug Dependence Serious Disabled;Other  
Outcomes;Life Threatening;Required Intervention Male 15-MAR-2022  
21-MAR-2022 Direct 36 YR 67.5 KG Fda-Ctu Consumer  
Not Specified - - 21-MAR-2022 Not Specified  
Not Specified - - -  
20613979 - Herbals\Mitragynine;Oxycodone;Gabapentin  
Drug Abuse Drug Abuse Serious Other Outcomes;Died  
Female - 19-MAR-2022 Expedited 47 YR Not  
Specified Alvogen Healthcare Professional Not Specified -  
04-MAR-2022 19-MAR-2022 US Not Specified US-  
ALVOGEN-2022-ALVOGEN-118997 "Gummin DD, Mowry JB, Beuhler MC,  
Spyker DA, Bronstein AC, Rivers LJ, Pham NPT, Weber J. 2020 Annual  
Report of the American Association of Poison Control Centers' National  
Poison Data System (NPDS): 38th Annual Report. Clin Toxicol (Phila).  
2021 Dec;59(12):1282-1501. doi: 10.1080/15563650.2021.1989785." -  
20608291 - Herbals\Mitragynine;Oxycodone Product Used  
For Unknown Indication Death Serious Died;Other Outcomes Male  
- 17-MAR-2022 Expedited 57 YR Not Specified  
Alvogen Healthcare Professional Not Specified - 04-  
MAR-2022 17-MAR-2022 US Not Specified US-  
ALVOGEN-2022-ALVOGEN-118971 "Gummin DD, Mowry JB, Beuhler MC,  
Spyker DA, Bronstein AC, Rivers LJ, Pham NPT, Weber J. 2020 Annual  
Report of the American Association of Poison Control Centers' National  
Poison Data System (NPDS): 38th Annual Report. Clin Toxicol (Phila).  
2021 Dec;59(12):1282-1501. doi: 10.1080/15563650.2021.1989785." -  
20605579 Trazodone Trazodone  
Hydrochloride;Fentanyl;Herbals\Mitragynine Drug Abuse Drug  
Abuse Serious Died;Other Outcomes Male - 17-MAR-2022  
Expedited 28 YR Not Specified Alvogen Healthcare  
Professional Not Specified - 04-MAR-2022 17-MAR-2022  
US Not Specified US-ALVOGEN-2022-  
ALVOGEN-118740 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Bronstein  
AC, Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the American

Association of Poison Control Centers' National Poison Data System (NPDS): 38th Annual Report. Clin Toxicol (Phila). 2021 Dec;59(12):1282-1501. doi: 10.1080/15563650.2021.1989785." -  
20601265 Venlafaxine Venlafaxine  
Hydrochloride;Buprenorphine Hydrochloride\Naloxone  
Hydrochloride;Herbals\Mitragynine;Quetiapine Drug Use  
Disorder;Product Used For Unknown Indication;Substance Use Disorder  
Drug Interaction;Electrocardiogram Qt Prolonged;Drug Level  
Above Therapeutic;Serotonin Syndrome;Off Label Use Serious  
Hospitalized Male - 16-MAR-2022 Expedited 36 YR  
Not Specified Mylan Healthcare Professional Not Specified  
Buprenorphine\Naloxone 07-MAR-2022 16-MAR-2022 US  
Not Specified US-MYLANLABS-2022M1019572 "Brogdon HD,  
McPhee MM, Paine MF, Cox EJ, Burns AG. A Case of Potential  
Pharmacokinetic Kratom-drug Interactions Resulting in Toxicity and  
Subsequent Treatment of Kratom Use Disorder With Buprenorphine/  
Naloxone. J-Addict-Med 2022;null:null." -  
20586698 Percocet;Alcohol (Alcohol)  
Alcohol;Acetaminophen\Oxycodone  
Hydrochloride;Herbals\Mitragynine;Benzodiazepine;Fentanyl  
Product Used For Unknown Indication Drug Abuse;Cardio-Respiratory  
Arrest Serious Died Male 2020 13-MAR-2022 Expedited  
16 YR Not Specified Endo Healthcare Professional Not  
Specified - 22-FEB-2022 13-MAR-2022 US Not  
Specified US-ENDO PHARMACEUTICALS INC-2022-001222 -  
20583134 Venlafaxine Venlafaxine  
Hydrochloride;Herbals\Mitragynine;Quetiapine -  
Electrocardiogram Qt Prolonged;Drug Interaction;Serotonin Syndrome  
Serious Other Outcomes Male - 11-MAR-2022  
Expedited 36 YR Not Specified Jubilant Healthcare  
Professional Not Specified - 28-FEB-2022 11-MAR-2022  
US Not Specified US-JUBILANT CADISTA  
PHARMACEUTICALS-2022JUB00051 "Brogdon HD, McPhee MM, Paine MF, Cox  
EJ, Burns AG. A Case of Potential Pharmacokinetic Kratom-drug  
Interactions Resulting in Toxicity and Subsequent Treatment of Kratom  
Use Disorder With Buprenorphine/Naloxone. J Addict Med. 2022" -  
20573098 - Herbals\Mitragynine Pain Drug  
Dependence;Withdrawal Syndrome;Socioeconomic Precarity Non-Serious  
Non-Serious Male - 09-MAR-2022 Direct 42 YR  
87.3 KG Fda-Ctu Consumer Not Specified - -  
09-MAR-2022 Not Specified Not Specified - -  
-  
20517346 Venlafaxine Quetiapine;Venlafaxine  
Hydrochloride;Herbals\Mitragynine Product Used For Unknown  
Indication Electrocardiogram Qt Prolonged;Sinus Tachycardia;Drug  
Interaction;Serotonin Syndrome;Drug Level Increased Serious  
Hospitalized;Other Outcomes Male - 09-MAR-2022  
Expedited 36 YR Not Specified Accord Healthcare  
Professional Not Specified - 02-MAR-2022 25-FEB-2022  
US Not Specified US-Accord-255103 "Brogdon HD,

McPhee MM, Paine MF, Cox EJ, Burns AG. A Case of Potential Pharmacokinetic Kratom-drug Interactions Resulting in Toxicity and Subsequent Treatment of Kratom Use Disorder With Buprenorphine/Naloxone. J Addict Med. 2022 Feb 14." -

20566946 Robaxin

Methocarbamol;Herbals\Mitragynine;Etizolam;Fentanyl Product Used For Unknown Indication Drug Abuse Serious Died Male 2020  
08-MAR-2022 Expedited 35 YR Not Specified Endo  
Healthcare Professional Not Specified - 22-FEB-2022  
08-MAR-2022 US Not Specified US-ENDO

PHARMACEUTICALS INC-2022-001248 - -

20565119 Venlafaxine Venlafaxine Hydrochloride;Quetiapine;Herbals\Mitragynine -  
Electrocardiogram Qt Prolonged;Drug Interaction;Dizziness;Serotonin Syndrome Serious Hospitalized;Other Outcomes Male -  
08-MAR-2022 Expedited 36 YR Not Specified Dexcel  
Healthcare Professional Not Specified - 22-FEB-2022  
08-MAR-2022 US Not Specified US-DEXPHARM-20220213  
"Brogdon, H. D., McPhee, M. M., Paine, M. F., Cox, E. J., & Burns, A. G. (2022). A Case of Potential Pharmacokinetic Kratom-drug Interactions Resulting in Toxicity and Subsequent Treatment of Kratom Use Disorder With Buprenorphine/Naloxone. Journal of addiction medicine, 10.1097/ADM.0000000000000968. Advance online publication. <https://doi.org/10.1097/ADM.0000000000000968>" -

20548596 - Herbals\Mitragynine - Overdose;Drug Abuse Serious Died Male 25-FEB-2022 03-MAR-2022 Direct  
37 YR Not Specified Fda-Ctu Consumer Not Specified  
- - 03-MAR-2022 Not Specified Not Specified  
- - -

20545337 - Herbals\Mitragynine;Quetiapine;Venlafaxine Hydrochloride Product Used For Unknown Indication Drug Level Increased;Toxicity To Various Agents;Serotonin Syndrome;Drug Interaction;Long Qt Syndrome Serious Hospitalized Male -  
03-MAR-2022 Expedited 36 YR Not Specified Emcure  
Healthcare Professional Not Specified - 22-FEB-2022  
03-MAR-2022 US Not Specified US-AVET LIFESCIENCES

LTD-2022-AVET-000038 "Brogdon HD, McPhee MM, Paine MF, Cox EJ, Burns AG. A Case of Potential Pharmacokinetic Kratom-drug Interactions Resulting in Toxicity and Subsequent Treatment of Kratom Use Disorder With Buprenorphine/Naloxone. J Addict Med. 2022" -

20545251 Venlafaxine Venlafaxine Hydrochloride;Herbals\Mitragynine;Quetiapine Product Used For Unknown Indication;Substance Use Disorder Electrocardiogram Change;Serotonin Syndrome;Drug Interaction Serious Other Outcomes Male - 03-MAR-2022 Expedited 36 YR Not Specified Atlantide Pharmaceuticals Ag Healthcare Professional Not Specified - 23-FEB-2022 03-MAR-2022 US Not Specified US-ATLANTIDE PHARMACEUTICALS

AG-2022ATL000010 "Brogdon HD, McPhee MM, Paine MF, Cox EJ, Burns AG. A Case of Potential Pharmacokinetic Kratom-drug Interactions

Resulting in Toxicity and Subsequent Treatment of Kratom Use Disorder With Buprenorphine/Naloxone.. J Addict Med. 2022;00" -

20517833 - Herbals\Mitragynine Drug Dependence  
 Alcohol Interaction Serious Died Male 11-DEC-2021 24-  
 FEB-2022 Direct 30 YR 101.25 KG Fda-Ctu Consumer  
 Not Specified - - 24-FEB-2022 Not Specified  
 Not Specified - - -

20506147 Venlafaxine Venlafaxine  
 Hydrochloride;Herbals\Mitragynine;Quetiapine Product Used For  
 Unknown Indication Serotonin Syndrome;Drug  
 Interaction;Electrocardiogram Qt Prolonged;Sinus Tachycardia;Drug  
 Level Increased Serious Other Outcomes;Hospitalized Male -  
 23-FEB-2022 Expedited 36 YR Not Specified Cadila  
 Healthcare Professional Not Specified - 17-FEB-2022  
 23-FEB-2022 US Not Specified US-

CPL-002766 "Brogdon HD, McPhee MM, Paine MF, Cox EJ, Burns AG. A Case of Potential Pharmacokinetic Kratom-drug Interactions Resulting in Toxicity and Subsequent Treatment of Kratom Use Disorder With Buprenorphine/Naloxone. J Addict Med. 2022 Feb 14." -

20492026 - Sertraline Hydrochloride;Herbals\Mitragynine  
 - Drug Abuse Serious Died;Other Outcomes Female  
 2020 18-FEB-2022 Expedited 51 YR Not Specified  
 Pfizer Healthcare Professional Not Specified - 10-  
 FEB-2022 18-FEB-2022 US Not Specified US-PFIZER

INC-202200250834 "Gummin, D.. 2020 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 38th Annual Report. Clinical Toxicology. 2021;59 (12):1282-1501" -

20491050 Methadone Methadone Hydrochloride;Sertraline Hydrochloride;Herbals\Mitragynine - Drug Abuse  
 Serious Other Outcomes;Died Male 2020 18-FEB-2022  
 Expedited 40 YR Not Specified Pfizer Healthcare  
 Professional Not Specified - 10-FEB-2022 18-FEB-2022  
 US Not Specified US-PFIZER

INC-202200255149 "Gummin, D.. 2020 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 38th Annual Report. Clinical Toxicology. 2021;59 (12):1282-1501" -

20490631 - Herbals\Mitragynine;Alcohol  
 Alcoholism;Product Used For Unknown Indication;Self-Medication  
 Aggression;Constipation;Insomnia;Confusional State;Weight  
 Decreased;Liver Disorder;Hypothyroidism;Ammonia Increased Non-  
 Serious Non-Serious Female - 18-FEB-2022 Direct 30 YR  
 120 LB Fda-Ctu Consumer Not Specified - -  
 18-FEB-2022 Not Specified Not Specified - -

-

20490616 - Herbals\Mitragynine Pain  
 Management;Substance Use Accidental Death;Substance  
 Use;Impaired Work Ability;Wernicke's  
 Encephalopathy;Dizziness;Overdose;Pulse

Abnormal;Nausea;Vomiting;Weight Decreased;Decreased Appetite;Cognitive Disorder;Dysphonia      Serious Died      Female 15-DEC-2021      18-FEB-2022      Direct 51 YR Not Specified      Fda-Ctu Consumer  
Not Specified - - 18-FEB-2022 Not Specified  
Y - -  
20490453      Methadone      Methadone Hydrochloride;Sertraline Hydrochloride;Herbals\Mitragynine - Death Serious Other Outcomes;Died Male 2020 18-FEB-2022 Expedited 41 YR  
Not Specified Pfizer Healthcare Professional Not Specified  
- 10-FEB-2022 18-FEB-2022 US Not Specified  
US-PFIZER INC-202200263226 "Gummin, D.. 2020 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 38th Annual Report. Clinical Toxicology. 2021;59 (12):1282-1501" -  
20487842      Sertraline;Alcohol (Alcohol)  
Atenolol;Alcohol;Herbals\Mitragynine;Sertraline Hydrochloride;Gabapentin;Amphetamine Product Used For Unknown Indication Cardio-Respiratory Arrest;Completed Suicide  
Serious Other Outcomes;Died Male - 18-FEB-2022  
Expedited 29 YR Not Specified Glenmark Healthcare  
Professional Not Specified - 04-FEB-2022 18-FEB-2022  
US Not Specified US-GLENMARK  
PHARMACEUTICALS-2022GMK070476 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Bronstein AC, Rivers LJ, Pham NPT, Weber J.. 2020 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 38th Annual Report.. Clinical Toxicology.. 2021;59 (12):1282-1501" -  
20486841      - Herbals\Mitragynine;Oxycodone;Gabapentin  
- Drug Abuse Serious Died Female 2020 17-FEB-2022 Expedited 47 YR Not Specified Pfizer  
Healthcare Professional Not Specified - 10-FEB-2022 17-FEB-2022 US Not Specified US-PFIZER INC-202200268604  
"Gummin, D.. 2020 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 38th Annual Report. Clinical Toxicology. 2021;59 (12):1282-1501" -  
20485465      - Herbals\Mitragynine Attention Deficit Hyperactivity Disorder;Bipolar Disorder;Substance Abuse Hostility;Mania;Impaired Quality Of Life;Neuralgia;Vomiting;Withdrawal Syndrome;Drug Dependence;Psychotic Disorder;Restless Legs Syndrome;Hyperhidrosis Serious Required Intervention;Hospitalized  
Male 26-NOV-2021 17-FEB-2022 Direct 29 YR 57.15  
KG Fda-Ctu Consumer Not Specified Adderall;Abilify  
- 17-FEB-2022 Not Specified Not Specified -  
- -  
20481834      - Herbals\Mitragynine;Fentanyl Citrate;Alprazolam - Drug Abuse Serious Died;Other Outcomes Male 2020 16-FEB-2022 Expedited 35 YR  
Not Specified Pfizer Healthcare Professional Not Specified  
- 10-FEB-2022 16-FEB-2022 US Not Specified  
US-PFIZER INC-202200257350 "Gummin, D.. 2020 Annual

Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 38th Annual Report. Clinical Toxicology. 2021;59 (12):1282-1501" -

20480419 - Sertraline  
Hydrochloride;Atenolol;Gabapentin;Amphetamine;Herbals\Mitragynine - Cardiac Arrest;Respiratory Arrest;Completed Suicide  
Serious Died;Hospitalized Male 2020 16-FEB-2022  
Expedited 29 YR Not Specified Pfizer Healthcare  
Professional Not Specified - 10-FEB-2022 16-FEB-2022  
US Not Specified US-PFIZER

INC-202200269872 "Gummin, D.. 2020 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 38th Annual Report. Clinical Toxicology. 2021;59 (12):1282-1501" -

20480144 Promethazine Promethazine  
Hydrochloride;Pregabalin;Hydrochlorothiazide\Triamterene;Herbals\Mitragynine - Respiratory Arrest;Completed Suicide;Cardiac Arrest  
Serious Other Outcomes;Hospitalized;Died Female 2020  
16-FEB-2022 Expedited 36 YR Not Specified Pfizer  
Healthcare Professional Not Specified - 10-FEB-2022  
16-FEB-2022 US Not Specified US-PFIZER

INC-202200254572 "Gummin, D.. 2020 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 38th Annual Report. Clinical Toxicology. 2021;59 (12):1282-1501" -

20479986 - Fentanyl Citrate;Morphine Sulfate;Herbals\Mitragynine;Etizolam;Methamphetamine Hydrochloride;Gabapentin - Drug Abuse Serious Died  
Female 2020 16-FEB-2022 Expedited 32 YR Not  
Specified Pfizer Healthcare Professional Not Specified -  
10-FEB-2022 16-FEB-2022 US Not Specified US-  
PFIZER INC-202200256075 "Gummin, D.. 2020 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 38th Annual Report. Clinical Toxicology. 2021;59 (12):1282-1501" -

20471969 - Herbals\Mitragynine;Oxycodone Hydrochloride Product Used For Unknown Indication Respiratory Arrest;Toxicity To Various Agents;Cardiac Arrest Serious Died  
Male 2020 14-FEB-2022 Expedited 57 YR Not  
Specified Genus Lifesciences Healthcare Professional Not  
Specified - 31-JAN-2022 14-FEB-2022 US Not  
Specified US-Genus\_Lifesciences-USA-POI0580202200026 Gummin  
D. 2020 Annual Report of the American Association of Poison Control Centers National Poison Data Systems (NPDS) 38th Annual Report. Clinical Toxicology. 2021 DEC 10;59(12):1282-1501. -

20466188 - Gabapentin;Oxycodone;Herbals\Mitragynine Product Used For Unknown Indication Drug Abuse  
Serious Died;Other Outcomes Female - 13-FEB-2022  
Expedited 47 YR Not Specified Glenmark Healthcare  
Professional Not Specified - 04-FEB-2022 13-FEB-2022

US Not Specified US-GLENMARK  
PHARMACEUTICALS-2022GMK070186 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Bronstein AC, Rivers LJ, Pham NPT, Weber J.. 2020 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 38th Annual Report.. Clinical Toxicology.. 2021;59 (12):1282-1501" -  
20466143 -  
Methamphetamine;Gabapentin;Herbals\Mitragynine;Fentanyl;Etizolam;Morphine Product Used For Unknown Indication Drug Abuse  
Serious Died;Other Outcomes Female - 13-FEB-2022  
Expedited 32 YR Not Specified Glenmark Healthcare  
Professional Not Specified - 04-FEB-2022 13-FEB-2022  
US Not Specified US-GLENMARK  
PHARMACEUTICALS-2022GMK070156 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Bronstein AC, Rivers LJ, Pham NPT, Weber J.. 2020 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 38th Annual Report.. Clinical Toxicology.. 2021;59 (12):1282-1501" -  
20466055 Heroin;Concerta Methylphenidate Hydrochloride;Diamorphine;Herbals\Mitragynine Product Used For Unknown Indication Drug Abuse;Toxicity To Various Agents  
Serious Died Male - 12-FEB-2022 Expedited 33 YR  
Not Specified Johnson And Johnson Healthcare  
Professional Not Specified - 31-JAN-2022 12-FEB-2022  
US Not Specified US-JNJFOC-20220218829 - -  
20438777 - Morphine Sulfate;Etizolam;Herbals\Mitragynine;Gabapentin;Fentanyl;Methamphetamine Drug Abuse Exposure To Toxic Agent Serious Died Female  
2020 07-FEB-2022 Expedited 32 YR Not Specified  
Galpharm International Healthcare Professional Not Specified  
- 03-FEB-2022 07-FEB-2022 US Not Specified  
US-PERRIGO-22US001641 - - -  
20261749 Rocuronium Rocuronium Bromide;Etomidate;Herbals\Mitragynine Agitation;Apnoea;Haemodynamic Instability;Hypotension;Hypotonia;Induction Of Anaesthesia;Product Used For Unknown Indication;Prophylaxis;Respiratory Rate Decreased;Toxicity To Various Agents Screaming;Toxicity To Various Agents;Distributive Shock;Hyperkalaemia;Clonus;Pain;Cardio-Respiratory Arrest;Deafness Neurosensory;Aggression;Metabolic Acidosis;Agitation;Cardiogenic Shock;Apnoea;Overdose;Grimacing;Muscle Rrigidity;Muscle Contractions Involuntary;Respiratory Failure  
Serious Other Outcomes;Life Threatening;Hospitalized Male -  
04-FEB-2022 Expedited 35 YR Not Specified Teva  
Healthcare Professional Not Specified  
Naloxone;Epinephrine;Sodium Chloride;Ketamine;Norepinephrine 26-  
JAN-2022 31-DEC-2021 US Not Specified US-TEVA-2021-US-1993083 "Hall A, Hall D. Kratom Ingestion and Emergency Care: Summary and a Case Report. J-Emerg-Nurs 2021;47(4):551-556.e1." -  
20429536 - Herbals\Mitragynine Energy Increased;Euphoric Mood Pyrexia;Illness;Product Physical Consistency

Issue;Suspected Product Contamination;Product Odour Abnormal;Vomiting  
 Serious Other Outcomes Female 02-FEB-2022 03-FEB-2022  
 Direct 44 YR 83.25 KG Fda-Ctu Consumer Not  
 Specified - - 03-FEB-2022 Not Specified Not  
 Specified - - Yes  
 20420716 Rexulti Brexpiprazole;Herbals\Mitragynine  
 Emotional Disorder Headache;Nausea;Peripheral Coldness;Heart Rate  
 Increased;Syncope;Drug Interaction Serious Other Outcomes Not  
 Specified 01-FEB-2022 02-FEB-2022 Direct 21 YR 45 KG  
 Fda-Ctu Consumer Not Specified - - 02-  
 FEB-2022 Not Specified Not Specified - - -  
 20364710 "Alcohol (Alcohol);Sertraline;Dextroamphetamine  
 Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate And  
 Amphetamine Sulfate" Amphetamine Aspartate\Amphetamine  
 Sulfate\Dextroamphetamine Saccharate\Dextroamphetamine  
 Sulfate;Gabapentin;Atenolol;Herbals\Mitragynine;Sertraline  
 Hydrochloride;Alcohol Product Used For Unknown Indication  
 Completed Suicide Serious Died Male 2020 22-JAN-2022  
 Expedited 29 YR Not Specified Specgx Healthcare  
 Professional Not Specified - 13-DEC-2021 22-JAN-2022  
 US Not Specified US-SPECGX-T202103801 "Gummin DD,  
 Mowry JB, Beuhler MC, Spyker DA, Bronstein AC, Rivers LJ et al. 2020  
 Annual Report of the American Association of Poison Control Centers'  
 National Poison Data System (NPDS): 38th Annual Report. Clinical  
 Toxicology. 2021;59(12):1282-501" -  
 20360846 Heroin Diamorphine;Methylphenidate  
 Hydrochloride;Herbals\Mitragynine Product Used For Unknown  
 Indication Drug Abuse Serious Died Male 2020 21-  
 JAN-2022 Expedited 33 YR Not Specified Specgx  
 Healthcare Professional Not Specified - 13-DEC-2021 21-  
 JAN-2022 US Not Specified US-SPECGX-  
 T202103469 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Bronstein  
 AC, Rivers LJ et al. 2020 Annual Report of the American Association of  
 Poison Control Centers' National Poison Data System (NPDS): 38th  
 Annual Report. Clinical Toxicology. 2021;59(12):1282-501" -  
 17256722 Sertraline;Heroin Diamorphine;Codeine;Sertraline  
 Hydrochloride;Bupropion;Herbals\Mitragynine;Chlorpheniramine;Dextromet  
 horphan;Cocaine Product Used For Unknown Indication Cardio-  
 Respiratory Arrest;Suspected Suicide;Overdose Serious Other  
 Outcomes;Hospitalized;Died Male 2018 21-JAN-2022  
 Expedited 32 YR Not Specified Glaxosmithkline Healthcare  
 Professional Not Specified - 21-JAN-2022 10-JAN-2020  
 US Not Specified US-GLAXOSMITHKLINE-US2020GSK001760  
 "Gummin DD, Mowry JB, Spyker DA, Brooks DE, Beuhler MC, Rivers  
 LJ, Hashem HA, Ryan ML. 2018 Annual Report of the American Association  
 of Poison Control Centers' National Poison Data System (NPDS): 36th  
 Annual Report. Clinical Toxicology. 2019;57 (12):1220-1413" -  
 20354842 Methadone Methadone  
 Hydrochloride;Herbals\Mitragynine;Tramadol Product Used For  
 Unknown Indication Completed Suicide Serious Died Male

2020 20-JAN-2022 Expedited 55 YR Not Specified  
 Specgx Healthcare Professional Not Specified - 13-  
 DEC-2021 20-JAN-2022 US Not Specified US-SPECGX-  
 T202102822 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Bronstein  
 AC, Rivers LJ et al. 2020 Annual Report of the American Association of  
 Poison Control Centers' National Poison Data System (NPDS): 38th  
 Annual Report. Clinical Toxicology. 2021;59(12):1282-501" -  
 14254346 Alcohol (Alcohol) Alcohol;Diphenhydramine  
 Hydrochloride;Bupropion;Herbals\Mitragynine;U-47700;Dextromethorphan  
 Product Used For Unknown Indication Death;Cardio-  
 Respiratory Arrest;Drug Abuse Serious Died;Other Outcomes Male  
 2016 20-JAN-2022 Expedited 27 YR Not Specified  
 Glaxosmithkline Healthcare Professional Not Specified -  
 20-JAN-2022 05-DEC-2017 US Not Specified US-  
 GLAXOSMITHKLINE-US2017GSK183857 "Gummin DD, Mowry JB, Spyker DA,  
 Brooks DE, Fraser MO, Banner W. 2016 Annual Report of the American  
 Association of Poison Control Centers' National Poison Data System  
 (NPDS): 34th Annual Report. Clinical Toxicology.  
 2017;55(10):1072-1252" -  
 20355961 - Herbals\Mitragynine Occupational Exposure  
 To Product Manufacturing Materials  
 Contamination;Nervousness;Muscular Weakness;Insomnia;Manufacturing  
 Process Control Procedure Issue;Withdrawal Syndrome;Occupational  
 Exposure To Product;Disturbance In Attention Serious Disabled  
 Male 13-JAN-2022 19-JAN-2022 Direct 57 YR 92.25  
 KG Fda-Ctu Consumer Not Specified - - 19-  
 JAN-2022 Not Specified Not Specified - - Yes  
 20340958 Sertraline;Alcohol (Alcohol)  
 Alcohol;Herbals\Mitragynine;Sertraline  
 Hydrochloride;Gabapentin;Atenolol;Amphetamine Product Used For  
 Unknown Indication Completed Suicide;Cardio-Respiratory Arrest  
 Serious Other Outcomes;Died;Hospitalized Male 2020  
 17-JAN-2022 Expedited 29 YR Not Specified Apotex  
 Healthcare Professional Not Specified - 03-JAN-2022  
 17-JAN-2022 US Not Specified US-APOTEX-2022AP001855  
 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Bronstein AC,  
 Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the American  
 Association of Poison Control Centers' National Poison Data System  
 (NPDS): 38th Annual Report. Clinical Toxicology. 2021;59 (12):1282-  
 1501" -  
 20340631 Promethazine Promethazine  
 Hydrochloride;Herbals\Mitragynine;Hydrochlorothiazide\Triamterene;Preg  
 abalin Product Used For Unknown Indication Completed  
 Suicide;Cardio-Respiratory Arrest Serious Hospitalized;Other  
 Outcomes;Died Female 2020 17-JAN-2022 Expedited 36 YR  
 Not Specified Apotex Healthcare Professional Not Specified  
 - 03-JAN-2022 17-JAN-2022 US Not Specified  
 US-APOTEX-2022AP001864 "Gummin DD, Mowry JB, Beuhler MC,  
 Spyker DA, Bronstein AC, Rivers LJ, Pham NPT, Weber J. 2020 Annual  
 Report of the American Association of Poison Control Centers' National

Poison Data System (NPDS): 38th Annual Report. Clinical Toxicology. 2021;59 (12):1282-1501" -

20334866 - Fentanyl;Alprazolam;Herbals\Mitragynine Product Used For Unknown Indication Drug Abuse Serious Other Outcomes;Died Male - 14-JAN-2022 Expedited 35 YR Not Specified Apotex Healthcare Professional Not Specified - 03-JAN-2022 14-JAN-2022 US Not Specified US-APOTEX-2022AP000670 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Bronstein AC, Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 38th Annual Report. Clinical Toxicology. 2021;59 (12):1282-1501" -

20328827 - Herbals\Mitragynine Anxiety Toxicity To Various Agents Serious Died Male 10-NOV-2021 12-JAN-2022 Direct 22 YR 62.1 KG Fda-Ctu Consumer Not Specified - - 12-JAN-2022 Not Specified Not Specified - - -

20327484 Methadone Methadone Hydrochloride;Herbals\Mitragynine;Tramadol Product Used For Unknown Indication Completed Suicide Serious Died;Hospitalized;Other Outcomes Male 2020 12-JAN-2022 Expedited 55 YR Not Specified Apotex Healthcare Professional Not Specified - 03-JAN-2022 12-JAN-2022 US Not Specified US-APOTEX-2022AP001141 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Bronstein AC, Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 38th Annual Report. Clinical Toxicology. 2021;59 (12):1282-1501" -

20327433 - Fentanyl;Herbals\Mitragynine;Trazodone Hydrochloride Product Used For Unknown Indication Drug Abuse Serious Died;Other Outcomes Male - 12-JAN-2022 Expedited 28 YR Not Specified Apotex Healthcare Professional Not Specified - 03-JAN-2022 12-JAN-2022 US Not Specified US-APOTEX-2022AP000403 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Bronstein AC, Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 38th Annual Report. Clinical Toxicology. 2021;59 (12):1282-1501" -

20325320 Alcohol (Alcohol);Oxycodone And Acetaminophen Acetaminophen\Oxycodone Hydrochloride;Herbals\Mitragynine;Alcohol;Fentanyl Product Used For Unknown Indication Drug Abuse;Cardio-Respiratory Arrest Serious Hospitalized;Died;Other Outcomes Male 2020 12-JAN-2022 Expedited 16 YR Not Specified Apotex Healthcare Professional Not Specified - 03-JAN-2022 12-JAN-2022 US Not Specified US-APOTEX-2022AP00068 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA, Bronstein AC, Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 38th Annual Report. Clinical Toxicology. 2021;59

(12):1282-1501" -  
20321650 - Fentanyl;Herbals\Mitragynine Product Used  
For Unknown Indication Drug Abuse Serious Other Outcomes;Died  
Male - 11-JAN-2022 Non-Expedited 31 YR Not  
Specified Apotex Healthcare Professional Not Specified -  
03-JAN-2022 11-JAN-2022 US Not Specified US-  
APOTEX-2022AP000530 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA,  
Bronstein AC, Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the  
American Association of Poison Control Centers' National Poison Data  
System (NPDS): 38th Annual Report. Clinical Toxicology. 2021;59  
(12):1282-1501" -  
20320856 - Fentanyl;Herbals\Mitragynine;Oxycodone  
Product Used For Unknown Indication Drug Abuse Serious  
Died;Other Outcomes Male - 11-JAN-2022 Non-Expedited  
46 YR Not Specified Apotex Healthcare Professional Not  
Specified - 03-JAN-2022 11-JAN-2022 US Not  
Specified US-APOTEX-2022AP000939 "Gummin DD, Mowry JB, Beuhler  
MC, Spyker DA, Bronstein AC, Rivers LJ, Pham NPT, Weber J. 2020 Annual  
Report of the American Association of Poison Control Centers' National  
Poison Data System (NPDS): 38th Annual Report. Clinical Toxicology.  
2021;59 (12):1282-1501" -  
20320466 - Gabapentin;Oxycodone;Herbals\Mitragynine  
Product Used For Unknown Indication Drug Abuse  
Serious Died;Other Outcomes Female - 11-JAN-2022  
Expedited 47 YR Not Specified Apotex Healthcare  
Professional Not Specified - 03-JAN-2022 11-JAN-2022  
US Not Specified US-APOTEX-2022AP000956 "Gummin DD,  
Mowry JB, Beuhler MC, Spyker DA, Bronstein AC, Rivers LJ, Pham NPT,  
Weber J. 2020 Annual Report of the American Association of Poison  
Control Centers' National Poison Data System (NPDS): 38th Annual  
Report. Clinical Toxicology. 2021;59 (12):1282-1501" -  
20320402 -  
Methamphetamine;Etizolam;Morphine;Gabapentin;Herbals\Mitragynine;Fenta  
nyl Product Used For Unknown Indication Drug Abuse  
Serious Died;Other Outcomes Female - 11-JAN-2022  
Expedited 32 YR Not Specified Apotex Healthcare  
Professional Not Specified - 03-JAN-2022 11-JAN-2022  
US Not Specified US-APOTEX-2022AP000577 "Gummin DD,  
Mowry JB, Beuhler MC, Spyker DA, Bronstein AC, Rivers LJ, Pham NPT,  
Weber J. 2020 Annual Report of the American Association of Poison  
Control Centers' National Poison Data System (NPDS): 38th Annual  
Report. Clinical Toxicology. 2021;59 (12):1282-1501" -  
20320849 - Herbals\Mitragynine Anxiety Blood Caffeine  
Increased;Hepatic Steatosis;Overdose;Obesity;Cardiovascular  
Disorder;Drug Screen Positive;Substance Use;Arteriosclerosis;Dilated  
Cardiomyopathy Serious Died Male 01-JUN-2021 10-JAN-2022  
Direct 38 YR Not Specified Fda-Ctu Healthcare  
Professional Not Specified Doxepin - 10-JAN-2022 Not  
Specified Not Specified - - -  
20318548 - Fentanyl;Herbals\Mitragynine Product Used

For Unknown Indication Drug Abuse Serious Other Outcomes;Died  
Male - 10-JAN-2022 Non-Expedited 50 YR Not  
Specified Apotex Healthcare Professional Not Specified -  
03-JAN-2022 10-JAN-2022 US Not Specified US-  
APOTEX-2022AP001058 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA,  
Bronstein AC, Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the  
American Association of Poison Control Centers' National Poison Data  
System (NPDS): 38th Annual Report. Clinical Toxicology. 2021;59  
(12):1282-1501" -

20318403 - Diazepam;Herbals\Mitragynine;Fentanyl  
Product Used For Unknown Indication Drug Abuse Serious  
Died;Other Outcomes Male - 10-JAN-2022 Non-Expedited  
31 YR Not Specified Apotex Healthcare Professional Not  
Specified - 03-JAN-2022 10-JAN-2022 US Not  
Specified US-APOTEX-2022AP000521 "Gummin DD, Mowry JB, Beuhler  
MC, Spyker DA, Bronstein AC, Rivers LJ, Pham NPT, Weber J. 2020 Annual  
Report of the American Association of Poison Control Centers' National  
Poison Data System (NPDS): 38th Annual Report. Clinical Toxicology.  
2021;59 (12):1282-1501" -

20317763 - Herbals\Mitragynine;Fentanyl Product Used  
For Unknown Indication Drug Abuse Serious Died;Other Outcomes  
Male - 10-JAN-2022 Non-Expedited 59 YR Not  
Specified Apotex Healthcare Professional Not Specified -  
03-JAN-2022 10-JAN-2022 US Not Specified US-  
APOTEX-2022AP001214 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA,  
Bronstein AC, Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the  
American Association of Poison Control Centers' National Poison Data  
System (NPDS): 38th Annual Report. Clinical Toxicology. 2021;59  
(12):1282-1501" -

20315563 - Herbals\Mitragynine;Fentanyl Product Used  
For Unknown Indication Drug Abuse Serious Died;Other Outcomes  
Male - 10-JAN-2022 Non-Expedited 22 YR Not  
Specified Apotex Healthcare Professional Not Specified -  
03-JAN-2022 10-JAN-2022 US Not Specified US-  
APOTEX-2022AP000206 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA,  
Bronstein AC, Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the  
American Association of Poison Control Centers' National Poison Data  
System (NPDS): 38th Annual Report. Clinical Toxicology. 2021;59  
(12):1282-1501" -

20315459 - Herbals\Mitragynine;Fentanyl Product Used  
For Unknown Indication Drug Abuse Serious Other Outcomes;Died  
Male - 10-JAN-2022 Non-Expedited 34 YR Not  
Specified Apotex Healthcare Professional Not Specified -  
03-JAN-2022 10-JAN-2022 US Not Specified US-  
APOTEX-2022AP000644 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA,  
Bronstein AC, Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the  
American Association of Poison Control Centers' National Poison Data  
System (NPDS): 38th Annual Report. Clinical Toxicology. 2021;59  
(12):1282-1501" -

20309243 Alcohol (Alcohol)

Alcohol;Herbals\Mitragynine;Fentanyl Product Used For Unknown  
Indication Drug Abuse Serious Died;Other Outcomes Female  
- 07-JAN-2022 Non-Expedited 36 YR Not Specified  
Apotex Healthcare Professional Not Specified - 03-  
JAN-2022 07-JAN-2022 US Not Specified US-  
APOTEX-2022AP000706 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA,  
Bronstein AC, Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the  
American Association of Poison Control Centers' National Poison Data  
System (NPDS): 38th Annual Report. Clinical Toxicology. 2021;59  
(12):1282-1501" -  
20309076 -

Oxymorphone;Fentanyl;Herbals\Mitragynine;Oxycodone Product Used  
For Unknown Indication Drug Abuse Serious Died;Other Outcomes  
Male - 07-JAN-2022 Non-Expedited 29 YR Not  
Specified Apotex Healthcare Professional Not Specified -  
03-JAN-2022 07-JAN-2022 US Not Specified US-  
APOTEX-2022AP000434 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA,  
Bronstein AC, Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the  
American Association of Poison Control Centers' National Poison Data  
System (NPDS): 38th Annual Report. Clinical Toxicology. 2021;59  
(12):1282-1501" -  
20308589 -

Fentanyl;Etizolam;Methocarbamol;Herbals\Mitragynine Product Used  
For Unknown Indication Drug Abuse Serious Other Outcomes;Died  
Male - 07-JAN-2022 Non-Expedited 35 YR Not  
Specified Apotex Healthcare Professional Not Specified -  
03-JAN-2022 07-JAN-2022 US Not Specified US-  
APOTEX-2022AP000674 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA,  
Bronstein AC, Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the  
American Association of Poison Control Centers' National Poison Data  
System (NPDS): 38th Annual Report. Clinical Toxicology. 2021;59  
(12):1282-1501" -  
20306968 - Herbals\Mitragynine;Fentanyl Product Used  
For Unknown Indication Drug Abuse Serious Other Outcomes;Died  
Male - 07-JAN-2022 Non-Expedited 26 YR Not  
Specified Apotex Healthcare Professional Not Specified -  
03-JAN-2022 07-JAN-2022 US Not Specified US-  
APOTEX-2022AP000325 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA,  
Bronstein AC, Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the  
American Association of Poison Control Centers' National Poison Data  
System (NPDS): 38th Annual Report. Clinical Toxicology. 2021;59  
(12):1282-1501" -  
20305852 - Herbals\Mitragynine Stress Suicidal  
Ideation;Apathy;Dependence Serious Life Threatening;Required  
Intervention Male 05-JAN-2022 06-JAN-2022 Direct 33 YR  
85.5 KG Fda-Ctu Consumer Not Specified - -  
06-JAN-2022 Not Specified Not Specified - -  
-

20305631 - Herbals\Mitragynine;Clobazam;Fentanyl  
Product Used For Unknown Indication Drug Abuse Serious Other

Outcomes;Died Female - 06-JAN-2022 Non-Expedited 29 YR  
 Not Specified Apotex Healthcare Professional Not Specified  
 - 03-JAN-2022 06-JAN-2022 US Not Specified  
 US-APOTEX-2022AP000439 "Gummin DD, Mowry JB, Beuhler MC,  
 Spyker DA, Bronstein AC, Rivers LJ, Pham NPT, Weber J. 2020 Annual  
 Report of the American Association of Poison Control Centers' National  
 Poison Data System (NPDS): 38th Annual Report. Clinical Toxicology.  
 2021;59 (12):1282-1501" -

20303503 - Fentanyl;Methamphetamine  
 Hydrochloride;Herbals\Mitragynine Product Used For Unknown  
 Indication Drug Abuse Serious Other Outcomes;Died Male  
 - 06-JAN-2022 Non-Expedited 24 YR Not Specified  
 Apotex Healthcare Professional Not Specified - 03-  
 JAN-2022 06-JAN-2022 US Not Specified US-  
 APOTEX-2022AP000271 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA,  
 Bronstein AC, Rivers LJ, Pham NPT, Weber J. 2020 Annual Report of the  
 American Association of Poison Control Centers' National Poison Data  
 System (NPDS): 38th Annual Report. Clinical Toxicology. 2021;59  
 (12):1282-1501" -

20249147 - Herbals\Mitragynine;Fentanyl;Diazepam  
 Product Used For Unknown Indication Drug Abuse Serious Died  
 Male - 29-DEC-2021 Expedited 31 YR Not  
 Specified Bausch And Lomb Healthcare Professional Not Specified  
 - 23-DEC-2021 29-DEC-2021 US Not Specified  
 US-BAUSCH-BL-2021-042390 "Gummin D, Mowry J, Beuhler M,  
 Spyker D, Bronstein A, Rivers L, Pham N, Weber J. 2020 Annual Report  
 of the American Association of Poison Control Centers' National Poison  
 Data System (NPDS): 38th Annual Report. Clinical Toxicology. 2021 DEC  
 10;59 (12):1282-1501. doi:10.1080/15563650.2021.1989785" -

20235966 Heroin  
 Diamorphine;Herbals\Mitragynine;Codeine;Methamphetamine;Morphine  
 Sulfate;6-Acetylmorphine Product Used For Unknown Indication  
 Toxicity To Various Agents Serious Died Male -  
 28-DEC-2021 Expedited 24 YR Not Specified Alkem  
 Healthcare Professional Not Specified - 13-DEC-2021  
 28-DEC-2021 TH Not Specified TH-ALKEM LABORATORIES  
 LIMITED-TH-ALKEM-2021-07658 "Jittasopa W, Srisont S.. The Causes  
 of Death and Pathological Findings of Kratom Users: A 5-Year  
 Retrospective Analysis. Am J Forensic Med Pathol. 2021;42:335-34" -

20232101 - Herbals\Mitragynine -  
 Irritability;Insomnia;Seizure Serious Life Threatening;Required  
 Intervention;Other Outcomes Male 11-DEC-2021 24-DEC-2021  
 Direct 40 YR 81 KG Fda-Ctu Consumer Not Specified  
 Tylenol Pm - 24-DEC-2021 Not Specified Not  
 Specified - - -

20221796 - Herbals\Mitragynine  
 Anxiety;Depression;Pain;Stress Seizure;Head Injury Serious Other  
 Outcomes Female 02-JUL-2021 22-DEC-2021 Direct 30 YR  
 90 KG Fda-Ctu Consumer Not Specified - -

22-DEC-2021 Not Specified Not Specified - - -  
 -  
 20208437 - Herbals\Mitragynine Product Used For  
 Unknown Indication Toxicity To Various Agents;Loss Of  
 Consciousness;Intentional Product Use Issue;Alcohol  
 Poisoning;Accidental Overdose Serious Died Male 21-JUL-2021  
 16-DEC-2021 Direct 31 YR Not Specified Fda-Ctu  
 Healthcare Professional Not Specified Vitamin  
 D3;Vraylar;Modafinil;Lunesta - 16-DEC-2021 Not Specified  
 Not Specified - - -  
 20193494 - Herbals\Mitragynine Anxiety;Back  
 Pain;Post-Traumatic Stress Disorder Substance  
 Use;Aggression;Serotonin Syndrome;Feeling Abnormal;Physical  
 Assault;Legal Problem;Anger;Screaming;Agitation;Glassy  
 Eyes;Flushing;Influenza Like Illness Serious Other Outcomes Male  
 27-SEP-2021 15-DEC-2021 Direct 57 YR 72 KG Fda-  
 Ctu Consumer Not Specified - - 15-DEC-2021  
 Not Specified Not Specified - - -  
 20174607 - Herbals\Mitragynine - Toxicity To  
 Various Agents Serious Died Male 09-JAN-2018 10-DEC-2021  
 Direct 27 YR Not Specified Fda-Ctu Healthcare  
 Professional Not Specified - - 10-DEC-2021 Not  
 Specified Not Specified - - -  
 20169082 - Herbals\Mitragynine - Substance  
 Use;Toxicologic Test Abnormal;Psychotic Disorder;Gun Shot  
 Wound;Completed Suicide Serious Died Male 02-OCT-2020 09-  
 DEC-2021 Direct 32 YR Not Specified Fda-Ctu Healthcare  
 Professional Not Specified Lexapro;Ibuprofen - 09-  
 DEC-2021 Not Specified Not Specified - - -  
 20169079 - Herbals\Mitragynine - Toxicity To  
 Various Agents;Substance Use Serious Died Male - 09-  
 DEC-2021 Direct 42 YR Not Specified Fda-Ctu Healthcare  
 Professional Not Specified Clonazepam - 09-DEC-2021  
 Not Specified Not Specified - - -  
 20164217 "Dextroamphetamine Saccharate, Amphetamine Aspartate,  
 Dextroamphetamine Sulfate And Amphetamine Sulfate"  
 Benzoyllecgonine;Amphetamine Aspartate\Amphetamine  
 Sulfate\Dextroamphetamine Saccharate\Dextroamphetamine  
 Sulfate;Midazolam;Ketamine;Herbals\Mitragynine;Acetaminophen;Cocaine  
 Product Used For Unknown Indication Toxicity To Various  
 Agents;Hydrocephalus;Unresponsive To Stimuli Serious Died;Other  
 Outcomes Male - 09-DEC-2021 Expedited 30 YR  
 Not Specified Specgx Healthcare Professional Not Specified  
 - 29-NOV-2021 09-DEC-2021 US Not Specified  
 US-SPECGX-T202102673 "Krotulski AJ, Papsun DM, Chronister  
 CW, Homan J, Crosby MM, Hoyer J et al. Eutylone intoxications-An  
 emerging synthetic stimulant in forensic investigations. Journal of  
 Analytical Toxicology. 2021;45:8-20" -  
 20170679 - Herbals\Mitragynine - Accidental  
 Death;Toxicity To Various Agents Serious Died Male -

08-DEC-2021 Direct 30 YR Not Specified Fda-Ctu Not  
 Specified Not Specified - - 08-DEC-2021 Not  
 Specified Not Specified - - -  
 20161037 - Herbals\Mitragynine - Toxicity To  
 Various Agents;Illness;Accidental Death Serious Died Male 27-  
 MAY-2020 08-DEC-2021 Direct 26 YR Not Specified Fda-  
 Ctu Healthcare Professional Not Specified  
 Gabapentin;Flualprazolam;Fluoxetine - 08-DEC-2021 Not  
 Specified Not Specified - - -  
 20152947 - Herbals\Mitragynine Affective  
 Disorder;Pain Skin  
 Discolouration;Nausea;Tremor;Blepharospasm;Vomiting;Seizure  
 Serious Other Outcomes Not Specified 12-JUN-2019 06-DEC-2021  
 Direct 41 YR 107.1 KG Fda-Ctu Consumer Not  
 Specified - - 06-DEC-2021 Not Specified Not  
 Specified - - -  
 20108152 - Herbals\Mitragynine - Unresponsive  
 To Stimuli;Autopsy;Pulmonary Congestion;Pulmonary Oedema;Herbal  
 Toxicity Serious Died Male 26-SEP-2020 23-NOV-2021  
 Direct 34 YR Not Specified Fda-Ctu Healthcare  
 Professional Not Specified - - 23-NOV-2021 Not  
 Specified Not Specified - - -  
 20107136 - Herbals\Mitragynine - Death  
 Serious Died Male - 23-NOV-2021 Direct 28 YR Not  
 Specified Fda-Ctu Consumer Not Specified - -  
 23-NOV-2021 Not Specified Not Specified - - -  
 -  
 20101858 - Garlic;Herbals\Mitragynine;Unspecified  
 Ingredient Product Used For Unknown Indication  
 Hallucination;Eye Disorder;Illness;Taste Disorder Serious  
 Hospitalized Male 22-NOV-2021 22-NOV-2021 Direct 35 YR  
 81 KG Fda-Ctu Consumer Not Specified  
 Seroquel;Vistaril;Wellbutrin;Flexeril;Zoloft;Buspar;Naltrexone -  
 22-NOV-2021 Not Specified Not Specified - - -  
 Yes  
 20090573 - Herbals\Mitragynine Depression;Pain;Post-  
 Traumatic Stress Disorder Completed Suicide;Hallucination;Drug  
 Dependence Serious Disabled;Died Male 21-OCT-2021 18-  
 NOV-2021 Direct 35 YR 108 KG Fda-Ctu Consumer Not  
 Specified - - 18-NOV-2021 Not Specified Not  
 Specified - - -  
 20085440 - Herbals\Mitragynine Anxiety;Pain  
 Suicidal Ideation;Seizure;Drug Dependence;Depression;Decreased  
 Appetite Serious Disabled;Required Intervention;Other  
 Outcomes;Hospitalized;Life Threatening Male 19-OCT-2021 17-  
 NOV-2021 Direct 35 YR 67.5 KG Fda-Ctu Consumer Not  
 Specified Vimpat;Paxil - 17-NOV-2021 Not Specified  
 Not Specified - - -  
 20057238 - Herbals\Mitragynine Affective  
 Disorder;Asthenia;Pain Decreased Appetite;Liver Function Test

Abnormal;Tachycardia;Hypertension;Nausea			Serious	Hospitalized
Female	05-NOV-2021	10-NOV-2021	Direct	43 YR 112.1
KG	Fda-Ctu Healthcare Professional	Not Specified	-	-
10-NOV-2021	Not Specified	Not Specified	-	-
-				
20054812	-	Herbals\Mitragynine	Depression;Pain	
Gastrointestinal Disorder;Panic Attack;Hot Flush;Withdrawal				
Syndrome;Anger;Insomnia;Rash;Restlessness;Depression;Anxiety;Malaise;D				
ependence;Nausea;Constipation;Vomiting				
Projectile;Acne;Hyperhidrosis;Irritability			Serious	Disabled
Female	26-DEC-2020	10-NOV-2021	Direct	22 YR 55.35
KG	Fda-Ctu Consumer	Not Specified	Vitamin	
B12;Trazodone;Probiotics Nos;Ambien;Fiber Nos;Wellbutrin;Ativan	-			
10-NOV-2021	Not Specified	Not Specified	-	-
-				
20016482	-	Herbals\Mitragynine	-	Hand
Fracture;Seizure;Herbal Toxicity			Serious	Died Male 21-
JUN-2020	03-NOV-2021	Direct	26 YR	Not Specified Fda-
Ctu Healthcare Professional	Not Specified		Vicodin	- 03-
NOV-2021	Not Specified	Not Specified	-	-
20015427	-	Herbals\Mitragynine	Insomnia	
Myoclonus;Monoplegia		Serious Other Outcomes	Male	25-OCT-2021
30-OCT-2021	Direct	56 YR 67.95 KG		Fda-Ctu
Healthcare Professional	Not Specified	Olmesartan;Quetiapine	-	
30-OCT-2021	Not Specified	Not Specified	-	-
-				
19990708	-	Herbals\Mitragynine	Product Used For	
Unknown Indication		Dependence;Product Formulation	Issue;Substance	
Use;Euphoric Mood		Serious Other Outcomes	Female	22-OCT-2021
24-OCT-2021	Direct	48 YR 89.55 KG		Fda-Ctu
Consumer	Consumer	Vitamin D;Vitamin B	-	24-
OCT-2021	US	Not Specified	-	-
19984837	-	Alprazolam;Herbals\Mitragynine	-	
Incoherent;Hallucination;Mental Status Changes;Aggression				
Serious Hospitalized;Life Threatening		Male	-	22-OCT-2021
Expedited	31 YR	Not Specified	Pfizer	Healthcare
Professional	Not Specified	-	11-OCT-2021	22-OCT-2021
US	Not Specified	US-PFIZER		
INC-202101352630	"Natarajan, V.. A DRUG ADDICT'S KRYPTONITE.			
Chest. 2021;160(4 Suppl):685A"	-			
19974115	-	Herbals\Mitragynine	-	Restless Legs
Syndrome;Alcoholism;Brain Fog;Aggression;Liver				
Injury;Nausea;Anxiety;Dependence;Insomnia;Yellow Skin			Serious Other	
Outcomes	Male	20-OCT-2021	20-OCT-2021	Direct 39 YR
103.5 KG	Fda-Ctu Consumer	Consumer	-	
-	20-OCT-2021	US	Not Specified	-
-				
19962945	-	Herbals\Mitragynine;Acetaminophen		
Product Used For Unknown Indication		Liver Injury;Drug Interaction		
Serious Other Outcomes;Hospitalized		Male	-	18-

OCT-2021            Expedited        44 YR     80 KG     Apotex     Healthcare  
 Professional     Not Specified  
 Desvenlafaxine;Indapamide;Perindopril;Vitamins     12-OCT-2021     18-  
 OCT-2021            CA              Not Specified     CA-APOTEX-2021AP044305     -  
 -  
 19962621            -              Herbals\Mitragynine     Pain     Substance Use  
 Serious Died     Male     02-OCT-2021     13-OCT-2021     Direct  
 64 YR     104.33 KG     Fda-Ctu     Healthcare Professional Health  
 Professional  
 Losartan;Atorvastatin;Omeprazole;Crestor;Lyrica;Duloxetine;Bupropion  
 Hydrochloride     -     13-OCT-2021     US     Not Specified     -  
 -  
 19958720            -              Herbals\Mitragynine     -     Death  
 Serious Died     Not Specified     -     12-OCT-2021     Direct     Not  
 Specified     Not Specified     Fda-Ctu     Consumer     Not Specified  
 -     -     12-OCT-2021     US     Not Specified     -  
 -  
 19928265            -              Herbals\Mitragynine     Neuralgia     Drug  
 Screen Positive     Serious Other Outcomes     Female     22-SEP-2021     06-  
 OCT-2021            Direct     60 YR     69.75 KG     Fda-Ctu     Consumer  
 Consumer     -     -     06-OCT-2021     US     Y  
 -     -     -  
 19912316            -              Herbals\Mitragynine     Anxiety     Abdominal Pain  
 Upper;Salmonellosis;Migraine;Nausea;Pyrexia;Vomiting     Serious Other  
 Outcomes     Female     02-SEP-2021     03-OCT-2021     Direct     50 YR  
 72 KG     Fda-Ctu     Consumer     Consumer     Paxil;Vitamin  
 B12;Magnesium     -     03-OCT-2021     US     Not Specified     -  
 -     Yes  
 19871032            -  
 Gabapentin;Herbals\Mitragynine;Morphine;Codeine Product Used For  
 Unknown Indication     Pulmonary Congestion;Accidental  
 Poisoning;Unresponsive To Stimuli;Foaming At Mouth     Serious  
 Died;Other Outcomes     Male     -     23-SEP-2021     Expedited  
 25 YR     Not Specified     Aurobindo     Healthcare  
 Professional     Not Specified  
 Cyclobenzaprine;Zolpidem;Sertraline;Clonidine;Mirtazapine;Trazodone  
 13-SEP-2021     23-SEP-2021     US     Not Specified     US-  
 AUROBINDO-AUR-APL-2021-039327 "Bishop-Freeman SC, Fox L, Winecker  
 RE, Hudson JS.. Death from poppy tea consumption.. Journal of  
 Analytical Toxicology. 2020;44(7):734-740"     -  
 19872781            -              Herbals\Mitragynine     -  
 Chromaturia;Hyperhidrosis;Abdominal Pain Upper;Overdose;Hepatic  
 Failure     Serious Other Outcomes;Hospitalized     Male     -     22-  
 SEP-2021            Direct     Not Specified     Not Specified     Fda-Ctu  
 Healthcare Professional Health Professional     -     -     22-  
 SEP-2021            US     Not Specified     -     -     -  
 19854041            Hydrocodone Bitartrate And Acetaminophen;Escitalopram  
 Escitalopram  
 Oxalate;Herbals\Mitragynine;Alprazolam;Hydrocodone;Acetaminophen\Hydro  
 codone Bitartrate;Oxycodone;Tramadol     Anxiety;Back

Pain;Depression;Intervertebral Disc Degeneration;Product Used For Unknown Indication Drug Ineffective;Intentional Product Misuse;Intentional Overdose;Drug Use Disorder;Drug Tolerance Serious Other Outcomes Male - 20-SEP-2021 Expedited  
 47 YR Not Specified Aurobindo Healthcare Professional Not Specified Hydroxyzine;Buprenorphine\Naloxone;Duloxetine 06-SEP-2021 20-SEP-2021 US Not Specified US-AUROBINDO-AUR-APL-2021-038857 "Bowe A, Kerr PL.. A Complex Case of Kratom Dependence, Depression, and Chronic Pain in Opioid Use Disorder: Effects of Buprenorphine in Clinical Management. JOURNAL OF PSYCHOACTIVE DRUGS. 2020;52(5):447-452" -

19855250	-	Herbals\Mitragynine	-	Drug
Dependence	Non-Serious	Non-Serious	Female	- 19-
SEP-2021	Direct	Not Specified	Not Specified	Fda-Ctu
Consumer	Consumer	-	-	19-SEP-2021 US
	Not Specified	-	-	-

19831043 Zolpidem;Trazodone Trazodone Hydrochloride;Herbals\Mitragynine;Zolpidem Tartrate;Gabapentin;Codeine;Thebaine;Morphine Product Used For Unknown Indication Toxicity To Various Agents;Accidental Overdose;Accidental Poisoning Serious Other Outcomes;Died Male - 15-SEP-2021 Expedited 25 YR Not Specified Apotex Healthcare Professional Not Specified Clonidine;Mirtazapine;Sertraline;Cyclobenzaprine 03-SEP-2021 15-SEP-2021 US Not Specified US-APOTEX-2021AP042496 "Bishop-Freeman SC, Fox L, Winecker RE, Hudson JS. Death from Poppy Tea Consumption. Journal of Analytical Toxicology. 2020;44(7):734-740" -

19829752	-	Herbals\Mitragynine	-	Pulseless
Electrical Activity;Unresponsive To Stimuli;Brain Injury;Cardiac Arrest	Serious Other Outcomes;Hospitalized;Life Threatening;Disabled	Male	11-SEP-2021 14-SEP-2021 Direct	21 YR 110.5
KG	Fda-Ctu Healthcare Professional Health Professional	-	-	-
	- 14-SEP-2021 US Not Specified	-	-	-
	-	-	-	-

19821099 - Herbals\Mitragynine;Thebaine;Diphenhydramine;Hydromorphone;Morphine;Codeine Product Used For Unknown Indication Accidental Poisoning;Accidental Overdose;Toxicity To Various Agents Serious Other Outcomes;Died Male - 13-SEP-2021 Expedited 25 YR Not Specified Apotex Healthcare Professional Not Specified Bupropion;Aripiprazole 03-SEP-2021 13-SEP-2021 US Not Specified US-APOTEX-2021AP042497 "Bishop-Freeman SC, Fox L, Winecker RE, Hudson JS. Death from Poppy Tea Consumption. Journal of Analytical Toxicology. 2020;44(7):734-740" -

19813199 Escitalopram Escitalopram Oxalate;Acetaminophen\Hydrocodone Bitartrate;Hydrocodone;Oxycodone;Herbals\Mitragynine;Tramadol;Alprazol

am Anxiety;Back Pain;Depression;Drug Withdrawal  
Syndrome;Intervertebral Disc Degeneration Drug Withdrawal  
Syndrome;Fatigue;Rhinorrhoea;Intentional Product  
Misuse;Pain;Restlessness;Anxiety;Hyperhidrosis;Drug Use  
Disorder;Abdominal Pain;Psychomotor Hyperactivity;Affective  
Disorder;Arthralgia;Withdrawal Syndrome;Depression;Back  
Pain;Yawning;Drug Dependence;Drug Ineffective Serious Hospitalized  
Male - 10-SEP-2021 Expedited 5 DEC Not  
Specified Mylan Healthcare Professional Not Specified -  
31-AUG-2021 10-SEP-2021 US Not Specified US-  
MYLANLABS-2021M1059798 "Bowe A, Kerr PL. A Complex Case of Kratom  
Dependence, Depression, and Chronic Pain in Opioid Use Disorder:  
Effects of Buprenorphine in Clinical Management. J-Psychoactive-Drugs  
2020;52(5):447-452." -  
19810602 - Codeine;Hydromorphone  
Hydrochloride;Herbals\Mitragynine;Morphine - Pulmonary  
Oedema;Toxicity To Various Agents Serious Died Male -  
09-SEP-2021 Expedited 25 YR Not Specified Pfizer  
Healthcare Professional Not Specified  
Bupropion;Diphenhydramine  
Hydrochloride;Thebaine;Atracurium;Aripiprazole 28-AUG-2021 09-  
SEP-2021 US Not Specified US-PFIZER INC-202101132415  
"Bishop-Freeman, S.. Death from poppy tea consumption. Journal  
of Analytical Toxicology. 2020;44(7):734-740" -  
19808931 Sertraline;Trazodone;Hydroxyzine;Zolpidem  
Hydroxyzine Hydrochloride;Zolpidem  
Tartrate;Gabapentin;Cyclobenzaprine;Clonidine;Morphine;Trazodone  
Hydrochloride;Thebaine;Codeine;Mirtazapine;Herbals\Mitragynine;Sertral  
ine Hydrochloride Product Used For Unknown Indication  
Accidental Poisoning Serious Died Male - 09-SEP-2021  
Expedited 25 YR Not Specified Novartis  
Healthcare Professional Not Specified - 06-SEP-2021 09-  
SEP-2021 US Not Specified  
NVSC2021US203910 "Bishop-Freeman SC, Fox L, Winecker RE, Hudson  
JS. Death from poppy tea consumption. JOURNAL OF ANALYTICAL  
TOXICOLOGY. 2020;44:734-40" -  
19807588 - Herbals\Mitragynine Drug Dependence  
Socioeconomic Precarity;Drug Dependence;Theft Serious Required  
Intervention Male - 08-SEP-2021 Direct Not Specified  
Not Specified Fda-Ctu Consumer Consumer Motrin  
- 08-SEP-2021 US Not Specified - -  
-  
19787993 Trazodone Trazodone  
Hydrochloride;Mirtazapine;Morphine;Sertraline  
Hydrochloride;Herbals\Mitragynine;Cyclobenzaprine;Clonidine;Gabapentin  
;Codeine;Hydroxyzine Pamoate;Zolpidem Tartrate - Respiratory  
Depression;Toxicity To Various Agents;Pulmonary Congestion  
Serious Other Outcomes;Died Male - 03-SEP-2021  
Expedited 25 YR Not Specified Pfizer Healthcare  
Professional Not Specified - 28-AUG-2021 03-SEP-2021

US Not Specified US-PFIZER  
 INC-202100929819 "Bishop-Freeman, S.. Death from poppy tea consumption. Journal of Analytical Toxicology. 2020;44(7):734-740"  
 -  
 19749424 - Herbals\Mitragynine - Withdrawal  
 Syndrome;Generalised Tonic-Clonic Seizure;Road Traffic Accident  
 Serious Other Outcomes Male 04-FEB-2018 25-AUG-2021 Direct  
 35 YR Not Specified Fda-Ctu Consumer Consumer  
 - - 25-AUG-2021 US Not Specified -  
 - -  
 19745347 - Herbals\Mitragynine Anxiety;Pain Drug  
 Withdrawal Syndrome Non-Serious Non-Serious Female -  
 24-AUG-2021 Direct 35 YR 68.4 KG Fda-Ctu Consumer  
 Consumer - - 24-AUG-2021 US Not  
 Specified - - -  
 19744967 - Herbals\Mitragynine Drug Dependence  
 Toxicity To Various Agents;Seizure Serious Died Male 21-  
 JUN-2020 24-AUG-2021 Direct 27 YR 67.5 KG Fda-Ctu  
 Consumer Consumer - - 24-AUG-2021 US  
 Not Specified - - -  
 19744942 - Herbals\Mitragynine Anxiety;Depression  
 Pancreatitis;Pain;Dizziness;Dependence;Libido  
 Decreased;Fatigue;Headache;Urticaria;Hypersensitivity Serious Other  
 Outcomes;Hospitalized;Life Threatening;Required Intervention;Disabled  
 Male 01-JAN-2020 24-AUG-2021 Direct 43 YR 72 KG  
 Fda-Ctu Consumer Consumer - - 24-  
 AUG-2021 US Not Specified - - -  
 18890962 - Herbals\Mitragynine;Tramadol Asthma;Back  
 Pain;Depression;Pain;Product Used For Unknown Indication Drug  
 Use Disorder;Drug Abuse;Drug Dependence Serious Other Outcomes Male  
 - 21-AUG-2021 Expedited 31 YR Not Specified  
 Aurobindo Healthcare Professional Not Specified  
 Gabapentin;Albuterol;Escitalopram 09-AUG-2021 15-FEB-2021  
 US Not Specified US-AUROBINDO-AUR-APL-2021-005338  
 "Kalin S, Dakhllalla S, Bhardwaj S.. Treatment for kratom abuse  
 in a contingency-management-based MAT setting: A case series.. J-  
 Opioid-Manag. 2020;16(5):391-394" -  
 18457982 Valacyclovir;Valtrex Valacyclovir  
 Hydrochloride;Valacyclovir  
 Hydrochloride;Loratadine;Herbals\Mitragynine;Acetaminophen\Methocarbamol;  
 Diphenhydramine;Albuterol;Acetaminophen\Codeine  
 Phosphate\Methocarbamol;Citalopram;Ranitidine;Methocarbamol  
 Product Used For Unknown Indication Caesarean Section;Live  
 Birth;Maternal Exposure During Pregnancy Serious Other Outcomes  
 Female - 18-AUG-2021 Expedited 37 YR Not  
 Specified Apotex Healthcare Professional Not Specified -  
 05-AUG-2021 03-NOV-2020 CA Not Specified CA-  
 APOTEX-2020AP020693 - -  
 19708082 - Herbals\Mitragynine Anxiety  
 Asthenia;Tremor;Gait Inability Serious Other Outcomes Male 25-

DEC-2020            17-AUG-2021        Direct    69 YR    94.5 KG Fda-Ctu  
 Consumer            Consumer            Aspirin;Lipitor;Lisinopril;Metoprolol  
 -                    17-AUG-2021        US        Not Specified    -    -  
 -  
 18290048           Valacyclovir;Valtrex    Valacyclovir  
 Hydrochloride;Albuterol;Acetaminophen;Herbals\Mitragynine;Valacyclovir  
 Hydrochloride;Citalopram;Diphenhydramine;Ranitidine;Loratadine;Methoca  
 rbamol;Acetaminophen\Codeine Phosphate\Methocarbamol    Product Used  
 For Unknown Indication    Foetal Exposure During Pregnancy;Drug  
 Withdrawal Syndrome Neonatal    Serious Other Outcomes;Hospitalized  
 Female    -    17-AUG-2021    Expedited    Not Specified  
 3 KG      Apotex    Healthcare Professional Not Specified  
 Citalopram    05-AUG-2021    21-SEP-2020    CA    Not Specified  
 CA-APOTEX-2020AP017746    -    -  
 19704407           -    Herbals\Mitragynine    -    No Adverse  
 Event;Product Use In Unapproved Indication    Non-Serious    Non-  
 Serious Not Specified    -    14-AUG-2021    Direct    Not Specified  
 79.38 KG           Fda-Ctu    Healthcare Professional Health  
 Professional    -    -    14-AUG-2021    US    Not Specified  
 -    -    -  
 19703810           -    Herbals\Mitragynine    Product Used For  
 Unknown Indication    Asthenia;Asocial  
 Behaviour;Depression;Withdrawal Syndrome;Anxiety;Restless Legs  
 Syndrome            Serious Other Outcomes    Male    04-AUG-2021    14-  
 AUG-2021           Direct    44 YR    83.25 KG    Fda-Ctu    Consumer  
 Consumer           Ambien;Lexapro;Vitamin  
 D;Singulair;Ademetonine;Omega-3 Fatty Acids;Magnesium    -    14-  
 AUG-2021           US    Not Specified    -    -    -  
 19695287           -    Herbals\Mitragynine    Depression    Drug  
 Dependence           Serious Disabled;Life Threatening;Required  
 Intervention        Male    10-AUG-2021    12-AUG-2021    Direct    40 YR  
 74.25 KG           Fda-Ctu    Consumer           Consumer    -  
 -    12-AUG-2021    US    Not Specified    -    -  
 -  
 19695260           -    Herbals\Mitragynine    Anxiety Autoimmune  
 Encephalopathy       Serious Disabled;Life Threatening;Hospitalized    Male  
 18-JAN-2018          12-AUG-2021    Direct    57 YR    78.75 KG  
 Fda-Ctu    Consumer           Consumer           Lipitor;Nexium    -  
 12-AUG-2021          US    Not Specified    -    -    -  
 19685184           -    Herbals\Mitragynine    -    Accidental  
 Death;Toxicity To Various Agents        Serious Died    Male    30-  
 AUG-2020            10-AUG-2021    Direct    38 YR    Not Specified    Fda-  
 Ct    Healthcare Professional Health Professional    -    -  
 10-AUG-2021          US    Not Specified    -    -    -  
 19685154           -    Herbals\Mitragynine    -    Death  
 Serious Died        Male    21-APR-2021    10-AUG-2021    Direct    26 YR  
 Not Specified       Fda-Ctu    Healthcare Professional Health  
 Professional        -    -    10-AUG-2021    US    Not Specified  
 -    -    -  
 19685083           -    Herbals\Mitragynine    -    Toxicity To

Various Agents;Diabetic Ketosis;Hypertension;Starvation  
 Ketoacidosis;Seizure;Aspiration;Arteriosclerosis Coronary Artery  
 Serious Died Male 21-FEB-2021 10-AUG-2021 Direct  
 26 YR Not Specified Fda-Ctu Healthcare Professional Health  
 Professional - - 10-AUG-2021 US Not Specified  
 - - -  
 19673405 - Herbals\Mitragynine - Anxiety;Loss  
 Of Personal Independence In Daily Activities;Poor Personal  
 Hygiene;Delusion;Asocial Behaviour Serious Disabled Female  
 15-MAR-2020 07-AUG-2021 Direct 31 YR 54.45 KG  
 Fda-Ctu Healthcare Professional Health Professional -  
 - 07-AUG-2021 US Not Specified - -  
 -  
 19666831 - Herbals\Mitragynine Anxiety Ejaculation  
 Disorder;Libido Disorder Serious Other Outcomes Female 04-  
 AUG-2021 06-AUG-2021 Direct 36 YR 63 KG Fda-Ctu  
 Consumer Consumer - - 06-AUG-2021 US  
 Not Specified - - -  
 18855338 - Herbals\Mitragynine;Tramadol  
 Anxiety;Depression;Detoxification;Drug Dependence;Pain Drug  
 Dependence;Drug Abuse;Drug Use Disorder Serious Other Outcomes Male  
 2013 04-AUG-2021 Expedited 31 YR Not Specified  
 Lupin Healthcare Professional Not Specified  
 Escitalopram;Venlafaxine 23-JUL-2021 06-FEB-2021 US  
 Not Specified US-LUPIN PHARMACEUTICALS INC.-2021-01191  
 "Kalin S, Dakhllalla S, Bhardwaj S. Treatment for kratom abuse  
 in a contingency-management-based MAT setting: A case series. Journal  
 of Opioid Management. 2020;16(5):391-394" -  
 19646974 - Naloxone;Diphenhydramine;Herbals\Mitragynine  
 Product Used For Unknown Indication Hypoxic-Ischaemic  
 Encephalopathy;Drug Abuse Serious Other  
 Outcomes;Hospitalized;Died Male - 02-AUG-2021  
 Expedited 27 YR Not Specified Apotex Healthcare  
 Professional Not Specified - 19-JUL-2021 02-AUG-2021  
 CA Not Specified CA-APOTEX-2021AP023854 "Solbeck P,  
 Woodall KL, Martin TL.. Strategic Decision-Making by a Forensic  
 Toxicology Laboratory in Response to an Emerging NPS: Detection,  
 Quantitation, and Interpretation of Carfentanil in Death  
 Investigations in Ontario, Canada, July 2017 to June 2018.. Journal of  
 Analytical Toxicology. 2021" -  
 19645353 - Herbals\Mitragynine Pain Drug  
 Dependence;Withdrawal Syndrome Non-Serious Non-Serious Female  
 01-JUN-2018 31-JUL-2021 Direct 37 YR 96.75 KG  
 Fda-Ctu Consumer Consumer - - 31-  
 JUL-2021 US Not Specified - - -  
 19645350 - Herbals\Mitragynine Product Used For  
 Unknown Indication Agitation;Kidney Infection;Dyspnoea;Drug  
 Abuser;Mood Swings;Weight Decreased Non-Serious Non-Serious  
 Male 20-JUL-2021 30-JUL-2021 Direct Not Specified  
 Not Specified Fda-Ctu Consumer Consumer

Gabapentin - 30-JUL-2021 US Not Specified -

- - Remeron;Hydroxyzine;Trazodone;Zolpidem;Sertraline  
 Sertraline Hydrochloride;Morphine;Codeine;Gabapentin;Zolpidem  
 Tartrate;Trazodone Hydrochloride;Thebaine;Mirtazapine;Hydroxyzine  
 Hydrochloride;Herbals\Mitragynine;Clonidine;Cyclobenzaprine -

Drug Abuse Serious Other Outcomes Male - 29-  
 JUL-2021 Expedited 25 YR Not Specified Organon  
 Healthcare Professional Not Specified - 19-JUL-2021 29-  
 JUL-2021 US Not Specified US-ORGANON-02107USA001983  
 "Bishop-Freeman SC, Fox L, Winecker RE, Hudson JS. Death from  
 poppy tea consumption. Journal of Analytical Toxicology. 2020;44  
 (7):734-40" -

19619958 - Herbals\Mitragynine Anxiety;Pain  
 Withdrawal Syndrome;Mood Swings;Anxiety;Personality  
 Change;Agitation;Dependence;Decreased Appetite Serious Disabled  
 Male - 27-JUL-2021 Direct Not Specified Not  
 Specified Fda-Ctu Consumer Consumer - -  
 27-JUL-2021 US Not Specified - - -

19613435 - Herbals\Mitragynine Drug Dependence Drug  
 Dependence;Vomiting;Headache;Withdrawal Syndrome;Gastrointestinal  
 Disorder Serious Disabled;Required Intervention Male 01-  
 JAN-2021 26-JUL-2021 Direct 29 YR 67.5 KG Fda-Ctu  
 Consumer Consumer - - 26-JUL-2021 US  
 Not Specified - - -

19608140 - Herbals\Mitragynine Anxiety Pulmonary  
 Oedema;Overdose Serious Died Male 26-SEP-2020 25-JUL-2021  
 Direct 34 YR 90.45 KG Fda-Ctu Consumer  
 Consumer - - 25-JUL-2021 US Not Specified  
 - - -

19597761 -  
 Herbals\Mitragynine;Oxycodone;Yohimbine;Alprazolam;Buprenorphine  
 Product Used For Unknown Indication Respiratory  
 Arrest;Cardiac Arrest Serious Other Outcomes;Hospitalized;Died  
 Male - 23-JUL-2021 Expedited 29 YR Not  
 Specified Aurobindo Healthcare Professional Not Specified  
 - 12-JUL-2021 23-JUL-2021 US Not Specified  
 US-AUROBINDO-AUR-APL-2021-030561 "Gummin DD, Mowry JB,  
 Beuhler MC, Spyker DA, Brooks DE, Dibert KW; et al.. 2019 Annual  
 Report of the American Association of Poison Control Centers' National  
 Poison Data System (NPDS): 37th Annual Report. Clinical Toxicology.  
 2020;58 (12):1360ñ1541" -

19587510 - Herbals\Mitragynine Narcolepsy  
 Product Use Issue;Respiratory Depression;Herbal Toxicity  
 Serious Died Male - 21-JUL-2021 Direct 31 YR 76.5  
 KG Fda-Ctu Consumer Consumer  
 Lunesta;Modafinil;Vitamin D3 - 21-JUL-2021 US Not  
 Specified - - -

19585434 Methadone Methadone  
 Hydrochloride;Herbals\Mitragynine;Fentanyl Product Used For

Unknown Indication Drug Abuse Serious Died;Other Outcomes  
 Male - 21-JUL-2021 Expedited 29 YR Not  
 Specified Aurobindo Healthcare Professional Not Specified  
 - 12-JUL-2021 21-JUL-2021 US Not Specified  
 US-AUROBINDO-AUR-APL-2021-030562 "Gummin DD, Mowry JB,  
 Beuhler MC, Spyker DA, Brooks DE, Dibert KW; et al.. 2019 Annual  
 Report of the American Association of Poison Control Centers' National  
 Poison Data System (NPDS): 37th Annual Report. Clinical Toxicology.  
 2020;58 (12):1360ñ1541" -

19561943 - Herbals\Mitragynine Depression  
 Aggression;Product Complaint;Depression;Illness;Vitamin B12  
 Deficiency;Memory Impairment;Brain Fog;Confusional  
 State;Delirium;Anxiety Serious Disabled;Hospitalized Female 13-  
 APR-2020 16-JUL-2021 Direct 26 YR 64.35 KG Fda-  
 Ctu Consumer Consumer Vitamin D;Gabapentin;Vitamin  
 B12;Advil - 16-JUL-2021 US Not Specified -

- -  
 19518304 - Herbals\Mitragynine - Withdrawal  
 Syndrome;Maternal Drugs Affecting Foetus Serious  
 Hospitalized;Required Intervention Not Specified 10-JUL-2021  
 11-JUL-2021 Direct Not Specified Not Specified Fda-  
 Ctu Healthcare Professional Health Professional - -  
 11-JUL-2021 US Not Specified - - -

19512063 - Herbals\Mitragynine Drug Dependence  
 Opiates Positive Serious Other Outcomes Female 05-JUL-2021  
 09-JUL-2021 Direct 50 YR Not Specified Fda-Ctu  
 Consumer Consumer - - 09-JUL-2021 US  
 Not Specified - - -

19506583 Venlafaxine Venlafaxine  
 Hydrochloride;Herbals\Mitragynine Anxiety Overdose  
 Serious Died Male 01-JUN-2021 08-JUL-2021 Direct 38 YR  
 137.7 KG Fda-Ctu Consumer Consumer  
 Doxepin;Clonazepam - 08-JUL-2021 US Not Specified  
 - - -

16593814 Valtrex Valacyclovir  
 Hydrochloride;Ranitidine;Valacyclovir  
 Hydrochloride;Herbals\Mitragynine;Methocarbamol;Citalopram;Albuterol;Acetaminophen;Loratadine;Diphenhydramine;Acetaminophen\Methocarbamol  
 Product Used For Unknown Indication Maternal Exposure  
 During Pregnancy;Caesarean Section;Drug Withdrawal Syndrome  
 Neonatal;Live Birth;Foetal Exposure During Pregnancy Serious Other  
 Outcomes;Hospitalized Female - 29-JUN-2021 Expedited  
 37 YR Not Specified Glaxosmithkline Healthcare  
 Professional Not Specified - 09-JUN-2021 18-JUL-2019  
 CA Not Specified CA-GLAXOSMITHKLINE-CA2019AMR125655  
 - -

19460010 Valtrex Valacyclovir  
 Hydrochloride;Albuterol;Loratadine;Acetaminophen\Methocarbamol;Ranitidine;Herbals\Mitragynine;Citalopram;Acetaminophen\Codeine  
 Phosphate\Methocarbamol;Diphenhydramine;Methocarbamol Product Used

For Unknown Indication Maternal Exposure During Pregnancy;Caesarean Section;Live Birth Serious Other Outcomes Female - 25-JUN-2021 Expedited 37 YR Not Specified Aurobindo Healthcare Professional Not Specified - 08-JUL-2019 25-JUN-2021 CA Not Specified CA-AUROBINDO-AUR-APL-2019-041488 - -

16607921 Valtrex Valacyclovir Hydrochloride;Methocarbamol;Acetaminophen\Codeine Phosphate\Methocarbamol;Acetaminophen;Diphenhydramine;Ranitidine;Albuterol;Valacyclovir Hydrochloride;Citalopram;Loratadine;Herbals\Mitragynine Product Used For Unknown Indication Drug Withdrawal Syndrome Neonatal;Foetal Exposure During Pregnancy Serious Hospitalized;Other Outcomes Female - 25-JUN-2021 Expedited Not Specified 3 KG Aurobindo Healthcare Professional Not Specified - 18-JUN-2021 22-JUL-2019 CA Not Specified CA-AUROBINDO-AUR-APL-2019-041481 - -

19455710 - Herbals\Mitragynine Drug Use Disorder Product Quality Issue;Swelling;Suspected Product Contamination;Malaise;Inflammation Serious Other Outcomes Male 01-JUN-2021 24-JUN-2021 Direct 56 YR 94.5 KG Fda-Ctu Consumer Consumer Pomegranate;Reishi;Taurine;Herbals\Turmeric;Vitamin D3;Jwh-018;Herbals\Withania Somnifera Root;Vitamin B12;Theanine - 24-JUN-2021 US Not Specified - - Yes

16593812 - Loratadine;Herbals\Mitragynine;Acetaminophen;Methocarbamol;Acetaminophen\Codeine Phosphate\Methocarbamol;Ranitidine;Albuterol;Diphenhydramine;Valacyclovir Hydrochloride Product Used For Unknown Indication Foetal Exposure During Pregnancy;Drug Withdrawal Syndrome Neonatal Serious Other Outcomes;Hospitalized Female - 21-JUN-2021 Expedited Not Specified 3 KG Glaxosmithkline Healthcare Professional Not Specified Citalopram 15-JUN-2021 18-JUL-2019 CA Not Specified CA-GLAXOSMITHKLINE-CA2019AMR125644 - -

19433030 Methadone Bucinnazine;Methadone Hydrochloride;Etizolam;Herbals\Mitragynine Product Used For Unknown Indication Somnolence;Unresponsive To Stimuli;Overdose;Mental Status Changes;Respiratory Depression Serious Other Outcomes Male - 18-JUN-2021 Expedited 31 YR Not Specified Aurobindo Healthcare Professional Not Specified - 07-JUN-2021 18-JUN-2021 US Not Specified US-AUROBINDO-AUR-APL-2021-025241 "Yeh M, Krotulski A, Therriault C, Eisenstat MD, Nguyen H, Papsun D, et al.. Acute opioid overdose following nasal atomization of a novel designer opioid, 2-methyl AP-237, with potentiation of designer benzodiazepines, pyrazolam and clonazolam.. J-Med-Toxicol. 2021;17:123" -

19441229 - Herbals\Mitragynine

Anxiety;Depression;Insomnia      Death      Serious      Died      Male      21-  
 FEB-2021      17-JUN-2021      Direct      26 YR      78.75 KG      Fda-  
 Ctu      Consumer      Consumer      -      -      -      17-JUN-2021  
 US      Not Specified      -      -      -  
 19429282      -      Herbals\Mitragynine      -      Quality Of  
 Life Decreased      Serious Disabled;Life Threatening;Other  
 Outcomes;Required Intervention;Hospitalized      Female      01-JUN-2021  
 17-JUN-2021      Direct      Not Specified      Not Specified      Fda-  
 Ctu      Consumer      Consumer      -      -      17-JUN-2021  
 US      Not Specified      -      -      -  
 19397869      -      Herbals\Mitragynine      -      Hepatic Enzyme  
 Increased      Serious Hospitalized      Male      06-MAY-2021      09-  
 JUN-2021      Direct      52 YR      89.1 KG      Fda-Ctu Healthcare  
 Professional      Health Professional      -      -      09-JUN-2021  
 US      Not Specified      -      -      Yes  
 19385905      -      Herbals\Mitragynine      Anxiety;Pain  
 Tachycardia;Panic Attack;Tremor;Disorientation;Dizziness  
 Serious Disabled;Hospitalized      Female      01-SEP-2019      05-JUN-2021  
 Direct      33 YR      53.1 KG      Fda-Ctu Consumer      Consumer  
  
 Promethazine;Herbals\Turmeric;Omeprazole;Xanax;Propranolol;Seroquel;Im-  
 itrex;Probiotics Nos;Vitamins;Wellbutrin;Fish  
 Oil;Hydroxyzine;Ibuprofen;Melatonin      -      05-JUN-2021      US  
 Not Specified      -      -      -  
 19373032      -      Herbals\Mitragynine      Substance Use  
 Product Quality Issue      Non-Serious      Non-Serious      Female      -  
 04-JUN-2021      Direct      25 YR      58.97 KG      Fda-Ctu Not  
 Specified      Not Specified      -      -      04-JUN-2021      US  
 Not Specified      -      -      -  
 19372922      -      Herbals\Mitragynine  
 Anxiety;Depression;Pain  
 Depression;Delusion;Anxiety;Dependence;Completed Suicide  
 Serious Died      Male      -      04-JUN-2021      Direct      60 YR      74.25  
 KG      Fda-Ctu Consumer      Consumer  
 Cymbalta;Metoprolol;Klonopin;Unspecified Ingredient      -      04-  
 JUN-2021      US      Not Specified      -      -      -  
 19365907      -      Herbals\Mitragynine      Substance Abuse  
 Seizure;Weight Decreased;Toxicity To Various Agents      Serious  
 Died;Other Outcomes      Male      30-AUG-2020      03-JUN-2021      Direct  
 38 YR      69.75 KG      Fda-Ctu Consumer      Consumer  
 -      -      03-JUN-2021      US      Not Specified      -  
 -      -  
 19302096      -      Fentanyl;Herbals\Mitragynine      -  
 Toxicologic Test Abnormal;Death Serious Died      Male      -      25-  
 MAY-2021      Direct      Not Specified      78.75 KG      Fda-Ctu  
 Consumer      Consumer      -      -      25-MAY-2021      US  
 Not Specified      -      -      -  
 19292670      -      Herbals\Mitragynine      Anxiety  
 Pain;Fatigue;Pyrexia;Nausea;Blood Bilirubin Increased;Withdrawal  
 Syndrome;Drug-Induced Liver Injury      Serious Hospitalized      Male

16-MAR-2021 23-MAY-2021 Direct 41 YR 103.5 KG  
 Fda-Ctu Consumer Consumer Cymbalta;Wellbutrin  
 - 23-MAY-2021 US Not Specified - - -

19282692 - Herbals\Mitragynine -  
 Insomnia;Seizure;Decreased Appetite;Choking;Overdose Serious Died  
 Male 21-APR-2021 20-MAY-2021 Direct 26 YR 87.75  
 KG Fda-Ctu Consumer Consumer - - 20-  
 MAY-2021 US Not Specified - - -

19278600 - Herbals\Mitragynine -  
 Dysuria;Gallbladder Disorder;Fluid Retention;Renal Disorder;Liver  
 Disorder;Abdominal Distension;Physical Product Label Issue;Peripheral  
 Swelling;Hepatitis Serious Life Threatening;Other Outcomes Male  
 16-APR-2021 20-MAY-2021 Direct 32 YR Not Specified  
 Fda-Ctu Consumer Consumer - - 20-  
 MAY-2021 US Not Specified - - -

19277947 - Herbals\Mitragynine Back Pain  
 Nausea;Pruritus;Pyrexia;Sneezing;Somnolence;Night  
 Sweats;Rhinorrhoea;Pulmonary  
 Pain;Arthralgia;Chromaturia;Cholelithiasis;Jaundice;Drug-Induced Liver  
 Injury;Asthenia;Dyspnoea;Tinnitus;Dizziness;Myalgia;Headache;Body  
 Temperature Fluctuation;Abdominal Pain Upper;Fatigue Serious  
 Hospitalized Female 19-MAR-2021 19-MAY-2021 Direct 48 YR  
 69.75 KG Fda-Ctu Consumer Consumer - -  
 - 19-MAY-2021 US Not Specified - -

19274283 - Herbals\Mitragynine Drug Therapy  
 Toxicity To Various Agents;Substance Use Serious Died Male  
 20-MAR-2021 19-MAY-2021 Direct 42 YR 121.5 KG  
 Fda-Ctu Consumer Consumer - -  
 Paroxetine;Clonazepam;Lamotrigine;Risperidone;Lisinopril And  
 Hydrochlorothiazide - 19-MAY-2021 US Not Specified

19205259 Paxil Paroxetine Hydrochloride;Herbals\Mitragynine  
 Anxiety;Depression;Drug Dependence Hallucination;Heart  
 Rate Increased;Seizure Serious Life Threatening;Other  
 Outcomes;Hospitalized Female 27-APR-2021 02-MAY-2021 Direct  
 53 YR Not Specified Fda-Ctu Consumer Consumer - -  
 Effexor;Tizanidine - 02-MAY-2021 US Not  
 Specified - - -

19205174 - Herbals\Mitragynine Pain  
 Diarrhoea;Product Contamination Physical Serious Other Outcomes  
 Male 03-FEB-2021 01-MAY-2021 Direct 40 YR 72 KG  
 Fda-Ctu Consumer Consumer - - 01-  
 MAY-2021 US Y - - -

18742407 Lexapro;Klonopin;Ativan;Viibryd;Trazodone;Suboxone  
 Buprenorphine Hydrochloride\Naloxone Hydrochloride;Trazodone  
 Hydrochloride;Vilazodone Hydrochloride;Escitalopram  
 Oxalate;Clonazepam;Herbals\Mitragynine;Lorazepam  
 Depression;Drug Withdrawal Maintenance Therapy;Product Used For

Unknown Indication      Panic Attack;Anxiety;Psychotic  
 Disorder;Inability To Afford  
 Medication;Fear;Hypertension;Delirium;Emotional Distress;Confusional  
 State;Suicidal Behaviour;Heart Rate  
 Increased;Malaise;Depression;Therapy Interrupted      Serious Other  
 Outcomes;Hospitalized    Male    JAN-2021    29-APR-2021  
 Expedited      Not Specified    Not Specified    Allergan  
 Consumer      Not Specified    -    15-APR-2021    14-JAN-2021  
                  US    Not Specified    US-ALLERGAN-2101856US    -    -  
 19188369      -    Herbals\Mitragynine    Product Used For  
 Unknown Indication      Seizure    Serious Other Outcomes    Male    27-  
 APR-2021      27-APR-2021    Direct    23 YR    74.25 KG    Fda-  
 Ctu    Consumer      Consumer      -    -    27-APR-2021  
                  US    Not Specified    -    -    -  
 19165441      -    Herbals\Mitragynine    Product Used For  
 Unknown Indication      Overdose;Seizure;Concussion    Serious Other  
 Outcomes;Hospitalized;Life Threatening    Male    31-MAR-2021    21-  
 APR-2021      Direct    26 YR    81 KG    Fda-Ctu    Consumer  
 Consumer      -    -    21-APR-2021    US    Not Specified  
                  -    -    -  
 19165432      -    Herbals\Mitragynine    Drug Dependence Drug  
 Level Increased;Product Complaint    Serious Died    Male    -  
                  21-APR-2021    Direct    21 YR    51.75 KG    Fda-Ctu  
 Consumer      Consumer      Gabapentin    -    21-APR-2021  
                  US    Not Specified    -    -    -  
 19139811      -  
 Cyclobenzaprine;Gabapentin;Cannabinol\Herbals;Benzoyllecgonine;Herbals\  
 Mitragynine;Hydroxyzine Pamoate -    Toxicity To Various Agents  
                  Serious Died    Male    2020    15-APR-2021    Expedited  
                  32 YR    Not Specified    Pfizer    Healthcare Professional Not  
 Specified      -    05-APR-2021    15-APR-2021    US    Not  
 Specified      US-PFIZER INC-2021393171    "Papson, D..  
 Flualprazolam Blood Concentrations in 197 Forensic Investigation  
 Cases.. Journal of analytical toxicology. 2021;45 (3):226-232" -  
 19097760      -    Herbals\Mitragynine    Drug Use Disorder  
                  Generalised Tonic-Clonic Seizure;Seizure    Serious Life  
 Threatening;Hospitalized    Male    27-MAR-2021    06-APR-2021  
                  Direct    35 YR    54 KG    Fda-Ctu    Consumer  
                  Keppra    -    06-APR-2021    US    Not Specified    -  
                  -    -  
 19082832      -    Herbals\Mitragynine    Anxiety;Arthralgia  
                  Dependence;Impaired Work Ability;Mental Disorder;Memory  
 Impairment;Confusional State;Cognitive Disorder;Withdrawal  
 Syndrome;Reading Disorder    Serious Other Outcomes    Female    01-  
 APR-2021      01-APR-2021    Direct    49 YR    58.5 KG    Fda-Ctu  
 Consumer      Consumer      Lamictal;Sertraline    -    01-  
 APR-2021      US    Not Specified    -    -    -  
 19068882      -    Herbals\Mitragynine    Pain    Cardio-  
 Respiratory Arrest;Qrs Axis Abnormal;Blood Calcium Decreased;Troponin  
 Increased;Electrocardiogram St Segment Depression;Bundle Branch Block

Right;Myoclonus;Pulseless Electrical Activity      Serious Died      Male  
 26-MAR-2021      28-MAR-2021      Direct 33 YR      70.5 KG Fda-  
 Ctu      Healthcare Professional Health Professional      -      -  
 28-MAR-2021      US      Not Specified      -      -  
 19051308      -      Herbals\Mitragynine      -      Death Non-  
 Serious Non-Serious      Male 16-NOV-2020      24-MAR-2021      Direct  
 34 YR 99 KG Fda-Ctu Consumer      Consumer      -  
 -      24-MAR-2021      US      Not Specified      -      -  
 -  
 19051300      -      Herbals\Mitragynine      -      Incorrect Dose  
 Administered;Drug Dependence;Mental Disorder      Serious Hospitalized  
 Male -      24-MAR-2021      Direct 41 YR      106.65 KG  
 Fda-Ctu Healthcare Professional Health Professional      -  
 -      24-MAR-2021      US      Not Specified      -      -  
 -  
 19030714      -      Herbals\Mitragynine      Pain;Weight Decreased  
 Withdrawal Syndrome;Urticaria;Drug Hypersensitivity  
 Serious Other Outcomes      Female 03-MAR-2021      19-MAR-2021      Direct  
 41 YR 76.05 KG Fda-Ctu Consumer      Consumer  
 Bentyl;Xanax;Unspecified  
 Ingredient;Viibryd;Flexeril;Tylenol;Lamictal;Wellbutrin  
 Xl;Restoril;Rexulti;Topamax      -      19-MAR-2021      US      Y  
 -      -      -  
 18973587      -      Herbals\Mitragynine      Product Used For  
 Unknown Indication      Loss Of Consciousness      Serious Died      Male  
 25-APR-2020      05-MAR-2021      Direct 38 YR      112.5 KG  
 Fda-Ctu Consumer      Consumer      Adderall      -  
 05-MAR-2021      US      Y      -      -      -  
 18967773      -      Herbals\Mitragynine      Drug Withdrawal  
 Syndrome      Product Complaint;Drug  
 Dependence;Hyperhidrosis;Abnormal  
 Behaviour;Aggression;Tachycardia;Syncope;Hypertension;Respiratory  
 Depression;Agitation;Depressed Level Of Consciousness;Pruritus  
 Serious Hospitalized;Life Threatening      Male 02-MAR-2021      04-  
 MAR-2021      Direct 29 YR 81 KG Fda-Ctu Consumer  
 Consumer      -      -      04-MAR-2021      US      Not Specified  
 -      -      -  
 18961521      -  
 Alprazolam;Herbals\Mitragynine;Butalbital;Morphine      Product Used  
 For Unknown Indication      Toxicity To Various Agents      Serious Died  
 Female -      03-MAR-2021      Expedited 28 YR Not  
 Specified      Ranbaxy Healthcare Professional Not Specified      -  
 17-FEB-2021      03-MAR-2021      US      Not Specified      US-SUN  
 PHARMACEUTICAL INDUSTRIES LTD-2021R1-282076      "Fagiola M, Hahn T,  
 Avella J. Screening of Novel Psychoactive Substances in Postmortem  
 Matrices by Liquid Chromatography-Tandem Mass Spectrometry (LC-MS-MS).  
 J Anal Toxicol. 2018;42:562-569"  
 18961246      Methadone      Methadone  
 Hydrochloride;Meperidine;Morphine;Phentermine;Herbals\Mitragynine  
 Product Used For Unknown Indication      Toxicity To Various

Agents Serious Died Male - 03-MAR-2021 Expedited  
 41 YR Not Specified Ranbaxy Healthcare Professional Not  
 Specified - 17-FEB-2021 03-MAR-2021 US Not  
 Specified US-SUN PHARMACEUTICAL INDUSTRIES LTD-2021R1-282072  
 "Fagiola M, Hahn T, Avella J. Screening of Novel Psychoactive Substances in Postmortem Matrices by Liquid Chromatography-Tandem Mass Spectrometry (LC-MS-MS). J Anal Toxicol. 2018;42:562-569" -  
 18983046 - Herbals\Mitragynine Product Used For Unknown Indication Product Quality Issue;Loss Of Consciousness;Tremor;Vomiting;Haemorrhage Serious Disabled;Other Outcomes Female 25-FEB-2021 26-FEB-2021 Direct 37 YR 60.75 KG Fda-Ctu Consumer Consumer Tylenol Extra Strength - 26-FEB-2021 US Y - -  
 - -  
 18897611 - Herbals\Mitragynine Vitamin Supplementation Palpitations;Hyperhidrosis Serious Other Outcomes Male 13-FEB-2021 14-FEB-2021 Direct 33 YR 74.25 KG Fda-Ctu Consumer Consumer - - 14- FEB-2021 US Not Specified - - -  
 18858148 - Herbals\Mitragynine Pain Malaise;Extra Dose Administered Serious Died Female - 06-FEB-2021 Direct Not Specified 90 KG Fda-Ctu Consumer Consumer Consumer - - 06-FEB-2021 US Not Specified - - -  
 18853580 Sertraline;Hydroxyzine Hydroxyzine Hydrochloride;Herbals\Mitragynine;Sertraline Hydrochloride;Olanzapine;Clonazepam;Temazepam Product Used For Unknown Indication Cardiomegaly;Toxicity To Various Agents Serious Other Outcomes;Died Not Specified - 05-FEB-2021 Expedited Not Specified Not Specified Ranbaxy Healthcare Professional Not Specified - 23-JAN-2021 05-FEB-2021 US Not Specified US-SUN PHARMACEUTICAL INDUSTRIES LTD-2021R1-277923 "Gershman K, Timm K, Frank M, Lampi L, Melamed J, Gerona R et al. Deaths in Colorado Attributed to Kratom. N Engl J Med. 2019;3Jan: 380(1):1-2" -  
 18850878 - Citalopram;Herbals\Mitragynine Product Used For Unknown Indication Toxicity To Various Agents Serious Other Outcomes;Died Not Specified - 05-FEB-2021 Expedited Not Specified Not Specified Ranbaxy Healthcare Professional Not Specified - 23-JAN-2021 05-FEB-2021 US Not Specified US-SUN PHARMACEUTICAL INDUSTRIES LTD-2021R1-277922 "Gershman K, Timm K, Frank M, Lampi L, Melamed J, Gerona R et al. Deaths in Colorado Attributed to Kratom. N Engl J Med. 2019;3Jan: 380(1):1-2" -  
 18850794 Zolpidem Zolpidem Tartrate;Oxycodone;Topiramate;Tramadol;Herbals\Mitragynine;Diphenhydramine Product Used For Unknown Indication Toxicity To Various Agents;Asphyxia Serious Died;Other Outcomes Not Specified - 05-FEB-2021 Expedited Not Specified Not Specified Ranbaxy Healthcare Professional Not Specified - 23-

JAN-2021 05-FEB-2021 US Not Specified US-SUN  
PHARMACEUTICAL INDUSTRIES LTD-2021R1-277921 "Gershman K, Timm K, Frank M, Lampi L, Melamed J, Gerona R et al. Deaths in Colorado Attributed to Kratom. N Engl J Med. 2019;JAN 380 1:1-2" -  
18832743 -  
Herbals\Mitragynine;Oxycodone;Alcohol;Fentanyl;Cocaine Product Used For Unknown Indication Portal Fibrosis;Portal Tract Inflammation;Toxicity To Various Agents Serious Died;Other Outcomes Not Specified - 03-FEB-2021 Expedited Not Specified Not Specified Ranbaxy Healthcare Professional Not Specified - 23-JAN-2021 03-FEB-2021 US Not Specified US-SUN PHARMACEUTICAL INDUSTRIES LTD-2021R1-277926 "Gershman K, Timm K, Frank M, Lampi L, Melamed J, Gerona R et al. Deaths in Colorado Attributed to Kratom. N Engl J Med. 2019;3Jan: 380(1):1-2" -  
18832735 Pseudoephedrine.;Fluoxetine Fluoxetine Hydrochloride;Herbals\Mitragynine;Oxycodone;Pseudoephedrine Hydrochloride Product Used For Unknown Indication Toxicity To Various Agents Serious Died;Other Outcomes Not Specified - 03-FEB-2021 Expedited Not Specified Not Specified Ranbaxy Healthcare Professional Not Specified - 23-JAN-2021 03-FEB-2021 US Not Specified US-SUN PHARMACEUTICAL INDUSTRIES LTD-2021R1-277918 "Gershman K, Timm K, Frank M, Lampi L, Melamed J, Gerona R et al. Deaths in Colorado Attributed to Kratom. N Engl J Med. 2019;3Jan: 380(1):1-2" -  
18832731 - Herbals\Mitragynine;Alcohol;Oxycodone Product Used For Unknown Indication Toxicity To Various Agents Serious Other Outcomes;Died Not Specified - 03-FEB-2021 Expedited Not Specified Not Specified Ranbaxy Healthcare Professional Not Specified - 23-JAN-2021 03-FEB-2021 US Not Specified US-SUN PHARMACEUTICAL INDUSTRIES LTD-2021R1-277925 "Gershman K, Timm K, Frank M, Lampi L, Melamed J, Gerona R et al. Deaths in Colorado Attributed to Kratom. N Engl J Med. 2019;3Jan: 380(1):1-2" -  
18831408 -  
Herbals\Mitragynine;Nordazepam;Etizolam;Mirtazapine Product Used For Unknown Indication Toxicity To Various Agents Serious Other Outcomes;Died Not Specified - 03-FEB-2021 Expedited Not Specified Not Specified Ranbaxy Healthcare Professional Not Specified - 23-JAN-2021 03-FEB-2021 US Not Specified US-SUN PHARMACEUTICAL INDUSTRIES LTD-2021R1-277924 "Gershman K, Timm K, Frank M, Lampi L, Melamed J, Gerona R et al. Deaths in Colorado Attributed to Kratom. N Engl J Med. 2019;3Jan:380(1):1-2" -  
18821696 - Tramadol;Herbals\Mitragynine;Buprenorphine Hydrochloride\Naloxone Hydrochloride Anxiety;Arthralgia;Depression;Detoxification;Drug Dependence;Drug Use Disorder Drug Abuse;Intentional Product Misuse;Headache;Drug Use Disorder;Drug Dependence;Constipation Serious Other Outcomes Male 2013 02-FEB-2021 Expedited 31 YR Not

Specified Mylan Healthcare Professional Not Specified  
Venlafaxine;Escitalopram 25-JAN-2021 02-FEB-2021 US  
Not Specified US-MYLANLABS-2021M1006239 "Kalin S,  
Dakhllalla S, Bhardwaj S. Treatment for kratom abuse in a contingency-  
management-based MAT setting: A case series. J-Opioid-Manag  
2020;16(5):391-394." -  
18777199 -  
Yohimbine;Alprazolam;Herbals\Mitragynine;Flualprazolam;Buprenorphine;Oxycodone Hydrochloride Product Used For Unknown Indication  
Respiratory Arrest;Cardiac Arrest;Poisoning Deliberate Serious Died  
Male 2019 22-JAN-2021 Expedited 29 YR Not  
Specified Genus Lifesciences Healthcare Professional Not  
Specified - 11-JAN-2021 22-JAN-2021 US Not  
Specified US-GENUS\_LIFESCIENCES-USA-POI0580202100046 Gummin  
D. 2019 Annual Report of the American Association of Poison Control  
Centers National Poison Data Systems (NPDS): 37th Annual Report.  
Clinical Toxicology. 2020 DEC;58(12):1360-1541. -  
18769925 - Alprazolam;Buprenorphine;Oxycodone Hydrochloride;Flualprazolam;Herbals\Mitragynine;Yohimbine  
Product Used For Unknown Indication Death;Cardio-Respiratory  
Arrest Serious Died Male 2019 21-JAN-2021 Expedited  
29 YR Not Specified Endo Healthcare Professional Not  
Specified - 05-JAN-2021 21-JAN-2021 US Not  
Specified US-ENDO PHARMACEUTICALS INC-2021-000335 - -  
18729811 -  
Yohimbine;Alprazolam;Buprenorphine;Oxycodone;Herbals\Mitragynine  
- Cardiac Arrest;Respiratory Arrest Serious  
Died;Hospitalized Male 2019 19-JAN-2021 Expedited  
29 YR Not Specified Pfizer Healthcare Professional Not  
Specified - 14-JAN-2021 12-JAN-2021 US Not  
Specified US-PFIZER INC-2021014296 "Gummin, D.. 2019  
Annual Report of the American Association of Poison Control Centers'  
National Poison Data System (NPDS): 37th Annual Report. Clinical  
Toxicology. 2020;58 (12):1360-1541" -  
18728069 Methadone Methadone  
Hydrochloride;Herbals\Mitragynine;Fentanyl Product Used For  
Unknown Indication Drug Abuse Serious Died;Other Outcomes  
Male 2019 15-JAN-2021 Non-Expedited 29 YR Not  
Specified Apotex Healthcare Professional Not Specified -  
04-JAN-2021 12-JAN-2021 US Not Specified US-  
APOTEX-2021AP000181 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA,  
Brooks DE, Dibert KW, Rivers LJ, Pham NPT, Ryan ML. 2019 Annual Report  
of the American Association of Poison Control Centers National Poison  
Data System (NPDS): 37th Annual Report. Clinical Toxicology. 2020;58  
(12):1360-1541" -  
18741064 - Herbals\Mitragynine - Illness;Drug  
Withdrawal Syndrome;Product Complaint;Substance Dependence Non-  
Serious Non-Serious Male 25-DEC-2020 14-JAN-2021 Direct  
36 YR 60.75 KG Fda-Ctu Consumer Consumer  
- - 14-JAN-2021 US Not Specified -

- -  
18740006 - Fentanyl;Herbals\Mitragynine Product Used  
For Unknown Indication Drug Abuse Serious Other Outcomes;Died  
Male - 14-JAN-2021 Non-Expedited 30 YR Not  
Specified Apotex Healthcare Professional Not Specified -  
04-JAN-2021 14-JAN-2021 US Not Specified US-  
APOTEX-2021AP000192 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA,  
Brooks DE, Dibert KW, Rivers LJ, Pham NPT, Ryan ML. 2019 Annual Report  
of the American Association of Poison Control Centers National Poison  
Data System (NPDS): 37th Annual Report. Clinical Toxicology. 2020;58  
(12):1360ñ1541" -

18738840 - Herbals\Mitragynine;Diphenhydramine;Etizolam  
Product Used For Unknown Indication Completed Suicide  
Serious Died;Other Outcomes Male 2019 14-JAN-2021  
Expedited 25 YR Not Specified Apotex Healthcare  
Professional Not Specified - 04-JAN-2021 14-JAN-2021  
US Not Specified US-APOTEX-2021AP000950 "Gummin DD,  
Mowry JB, Beuhler MC, Spyker DA, Brooks DE, Dibert KW, Rivers LJ, Pham  
NPT, Ryan ML. 2019 Annual Report of the American Association of Poison  
Control Centers National Poison Data System (NPDS): 37th Annual  
Report. Clinical Toxicology. 2020;58 (12):1360ñ1541" -

18726140 - Herbals\Mitragynine;Fentanyl Product Used  
For Unknown Indication Drug Abuse;Cardio-Respiratory Arrest  
Serious Died;Hospitalized;Other Outcomes Male 2019 14-  
JAN-2021 Expedited 25 YR Not Specified Apotex  
Healthcare Professional Not Specified - 04-JAN-2021 11-  
JAN-2021 US Not Specified US-  
APOTEX-2021AP000153 "Gummin DD, Mowry JB, Beuhler MC, Spyker DA,  
Brooks DE, Dibert KW, Rivers LJ, Pham NPT, Ryan ML. 2019 Annual Report  
of the American Association of Poison Control Centers National Poison  
Data System (NPDS): 37th Annual Report. Clinical Toxicology. 2020;58  
(12):1360ñ1541" -

18731400 - Herbals\Mitragynine;Fentanyl Citrate -  
Cardiac Arrest;Respiratory Arrest;Drug Abuse Serious Other  
Outcomes;Died;Hospitalized Male 2019 12-JAN-2021  
Expedited 25 YR Not Specified Pfizer Healthcare  
Professional Not Specified - 08-JAN-2021 12-JAN-2021  
US Not Specified US-PFIZER  
INC-2021015009 "Gummin, D.. 2019 Annual Report of the American  
Association of Poison Control Centers' National Poison Data System  
(NPDS): 37th Annual Report. Clinical Toxicology. 2020;58  
(12):1360-1541" -

18686259 Alcohol (Alcohol)  
Alcohol;Lysergide;Etizolam;Ketamine;Getacatetide  
Acetate;Herbals\Mitragynine Product Used For Unknown Indication  
Toxicity To Various Agents;Bradycardia;Metabolic  
Acidosis;Hypotension;Brain Herniation Serious Died;Hospitalized  
Male - 30-DEC-2020 Expedited 25 YR Not  
Specified Johnson And Johnson Healthcare Professional Not  
Specified - 23-DEC-2020 30-DEC-2020 US Not

Specified US-JNJF0C-20201249395 - -

18684086 - Herbals\Mitragynine;Diphenhydramine  
 Hydrochloride;Etizolam Product Used For Unknown Indication  
 Toxicity To Various Agents;Completed Suicide Serious Died Male  
 - 30-DEC-2020 Expedited 25 YR Not Specified  
 Johnson And Johnson Healthcare Professional Not Specified  
 - 23-DEC-2020 30-DEC-2020 US Not Specified  
 US-JNJF0C-20201249785 - -

18674050 Duragesic Fentanyl;Herbals\Mitragynine  
 Product Used For Unknown Indication Drug Abuse;Toxicity To Various  
 Agents Serious Died;Hospitalized Male - 28-DEC-2020  
 Non-Expedited 25 YR Not Specified Johnson And Johnson  
 Healthcare Professional Not Specified - 23-DEC-2020  
 28-DEC-2020 US Not Specified US-JNJF0C-20201246672  
 - -

18667974 Duragesic Fentanyl;Herbals\Mitragynine  
 Product Used For Unknown Indication Toxicity To Various  
 Agents;Drug Abuse Serious Died Male - 28-DEC-2020  
 Non-Expedited 30 YR Not Specified Johnson And Johnson  
 Healthcare Professional Not Specified - 23-DEC-2020  
 28-DEC-2020 US Not Specified US-JNJF0C-20201246704  
 - -

18611246 - Herbals\Mitragynine Procedural Pain  
 Hallucination;Myocardial Infarction;Delusion;Dependence;Adulterated  
 Product;Drug Withdrawal Syndrome;Dyspnoea;Loss Of Consciousness;Tremor  
 Serious Hospitalized Female 16-NOV-2020 14-DEC-2020  
 Direct 47 YR Not Specified Fda-Ctu Consumer  
 Consumer - - 14-DEC-2020 US Not Specified

- - -

18603578 - Herbals\Mitragynine Anxiety;Pain Drug  
 Dependence;Drug Abuser Serious Other Outcomes Male 10-DEC-2020  
 10-DEC-2020 Direct 37 YR Not Specified Fda-Ctu  
 Consumer Consumer - - 10-DEC-2020 US  
 Not Specified - - -

18595363 - Herbals\Mitragynine Substance Use  
 Insomnia;Drug Dependence;Drug Withdrawal Syndrome;Toxicity To Various  
 Agents;Abnormal Loss Of Weight Serious Other Outcomes Male 04-  
 DEC-2020 09-DEC-2020 Direct 39 YR 54.9 KG Fda-Ctu  
 Healthcare Professional Health Professional - - 09-  
 DEC-2020 US Not Specified - - -

18582334 - Herbals\Mitragynine;Venlafaxine Hydrochloride  
 - Hyperthermia;Encephalopathy;Serotonin  
 Syndrome;Psychotic Disorder Serious Hospitalized;Life Threatening  
 Female 02-DEC-2020 04-DEC-2020 Direct 77 YR 60 KG  
 Fda-Ctu Healthcare Professional Health Professional -  
 - 04-DEC-2020 US Not Specified - - -

- -

18573518 Fluoxetine Fluoxetine  
 Hydrochloride;Herbals\Mitragynine;Flualprazolam;Gabapentin  
 Product Used For Unknown Indication Toxicity To Various Agents

Serious Died Male 27-MAY-2020 01-DEC-2020 Direct  
 26 YR 84.15 KG Fda-Ctu Consumer Consumer  
 - - 01-DEC-2020 US Not Specified -  
 - -

18469668 Sertraline Sertraline  
 Hydrochloride;Bupropion;Perphenazine;Amitriptyline;Phenethylamine;Herbals\Mitragynine Anxiety;Mood Altered Drug  
 Ineffective;Rhabdomyolysis;Hypertransaminasaemia;Serotonin Syndrome;Metabolic Acidosis Serious Hospitalized Male -  
 25-NOV-2020 Expedited 20 YR Not Specified Teva  
 Healthcare Professional Not Specified - 17-NOV-2020  
 05-NOV-2020 US Not Specified US-TEVA-2020-US-1843957 "Mantilla B, Vega MV, Solis X, Makram J, Mallah H, Test V. A DANGEROUS DRUG AND HERBAL MIXTURE. Chest 2020;158 (Suppl.) (4):A812 (plus poster)."-  
 18540051 - Herbals\Mitragynine Drug Withdrawal  
 Syndrome "Feeling Abnormal;Nocturnal Dyspnoea;Intentional Self-Injury;Dysarthria;Gait Disturbance;Hallucination, Auditory;Fatigue;Completed Suicide;Irritability;Gun Shot Wound;Hypertension;Overdose;Fine Motor Skill Dysfunction;Aggression;Fear Of Death" Serious Disabled;Life Threatening;Other Outcomes;Died Male 02-OCT-2020 24-NOV-2020  
 Direct 31 YR 103.5 KG Fda-Ctu Consumer  
 Consumer Lexapro - 24-NOV-2020 US Not Specified  
 - - -

18538994 - Herbals\Mitragynine Substance Use  
 Withdrawal Syndrome;Near Death Experience;Euphoric Mood;Drug Dependence Serious Life Threatening;Other Outcomes Male 20-NOV-2020 23-NOV-2020 Direct 35 YR 76.5 KG Fda-Ctu  
 Consumer Consumer - - 23-NOV-2020 US  
 Not Specified - - -

18532204 -  
 Morphine;Gabapentin;Codeine;Herbals\Mitragynine Product Used For Unknown Indication Pulmonary Congestion;Accidental Poisoning;Toxicity To Various Agents Serious Other Outcomes;Died Not Specified - 23-NOV-2020 Expedited Not Specified Not Specified Cipla Healthcare Professional Not Specified  
 Mirtazapine;Clonidine;Cyclobenzaprine;Trazodone;Zolpidem;Sertraline 10-NOV-2020 23-NOV-2020 US Not Specified US-CIPLA LTD.-2020US08728 "Bishop freeman SC, Fox L, Winecker RE, Hudson JS. Death from Poppy Tea Consumption. Journal of Analytical Toxicology. 2020;44:734-740"-  
 18497717 Alcohol (Alcohol) Alcohol;Gabapentin  
 Enacarbil;Herbals\Mitragynine;Diazepam Product Used For Unknown Indication Toxicity To Various Agents;Intentional Product Misuse Serious Died Male 2018 12-NOV-2020 Expedited  
 41 YR Not Specified Arbor Healthcare Professional Not Specified - 02-NOV-2020 12-NOV-2020 US Not Specified "US-ARBOR PHARMACEUTICALS, LLC-US-2020ARB000997"

"Gummin DD, Mowry JB, Spyker DA, Brooks DE, Beuhler MC, Rivers LJ, Hashem HA, Ryan ML. 2018 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 36 Annual Report. Clinical Toxicology. 2019;57 (12):1220-1413" -  
18467255 -

Herbals\Mitragynine;Perphenazine;Phenethylamine;Amitriptyline  
Affective Disorder;Anxiety  
Insomnia;Hypertransaminasaemia;Tachypnoea;Tachycardia;Decreased  
Appetite;Rhabdomyolysis;Cough;Metabolic Acidosis;Serotonin Syndrome  
Serious Other Outcomes;Hospitalized Male - 05-  
NOV-2020 Expedited 20 YR Not Specified Ranbaxy  
Healthcare Professional Not Specified - 21-OCT-2020 05-  
NOV-2020 US Not Specified US-SUN PHARMACEUTICAL  
INDUSTRIES LTD-2020R1-266428 "Mantilla B, Vega MV, Solis X, Makram J, Mallah H, Test V. A Dangerous Drug and Herbal Mixture. Chest. 2020;Oct 18-21:812A" -

18467751 - Herbals\Mitragynine Product Used For  
Unknown Indication Coma Serious Hospitalized Female 04-  
NOV-2020 04-NOV-2020 Direct 50 YR Not Specified Fda-  
Ctu Consumer Consumer - - 04-NOV-2020  
US Not Specified - - -

18447155 - Herbals\Mitragynine - Withdrawal  
Syndrome;Insomnia;Product Complaint;Drug Dependence Serious Other  
Outcomes;Disabled Male 01-SEP-2020 30-OCT-2020 Direct  
45 YR 90 KG Fda-Ctu Consumer Consumer -  
- 30-OCT-2020 US Not Specified - -  
-

18435485 - Herbals\Mitragynine Pain In Extremity  
Herbal Toxicity Serious Died Male 23-AUG-2020 28-  
OCT-2020 Direct 42 YR 85.05 KG Fda-Ctu Consumer  
Consumer Clozaril - 28-OCT-2020 US  
Not Specified - - -

18377802 Adderall Xr Amphetamine Aspartate\Amphetamine  
Sulfate\Dextroamphetamine Saccharate\Dextroamphetamine  
Sulfate;Herbals\Mitragynine Depression;Insomnia;Product Used For  
Unknown Indication Posterior Reversible Encephalopathy Syndrome  
Serious Other Outcomes Male - 18-OCT-2020  
Expedited 22 YR Not Specified Shire Healthcare  
Professional Not Specified

Acetaminophen;Dextroamphetamine;Cannabis Sativa Subsp. Indica  
Top;Nicardipine;Quetiapine;Fluoxetine 13-OCT-2020 13-OCT-2020  
US Not Specified US-SHIRE-US202033153 - -

18392125 - Herbals\Mitragynine - Drug  
Dependence Serious Disabled Male 10-OCT-2020 16-  
OCT-2020 Direct 56 YR 87.75 KG Fda-Ctu Consumer  
Consumer - - 16-OCT-2020 US Not  
Specified - - -

18386066 - Herbals\Mitragynine - Withdrawal  
Syndrome;Paranoia;Depression;Completed Suicide Serious Died Male  
05-SEP-2020 14-OCT-2020 Direct 36 YR 76.5 KG Fda-

Ctu Consumer Consumer Antihistamines Nos -  
 14-OCT-2020 US Not Specified - - -  
 18348131 - Herbals\Mitragynine - Movement  
 Disorder;Product Use Issue;Dizziness;Vomiting;Malaise;Hyperhidrosis  
 Serious Hospitalized Female 05-OCT-2020 05-OCT-2020  
 Direct 36 YR Not Specified Fda-Ctu Consumer  
 Consumer Prozac - 05-OCT-2020 US Not Specified  
 - - -

18280433 Alcohol (Alcohol)  
 Alcohol;Acetaminophen;Herbals\Mitragynine Asthenia;Product Used  
 For Unknown Indication Liver Transplant;Acute Hepatic Failure  
 Serious Other Outcomes;Hospitalized Not Specified - 18-  
 SEP-2020 Expedited Not Specified Not Specified Apotex  
 Healthcare Professional Not Specified - 09-SEP-2020  
 18-SEP-2020 CA Not Specified CA-APOTEX-2020AP017853  
 - -

16099193 -  
 Herbals\Mitragynine;Acetaminophen\Methocarbamol;Albuterol;Ranitidine;L  
 oratadine;Citalopram;Diphenhydramine;Valacyclovir Hydrochloride -  
 Drug Withdrawal Syndrome Neonatal;Foetal Exposure During  
 Pregnancy Serious Other Outcomes;Hospitalized Female -  
 14-SEP-2020 Expedited Not Specified 3.68 KG Bayer  
 Healthcare Professional Not Specified - 07-SEP-2020  
 21-MAR-2019 CA Not Specified CA-BAYER-2019-054327  
 "Murthy P, Clark D. An unusual cause for neonatal abstinence  
 syndrome. Paediatrics and Child Health (Canada). 2019;24:1:12-14"  
 -

18241216 - Naltrexone;Herbals\Mitragynine Pain  
 Abdominal Pain Upper;Restlessness;Chills;Drug Withdrawal Syndrome;Drug  
 Interaction;Rhinorrhoea;Hyperhidrosis;Dyspnoea;Nausea;Muscle  
 Spasms;Mental Impairment Serious Life Threatening Female  
 20-AUG-2020 05-SEP-2020 Direct 41 YR 60.75 KG  
 Fda-Ctu Consumer Consumer Vitamin  
 B6;Herbals\Turmeric;Ativan;Multi-Vitamin - 05-SEP-2020  
 US Not Specified - - -

18231742 - Herbals\Mitragynine Alcohol Withdrawal  
 Syndrome Drug Dependence;Family Stress Serious Disabled  
 Female 18-AUG-2020 03-SEP-2020 Direct 29 YR 48.15  
 KG Fda-Ctu Consumer Consumer - - 03-  
 SEP-2020 US Not Specified - - -

18091085 - Herbals\Mitragynine Analgesic Therapy  
 Sleep Disorder;Myalgia;Vomiting;Dependence;Decreased  
 Appetite;Mood Swings;Cognitive Disorder Serious Disabled Male  
 29-JUL-2020 29-JUL-2020 Direct 23 YR 65.25 KG  
 Fda-Ctu Consumer Consumer - - 29-  
 JUL-2020 US Not Specified - - -

17939201 Oxycontin;Lyrica  
 Pregabalin;Oxycodone;Neomycin;Baclofen;Duloxetine  
 Hydrochloride;Oxycodone  
 Hydrochloride;Ibuprofen;Lidocaine;Herbals\Mitragynine Product Used

For Unknown Indication Drug Dependence;Toxicity To Various Agents  
 Serious Died;Other Outcomes Male - 27-JUL-2020  
 Expedited Not Specified Not Specified Lupin  
 Consumer Not Specified - 13-JUL-2020 24-JUN-2020  
 US Not Specified US-HORMOSAN PHARMA GMBH-2020-02887  
 - -  
 16458096 Fluoxetine;Amlodipine Fluoxetine  
 Hydrochloride;Amlodipine Besylate;Trimipramine;Sildenafil;Herbals\Mitragynine;Bentiamine\Bucetin\Caffeine\Ethenzamide;Diphenhydramine Product Used For Unknown  
 Indication Toxicity To Various Agents;Pneumonia;Pulmonary Oedema;Drug Abuse Serious Other Outcomes;Died Male -  
 18-JUL-2020 Expedited 56 YR Not Specified  
 Novartis Healthcare Professional Not Specified - 15-JUL-2020 20-JUN-2019 DE Not Specified  
 PHHY2019DE139906 "Fels H, Lottner-Nau S, Sax T, Roider G, Graw M, Auwarter V et al.. Postmortem concentrations of the synthetic opioid U-47700 in 26 fatalities associated with the drug. FORENSIC SCI. INT.. 2019"  
 18011399 Alcohol (Alcohol)  
 Alcohol;Gabapentin;Diazepam;Herbals\Mitragynine Product Used For Unknown Indication Intentional Product Misuse Serious Died  
 Male - 12-JUL-2020 Expedited 41 YR Not Specified  
 Specified Aurobindo Healthcare Professional Not Specified - 30-JUN-2020 12-JUL-2020 US Not Specified  
 US-AUROBINDO-AUR-APL-2020-033385 "Gummin DD, Spyker DA, Brooks DE, Beuhler MC, Mowry JB, Rivers LJ et al.. 2018 Annual Report of the American Association of Poison Control Centers National Poison Data System: 36th Annual Report. Clinical Toxicology. 2019;57(12):1220-1413"  
 -  
 18003648 Sertraline Sertraline  
 Hydrochloride;Herbals\Mitragynine Product Used For Unknown  
 Indication Respiratory Arrest;Cardiac Arrest;Drug Abuse  
 Serious Other Outcomes;Died;Hospitalized Male - 10-JUL-2020  
 Expedited 36 YR Not Specified Aurobindo  
 Healthcare Professional Not Specified - 30-JUN-2020  
 10-JUL-2020 US Not Specified US-AUROBINDO-AUR-  
 APL-2020-033359 "Gummin DD, Spyker DA, Brooks DE, Beuhler MC, Mowry JB, Rivers LJ et al.. 2018 Annual Report of the American Association of Poison Control Centers National Poison Data System (NPDS): 36th Annual Report. Clinical Toxicology. 2019;57(12):1220-1413"  
 18003374 Venlafaxine Venlafaxine  
 Hydrochloride;Herbals\Mitragynine Product Used For Unknown  
 Indication Drug Abuse Serious Hospitalized;Other  
 Outcomes;Died Male - 10-JUL-2020 Expedited 40 YR  
 Not Specified Aurobindo Healthcare Professional Not  
 Specified - 30-JUN-2020 10-JUL-2020 US Not  
 Specified US-AUROBINDO-AUR-APL-2020-033380 "Gummin DD,  
 Spyker DA, Brooks DE, Beuhler MC, Mowry JB, Rivers LJ et al.. 2018 Annual Report of the American Association of Poison Control Centers

National Poison Data System (NPDS): 36th Annual Report. Clinical Toxicology. 2019;57(12):1220-1413" -  
18003300 Heroin;Sertraline Sertraline  
Hydrochloride;Herbals\Mitragynine;Diamorphine;Dextromethorphan;Cocaine ;Bupropion;Chlorpheniramine Product Used For Unknown Indication Completed Suicide;Respiratory Arrest;Cardiac Arrest  
Serious Hospitalized;Other Outcomes;Died Male - 10-  
JUL-2020 Expedited 32 YR Not Specified Aurobindo Healthcare Professional Not Specified - 30-JUN-2020  
10-JUL-2020 US Not Specified US-AUROBINDO-AUR-  
APL-2020-033341 "Gummin DD, Spyker DA, Brooks DE, Beuhler MC, Mowry JB, Rivers LJ et al.. 2018 Annual Report of the American Association of Poison Control Centers National Poison Data System (NPDS): 36th Annual Report.. Clinical Toxicology. 2019;57(12):1220-1413" -  
18005886 - Loperamide;Herbals\Mitragynine Product Used For Unknown Indication Drug Abuse Serious Died;Other Outcomes;Hospitalized Male - 09-JUL-2020 Expedited 21 YR Not Specified Aurobindo Healthcare Professional Not Specified - 30-JUN-2020 09-JUL-2020 US Not Specified US-AUROBINDO-AUR-APL-2020-033157  
"Gummin DD, Mowry JB, Spyker DA, Brooks DE, Beuhler MC, Rivers LJ et al.. 2018 Annual Report of the American Association of Poison Control Centers National Poison Data System (NPDS): 36th Annual Report. Clinical Toxicology. 2019;57(12):1220-1413" -  
17996854 - Loperamide;Herbals\Mitragynine Product Used For Unknown Indication Drug Abuse Serious Died;Other Outcomes Male - 09-JUL-2020 Expedited 22 YR Not Specified Aurobindo Healthcare Professional Not Specified - 30-JUN-2020 09-JUL-2020 US Not Specified US-AUROBINDO-AUR-APL-2020-033158 "Gummin DD, Mowry JB, Spyker DA, Brooks DE, Beuhler MC, Rivers LJ et al.. 2018 Annual Report of the American Association of Poison Control Centers National Poison Data System (NPDS): 36th Annual Report. Clinical Toxicology. 2019;57(12):1220-1413" -  
17996747 -  
Oxycodone;Fentanyl;Mirtazapine;Herbals\Mitragynine Product Used For Unknown Indication Cardiac Arrest;Drug Abuse;Respiratory Arrest Serious Other Outcomes;Died Male - 09-JUL-2020 Expedited 57 YR Not Specified Aurobindo Healthcare Professional Not Specified - 30-JUN-2020 09-JUL-2020 US Not Specified US-AUROBINDO-AUR-  
APL-2020-032587 "Gummin DD, Spyker DA, Brooks DE, Beuhler MC, Mowry JB, Rivers LJ et al.. 2018 Annual Report of the American Association of Poison Control Centers National Poison Data System (NPDS): 36th Annual Report. Clinical Toxicology. 2019;57(12):1220-1413" -  
17948882 - Gabapentin;Herbals\Mitragynine;Clonazepam Product Used For Unknown Indication Fibromyalgia;Streptococcal Infection;Anxiety;Back Pain;Maternal Exposure During Pregnancy Non-Serious Non-Serious Female - 25-JUN-2020 Expedited 29 YR Not Specified

Roche Healthcare Professional Not Specified - 27-  
APR-2019 25-JUN-2020 US Not Specified US-  
ROCHE-2310324 "Davidson L, Rawat M, Stojanovski S, and  
Chandrasekharan P Natural drugs, not so natural effects: Neonatal  
abstinence syndrome secondary to 'kratom'. Journal of Neonatal-  
Perinatal Medicine 2019;12 (1):109-112." -  
17948871 - Herbals\Mitragynine;Gabapentin;Clonazepam  
Product Used For Unknown Indication Foetal Exposure During  
Pregnancy;Small For Dates Baby;Drug Withdrawal Syndrome Neonatal  
Non-Serious Non-Serious Female - 25-JUN-2020  
Expedited Not Specified Not Specified Roche  
Healthcare Professional Not Specified - 27-APR-2019 25-  
JUN-2020 US Not Specified US-  
ROCHE-2313953 "Davidson L, Rawat M, Stojanovski S and  
Chandrasekharan P Natural drugs, not so natural effects: Neonatal  
abstinence syndrome secondary to 'kratom'. Journal of Neonatal-  
Perinatal Medicine 2019;12 (1):109-112." -  
17852150 Zolpidem Zolpidem  
Tartrate;Alprazolam;Herbals\Mitragynine - Toxicity To Various  
Agents;Acute Kidney Injury;Drug Withdrawal Syndrome;Coagulopathy;Acute  
Hepatic Failure;Intentional Overdose Serious Hospitalized;Life  
Threatening Female - 20-JUN-2020 Expedited 36 YR  
Not Specified Teva Healthcare Professional Not Specified  
- 12-JUN-2020 02-JUN-2020 US Not Specified  
US-TEVA-2020-US-1242236 "Fishburn SJ, Mullins ME. Kratom  
(mitragynine speciosa) induced acute liver failure. J-Med-Toxicol  
2020;16(2):143-144 (plus poster) abstr. 094." -  
17895244 Trazodone Trazodone  
Hydrochloride;Bupropion;Herbals\Mitragynine;Desvenlafaxine;Ziprasidone  
;Buspirone Hydrochloride Depression Facial  
Paralysis;Aphasia;Hyperreflexia;Clonus;Serotonin  
Syndrome;Tremor;Dysarthria;Flushing;Drug  
Interaction;Hyperhidrosis;Confusional State Serious Hospitalized  
Male - 15-JUN-2020 Expedited 63 YR Not  
Specified Strides Healthcare Professional Not Specified -  
08-JUN-2020 15-JUN-2020 US Not Specified US-  
STRIDES ARCOLAB LIMITED-2020SP007014 "Eudaley ST, Hamilton LA. Case  
report: Successful treatment of suspected kratominduced serotonin  
syndrome. JACCP Journal of the American College of Clinical Pharmacy.  
2020;3(1):347" -  
17878785 Venlafaxine Venlafaxine  
Hydrochloride;Herbals\Mitragynine Product Used For Unknown  
Indication Drug Abuse Serious Died Not Specified -  
10-JUN-2020 Expedited Not Specified Not Specified  
Zydus Pharm Healthcare Professional Not Specified -  
18-FEB-2020 10-JUN-2020 US Not Specified US-  
CADILA HEALTHCARE LIMITED-US-ZYDUS-048140 "Gummin DD, Mowry JB,  
Spyker DA, Brooks DE, Beuhler MC, Rivers LJ, et al.. 2018 Annual  
report of the american association of poison control centers' national  
poison data system (npds): 36th annual report.. Clinical Toxicology.

2019;57(12:1220-1413" -  
17869984 Zolpidem Zolpidem  
Tartrate;Herbals\Mitragynine;Alprazolam Product Used For Unknown  
Indication Coagulopathy;Toxicity To Various Agents;Acute Kidney  
Injury;Intentional Overdose;Acute Hepatic Failure Serious Other  
Outcomes;Hospitalized Female - 08-JUN-2020 Expedited  
36 YR Not Specified Aurobindo Healthcare  
Professional Not Specified - 25-MAY-2020 08-JUN-2020  
US Not Specified US-AUROBINDO-AUR-APL-2020-026983  
"Fishburn SJ, Mullins ME.. Kratom (mitragynine speciosa)  
induced acute liver failure.. J-Med-Toxicol.. 2020;16(2):143-144"  
-  
17856606 - Naloxone Hydrochloride;Herbals\Mitragynine  
Drug Dependence;Overdose Hypokalaemia;Electrocardiogram  
Qt Prolonged;Electrocardiogram St Segment Abnormal Serious  
Hospitalized Male - 03-JUN-2020 Expedited 17 YR  
Not Specified Emergent Biosolutions Healthcare  
Professional Not Specified - 20-MAY-2020 03-JUN-2020  
US Not Specified "US-EMERGENT BIOSOLUTIONS,-20000366LT"  
"Baumgartner K.T, Mullins M.E. A case of Kratom poisoning  
causing cardiotoxicity. J. Med. Toxicol. 2020;16(2):165-6" -  
17852355 Zolpidem Zolpidem  
Tartrate;Herbals\Mitragynine;Alprazolam Product Used For Unknown  
Indication Coagulopathy;Hepatic Enzyme Increased;Acute Kidney  
Injury;Intentional Overdose Serious Hospitalized Female -  
03-JUN-2020 Expedited 36 YR Not Specified  
Ranbaxy Healthcare Professional Not Specified - 20-MAY-2020  
03-JUN-2020 US Not Specified US-SUN PHARMACEUTICAL  
INDUSTRIES LTD-2020R1-248876 "Fishburn SJ, Mullins ME. Kratom  
(mitragynine speciosa) induced acute liver failure. J Med Toxicol.  
2020;16(2):143-144" -  
17846339 Zolpidem Zolpidem  
Tartrate;Herbals\Mitragynine;Alprazolam Product Used For Unknown  
Indication Acute Kidney Injury;Toxicity To Various  
Agents;Intentional Overdose;Coagulopathy;Acute Hepatic Failure  
Serious Hospitalized Female - 01-JUN-2020 Expedited  
36 YR Not Specified Strides Healthcare Professional Not  
Specified - 25-MAY-2020 01-JUN-2020 US Not  
Specified US-STRIDES ARCOLAB LIMITED-2020SP006500 "Fishburn SJ,  
Mullins ME.. Kratom (mitragynine speciosa) induced acute liver  
failure.. Journal of Medical Toxicology. 2020;16(2):143-144" -  
17845528 Zolpidem Zolpidem  
Tartrate;Alprazolam;Herbals\Mitragynine Product Used For Unknown  
Indication Coagulopathy;Acute Kidney Injury;Intentional  
Overdose;Hepatic Enzyme Increased Serious Hospitalized;Other  
Outcomes;Life Threatening Female - 01-JUN-2020  
Expedited 36 YR Not Specified Lupin Healthcare  
Professional Not Specified - 20-MAY-2020 01-JUN-2020  
US Not Specified US-LUPIN PHARMACEUTICALS  
INC.-2020-02533 "Fishburn SJ, Mullins ME. Kratom (Mitragynine

speciosa) Induced Acute Liver Failure. Journal of Medical Toxicology. 2020;16:143-144" -

17835102 Zolpidem Zolpidem Tartrate;Herbals\Mitragynine;Alprazolam Product Used For Unknown Indication Toxicity To Various Agents;Coagulopathy;Acute Kidney Injury;Intentional Overdose;Acute Hepatic Failure Serious Hospitalized;Life Threatening Female - 28-MAY-2020 Expedited 36 YR Not Specified Mylan Healthcare Professional Not Specified - 20-MAY-2020 28-MAY-2020 US Not Specified US- MYLANLABS-2020M1052100 "Fishburn SJ, Mullins ME. Kratom (mitragynine speciosa) induced acute liver failure. J-Med-Toxicol 2020;16(2):143-144 (plus poster) abstr. 094." -

17827249 - Zolpidem Tartrate;Alprazolam;Herbals\Mitragynine Overdose Hepatic Enzyme Increased;Drug Withdrawal Syndrome;Intentional Overdose;Coagulopathy;Acute Kidney Injury Serious Hospitalized;Other Outcomes Female - 27-MAY-2020 Expedited 36 YR Not Specified Sanofi Aventis Healthcare Professional Not Specified - 19-MAY-2020 27-MAY-2020 US Not Specified US-SA-2020SA130645 "Fishburn S.J., Mullins M.E.. Kratom (mitragynine speciosa) induced acute liver failure. J Med Toxicol.. 2020;16(2):143-144" -

17823882 Zolpidem Alprazolam;Zolpidem Tartrate;Herbals\Mitragynine Product Used For Unknown Indication Hepatic Enzyme Increased;Acute Kidney Injury;Intentional Overdose;Coagulopathy Serious Hospitalized Female - 26-MAY-2020 Expedited 36 YR Not Specified Torrent Healthcare Professional Not Specified - 19-MAY-2020 26-MAY-2020 US Not Specified US-TORRENT-00010235 -

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17489705 Valtrex Valacyclovir Hydrochloride;Diphenhydramine;Albuterol;Acetaminophen;Citalopram;Loratadine;Methocarbamol;Ranitidine;Herbals\Mitragynine Product Used For Unknown Indication Foetal Exposure During Pregnancy;Drug Withdrawal Syndrome Neonatal Serious Hospitalized;Other Outcomes Female - 26-MAY-2020 Expedited Not Specified 3 KG Teva Healthcare Professional Not Specified - 21-MAY-2020 03-MAR-2020 CA Not Specified CA- TEVA-2020-CA-1192120 - -

17823488 - Herbals\Mitragynine - Product Contamination Physical;Poisoning;Visual Impairment;Chest Pain;Product Contamination Serious Other Outcomes Male 25-MAY-2020 25-MAY-2020 Direct 55 YR 78.75 KG Fda-Ctu Consumer Consumer Omeprazole - 25-MAY-2020 US Not Specified - - -

17819090 Zolpidem Alprazolam;Zolpidem Tartrate;Herbals\Mitragynine Product Used For Unknown Indication Intentional Overdose;Coagulopathy;Acute Kidney Injury;Hepatic Enzyme Increased Serious Hospitalized;Other Outcomes Male

- 23-MAY-2020 Expedited 36 YR Not Specified  
 Hikma Healthcare Professional Not Specified - 19-  
 MAY-2020 23-MAY-2020 US Not Specified US-HIKMA  
 PHARMACEUTICALS USA INC.-US-H14001-20-02535 - -  
 16318360 Methadone Methadone  
 Hydrochloride;Oxazepam;Morphine;Herbals\Mitragynine;Bromazepam  
 Product Used For Unknown Indication Pulmonary  
 Oedema;Gastritis;Pancreatitis;Asphyxia;Toxicity To Various Agents;Drug  
 Abuse Serious Died Male - 21-MAY-2020 Expedited  
 36 YR Not Specified Ranbaxy Healthcare Professional Not  
 Specified Cocaine;Heroin 07-MAY-2020 16-MAY-2019 FR  
 Not Specified FR-SUN PHARMACEUTICAL INDUSTRIES  
 LTD-2019R1-208015 "Bourgine J, Garnier Jardin C, Chretien B, Le  
 Boisselier R, Loilier M, Lelong Boulovard V, et al. Fatal intoxication  
 with Kratom: A case report. Fundam Clin Pharmacol. 2019;33 (Suppl.  
 1):72 (PS2-013)" -  
 17808160 - Herbals\Mitragynine Stress Drug  
 Dependence;Irritability;Socioeconomic Precarity;Aggression  
 Serious Other Outcomes;Life Threatening Male 26-MAY-2019 20-  
 MAY-2020 Direct 42 YR 90 KG Fda-Ctu Consumer  
 Consumer - - 20-MAY-2020 US Not Specified  
 - - -  
 17807667 - Herbals\Mitragynine Phytotherapy  
 Seizure Serious Hospitalized Male 10-MAR-2020 20-MAY-2020  
 Direct 30 YR 96.75 KG Fda-Ctu Consumer  
 Consumer - - 20-MAY-2020 US Not Specified  
 - - -  
 17802026 - Herbals\Mitragynine Opiates Intentional  
 Self-Injury;Drug Withdrawal Syndrome Serious Life  
 Threatening;Hospitalized Male 13-MAY-2020 15-MAY-2020  
 Direct 20 YR 52.16 KG Fda-Ctu Consumer Not  
 Specified - - 15-MAY-2020 US Not Specified  
 - - -  
 17791274 - Herbals\Mitragynine Anxiety;Depression  
 Withdrawal Syndrome;Drug Dependence;Self-Injurious Ideation  
 Serious Hospitalized;Life Threatening Male 13-MAY-2020  
 15-MAY-2020 Direct 20 YR 49.5 KG Fda-Ctu Consumer  
 Consumer Zoloft;Melatonin;Claritin;Intuniv -  
 15-MAY-2020 US Not Specified - - -  
 17779878 -  
 Mirtazapine;Caffeine;Herbals\Mitragynine;Citalopram Product Used  
 For Unknown Indication Death;Cardiac Arrest;Respiratory Arrest  
 Serious Other Outcomes;Died Male - 14-MAY-2020  
 Expedited 32 YR Not Specified Aurobindo Healthcare  
 Professional Not Specified - 04-MAY-2020 14-MAY-2020  
 US Not Specified US-AUROBINDO-AUR-APL-2020-023710  
 "Gummin DD, Spyker DA, Brooks DE, Banner W, Mowry JB,  
 Osterthaler KM. 2017 Annual Report of the American Association of  
 Poison Control Centers' National Poison Data System (NPDS): 35th  
 Annual Report.. CLINICAL TOXICOLOGY. 2018;56(12):1213-1415" -

17779112 Heroin Diamorphine;Oxycodone;Herbals\Mitragynine Product Used For Unknown Indication Drug Abuse  
Serious Other Outcomes;Died Male - 14-MAY-2020  
Expedited 44 YR Not Specified Aurobindo Healthcare  
Professional Not Specified - 04-MAY-2020 14-MAY-2020  
US Not Specified US-AUROBINDO-AUR-APL-2020-023779  
"Gummin DD, Mowry JB, Spyker DA, Brooks DE, Osterthaler KM, Banner W.. 2017 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 35th Annual Report.. CLINICAL TOXICOLOGY. 2018;56(12):1213-1415" -  
17766377 - Herbals\Mitragynine Drug Withdrawal  
Syndrome Cardiac Arrest;Seizure Serious Died Male 08-  
MAY-2020 11-MAY-2020 Direct 25 YR 67.5 KG Fda-Ctu  
Healthcare Professional Health Professional - - 11-  
MAY-2020 US Not Specified - - -  
17765206 - Herbals\Mitragynine Inflammation;Pain  
Withdrawal Syndrome;Drug Dependence;Anxiety;Condition  
Aggravated;Partner Stress;Product Complaint;Unevaluable Event;Loss Of  
Libido;Hypertension;Decreased Appetite;Dehydration;Weight Decreased  
Serious Disabled Male 08-MAY-2020 09-MAY-2020  
Direct 39 YR 69.75 KG Fda-Ctu Consumer  
Consumer Vitamin D;Melatonin - 09-MAY-2020 US  
Y - - -  
17740188 - Herbals\Mitragynine - Torsade De  
Pointes;Cardiac Arrest Serious Life Threatening Male -  
03-MAY-2020 Direct Not Specified Not Specified Fda-  
Ctu Healthcare Professional Health Professional - -  
03-MAY-2020 US Not Specified - - -  
17717542 Prozac Fluoxetine Hydrochloride;Herbals\Mitragynine  
Antidepressant Therapy Suicide Attempt;Hanging;Drug  
Withdrawal Syndrome;Psychotic Disorder Serious Hospitalized;Life  
Threatening Male 21-FEB-2020 27-APR-2020 Direct 20 YR  
74.25 KG Fda-Ctu Consumer Consumer -  
- 27-APR-2020 US Y - - -  
17713029 - Herbals\Mitragynine Depression;Fatigue  
Depression;Compulsive Shopping;Drug Withdrawal  
Syndrome;Insomnia;Irritability;Restless Legs Syndrome;Morbid  
Thoughts;Drug Dependence Serious Other Outcomes Female 22-  
APR-2020 27-APR-2020 Direct 49 YR 63 KG Fda-Ctu  
Consumer Consumer Ibuprofen;Probiotics  
Nos;Zoloft;Klonopin;Acetylcysteine - 27-APR-2020 US  
Not Specified - - -  
17670057 - Herbals\Mitragynine Anxiety  
Dependence;Product Complaint Serious Other Outcomes Male 01-  
JAN-2019 15-APR-2020 Direct 34 YR Not Specified Fda-  
Ctu Consumer Consumer Albuterol - 15-  
APR-2020 US Y - - -  
17539695 Latuda Lurasidone Hydrochloride;Herbals\Mitragynine  
Extrapyramidal Disorder;Mania Off Label Use;Heart Rate  
Increased;Anxiety;Feeling Abnormal Non-Serious Non-Serious

Male - 27-MAR-2020 Non-Expedited 24 YR Not Specified  
 Specified Sunovion Healthcare Professional Not Specified  
 Cogentin 18-MAR-2020 13-MAR-2020 US Not Specified  
 Specified US-SUNOVION-2020SUN000782 - -  
 17575493 - Herbals\Mitragynine Pain Unresponsive  
 To Stimuli;Suicide Attempt;Aggression Serious Other  
 Outcomes;Hospitalized Male 21-JUN-2019 23-MAR-2020 Direct  
 26 YR 85.5 KG Fda-Ctu Consumer Consumer Celexa  
 - 23-MAR-2020 US Not Specified - -  
 -  
 17575488 - Herbals\Mitragynine Back Pain Brain  
 Stem Stroke Serious Died Male 06-FEB-2020 23-MAR-2020  
 Direct 13 DAY 78.75 KG Fda-Ctu Consumer  
 Consumer Unspecified Ingredient - 23-MAR-2020 US  
 Not Specified - - -  
 17538320 Kava Piper Methysticum Root;Herbals\Mitragynine  
 Anxiety Psychomotor Skills Impaired;Speech Disorder;Movement  
 Disorder;Impaired Work Ability;Quality Of Life Decreased;Weight  
 Decreased Serious Other Outcomes;Hospitalized Female 04-  
 MAR-2020 13-MAR-2020 Direct 37 YR 55.35 KG Fda-  
 Ctu Consumer Consumer Ativan;Probiotics Nos;Pristiq  
 Extended-Release - 13-MAR-2020 US Not Specified  
 - - -  
 17490986 "Butalbital, Acetaminophen, And Caffeine;Heroin"  
 Diamorphine;Acetaminophen\Butalbital\Caffeine;Diazepam;Hydrocodone;Amp  
 hetamine;Oxycodone;Herbals\Mitragynine Product Used For Unknown  
 Indication Toxicity To Various Agents Serious Other Outcomes  
 Not Specified - 03-MAR-2020 Expedited Not Specified  
 Specified Not Specified Mayne Pharma Healthcare  
 Professional Not Specified - 19-FEB-2020 03-MAR-2020  
 US Not Specified US-MAYNE PHARMA-2020MYN000107 -  
 -  
 17489713 Valacyclovir Methocarbamol;Valacyclovir  
 Hydrochloride;Ranitidine;Acetaminophen;Loratadine;Citalopram;Albuterol  
 ;Diphenhydramine;Herbals\Mitragynine Product Used For Unknown  
 Indication Foetal Exposure During Pregnancy;Drug Withdrawal  
 Syndrome Neonatal Serious Other Outcomes;Hospitalized Female  
 - 03-MAR-2020 Expedited Not Specified 3 KG  
 Teva Consumer Not Specified - 25-FEB-2020  
 03-MAR-2020 CA Not Specified CA-TEVA-2020-  
 CA-1192110 - -  
 17468080 - Herbals\Mitragynine  
 Anxiety;Depression;Insomnia Withdrawal Syndrome;Death;Product  
 Quality Issue Serious Died Male 01-JAN-2016 25-FEB-2020  
 Direct 25 YR 69.75 KG Fda-Ctu Consumer  
 Consumer - - 25-FEB-2020 US Not Specified  
 - - -  
 17456139 Venlafaxine Venlafaxine  
 Hydrochloride;Herbals\Mitragynine Product Used For Unknown

Indication Toxicity To Various Agents;Drug Abuse Serious  
Died;Hospitalized Male - 25-FEB-2020 Expedited  
40 YR Not Specified Torrent Healthcare Professional Not  
Specified - 18-FEB-2020 25-FEB-2020 US Not  
Specified US-TORRENT-00009933 - -  
17417214 - Herbals\Mitragynine Pain  
Vomiting;Nausea Serious Other Outcomes Female 14-JUL-2019 14-  
FEB-2020 Direct 62 YR Not Specified Fda-Ctu Healthcare  
Professional Health Professional - - 14-FEB-2020  
US Not Specified - - -  
17413340 Heroin  
Hydrocodone;Butalbital;Diamorphine;Diazepam;Herbals\Mitragynine;Amphet-  
amine Product Used For Unknown Indication Toxicity To Various  
Agents Serious Died Male - 13-FEB-2020 Expedited  
52 YR Not Specified Mylan Healthcare Professional Not  
Specified - 04-FEB-2020 13-FEB-2020 US Not  
Specified US-MYLANLABS-2020M1016392 - -  
17406570 - Herbals\Mitragynine Pain;Routine Health  
Maintenance Anxiety;Panic Attack;Irritability Serious  
Hospitalized;Other Outcomes Male 09-FEB-2020 11-FEB-2020  
Direct 57 YR 83.25 KG Fda-Ctu Consumer  
Consumer  
Irbesartan;Coreg;Calcium;Lasix;Iron;Ibuprofen;Tylenol;Lorazepam;Vitami-  
n D;Sodium Bicarbonate;Vitamins;Magnesium - 11-FEB-2020  
US Not Specified - - -  
17404248 - Alcohol;Unspecified  
Ingredient;Herbals\Mitragynine;Gabapentin;Diazepam Product Used  
For Unknown Indication Intentional Product Misuse Serious Died  
Male 2018 11-FEB-2020 Expedited 41 YR Not  
Specified Endo Healthcare Professional Not Specified -  
14-JAN-2020 11-FEB-2020 US Not Specified US-  
ENDO PHARMACEUTICALS INC-2020-001211 "Gummin DD, Mowry JB, Spyker  
DA, Brooks DE, Beuhler MC, Rivers LJ, et al.. 2018 Annual Report of  
the American Association of Poison Control Centers' National Poison  
Data System (NPDS): 36th Annual Report. Clinical Toxicology.  
2019;57(12):1220-1413" -  
17401864 - Herbals\Mitragynine;Oxycodone  
Hydrochloride;Fentanyl Product Used For Unknown Indication Drug  
Abuse;Cardio-Respiratory Arrest Serious Died Male 2018 11-  
FEB-2020 Expedited 57 YR Not Specified Endo  
Healthcare Professional Not Specified - 14-JAN-2020 11-  
FEB-2020 US Not Specified US-ENDO PHARMACEUTICALS  
INC-2020-000677 "Gummin DD, Mowry JB, Spyker DA, Brooks DE, Beuhler  
MC, Rivers LJ, et al.. 2018 Annual Report of the American Association  
of Poison Control Centers' National Poison Data System (NPDS): 36th  
Annual Report. Clinical Toxicology. 2019;57(12):1220-1413" -  
17396453 -  
Cyclobenzaprine;Doxylamine;Herbals\Mitragynine;Alprazolam  
Anxiety;Obsessive-Compulsive Disorder;Sleep Disorder Accidental  
Overdose;Seizure;Influenza;Anxiety Serious Died;Hospitalized

Male 26-JUL-2018 07-FEB-2020 Direct 27 YR 72 KG  
 Fda-Ctu Consumer Consumer Xanax;Melatonin -  
 07-FEB-2020 US Not Specified - - -

17395799 - Herbals\Mitragynine Anxiety;Drug  
 Dependence Cardio-Respiratory Arrest;Withdrawal Of Life  
 Support;Seizure Serious Died;Hospitalized Male 25-JAN-2020  
 07-FEB-2020 Direct 39 YR 85.5 KG Fda-Ctu Consumer  
 Consumer - - 07-FEB-2020 US Not  
 Specified - - -

17375186 - Bupropion;Phentermine;Herbals\Mitragynine  
 Product Used For Unknown Indication Death Serious Died  
 Female - 06-FEB-2020 Expedited 40 YR Not  
 Specified Alvogen Healthcare Professional Not Specified -  
 22-JAN-2020 06-FEB-2020 US Not Specified US-  
 ALVOGEN-2020-ALVOGEN-107509 "Gummin DD, Mowry JB, Spyker DA,  
 Brooks DE, Beuhler MC, Rivers LJ, et al. 2018 Annual Report of the  
 American Association of Poison Control Centers' National Poison Data  
 System (NPDS): 36th Annual Report. Clin Toxicol (Phila). 2019  
 Dec;57(12):1220-1413." -

17370294 Sertraline Sertraline  
 Hydrochloride;Cocaine;Diamorphine;Bupropion;Herbals\Mitragynine;Dextro-  
 methorphan;Chlorpheniramine Maleate Suicide Attempt Completed  
 Suicide Serious Died;Hospitalized Male - 05-FEB-2020  
 Expedited 32 YR Not Specified Alvogen Healthcare  
 Professional Not Specified - 22-JAN-2020 05-FEB-2020  
 US Not Specified US-ALVOGEN-2020-  
 ALVOGEN-103748 "Gummin DD, Mowry JB, Spyker DA, Brooks DE, Beuhler  
 MC, Rivers LJ, et al. 2018 Annual Report of the American Association  
 of Poison Control Centers' National Poison Data System (NPDS): 36th  
 Annual Report. Clin Toxicol (Phila). 2019 Dec;57(12):1220-1413." -

17375069 - Herbals\Mitragynine Alcoholism Drug  
 Dependence Serious Disabled Male 02-DEC-2019 04-  
 FEB-2020 Direct 38 YR Not Specified Fda-Ctu Consumer  
 Consumer Zoloft - 04-FEB-2020 US Not  
 Specified - - -

17335034 Venlafaxine Venlafaxine  
 Hydrochloride;Herbals\Mitragynine Product Used For Unknown  
 Indication Drug Abuse Serious Died Male - 28-  
 JAN-2020 Expedited 40 YR Not Specified Bausch And  
 Lomb Healthcare Professional Not Specified - 17-JAN-2020  
 28-JAN-2020 US Not Specified US-BAUSCH-  
 BL-2020-001913 "Gummin D, Mowry J, Spyker D, Brooks D, Beuhler M,  
 Rivers L, Hashem H, Ryan M. 2018 Annual Report of the American  
 Association of Poison Control Centers' National Poison Data System  
 (NPDS): 36th Annual Report. Clinical Toxicology. 2019 NOV  
 21;57(12):1220-1413. doi:10.1080/15563650.2019.1677022" -

17323469 - Herbals\Mitragynine - Dyspnoea;Chest  
 Discomfort;Abdominal Pain Upper;Influenza Like Illness Serious Other  
 Outcomes Female 02-JAN-2018 24-JAN-2020 Direct 58 YR

74.84 KG Fda-Ctu Not Specified Not Specified -  
- 24-JAN-2020 US Not Specified - -  
-

17282735 Heroin Diamorphine;Herbals\Mitragynine;Sertraline Hydrochloride;Bupropion;Cocaine;Codeine;Chlorpheniramine;Dextromethorphan Hydrobromide - Respiratory Arrest;Completed Suicide;Cardiac Arrest Serious Died;Hospitalized Male 2018 24-JAN-2020 Expedited 32 YR Not Specified Pfizer Healthcare Professional Not Specified - 11-JAN-2020 17-JAN-2020 US Not Specified US-PFIZER

INC-2020016502 "Gummin, D.. 2018 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 36th Annual Report. Clinical Toxicology. 2019;57(12):1220-1413" -

17332257 - Herbals\Mitragynine Anxiety Tremor;Anxiety;Muscle Spasms;Somnolence Serious Disabled Male 14-JAN-2020 23-JAN-2020 Direct 44 YR 81 KG Fda-Ctu Consumer Consumer - - 23-JAN-2020 US Not Specified - - -

17332248 - Herbals\Mitragynine;Lisinopril Hypertension Angioedema Serious Hospitalized Male 23-JAN-2020 23-JAN-2020 Direct 46 YR 84.8 KG Fda-Ctu Healthcare Professional Health Professional - - 23-JAN-2020 US Not Specified - - -

17310367 Heroin;Goprelto;Sertraline Sertraline Hydrochloride;Cocaine Hydrochloride;Chlorpheniramine;Herbals\Mitragynine;Bupropion;Diamorphine;Dextromethorphan Product Used For Unknown Indication Completed Suicide;Respiratory Arrest;Cardiac Arrest Serious Died Male 2018 23-JAN-2020 Expedited 32 YR Not Specified Genus Lifesciences Healthcare Professional Not Specified - 13-JAN-2020 23-JAN-2020 US Not Specified US-GENUS\_LIFESCIENCES-USA-POI0580202000150 Gummin D. 2018 Annual Report of the American Association of Poison Control Centers National Poison Data System (NPDS): 36th Annual Report. Clinical Toxicology. 2019;57(12):1220-1413. -

17277794 - Diazepam;Gabapentin;Herbals\Mitragynine - Intentional Product Misuse Serious Died Male 2018 23-JAN-2020 Expedited 41 YR Not Specified Pfizer Healthcare Professional Not Specified - 22-JAN-2020 16-JAN-2020 US Not Specified US-PFIZER

INC-2020015208 "Gummin, D.. 2018 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 36th Annual Report. Clinical Toxicology. 2019;57(12):1220-1413" -

17301302 - Herbals\Mitragynine - Death Serious Died Male 24-DEC-2019 21-JAN-2020 Direct 38 YR 65.7 KG Fda-Ctu Consumer Consumer - 21-JAN-2020 US Not Specified Cannabidiol\Herbals - - -

17286246 -  
Herbals\Mitragynine;Alcohol;Gabapentin;Diazepam Product Used For  
Unknown Indication Intentional Product Misuse Serious Died  
Male - 18-JAN-2020 Expedited 41 YR Not  
Specified Apotex Healthcare Professional Not Specified -  
06-JAN-2020 18-JAN-2020 US Not Specified US-  
APOTEX-2020AP005595 "Gummin DD, MowryJB, Spyker DA, Brooks DE,  
Beuhler MC, Rivers LJ, Hashem HA, Ryan ML. 2018 Annual Report of the  
American Association of Poison Control Centersí National Poison Data  
System (NPDS): 36th Annual Report. DOI: 10.1080/15563650.2019.1677022.  
Clinical Toxicology. 2019;57 (12):1220-1413" -

17293120 - Herbals\Mitragynine Anxiety  
Dependence;Product Complaint;Drug Withdrawal Syndrome Serious Other  
Outcomes;Hospitalized Male 13-JAN-2020 17-JAN-2020 Direct  
23 YR 56.25 KG Fda-Ctu Consumer Consumer  
Clonazepam;Vitamin B12 - 17-JAN-2020 US Not  
Specified - - -

17277216 - Sertraline Hydrochloride;Herbals\Mitragynine  
- Cardiac Arrest;Drug Abuse;Respiratory Arrest  
Serious Hospitalized;Died Male 2018 16-JAN-2020  
Expedited 36 YR Not Specified Pfizer Healthcare  
Professional Not Specified - 11-JAN-2020 16-JAN-2020  
US Not Specified US-PFIZER  
INC-2020016503 "Gummin, D.. 2018 Annual Report of the American  
Association of Poison Control Centers' National Poison Data System  
(NPDS): 36th Annual Report. Clinical Toxicology. 2019;57  
(12):1220-1413" -

17276448 Sertraline Sertraline  
Hydrochloride;Herbals\Mitragynine Product Used For Unknown  
Indication Cardio-Respiratory Arrest;Drug Abuse Serious Other  
Outcomes;Died;Hospitalized Male 2018 16-JAN-2020  
Expedited 36 YR Not Specified Apotex Healthcare  
Professional Not Specified - 06-JAN-2020 16-JAN-2020  
US Not Specified US-APOTEX-2020AP006348 "Gummin DD,  
MowryJB, Spyker DA, Brooks DE, Beuhler MC, Rivers LJ, Hashem HA, Ryan  
ML. 2018 Annual Report of the American Association of Poison Control  
Centersí National Poison Data System (NPDS): 36th Annual Report. DOI:  
10.1080/15563650.2019.1677022. Clinical Toxicology. 2019;57  
(12):1220-1413" -

17276446 Sertraline;Heroin  
Cocaine;Diamorphine;Dextromethorphan;Bupropion;Sertraline  
Hydrochloride;Herbals\Mitragynine;Chlorpheniramine Product Used  
For Unknown Indication Completed Suicide;Cardio-Respiratory Arrest  
Serious Died;Other Outcomes;Hospitalized Male 2018  
16-JAN-2020 Expedited 32 YR Not Specified Apotex  
Healthcare Professional Not Specified - 06-JAN-2020  
16-JAN-2020 US Not Specified US-APOTEX-2020AP006347  
"Gummin DD, MowryJB, Spyker DA, Brooks DE, Beuhler MC, Rivers  
LJ, Hashem HA, Ryan ML. 2018 Annual Report of the American Association  
of Poison Control Centersí National Poison Data System (NPDS): 36th

Annual Report. DOI: 10.1080/15563650.2019.1677022. Clinical Toxicology. 2019;57 (12):1220-1413" -  
17269189 Heroin;Sertraline Bupropion;Sertraline Hydrochloride;Dextromethorphan;Cocaine;Diamorphine;Chlorpheniramine Maleate;Herbals\Mitragynine - Completed Suicide;Toxicity To Various Agents Serious Hospitalized;Died Male - 14-JAN-2020 Expedited 32 YR Not Specified Bayer Healthcare Professional Not Specified - 02-JAN-2020 14-JAN-2020 US Not Specified US-BAYER-2020-004931 Gummin DD; Mowry JB; Spyker DA; Brooks DE; Beuhler MC; Rivers LJ; Hashem HA; Ryan ML. 2018 Annual Report of the American Association of Poison Control Centers. National Poison Data System (NPDS): 36th Annual Report. Clinical Toxicology. 2019;54:12:1220-1413 -  
17268379 - Herbals\Mitragynine;Fentanyl Product Used For Unknown Indication Drug Abuse Serious Died;Other Outcomes Male - 14-JAN-2020 Non-Expedited 25 YR Not Specified Apotex Healthcare Professional Not Specified - 06-JAN-2020 14-JAN-2020 US Not Specified US-APOTEX-2020AP005256 "Gummin DD, MowryJB, Spyker DA, Brooks DE, Beuhler MC, Rivers LJ, Hashem HA, Ryan ML. 2018 Annual Report of the American Association of Poison Control Centersí National Poison Data System (NPDS): 36th Annual Report. DOI: 10.1080/15563650.2019.1677022. Clinical Toxicology. 2019;57 (12):1220-1413" -  
17267222 - Fentanyl;Herbals\Mitragynine Product Used For Unknown Indication Drug Abuse Serious Died;Other Outcomes Male - 14-JAN-2020 Non-Expedited 33 YR Not Specified Apotex Healthcare Professional Not Specified - 06-JAN-2020 14-JAN-2020 US Not Specified US-APOTEX-2020AP005575 "Gummin DD, MowryJB, Spyker DA, Brooks DE, Beuhler MC, Rivers LJ, Hashem HA, Ryan ML. 2018 Annual Report of the American Association of Poison Control Centersí National Poison Data System (NPDS): 36th Annual Report. DOI: 10.1080/15563650.2019.1677022. Clinical Toxicology. 2019;57 (12):1220-1413" -  
17267041 - Fentanyl;Cocaine;Herbals\Mitragynine Product Used For Unknown Indication Drug Abuse Serious Other Outcomes;Died Male - 14-JAN-2020 Non-Expedited 38 YR Not Specified Apotex Healthcare Professional Not Specified - 06-JAN-2020 14-JAN-2020 US Not Specified US-APOTEX-2020AP005359 "Gummin DD, MowryJB, Spyker DA, Brooks DE, Beuhler MC, Rivers LJ, Hashem HA, Ryan ML. 2018 Annual Report of the American Association of Poison Control Centersí National Poison Data System (NPDS): 36th Annual Report. DOI: 10.1080/15563650.2019.1677022. Clinical Toxicology. 2019;57 (12):1220-1413" -  
17264540 - Bupropion;Herbals\Mitragynine;Phentermine Product Used For Unknown Indication Intentional Product Use Issue Serious Died Female - 13-JAN-2020 Expedited 40 YR Not Specified Apotex Healthcare Professional Not Specified - 06-JAN-2020 13-JAN-2020 US Not Specified US-APOTEX-2020AP006072 "Gummin DD,

MowryJB, Spyker DA, Brooks DE, Beuhler MC, Rivers LJ, Hashem HA, Ryan ML. 2018 Annual Report of the American Association of Poison Control Centersí National Poison Data System (NPDS): 36th Annual Report. DOI: 10.1080/15563650.2019.1677022. Clinical Toxicology. 2019;57(12):1220-1413" -

17264092 Venlafaxine Hcl Venlafaxine Hydrochloride;Herbals\Mitragynine - Drug Abuse Serious Died Male 2018 13-JAN-2020 Expedited 40 YR Not Specified Pfizer Healthcare Professional Not Specified - 11-JAN-2020 13-JAN-2020 US Not Specified US-PFIZER INC-2020013628 "Gummin, D.. 2018 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 36th Annual Report. Clinical Toxicology. 2019;57 (12):1220-1413" -

17236200 - Herbals\Mitragynine Product Used For Unknown Indication Mobility Decreased;Dizziness;Heart Rate Irregular;Dyspnoea Serious Life Threatening;Disabled Female 02-JAN-2020 03-JAN-2020 Direct 26 YR 65.25 KG Fda-Ctu Consumer Consumer Fish Oil;Magnesium;Vitamin D - 03-JAN-2020 US Y - - -

17225354 - Acetaminophen\Methocarbamol;Diphenhydramine;Herbals\Mitragynine;Albuterol Sulfate;Citalopram;Ranitidine;Loratadine;Valacyclovir Hydrochloride - Caesarean Section;Maternal Exposure During Pregnancy Serious Other Outcomes Female - 02-JAN-2020 Expedited 37 YR Not Specified Sanofi Aventis Healthcare Professional Not Specified - 20-DEC-2019 02-JAN-2020 CA Not Specified CA-SA-2019SA354821 - -

17218104 - Herbals\Mitragynine Depression;Pain Joint Injury;Myalgia;Systemic Lupus Erythematosus;Inflammation;Arthralgia;Antinuclear Antibody Positive;Pain Serious Disabled;Other Outcomes Male - 28-DEC-2019 Direct 37 YR 94.5 KG Fda-Ctu Consumer Consumer Vitamins;Minerals - 28-DEC-2019 US Not Specified - - -

17175499 - Herbals\Mitragynine Pain Emergency Care;Depression;Mood Swings;Weight Decreased;Product Complaint;Drug Dependence Serious Disabled Male 01-AUG-2018 19-DEC-2019 Direct 46 YR Not Specified Fda-Ctu Consumer Consumer - - 19-DEC-2019 US Not Specified - - -

17173525 - Herbals\Mitragynine Insomnia Toxicity To Various Agents;Injury Serious Hospitalized Female 03-DEC-2019 18-DEC-2019 Direct 58 YR 85.4 KG Fda-Ctu Healthcare Professional Health Professional - - 18-DEC-2019 US Not Specified - - -

17159096 - Herbals\Mitragynine Product Used For Unknown Indication Delusion;Anxiety Disorder;Anger;Bone Pain;Drug

Dependence;Condition Aggravated;Product Complaint;Crying;Emotional Distress;Bipolar I Disorder;Aggression;Homicidal Ideation;Mania  
 Serious Other Outcomes;Hospitalized;Disabled Female 15-NOV-2019  
 14-DEC-2019 Direct 23 YR 83.25 KG Fda-Ctu  
 Consumer Consumer Trazodone;Senna;Clonidine;Vitamin D3;Topiramate;Melatonin;Lamictal;Suboxone;Seroquel;Stool Softener (Docusate);Ibuprofen;Omeprazole;Claritin - 14-DEC-2019  
 US Not Specified - - -  
 17115142 - Herbals\Mitragynine Depression;Pain  
 Malaise Serious Other Outcomes Female 16-AUG-2019 03-DEC-2019  
 Direct 29 YR 61.2 KG Fda-Ctu Consumer Consumer  
 - - 03-DEC-2019 US Y - -  
 -  
 17049729 - Herbals\Mitragynine - Product  
 Complaint;Drug Dependence Serious Other Outcomes Male 12-  
 NOV-2019 19-NOV-2019 Direct 40 YR 81 KG Fda-Ctu  
 Consumer Consumer - - 19-NOV-2019 US  
 Not Specified - - -  
 17039019 Amlodipine;Fluoxetine Fluoxetine  
 Hydrochloride;Herbals\Mitragynine;Bentiamine\Bucetin\Caffeine\Ethenzamide;Diphenhydramine;Trimipramine;Amlodipine Besylate;Sildenafil Product Used For Unknown Indication Pneumonia;Pulmonary  
 Oedema;Toxicity To Various Agents Serious Other Outcomes;Died  
 Male - 15-NOV-2019 Expedited 56 YR Not  
 Specified Mylan Consumer Not Specified - 12-  
 NOV-2019 15-NOV-2019 DE Not Specified DE-  
 MYLANLABS-2019M1109866 "Fels H, Lottner-Nau S, Sax T, Roider G, Graw M, Auwärter V et. al.. Postmortem concentrations of the synthetic opioid U-47700 in 26 fatalities associated with the drug. Forensic Sci Int.. 2019" -  
 17024940 - Herbals\Mitragynine;Fentanyl Product Used  
 For Unknown Indication Toxicity To Various Agents Non-Serious  
 Non-Serious Female - 13-NOV-2019 Non-Expedited  
 31 YR Not Specified Mylan Healthcare Professional Not  
 Specified - 28-OCT-2019 13-NOV-2019 US Not  
 Specified US-MYLANLABS-2019M1103820 - -  
 17021954 - Herbals\Mitragynine Drug Abuse Drug  
 Dependence;Socioeconomic Precarity;Loss Of Personal Independence In Daily Activities Non-Serious Non-Serious Male 01-  
 NOV-2018 10-NOV-2019 Direct 36 YR 63 KG Fda-Ctu  
 Consumer Consumer Adderall;Tylenol - 10-  
 NOV-2019 US Not Specified - - -  
 17005702 - Herbals\Mitragynine Back Pain Night  
 Sweats;Pruritus;Weight Decreased;Anxiety;Loss Of Personal Independence In Daily Activities;Diarrhoea;Affective  
 Disorder;Insomnia;Depression;Drug Dependence;Dyskinesia;Drug Withdrawal Syndrome;Anger Serious Life Threatening Male  
 05-NOV-2019 05-NOV-2019 Direct 36 YR 63 KG Fda-  
 Ctu Consumer Consumer - - 05-NOV-2019  
 US Not Specified - - -

16997145 - Herbals\Mitragynine Substance Use  
 Tachyphrenia;Drug Dependence;Overdose;Withdrawal Syndrome  
 Serious Hospitalized;Disabled Male - 01-NOV-2019 Direct  
 Not Specified 81 KG Fda-Ctu Consumer Consumer  
 - - 01-NOV-2019 US Not Specified -  
 - -  
 16946302 - Herbals\Mitragynine Anxiety;Pain  
 Insomnia;Stress;Influenza;Depression;Rash;Nausea;Decreased  
 Appetite;Weight Decreased;Weight Increased;Anxiety;Diarrhoea  
 Serious Other Outcomes Female 10-OCT-2019 18-OCT-2019 Direct  
 31 YR 65.25 KG Fda-Ctu Consumer Consumer  
 Omega-3 Fatty Acids - 18-OCT-2019 US Not  
 Specified - - -  
 16934585 - Herbals\Mitragynine - Socioeconomic  
 Precarity;Impaired Reasoning;Loss Of Employment;Anger;Aggression;Drug  
 Dependence Non-Serious Non-Serious Male 01-JUL-2019  
 17-OCT-2019 Direct 60 YR 74.25 KG Fda-Ctu  
 Consumer Consumer - - 17-OCT-2019 US  
 Not Specified - - -  
 16928532 Amlodipine;Fluoxetine Trimipramine;Fluoxetine  
 Hydrochloride;Sildenafil;Amlodipine  
 Besylate;Herbals\Mitragynine;Diphenhydramine Product Used For  
 Unknown Indication Pulmonary Haemorrhage;Toxicity To Various  
 Agents;Pneumonia Aspiration;Pulmonary Oedema Serious Died;Other  
 Outcomes Male - 17-OCT-2019 Expedited 56 YR  
 Not Specified Lupin Healthcare Professional Not Specified  
 - 07-OCT-2019 17-OCT-2019 DE Not Specified  
 DE-LUPIN PHARMACEUTICALS INC.-2019-06639 "Fels H,  
 Lottner-Nau S, Sax T, Roider G, Graw M, Auwarter V et al. Postmortem  
 concentrations of the synthetic opioid U-47700 in 26 fatalities  
 associated with the drug. Forensic Science International.  
 2019;301:E20-E28"  
 16934580 - Herbals\Mitragynine Anxiety;Stress  
 Seizure Serious Died Male 20-AUG-2019 16-OCT-2019 Direct  
 36 YR 72 KG Fda-Ctu Consumer Consumer  
 Zoloft;Librium;Zofran;Lopressor;Lantus;Gabapentin - 16-  
 OCT-2019 US Not Specified - - -  
 16861331 - Herbals\Mitragynine Substance Use  
 Musculoskeletal Disorder;Cardiac Arrest;Headache;Dysstasia  
 Serious Died Male - 23-SEP-2019 Direct 69 YR 170 LB  
 Fda-Ctu Consumer Consumer - - 23-  
 SEP-2019 US Y - - Yes  
 16838587 - Herbals\Mitragynine Anxiety  
 Hyperhidrosis;Intentional Overdose;Depression;Vomiting;Sensitive  
 Skin;Product Contamination Physical;Drug  
 Diversion;Nightmare;Irritability Serious Disabled Not  
 Specified 14-SEP-2019 20-SEP-2019 Direct 38 YR 83.25  
 KG Fda-Ctu Consumer Consumer Melatonin;Lecithin  
 - 20-SEP-2019 US Not Specified - -  
 -

16053365 Propranolol;Buspirone Buspirone  
 Hydrochloride;Mirtazapine;Propranolol  
 Hydrochloride;Gabapentin;Nordazepam;Diazepam;Herbals\Mitragynine  
     Product Used For Unknown Indication Drug  
 Interaction;Unresponsive To Stimuli;Toxicity To Various Agents  
 Serious Died Not Specified 2017 19-SEP-2019 Expedited  
     Not Specified Not Specified Lannett Healthcare  
 Professional Not Specified - 25-FEB-2019 08-MAR-2019  
     US Not Specified "US-LANNETT COMPANY, INC.-  
 US-2019LAN00226" "Gershman K, Timm K, Frank M, Lampi L, Melamed  
 J, Gerona R, et al.. Deaths in Colorado attributed to Kratom. N-Engl-  
 J-Med. 2019;380(1):97-98"  
 16822803 - Herbals\Mitragynine;Device - Drug  
 Dependence Non-Serious Non-Serious Not Specified 01-  
 SEP-2018 18-SEP-2019 Direct Not Specified Not Specified  
     Fda-Ctu Consumer Consumer - - 18-  
 SEP-2019 US Not Specified - - -  
 16767623 - Herbals\Mitragynine Anxiety;Depression  
     Decreased Appetite;Mood  
 Swings;Amnesia;Insomnia;Vomiting;Hallucination;Depression;Muscle  
 Twitching;Psychotic Disorder;Withdrawal Syndrome Non-Serious  
     Non-Serious Male 15-AUG-2019 29-AUG-2019 Direct  
     58 YR 81 KG Fda-Ctu Consumer Consumer -  
     - 29-AUG-2019 US Not Specified - -  
 -  
 16692189 - Herbals\Mitragynine - Confusional  
 State;Hallucination;Agitation;Miosis;Paranoia Serious Other  
 Outcomes;Hospitalized Female 10-AUG-2019 10-AUG-2019 Direct  
     58 YR 116 KG Fda-Ctu Healthcare Professional Health  
 Professional - - 10-AUG-2019 US Not Specified  
 - - -  
 16668064 - Herbals\Mitragynine Anxiolytic Therapy  
     Toxicity To Various Agents;Accidental Death Serious Died  
     Male 08-MAY-2019 04-AUG-2019 Direct 30 YR 85.5  
 KG Fda-Ctu Consumer Consumer - - 04-  
 AUG-2019 US Not Specified - - -  
 16286856 Methadone Herbals\Mitragynine;Oxazepam;Methadone  
 Hydrochloride;Bromazepam;Morphine Sulfate - Toxicity To  
 Various Agents Serious Died Male - 26-JUL-2019  
 Expedited 36 YR Not Specified Pfizer Healthcare  
 Professional Not Specified - 22-JUL-2019 08-MAY-2019  
     FR Not Specified FR-PFIZER  
 INC-2019194321 "Bourgine, J.. Fatal intoxication with Kratom: A case  
 report. Toxicologie Analytique et Clinique. 2019;31 (Suppl 2):S36-S37"  
 -  
 16608035 - Herbals\Mitragynine - Blood Creatine  
 Phosphokinase  
     Increased;Nausea;Vomiting;Hypertransaminasaemia;Abdominal Pain  
 Serious Life Threatening;Hospitalized Female 21-JUN-2019 19-  
 JUL-2019 Direct 27 YR Not Specified Fda-Ctu Healthcare

Professional	Health Professional	-	-	19-JUL-2019
US	Not Specified	-	-	
16597702	-	Herbals\Mitragynine	-	Hepatotoxicity
Serious	Hospitalized	Male	09-JUN-2019	18-JUL-2019
Direct	18 YR	58.5 KG	Fda-Ctu Healthcare Professional	Health
Professional	-	-	18-JUL-2019	US
-	-	-		Not Specified
16565419	-	Herbals\Mitragynine	-	Abdominal
Discomfort;Malaise;Pain;Vomiting			Non-Serious	Non-Serious
Female	18-MAY-2019	12-JUL-2019	Direct	22 YR 51.75
KG	Fda-Ctu Consumer	Consumer	-	- 12-
JUL-2019	US	Not Specified	-	-
16534204	-	Herbals\Mitragynine	Decreased Appetite	
Loss Of Consciousness;Seizure		Serious	Other Outcomes	Male
02-JUL-2019	04-JUL-2019	Direct	37 YR	94.5 KG Fda-
Ctu	Consumer	Consumer	Ibuprofen	- 04-
JUL-2019	US	Not Specified	-	-
16516317	-	Herbals\Mitragynine	-	Toxicity To
Various Agents	Serious	Other Outcomes;Hospitalized;Died		Male
OCT-2018	02-JUL-2019	Direct	37 YR	Not Specified
Fda-Ctu Not Specified	Not Specified	Not Specified	-	- 02-
JUL-2019	US	Not Specified	-	-
16502543	-	Herbals\Mitragynine	-	Death
Serious Died	Female	-	01-JUL-2019	Direct 56 YR Not
Specified	Fda-Ctu	Not Specified	Not Specified	- -
01-JUL-2019	US	Not Specified	-	-
16489051	-	Herbals\Mitragynine	-	Death
Serious Died	Male	08-APR-2019	26-JUN-2019	Direct 22 YR
Not Specified	Fda-Ctu	Not Specified	Not Specified	-
-	26-JUN-2019	US	Not Specified	- -
-				
16480216	-	Herbals\Mitragynine;Dextroamphetamine Sulfate		
Depression;Insomnia;Product Used For Unknown Indication				
Posterior Reversible Encephalopathy Syndrome;Drug Abuse				
Serious Hospitalized	Male	-	26-JUN-2019	Expedited 22 YR
Not Specified	Arbor	Healthcare Professional	Not Specified	
Cannabis Sativa Subsp.	Indica Top;Quetiapine;Fluoxetine 13-			
JUN-2019	26-JUN-2019	US	Not Specified	"US-ARB0R
PHARMACEUTICALS, LLC-US-2019ARB000987"	"Castillo A, Payne JD, Nugent			
K. Posterior reversible leukoencephalopathy syndrome after kratom				
ingestion. BAYLOR UNIV MED CENT PROC. 2017;30(3):355-357"				-
16486428	-	Herbals\Mitragynine	Therapy Cessation	
Vomiting;Anxiety;Toxicity To Various Agents;Abdominal				
Pain;Drug Abuse	Serious Hospitalized	Male	24-JUN-2019	25-
JUN-2019	Direct	30 YR 73.35 KG	Fda-Ctu Healthcare	
Professional	Health Professional	-	-	25-JUN-2019
US	Not Specified	-	-	
16474228	-	Herbals\Mitragynine	Disturbance In	
Attention;Feeling Of Relaxation;Insomnia			Vitamin D	
Decreased;Drug Dependence;Alopecia;Weight Decreased;Blood Test				

Abnormal;Hepatic Function Abnormal      Serious Hospitalized;Life Threatening      Male      01-JUN-2019      25-JUN-2019      Direct      20 YR  
 Threatening      Male      01-JUN-2019      25-JUN-2019      Direct      20 YR  
 58.06 KG      Fda-Ctu Consumer      Consumer      Consumer      -  
 -      25-JUN-2019      US      Not Specified      -      -  
 -  
 16474739      -      Herbals\Mitragynine      Anxiety      Lung  
 Adenocarcinoma      Serious Disabled;Life Threatening      Female      24-  
 MAY-2019      24-JUN-2019      Direct      26 YR      48.6 KG Fda-Ctu  
 Consumer      Consumer      Carbamazepine;Topamax      -      24-  
 JUN-2019      US      Not Specified      -      -  
 16462155      -  
 Nicotine;Herbals\Mitragynine;Carisoprodol;Doxylamine;Dextromethorphan;  
 Caffeine;Hydrocodone;Meprobamate;Etizolam      Product Used For  
 Unknown Indication      Fall;Tachycardia;Confusional  
 State;Dyskinesia;Tremor      Serious Hospitalized      Not Specified      -  
 21-JUN-2019      Expedited      Not Specified      Not Specified  
 Alembic Healthcare Professional      Not Specified      -      07-  
 JUN-2019      21-JUN-2019      US      Not Specified      US-ALEMBIC  
 PHARMACUETICALS LIMITED-2019SCAL000383 "Scoccimarro A, Marino R,  
 Shulman J. A case of etizolam withdrawal syndrome. Clinical  
 Toxicology.. 2019;57 (6):427" -  
 16464326      -      Herbals\Mitragynine      -      Loss Of  
 Consciousness;Depression;Dyspnoea      Serious Other Outcomes;Life  
 Threatening      Female      29-APR-2019      20-JUN-2019      Direct      49 YR  
 73.35 KG      Fda-Ctu Consumer      Consumer  
 Xanax;Aimovig;Lunesta;Lamictal      -      20-JUN-2019      US      Y  
 -      -      -  
 16474745      -      Herbals\Mitragynine      -      Chest  
 Pain;Adulterated Product;Dysgeusia;Nausea;Heart Rate  
 Increased;Agitation;Vomiting      Non-Serious      Non-Serious      Not  
 Specified      09-JUN-2019      14-JUN-2019      Direct      Not Specified  
 58.5 KG Fda-Ctu Consumer      Consumer      -      -  
 14-JUN-2019      US      Not Specified      -      -  
 16430163      -      Herbals\Mitragynine      -      Nausea;Chest  
 Pain;Heart Rate Increased;Agitation;Suspected Product  
 Contamination;Vomiting;Dysgeusia;Anxiety;Adulterated Product      Non-  
 Serious Non-Serious      Male      09-JUN-2019      14-JUN-2019      Direct  
 24 YR      58.5 KG Fda-Ctu Consumer      Consumer      -  
 -      14-JUN-2019      US      Not Specified      -      -  
 -  
 15749102      -      Herbals\Mitragynine;Quetiapine      Product Used  
 For Unknown Indication      Seizure Like Phenomena;Drug  
 Interaction;Toxicity To Various Agents;Hyperthermia;Drug Level  
 Increased;Herbal Interaction      Serious Other Outcomes;Died      Male  
 -      07-JUN-2019      Expedited      27 YR      Not Specified  
 Ranbaxy Healthcare Professional      Not Specified      -      23-  
 MAY-2019      21-DEC-2018      US      Not Specified      US-SUN  
 PHARMACEUTICAL INDUSTRIES LTD-2018R1-194438 Hughes RL. Fatal  
 combination of mitragynine and quetiapine-a case report with  
 discussion of a potential herb-drug interaction. Forensic Sci Med

Pathol. 2019;15(1):110–113 –

16392938 – Herbals\Mitragynine – Acute Myocardial Infarction;Hypertensive Emergency;Ventricular Fibrillation;Coronary Artery Occlusion Serious Hospitalized Male 31-MAY-2019 04-JUN-2019 Direct 44 YR Not Specified Fda-Ctu Healthcare Professional Health Professional – – 04-JUN-2019 US Not Specified – – –

16389981 – Herbals\Mitragynine;Morphine Sulfate Product Used For Unknown Indication Death Serious Died Not Specified – 04-JUN-2019 Expedited Not Specified Not Specified Allergan Healthcare Professional Not Specified – 29-MAY-2019 04-JUN-2019 US Not Specified US-ALLERGAN-1923449US Monte AA. Kratom-Only Deaths In Colorado Are Not Kratom Only. Academic Emergency Medicine. 2019;26(S1):S282 –

16370019 Zolpidem Zolpidem Tartrate;Oxycodone;Topiramate;Herbals\Mitragynine;Diphenhydramine;Tramadol Product Used For Unknown Indication Toxicity To Various Agents;Unresponsive To Stimuli Serious Died;Other Outcomes Not Specified – 30-MAY-2019 Non-Expedited Not Specified Not Specified Vivimed Labs Healthcare Professional Not Specified – 26-FEB-2019 30-MAY-2019 US Not Specified US-VIVIMED-2019SP001962 "Gershman K, Timm K, Frank M, Lampi L, Melamed J, Gerona R et al. Deaths in Colorado Attributed to Kratom. N Engl J Med. 2019;380(1):97–98" –

16371118 – Herbals\Mitragynine – Toxicity To Various Agents Serious Died Male – 29-MAY-2019 Direct 33 YR Not Specified Fda-Ctu Not Specified Not Specified – 29-MAY-2019 US Not Specified – –

16357334 – Quetiapine;Herbals\Mitragynine;Valproic Acid – Drug Interaction;Toxicity To Various Agents Serious Died Male – 27-MAY-2019 Non-Expedited 27 YR Not Specified Sciegen Healthcare Professional Not Specified – 16-MAY-2019 27-MAY-2019 US Not Specified US-SCIEGEN PHARMACEUTICALS INC-2019SCILIT00181 "Rhome L. Hughes et.al.,;Fatal combination of mitragynine and quetiapine-a case report with discussion of a potential herb-drug interaction;Forensic Science Medicine and Pathology;29-NOV-2018;" –

16347037 – Quetiapine Fumarate;Herbals\Mitragynine Bipolar Disorder;Product Used For Unknown Indication Neuroleptic Malignant Syndrome;Drug Interaction;Hyperthermia;Toxicity To Various Agents;Muscle Rigidity;Tongue Haemorrhage;Discharge;Seizure Serious Died Not Specified – 23-MAY-2019 Expedited Not Specified Not Specified Alembic Healthcare Professional Not Specified Valproic Acid 09-MAY-2019 23-MAY-2019 US Not Specified US-ALEMBIC PHARMACUETICALS LIMITED-2019SCAL000311 "Hughes R L. Fatal combination of mitragynine and quetiapine - a case report with discussion of a potential herb-

drug interaction. Forensic science, medicine, and pathology. 2019;15 (1):110-113" -

16024013 - Herbals\Mitragynine;Quetiapine Fumarate Product Used For Unknown Indication Herbal Interaction;Toxicity To Various Agents;Seizure;Hyperthermia Serious Died Male - 17-MAY-2019 Expedited 27 YR Not Specified Intellipharmaceutics Healthcare Professional Not Specified - 07-MAY-2019 01-MAR-2019 US Not Specified US- INTELLIPHARMACEUTICS CORP.-2063404 "Journal: Forensic science, medicine, and pathology Author: Hughes RL Title: Fatal combination of mitragynine and quetiapine – a case report with discussion of a potential herb-drug interaction Volume: 15 (1) Year: 2019 Pages: 110-3" -

16316296 - Quetiapine Fumarate;Herbals\Mitragynine Product Used For Unknown Indication Drug Interaction;Toxicity To Various Agents Serious Died;Other Outcomes Male - 15- MAY-2019 Expedited 27 YR Not Specified Endo Healthcare Professional Not Specified - 07-MAY-2019 15- MAY-2019 US Not Specified US-ENDO PHARMACEUTICALS INC-2019-104558 "Hughes RL. Fatal combination of mitragynine and quetiapine – a case report with discussion of a potential herb-drug interaction. Forensic Science, Medicine, and Pathology. 2019;15(1):110-113" -

16307114 - Herbals\Mitragynine - Toxicity To Various Agents Serious Hospitalized;Died Not Specified OCT-2018 13-MAY-2019 Direct 37 YR Not Specified Fda- Ctu Not Specified Not Specified - - 13-MAY-2019 US Not Specified - - -

16289668 Methadone Methadone Hydrochloride;Oxazepam;Cocaine;Bromazepam;Morphine;Herbals\Mitragynine Product Used For Unknown Indication Toxicity To Various Agents;Pulmonary Oedema;Gastritis;Asphyxia;Pancreatitis Serious Other Outcomes;Died Male - 09-MAY-2019 Expedited 36 YR Not Specified Fresenius Kabi Healthcare Professional Not Specified - 01-MAY-2019 09-MAY-2019 FR Not Specified FR-FRESENIUS KABI-FK201905280 "Bourgine J, Garnier-Jardin C, Chretien B, Le Boisselier R, Loilier M, Lelong-Boulouard V, et al.. Fatal intoxication with Kratom: A case report. Toxicologie Analytique et Clinique. 2019 MAY;VOL. 31:S36-S37." -

16288357 - Herbals\Mitragynine;Quetiapine - Toxicity To Various Agents;Drug Interaction Serious Other Outcomes;Died Male - 08-MAY-2019 Expedited 27 YR Not Specified Alignscience Pharma Healthcare Professional Not Specified Valproic Acid 22-APR-2019 08- MAY-2019 US Not Specified US-ALS-2019-000002 Hughes RL. Fatal combination of mitragynine and quetiapine-a case report with discussion of a potential herb-drug interaction. Forensic Sci Med Pathol. 2019; 15(1): 110-3. -

16266419 - Herbals\Mitragynine;Quetiapine Product Used

For Unknown Indication Drug Interaction;Toxicity To Various Agents  
Serious Died Male - 06-MAY-2019 Expedited  
27 YR Not Specified Sandoz Healthcare Professional Not  
Specified Valproic Acid 02-MAY-2019 02-MAY-2019 US  
Not Specified PHHY2019US099059 "Hughes RL. Fatal  
combination of mitragynine and quetiapine - a case report with  
discussion of a potential herb-drug interaction. FORENSIC SCIENCE,  
MEDICINE, AND PATHOLOGY. 2019;15(1):110-3" -  
16268989 Oxycodone And Acetaminophen;Methadone Methadone  
Hydrochloride;Herbals\Mitragynine;Acetaminophen\Oxycodone  
Hydrochloride;Tramadol Pain;Product Used For Unknown Indication  
Accidental Overdose;Irritability;Rhinorrhoea;Pain;Drug  
Withdrawal Syndrome Serious Hospitalized Female - 03-  
MAY-2019 Non-Expedited 60 YR Not Specified Apotex  
Healthcare Professional Not Specified  
Buprenorphine;Pregabalin;Duloxetine 23-APR-2019 03-MAY-2019  
US Not Specified US-APOTEX-2019AP013423 Buresh M..  
Treatment of Kratom Dependence With Buprenorphine-Naloxone  
Maintenance;DOI:10.1097/ADM.0000000000000428. Journal of Addiction  
Medicine. 2018;12:481-483 -  
16383121 - Herbals\Mitragynine Substance Use  
Respiratory Arrest;Skin Discolouration;Loss Of Consciousness  
Serious Other Outcomes Female 29-APR-2019 02-MAY-2019 Direct  
49 YR 73.35 KG Fda-Ctu Consumer Consumer  
Fluvoxamine;Lunesta;Lamictal;Wellbutrin - 02-MAY-2019  
US Not Specified - - -  
16265229 - Herbals\Mitragynine Pain In Extremity  
Dizziness;Chest Discomfort;Cardiac Flutter;Presyncope  
Serious Life Threatening Male 30-APR-2019 02-MAY-2019  
Direct 53 YR 83.01 KG Fda-Ctu Not Specified Not  
Specified Diazepam;Fludrocortisone - 02-MAY-2019  
US Not Specified - - -  
16260968 - Herbals\Mitragynine Substance Use  
Seizure;Withdrawal Syndrome;Insomnia;Drug Dependence Serious  
Disabled;Hospitalized Male 27-APR-2019 30-APR-2019 Direct  
19 YR 74.84 KG Fda-Ctu Not Specified Not Specified  
- - 30-APR-2019 US Not Specified -  
- -  
16242868 - Herbals\Mitragynine - Drug  
Dependence;Overdose Serious Required Intervention;Other Outcomes  
Female 06-MAR-2019 25-APR-2019 Direct 62 YR Not  
Specified Fda-Ctu Not Specified Not Specified - -  
25-APR-2019 US Not Specified - - -  
16227577 - Herbals\Mitragynine Self-Medication  
Overdose;Drug Dependence Serious Disabled;Hospitalized;Life  
Threatening Female 06-MAR-2019 22-APR-2019 Direct 62 YR  
63 KG Fda-Ctu Consumer Consumer - -  
22-APR-2019 US Not Specified - - -  
16228506 - Herbals\Mitragynine Drug Use Disorder  
Homeless;Drug Dependence;Loss Of Employment;Drug Withdrawal

Syndrome              Serious Disabled;Hospitalized      Male      16-SEP-2016  
 21-APR-2019              Direct 30 YR 81 KG Fda-Ctu Consumer  
 Consumer              - - 21-APR-2019 US Not  
 Specified              - - -  
 16218126              -  
 Herbals\Mitragynine;Caffeine;Citalopram;Mirtazapine      Product Used  
 For Unknown Indication      Cardio-Respiratory Arrest;Toxicity To Various  
 Agents      Serious Hospitalized;Died      Male - 19-APR-2019  
 Expedited      32 YR Not Specified      Torrent Healthcare  
 Professional      Not Specified - 12-APR-2019 19-APR-2019  
 US      Not Specified US-TORRENT-00008321 - -  
 16212272              -      Herbals\Mitragynine      Substance Use  
 Withdrawal Syndrome;Seizure      Serious Life  
 Threatening;Died;Disabled;Hospitalized      Male 01-APR-2019 18-  
 APR-2019      Direct Not Specified Not Specified Fda-Ctu Not  
 Specified      Not Specified - - 18-APR-2019 US  
 Not Specified - - -  
 16212271              -      Herbals\Mitragynine      -      Unresponsive  
 To Stimuli      Serious Died      Male - 18-APR-2019 Direct  
 35 YR Not Specified Fda-Ctu Not Specified Not Specified  
 - - 18-APR-2019 US Not Specified -  
 - -  
 16212240              -      Herbals\Mitragynine      -      Cardiac Arrest  
 Serious Died      Male - 18-APR-2019 Direct 27 YR  
 Not Specified Fda-Ctu Not Specified Not Specified -  
 - 18-APR-2019 US Not Specified - -  
 -  
 16212231              -      Herbals\Mitragynine      -      Unresponsive  
 To Stimuli      Serious Died      Male - 18-APR-2019 Direct  
 26 YR Not Specified Fda-Ctu Not Specified Not Specified  
 - - 18-APR-2019 US Not Specified -  
 - -  
 16202264              -      Herbals\Mitragynine      -      Drug Screen  
 Positive;Vomiting;Headache      Non-Serious      Non-Serious      Female  
 02-APR-2019              15-APR-2019 Direct 30 YR 54 KG Fda-  
 Ctu      Consumer      Consumer - - 15-APR-2019  
 US Y - - -  
 16197682              -      Herbals\Mitragynine      Restless Legs Syndrome  
 Blepharospasm;Product Contamination Physical;Near Death  
 Experience;Bruxism;Product Contamination  
 Microbial;Hallucination;Cognitive Disorder;Constipation Non-Serious  
 Non-Serious      Male 12-APR-2019 14-APR-2019 Direct  
 66 YR 110.25 KG Fda-Ctu Consumer Consumer  
 Hydroxyzine;Losartan;Vitamin D  
 Nos;Anastrozole;Metformin;Cinnamon;Fish  
 Oil;Vitamins;Magnesium;Lecithin;Testosterone;Atorvastatin -  
 14-APR-2019      US Not Specified - - -  
 16197668              -      Herbals\Mitragynine      Drug Dependence  
 Product Complaint;Drug Dependence;Impaired Quality Of Life  
 Serious Other Outcomes;Life Threatening;Hospitalized      Male 01-

MAR-2015 12-APR-2019 Direct 34 YR 81 KG Fda-Ctu  
 Consumer Consumer - - 12-APR-2019 US  
     Not Specified - - -  
 16187592 Alcohol (Alcohol)  
 Diphenhydramine;Alcohol;Lorazepam;Herbals\Mitragynine;Buprenorphine  
     - Road Traffic Accident;Miosis;Loss Of Consciousness  
     Serious Other Outcomes Male - 12-APR-2019  
 Expedited 63 YR Not Specified Sanofi Aventis Healthcare  
 Professional Not Specified - 05-APR-2019 12-APR-2019  
     US Not Specified US-SA-2019SA097014 "Tiscione  
 N.B., Alford I.K., Miller R., Shan X., Yeatman D.T.. Driving under the  
 Influence of Drugs: When the Law Misses the Mark. Journal of  
 Analytical Toxicology. 2019;43:138-143" -  
 16166917 Methadone;Trazodone;Zolpidem Lamotrigine;Zolpidem  
 Tartrate;Buprenorphine;Doxylamine;Diphenhydramine;Chlorpheniramine;Lev  
 orphanol;Trazodone Hydrochloride;Methadone  
 Hydrochloride;Herbals\Mitragynine;Gabapentin;Fentanyl;Cyclobenzaprine;  
 Topiramate;Carisoprodol;Tramadol;Oxycodone Product Used For  
 Unknown Indication Injury;Accident;Impaired Driving Ability  
     Serious Died;Other Outcomes Not Specified - 09-  
 APR-2019 Expedited Not Specified Not Specified  
 Johnson And Johnson Healthcare Professional Not Specified -  
     26-MAR-2019 08-APR-2019 US Not Specified US-  
 JNJFOC-20190407184 "Tiscione NB, Alford IK, Miller R, Shan X,  
 Yeatman DT. Driving Under the Influence of Drugs: When the Law Misses  
 the Mark. Journal of Analytical Toxicology 2019;43:138-143." -  
 16166904 Alcohol (Alcohol)  
 Alcohol;Buprenorphine;Lorazepam;Diphenhydramine;Herbals\Mitragynine  
     Product Used For Unknown Indication Miosis;Loss Of  
     Consciousness;Accident Serious Other Outcomes Male - 08-  
 APR-2019 Expedited 63 YR Not Specified Johnson And  
 Johnson Healthcare Professional Not Specified - 26-MAR-2019  
     08-APR-2019 US Not Specified US-JNJFOC-20190405655  
     "Tiscione NB, Alford IK, Miller R, Shan X, Yeatman DT. Driving  
     Under the Influence of Drugs: When the Law Misses the Mark. Journal of  
     Analytical Toxicology 01-Oct-2018;2019;43:138-143." -  
 16156491 Alcohol (Alcohol) Diphenhydramine  
 Hydrochloride;Alcohol;Carfentanil;Buprenorphine;Herbals\Mitragynine;Lo  
 razepam;Norbuprenorphine - Labelled Drug-Food Interaction  
 Medication Error;Benzodiazepine Drug Level Increased;Road Traffic  
 Accident;Loss Of Consciousness;Miosis;Drug Screen Positive  
     Serious Other Outcomes Male - 04-APR-2019 Expedited  
     63 YR Not Specified Procter And Gamble Healthcare  
 Professional Not Specified - 23-MAR-2019 04-APR-2019  
     US Not Specified US-PROCTER\_AND\_GAMBLE-GS19035001  
     "Tiscione NB, Alford IK, Miller R, Shan X, Yeatman DT. Driving  
     Under the Influence of Drugs: When the Law Misses the Mark. J Anal  
     Toxicol. 2019;43:138-143" -  
 16141629 - Herbals\Mitragynine Anxiety;Pain  
 Toxicity To Various Agents;Intentional Product Misuse Serious Died

KG Male 18-JAN-2019 31-MAR-2019 Direct 36 YR 125.1  
 Fda-Ctu Consumer Consumer Alprazolam;Effexor  
 - 31-MAR-2019 US Not Specified - -  
 -  
 16139348 - Herbals\Mitragynine - Drug Screen  
 Positive;Abdominal Pain;Vomiting;Nausea;Tremor Non-Serious Non-  
 Serious Not Specified 23-MAR-2019 28-MAR-2019 Direct Not  
 Specified Not Specified Fda-Ctu Not Specified Not Specified  
 - 28-MAR-2019 US Not Specified -  
 -  
 16102392 - Herbals\Mitragynine;Citalopram  
 Hydrobromide;Mirtazapine;Caffeine Product Used For Unknown  
 Indication Drug Abuse;Cardio-Respiratory Arrest;Toxicity To  
 Various Agents Serious Died Male 2017 21-MAR-2019  
 Expedited 32 YR Not Specified Lannett Healthcare  
 Professional Not Specified - 06-MAR-2019 21-MAR-2019  
 US Not Specified "US-LANNETT COMPANY, INC.-  
 US-2019LAN000321" "Gummin DD, Mowry JB, Spyker DA, Brooks DE,  
 Osterthaler KM, Banner W. 2017 Annual Report of the American  
 Association of Poison Control Centersí National Poison Data System  
 (NPDS): 35th Annual Report. CLINICAL TOXICOLOGY. 2018;56:12:1213-1415"  
 -  
 16101916 Heroin Diamorphine;Oxycodone  
 Hydrochloride;Herbals\Mitragynine Product Used For Unknown  
 Indication Toxicity To Various Agents;Drug Abuse Serious Died  
 Male 2017 21-MAR-2019 Expedited 44 YR Not  
 Specified Lannett Healthcare Professional Not Specified -  
 06-MAR-2019 21-MAR-2019 US Not Specified "US-  
 LANNETT COMPANY, INC.-US-2019LAN000655" "David D. Gummin MD, James B.  
 Mowry PharmD, Daniel A. Spyker PhD, MDd, Daniel E. Brooks MD. 2017  
 Annual Report of the American Association of Poison Control Centersí  
 National Poison Data System (NPDS): 35th Annual Report. Clinical  
 Toxicology. CLINICAL TOXICOLOGY. 2018;56:12:1213-1415" -  
 16099194 -  
 Herbals\Mitragynine;Citalopram;Ranitidine;Albuterol;Diphenhydramine;Ac  
 etaminophen\Methocarbamol;Loratadine;Valacyclovir Hydrochloride -  
 Maternal Exposure During Pregnancy;Caesarean Section  
 Serious Other Outcomes Female - 21-MAR-2019 Expedited  
 37 YR Not Specified Bayer Healthcare Professional Not  
 Specified - 15-MAR-2019 21-MAR-2019 CA Not  
 Specified CA-BAYER-2019-054297 "Murthy P, Clark D. An unusual  
 cause for neonatal abstinence syndrome. Paediatrics and Child Health  
 (Canada). 2019;24:1:12-14" -  
 16100702 - Herbals\Mitragynine Pain  
 Gastroenteritis Salmonella Serious Hospitalized Male 01-  
 MAR-2019 19-MAR-2019 Direct 47 YR 67.5 KG Fda-Ctu  
 Consumer Consumer - - 19-MAR-2019 US  
 Not Specified - - -  
 16088643 - Herbals\Mitragynine - Death  
 Serious Died Male 2018 18-MAR-2019 Direct 24 YR Not

Specified Fda-Ctu Not Specified Not Specified - - -  
 18-MAR-2019 US Not Specified - - -  
 16089459 - Herbals\Mitragynine Depression Drug  
 Dependence;Withdrawal Syndrome;Adulterated Product Non-Serious  
 Non-Serious Male 08-MAR-2019 17-MAR-2019 Direct  
 31 YR 58.5 KG Fda-Ctu Consumer Consumer  
 Mirtazapine;Suboxone - 17-MAR-2019 US Y -  
 - - -  
 16117172 - Herbals\Mitragynine - -  
 Seizure;Cardiac Arrest Serious Died Male 24-NOV-2018 15-  
 MAR-2019 Direct 40 YR Not Specified Fda-Ctu Not Specified  
 Not Specified - - 15-MAR-2019 US Not  
 Specified - - -  
 16083408 - Herbals\Mitragynine - Multiple Organ  
 Dysfunction Syndrome Serious Died Male 16-FEB-2018 15-  
 MAR-2019 Direct 41 YR Not Specified Fda-Ctu Not Specified  
 Not Specified - - 15-MAR-2019 US Not  
 Specified - - -  
 16060417 Escitalopram Escitalopram  
 Oxalate;Herbals\Mitragynine Back Pain;Major Depression;Product  
 Used For Unknown Indication Aspartate Aminotransferase  
 Increased;Pruritus;Hyperbilirubinaemia;Blood Bilirubin Increased;Drug  
 Interaction;Drug-Induced Liver Injury;Serum Ferritin  
 Increased;Vomiting;Pollakiuria;Fatigue;Dysuria;Micturition  
 Urgency;Blood Alkaline Phosphatase  
 Increased;Chromaturia;Pyrexia;Decreased Appetite;Malaise;Alanine  
 Aminotransferase Increased;Cytomegalovirus Test Positive;Hepatic  
 Steatosis Serious Other Outcomes Not Specified - 12-  
 MAR-2019 Expedited Not Specified Not Specified  
 Aurobindo Healthcare Professional Not Specified  
 Valsartan;Metoprolol Tartrate;Fexofenadine;Clonazepam 25-FEB-2019  
 12-MAR-2019 US Not Specified US-AUROBINDO-AUR-  
 APL-2019-012534 "Osborne CS, Overstreet AN, Rockey DC and Schreiner  
 AD.. Drug-Induced Liver Injury Caused by Kratom Use as an Alternative  
 Pain Treatment Amid an Ongoing Opioid Epidemic.. Journal of  
 Investigative Medicine High Impact Case Reports.. 2019;7:1-5" -  
 16058080 Escitalopram Escitalopram  
 Oxalate;Herbals\Mitragynine Back Pain;Product Used For Unknown  
 Indication Drug-Induced Liver Injury;Drug Interaction  
 Serious Other Outcomes Male - 11-MAR-2019 Expedited  
 47 YR Not Specified Taro Healthcare Professional Not  
 Specified  
 Clonazepam;Fexofenadine;Acetaminophen;Valsartan;Metoprolol Tartrate  
 25-FEB-2019 11-MAR-2019 US Not Specified "US-  
 TARO PHARMACEUTICALS USA., INC-2019SUN00102" "Osborne CS,  
 Overstreet AN, Rockey DC, Schreiner AD. Drug-Induced Liver Injury  
 Caused by Kratom Use as an Alternative Pain Treatment Amid an Ongoing  
 Opioid Epidemic. J Investig Med High Impact Case Rep. 2019;7:1-5"  
 -  
 16053467 Alcohol (Alcohol)

Alcohol;Cocaine;Fentanyl;Oxycodone Hydrochloride;Herbals\Mitragynine Product Used For Unknown Indication Drug Interaction;Unresponsive To Stimuli;Toxicity To Various Agents Serious Died Not Specified 2017 08-MAR-2019 Expedited Not Specified Not Specified Lannett Healthcare Professional Not Specified - 25-FEB-2019 08-MAR-2019 US Not Specified "US-LANNETT COMPANY, INC.-US-2019LAN000228" "Gershman K, Timm K, Frank M, Lampi L, Melamed J, Gerona R, et al.. Deaths in Colorado attributed to Kratom. N-Engl-J-Med. 2019;380(1):97-98" -

16053436 Alcohol (Alcohol) Alcohol;Oxycodone Hydrochloride;Herbals\Mitragynine Product Used For Unknown Indication Drug Interaction;Toxicity To Various Agents Serious Died Not Specified 2017 08-MAR-2019 Expedited Not Specified Not Specified Lannett Healthcare Professional Not Specified - 25-FEB-2019 08-MAR-2019 US Not Specified "US-LANNETT COMPANY, INC.-US-2019LAN000227" "Gershman K, Timm K, Frank M, Lampi L, Melamed J, Gerona R, et al.. Deaths in Colorado attributed to Kratom. N-Engl-J-Med. 2019;380(1):97-98" -

16053239 Sertraline Sertraline Hydrochloride;Hydroxyzine Hydrochloride;Temazepam;Clonazepam;Olanzapine;Herbals\Mitragynine Product Used For Unknown Indication Toxicity To Various Agents;Drug Interaction;Unresponsive To Stimuli Serious Died Not Specified 2017 08-MAR-2019 Expedited Not Specified Not Specified Lannett Healthcare Professional Not Specified - 25-FEB-2019 08-MAR-2019 US Not Specified "US-LANNETT COMPANY, INC.-US-2019LAN000225" "Gershman K, Timm K, Frank M, Lampi L, Melamed J, Gerona R, et al.. Deaths in Colorado attributed to Kratom. N-Engl-J-Med. 2019;380(1):97-98" -

16053177 - Citalopram Hydrobromide;Herbals\Mitragynine Product Used For Unknown Indication Unresponsive To Stimuli;Toxicity To Various Agents;Drug Interaction Serious Died Not Specified 2016 08-MAR-2019 Expedited Not Specified Not Specified Lannett Healthcare Professional Not Specified - 25-FEB-2019 08-MAR-2019 US Not Specified "US-LANNETT COMPANY, INC.-US-2019LAN000224" "Gershman K, Timm K, Frank M, Lampi L, Melamed J, Gerona R, et al.. Deaths in Colorado attributed to Kratom. N-Engl-J-Med. 2019;380(1):97-98" -

16053097 Zolpidem Zolpidem Tartrate;Diphenhydramine Hydrochloride;Herbals\Mitragynine;Tramadol;Topiramate;Oxycodone Hydrochloride Product Used For Unknown Indication Unresponsive To Stimuli;Toxicity To Various Agents;Asphyxia;Drug Interaction Serious Died Not Specified 2016 08-MAR-2019 Expedited Not Specified Not Specified Lannett Healthcare Professional Not Specified - 25-FEB-2019 08-MAR-2019 US Not Specified "US-LANNETT COMPANY, INC.-US-2019LAN000223" "Gershman K, Timm K, Frank M, Lampi L, Melamed J, Gerona R, et al.. Deaths in Colorado attributed to Kratom. N-Engl-

J-Med. 2019;380(1):97-98" -

16053031 - Codeine Sulfate;Morphine;Herbals\Mitragynine Product Used For Unknown Indication Toxicity To Various Agents;Drug Interaction;Unresponsive To Stimuli Serious Died Not Specified 2016 08-MAR-2019 Expedited Not Specified Not Specified Lannett Healthcare Professional Not Specified - 25-FEB-2019 08-MAR-2019 US Not Specified "US-LANNETT COMPANY, INC.-US-2019LAN000222" "Gershman K, Timm K, Frank M, Lampi L, Melamed J, Gerona R, et al.. Deaths in Colorado attributed to Kratom. N-Engl-J-Med. 2019;380(1):97-98" -

16052938 Alcohol (Alcohol) Alcohol;Herbals\Mitragynine;Hydroxyzine Hydrochloride;Gabapentin;Etizolam;Naltrexone;Bupropion;Clonidine;Diazepam;Polyethylene Glycol 3350 Product Used For Unknown Indication Toxicity To Various Agents;Drug Interaction Serious Died Not Specified 2016 08-MAR-2019 Expedited Not Specified Not Specified Lannett Healthcare Professional Not Specified - 25-FEB-2019 08-MAR-2019 US Not Specified "US-LANNETT COMPANY, INC.-US-2019LAN000221" "Gershman K, Timm K, Frank M, Lampi L, Melamed J, Gerona R, et al. Deaths in Colorado attributed to Kratom. N-Engl-J-Med. 2019;380(1):97-98" -

16052848 Lidoderm;Pseudoephedrine.;Fetzima;Trazadone Gabapentin;Lithium;Trazadone Hydrochloride;Benztropine;Levomilnacipran Hydrochloride;Herbals\Mitragynine;Pseudoephedrine Hydrochloride;Morphine;Lidocaine;Oxycodone Hydrochloride;Fluoxetine Hydrochloride Product Used For Unknown Indication Unresponsive To Stimuli;Drug Interaction;Toxicity To Various Agents Serious Died Not Specified 2016 08-MAR-2019 Expedited Not Specified Not Specified Lannett Healthcare Professional Not Specified - 25-FEB-2019 08-MAR-2019 US Not Specified "US-LANNETT COMPANY, INC.-US-2019LAN000220" "Gershman K, Timm K, Frank M, Lampi L, Melamed J, Gerona R, et al.. Deaths in Colorado attributed to Kratom. N-Engl-J-Med. 2019;380(1):97-98" -

16052606 - Diphenhydramine Hydrochloride;Etizolam;Herbals\Mitragynine;Oxycodone Hydrochloride Product Used For Unknown Indication Toxicity To Various Agents;Unresponsive To Stimuli;Drug Interaction Serious Died Not Specified 2015 08-MAR-2019 Expedited Not Specified Not Specified Lannett Healthcare Professional Not Specified - 25-FEB-2019 08-MAR-2019 US Not Specified "US-LANNETT COMPANY, INC.-US-2019LAN000219" "Gershman K, Timm K, Frank M, Lampi L, Melamed J, Gerona R, et al. Deaths in Colorado attributed to Kratom. N-Engl-J-Med. 2019;380(1):97-98" -

16054998 - Herbals\Mitragynine - Nausea;Decreased Appetite;Schizophrenia;Amnesia Serious Other Outcomes Not Specified FEB-2019 07-MAR-2019 Direct Not Specified Not Specified Fda-Ctu Not Specified Not Specified - 07-MAR-2019 US Not Specified -

- - -  
16051419 - Herbals\Mitragynine Product Used For  
Unknown Indication Palpitations;Product Complaint;Heart Rate  
Increased;Food Interaction;Drug Interaction Serious Other Outcomes  
Male 10-FEB-2019 07-MAR-2019 Direct 40 YR 100.8  
KG Fda-Ctu Consumer Consumer Melatonin;Ibuprofen  
- 07-MAR-2019 US Not Specified - - -  
-  
16019281 Zolpidem Zolpidem  
Tartrate;Tramadol;Diphenhydramine;Herbals\Mitragynine;Oxycodone;Topira  
mate - Toxicity To Various Agents Serious Died Not  
Specified - 05-MAR-2019 Expedited Not Specified  
Not Specified Teva Healthcare Professional Not Specified  
- 18-FEB-2019 28-FEB-2019 US Not Specified  
US-TEVA-2019-US-1017582 "Gershman K, Timm K, Frank M, Lampi L,  
Melamed J, Gerona R, et al. Deaths in Colorado attributed to Kratom.  
N-Engl-J-Med 2019;380(1):97-98."  
-  
16034667 - Herbals\Mitragynine;Fentanyl -  
Accidental Death;Toxicity To Various Agents Serious Died Male  
01-JAN-2019 04-MAR-2019 Direct 26 YR Not Specified  
Fda-Ctu Not Specified Not Specified  
Acetyl fentanyl;Xylazine - 04-MAR-2019 US Not Specified  
- - -  
16032579 Escitalopram Escitalopram  
Oxalate;Herbals\Mitragynine Back Pain;Major Depression;Product  
Used For Unknown Indication Drug Interaction;Drug-Induced Liver  
Injury Serious Other Outcomes Male - 04-MAR-2019  
Expedited 47 YR Not Specified Hetero Healthcare  
Professional Not Specified Metoprolol  
Tartrate;Clonazepam;Fexofenadine;Valsartan 18-FEB-2019 04-  
MAR-2019 US Not Specified US-HETERO CORPORATE-  
HET2019US00249 "Osborne Caroline Stokes, Overstreet Amanda N, Rockey  
Don C, Schreiner Andrew D. Drug-Induced Liver Injury Caused by Kratom  
Use as an Alternative Pain Treatment Amid an Ongoing Opioid Epidemic.  
Journal of Investigative Medicine High Impact Case Reports. 2019"  
-  
16025669 Hydroxyzine Hydroxyzine  
Hydrochloride;Gabapentin;Bupropion Hydrochloride;Diazepam;Polyethylene  
Glycols;Naltrexone;Clonidine;Herbals\Mitragynine;Etizolam  
Product Used For Unknown Indication Death Serious Died;Other  
Outcomes Not Specified 2016 02-MAR-2019 Expedited  
Not Specified Not Specified Zydus Pharm Healthcare  
Professional Not Specified - 18-FEB-2019 02-MAR-2019  
US Not Specified US-ZYDUS-034105 "Gershman K, Timm K,  
Frank M, Lampi L, Melamed J, Gerona R, et al. Deaths in Colorado  
attributed to Kratom. N-Engl-J-Med 2019;380(1):97-98."  
-  
16025668 Fluoxetine;Pseudoephedrine.;Trazodone;Hydroxyzine  
Hydroxyzine  
Hydrochloride;Lidocaine;Gabapentin;Oxycodone;Herbals\Mitragynine;Lithi  
um;Trazodone Hydrochloride;Morphine\Hydrochloride\Hydroxyzine

Sulfate\Morphine Tartrate;Levomilnacipran;Pseudoephedrine Hydrochloride;Fluoxetine Hydrochloride;Benztropine Product Used For Unknown Indication Unresponsive To Stimuli;Death Serious Died;Other Outcomes Not Specified 2016 02-MAR-2019 Expedited Not Specified Not Specified Zydus Pharm Healthcare Professional Not Specified - 18-FEB-2019 02-MAR-2019 US Not Specified US-ZYDUS-034104 "Gershman K, Timm K, Frank M, Lampi L, Melamed J, Gerona R, et al. Deaths in Colorado attributed to Kratom. N-Engl-J-Med 2019;380(1):97-98." - 16025661 Propranolol;Buspirone Buspirone Hydrochloride;Propranolol Hydrochloride;Nordazepam;Diazepam;Etizolam;Mirtazapine;Herbals\Mitragynine;Gabapentin Product Used For Unknown Indication Death Serious Died;Other Outcomes Not Specified 2017 02-MAR-2019 Expedited Not Specified Not Specified Zydus Pharm Healthcare Professional Not Specified - 18-FEB-2019 02-MAR-2019 US Not Specified US- ZYDUS-034109 "Gershman K, Timm K, Frank M, Lampi L, Melamed J, Gerona R, et al. Deaths in Colorado attributed to Kratom. N-Engl-J-Med 2019;380(1):97-98." - 16025650 Hydroxyzine;Sertraline Hydroxyzine Hydrochloride;Sertraline Hydrochloride;Temazepam;Olanzapine;Herbals\Tetrahydrocannabinol Unspecified;Clonazepam;Herbals\Mitragynine Product Used For Unknown Indication Unresponsive To Stimuli;Death;Cardiomegaly Serious Other Outcomes;Died Not Specified 2017 02-MAR-2019 Expedited Not Specified Not Specified Zydus Pharm Healthcare Professional Not Specified - 18-FEB-2019 02-MAR-2019 US Not Specified US- ZYDUS-034108 "Gershman K, Timm K, Frank M, Lampi L, Melamed J, Gerona R, et al. Deaths in Colorado attributed to Kratom. N-Engl-J-Med 2019;380(1):97-98." - 16019298 Fluoxetine;Pseudoephedrine. Oxycodone;Pseudoephedrine Hydrochloride;Fluoxetine Hydrochloride;Herbals\Mitragynine - Drug Screen Positive Serious Died Not Specified - 28-FEB-2019 Expedited Not Specified Not Specified Teva Healthcare Professional Not Specified - 18-FEB-2019 28-FEB-2019 US Not Specified US-TEVA-2019-US-1017586 "Gershman K, Timm K, Frank M, Lampi L, Melamed J, Gerona R, et al. Deaths in Colorado attributed to Kratom. N-Engl-J-Med 2019;380(1):97-98." - 16019295 - Cocaine;Fentanyl;Herbals\Mitragynine;Oxycodone Product Used For Unknown Indication Hepatic Fibrosis;Portal Tract Inflammation;Drug Screen Positive Serious Died Not Specified - 28-FEB-2019 Expedited Not Specified Not Specified Teva Healthcare Professional Not Specified - 18-FEB-2019 28-FEB-2019 US Not Specified US-TEVA-2019-US-1017577 "Gershman K, Timm K, Frank M, Lampi L, Melamed J, Gerona R, et al. Deaths in Colorado attributed to Kratom. N-Engl-J-Med 2019;380(1):97-98." -

16019294            Sertraline        Sertraline  
Hydrochloride;Olanzapine;Temazepam;Herbals\Mitragynine;Clonazepam  
-            Drug Screen Positive    Serious Died    Not Specified  
-            28-FEB-2019            Expedited        Not Specified    Not  
Specified            Teva            Healthcare Professional    Not Specified    -  
18-FEB-2019            28-FEB-2019            US            Not Specified    US-  
TEVA-2019-US-1017581            "Gershman K, Timm K, Frank M, Lampi L, Melamed  
J, Gerona R, et al. Deaths in Colorado attributed to Kratom. N-Engl-J-  
Med 2019;380(1):97-98." -  
16019293            -  
Etizolam;Herbals\Mitragynine;Nordazepam;Mirtazapine        -        Drug  
Screen Positive    Serious Died    Not Specified    -        28-FEB-2019  
Expedited            Not Specified        Not Specified    Teva  
Healthcare Professional    Not Specified    -        18-FEB-2019        28-  
FEB-2019            US            Not Specified        US-TEVA-2019-  
US-1017579            "Gershman K, Timm K, Frank M, Lampi L, Melamed J,  
Gerona R, et al. Deaths in Colorado attributed to Kratom. N-Engl-J-Med  
2019;380(1):97-98." -  
16019287            -            Herbals\Mitragynine;Oxycodone        -        Drug  
Screen Positive    Serious Died    Not Specified    -        28-FEB-2019  
Expedited            Not Specified        Not Specified    Teva  
Healthcare Professional    Not Specified    -        18-FEB-2019        28-  
FEB-2019            US            Not Specified        US-TEVA-2019-  
US-1017578            "Gershman K, Timm K, Frank M, Lampi L, Melamed J,  
Gerona R, et al. Deaths in Colorado attributed to Kratom. N-Engl-J-Med  
2019;380(1):97-98." -  
16019283            -            Codeine;Herbals\Mitragynine;Morphine        -  
Drug Screen Positive    Serious Died    Not Specified    -  
28-FEB-2019            Expedited        Not Specified        Not Specified  
Teva            Healthcare Professional    Not Specified    -        18-  
FEB-2019            28-FEB-2019            US            Not Specified        US-TEVA-2019-  
US-1017583            "Gershman K, Timm K, Frank M, Lampi L, Melamed J,  
Gerona R, et al. Deaths in Colorado attributed to Kratom. N-Engl-J-Med  
2019;380(1):97-98." -  
16019282            -            Herbals\Mitragynine;Selegiline        -        Herbal  
Toxicity;Drug Screen Positive    Serious Died    Male        -        28-  
FEB-2019            Expedited        Not Specified        Not Specified    Teva  
Healthcare Professional    Not Specified    -        18-FEB-2019  
28-FEB-2019            US            Not Specified        US-TEVA-2019-  
US-1017580            "Gershman K, Timm K, Frank M, Lampi L, Melamed J,  
Gerona R, et al. Deaths in Colorado attributed to Kratom. N-Engl-J-Med  
2019;380(1):97-98." -  
16018913            -            Herbals\Mitragynine;Quetiapine        -  
Hyperthermia;Seizure;Drug Interaction    Serious Died;Other Outcomes  
Male        -        28-FEB-2019            Expedited        27 YR    Not  
Specified            Jubilant            Healthcare Professional    Not Specified  
Valproic Acid        18-FEB-2019            28-FEB-2019            US    Not  
Specified            US-JUBILANT CADISTA PHARMACEUTICALS-2019JUB00065  
Hughes R. Fatal combination of mitragynine and quetiapine ñ a  
case report with discussion of a potential herb-drug interaction.

Forensic Sci Med Pathol. 2019;15(1):110–113 –  
 16017227 –  
 Herbals\Mitragynine;Gabapentin;Etizolam;Acetaminophen – Herbal  
 Toxicity;Drug Screen Positive Serious Died Male – 28–  
 FEB-2019 Expedited Not Specified Not Specified Teva  
     Healthcare Professional Not Specified – 18-FEB-2019  
     28-FEB-2019 US Not Specified US-TEVA-2019–  
 US-1017585 "Gershman K, Timm K, Frank M, Lampi L, Melamed J,  
 Gerona R, et al. Deaths in Colorado attributed to Kratom. N Engl J Med  
 2019;380(1):97–98." –  
 16005617 – Herbals\Mitragynine – Product  
 Substitution Issue;Psychomotor Hyperactivity Serious Life  
 Threatening;Other Outcomes;Hospitalized Female 24-JAN-2019 26–  
 FEB-2019 Direct 35 YR Not Specified Fda-Ctu Not Specified  
     Not Specified – – 26-FEB-2019 US Not  
     Specified – – –  
 16005421 – Herbals\Mitragynine – Physical  
 Disability;Mental Disorder;Pollakiuria;Self-Medication;Emotional  
 Distress;Anxiety;Thinking Abnormal;Insomnia;Weight Decreased  
 Serious Disabled Male 02-FEB-2019 25-FEB-2019 Direct  
     69 YR 72.57 KG Fda-Ctu Not Specified Not Specified  
     – – 25-FEB-2019 US Not Specified –  
     – –  
 15793100 – Quetiapine;Herbals\Mitragynine Product Used  
 For Unknown Indication Discharge;Hyperthermia;Toxicity To Various  
 Agents;Seizure;Herbal Interaction;Tongue Haemorrhage Serious Life  
 Threatening;Other Outcomes;Died Male – 25-FEB-2019  
 Expedited 27 YR Not Specified Lupin Healthcare  
 Professional Not Specified Valproic Acid 13-FEB-2019 07–  
 JAN-2019 US Not Specified US-LUPIN PHARMACEUTICALS  
 INC.-2018-09251 "Hughes RL. Fatal combination of mitragynine and  
 quetiapine – a case report with discussion of a potential herb-drug  
 interaction. Journal Forensic Science, Medicine and Pathology.  
 2019;15:110–113" –  
 15993191 – Quetiapine;Herbals\Mitragynine –  
 Hyperthermia;Seizure;Drug Interaction;Toxicity To Various Agents  
     Serious Other Outcomes;Died Male – 22-FEB-2019  
     Expedited 27 YR Not Specified Unichem Healthcare  
 Professional Not Specified Valproic Acid 13-FEB-2019 22–  
 FEB-2019 US Not Specified US-UNICHEM PHARMACEUTICALS  
 (USA) INC-UCM201902-000077 – –  
 15992724 – Citalopram;Herbals\Mitragynine Product Used  
 For Unknown Indication Death Serious Died Not Specified –  
     21-FEB-2019 Expedited Not Specified Not Specified  
     Mylan Healthcare Professional Not Specified – 12–  
 FEB-2019 21-FEB-2019 US Not Specified US–  
 MYLANLABS-2019M1015382 "Gershman K, Timm K, Frank M, Lampi L, Melamed  
 J, Gerona R, et al. Deaths in Colorado attributed to Kratom. N Engl J–  
 Med 2019;380(1):97–98." –  
 15990743 –

Etizolam;Nordazepam;Herbals\Mitragynine;Mirtazapine Product Used  
For Unknown Indication Death Serious Died Not Specified -  
21-FEB-2019 Expedited Not Specified Not Specified  
Mylan Healthcare Professional Not Specified - 12-  
FEB-2019 21-FEB-2019 US Not Specified US-  
MYLANLABS-2019M1015413 "Gershman K, Timm K, Frank M, Lampi L, Melamed  
J, Gerona R, et al. Deaths in Colorado attributed to Kratom. N-Engl-J-  
Med 2019;380(1):97-98." -

15990516 - Selegiline;Herbals\Mitragynine Product Used  
For Unknown Indication Herbal Toxicity;Postmortem Blood Drug Level  
Serious Died Male - 21-FEB-2019 Expedited  
Not Specified Not Specified Mylan Healthcare  
Professional Not Specified - 12-FEB-2019 21-FEB-2019  
US Not Specified US-  
MYLANLABS-2019M1015377 "Gershman K, Timm K, Frank M, Lampi L, Melamed  
J, Gerona R, et al. Deaths in Colorado attributed to Kratom. N-Engl-J-  
Med 2019;380(1):97-98." -

15990507 - Herbals\Mitragynine;Oxycodone;Fentanyl  
Product Used For Unknown Indication Death Serious Died Not  
Specified - 21-FEB-2019 Expedited Not Specified  
Not Specified Mylan Healthcare Professional Not Specified  
- 12-FEB-2019 21-FEB-2019 US Not Specified  
US-MYLANLABS-2019M1015391 "Gershman K, Timm K, Frank M,  
Lampi L, Melamed J, Gerona R, et al. Deaths in Colorado attributed to  
Kratom. N-Engl-J-Med 2019;380(1):97-98." -

15988717 Escitalopram Escitalopram  
Oxalate;Herbals\Mitragynine Back Pain;Major Depression;Product  
Used For Unknown Indication Pollakiuria;Pyrexia;Drug-Induced Liver  
Injury;Hepatic Steatosis;Micturition  
Urgency;Malaise;Jaundice;Fatigue;Decreased  
Appetite;Vomiting;Potentiating Drug  
Interaction;Chromaturia;Hyperbilirubinaemia;Dysuria;Pruritus  
Serious Other Outcomes Male - 21-FEB-2019 Expedited  
47 YR Not Specified Zydus Pharm Healthcare  
Professional Not Specified  
Valsartan;Fexofenadine;Clonazepam;Metoprolol 18-FEB-2019 21-  
FEB-2019 US Not Specified US-ZYDUS-034032 "Osborne CS,  
Overstreet AN, Rockey DC, Schreiner AD. Drug-Induced Liver Injury  
Caused by Kratom Use as an Alternative Pain Treatment Amid an Ongoing  
Opioid Epidemic. J-Investig-Med-High-Impact-Case-Rep 2019;." -

15982779 -  
Oxycodone;Etizolam;Diphenhydramine;Herbals\Mitragynine;Butyrfentanyl  
Product Used For Unknown Indication Death Serious Died  
Not Specified - 19-FEB-2019 Expedited Not  
Specified Not Specified Mylan Healthcare Professional Not  
Specified - 12-FEB-2019 19-FEB-2019 US Not  
Specified US-MYLANLABS-2019M1015418 "Gershman K, Timm K,  
Frank M, Lampi L, Melamed J, Gerona R, et al. Deaths in Colorado  
attributed to Kratom. N-Engl-J-Med 2019;380(1):97-98." -

15982699 -

Etizolam;Gabapentin;Acetaminophen;Herbals\Mitragynine Product Used  
For Unknown Indication Death Serious Died Male - 19-  
FEB-2019 Expedited Not Specified Not Specified Mylan  
Healthcare Professional Not Specified - 12-FEB-2019  
19-FEB-2019 US Not Specified US-  
MYLANLABS-2019M1015388 "Gershman K, Timm K, Frank M, Lampi L, Melamed  
J, Gerona R, et al. Deaths in Colorado attributed to Kratom. N-Engl-J-  
Med 2019;380(1):97-98." -  
15982698 - Codeine;Herbals\Mitragynine;Morphine  
Product Used For Unknown Indication Death Serious Died Not  
Specified - 19-FEB-2019 Expedited Not Specified  
Not Specified Mylan Healthcare Professional Not Specified  
- 12-FEB-2019 19-FEB-2019 US Not Specified  
US-MYLANLABS-2019M1015417 "Gershman K, Timm K, Frank M,  
Lampi L, Melamed J, Gerona R, et al. Deaths in Colorado attributed to  
Kratom. N-Engl-J-Med 2019;380(1):97-98." -  
15981023 Zolpidem Zolpidem  
Tartrate;Tramadol;Oxycodone;Herbals\Mitragynine;Topiramate;Diphenhydramine  
Product Used For Unknown Indication Toxicity To Various  
Agents Serious Died Not Specified - 19-FEB-2019  
Expedited Not Specified Not Specified Mylan Healthcare  
Professional Not Specified - 12-FEB-2019 19-FEB-2019  
US Not Specified US-  
MYLANLABS-2019M1015415 "Gershman K, Timm K, Frank M, Lampi L, Melamed  
J, Gerona R, et al. Deaths in Colorado attributed to Kratom. N-Engl-J-  
Med 2019;380(1):97-98." -  
15981022 Sertraline Sertraline  
Hydrochloride;Temazepam;Clonazepam;Olanzapine;Herbals\Mitragynine  
Product Used For Unknown Indication Death Serious Died  
Not Specified - 19-FEB-2019 Expedited Not  
Specified Not Specified Mylan Healthcare Professional Not  
Specified - 12-FEB-2019 19-FEB-2019 US Not  
Specified US-MYLANLABS-2019M1015403 "Gershman K, Timm K,  
Frank M, Lampi L, Melamed J, Gerona R, et al. Deaths in Colorado  
attributed to Kratom. N-Engl-J-Med 2019;380(1):97-98." -  
15981017 Escitalopram Escitalopram  
Oxalate;Herbals\Mitragynine Anxiety;Back Pain;Hypertension;Major  
Depression;Product Used For Unknown Indication Drug-Induced Liver  
Injury;Drug Interaction Serious Other Outcomes Male - 19-  
FEB-2019 Expedited 47 YR Not Specified Mylan  
Healthcare Professional Not Specified Valsartan;Metoprolol  
Tartrate;Fexofenadine;Acetaminophen;Clonazepam 12-FEB-2019 19-  
FEB-2019 US Not Specified US-MYLANLABS-2019M1015420  
"Osborne CS, Overstreet AN, Rockey DC, Schreiner AD. Drug-  
Induced Liver Injury Caused by Kratom Use as an Alternative Pain  
Treatment Amid an Ongoing Opioid Epidemic. J-Investig-Med-High-Impact-  
Case-Rep 2019;::." -  
15980857 Fluoxetine;Pseudoephedrine. Pseudoephedrine  
Hydrochloride;Oxycodone;Fluoxetine Hydrochloride;Herbals\Mitragynine  
Product Used For Unknown Indication Death Serious Died

Not Specified - 19-FEB-2019 Expedited Not  
 Specified Not Specified Mylan Healthcare Professional Not  
 Specified - 12-FEB-2019 19-FEB-2019 US Not  
 Specified US-MYLANLABS-2019M1015390 "Gershman K, Timm K,  
 Frank M, Lampi L, Melamed J, Gerona R, et al. Deaths in Colorado  
 attributed to Kratom. N-Engl-J-Med 2019;380(1):97-98." -  
 15967937 - Herbals\Mitragynine Drug Dependence Renal  
 Failure;Lung Disorder;Pneumonia;Rhabdomyolysis;Overdose Serious  
 Hospitalized Male 29-JAN-2010 15-FEB-2019 Direct 34 YR  
 231.3 KG Fda-Ctu Consumer Consumer  
 Klonopin;Ambien;Tylenol;Lisinopril - 15-FEB-2019 US  
 Not Specified - - -  
 15960718 - Oxycodone;Herbals\Mitragynine -  
 Toxicity To Various Agents;Accidental Death Serious Died Female  
 25-OCT-2017 13-FEB-2019 Direct 32 YR Not Specified  
 Fda-Ctu Not Specified Not Specified - - 13-  
 FEB-2019 US Not Specified - - -  
 15945096 - Herbals\Mitragynine;Butyrfentanyl -  
 Toxicity To Various Agents;Accidental Death Serious Died  
 Male 07-DEC-2015 11-FEB-2019 Direct 24 YR Not  
 Specified Fda-Ctu Not Specified Not Specified  
 Diphenhydramine;Oxycodone;Etizolam - 11-FEB-2019 US  
 Not Specified - - -  
 15944968 - Furanylentanyl;Herbals\Mitragynine -  
 Toxicity To Various Agents;Accidental Death Serious Died  
 Male 10-DEC-2016 11-FEB-2019 Direct 28 YR Not  
 Specified Fda-Ctu Not Specified Not Specified - -  
 11-FEB-2019 US Not Specified - - -  
 15944960 - Herbals\Mitragynine;Etizolam -  
 Toxicity To Various Agents Serious Died Male 08-APR-2017  
 11-FEB-2019 Direct 29 YR Not Specified Fda-Ctu Not  
 Specified Not Specified Mirtazapine;Diazepam - 11-  
 FEB-2019 US Not Specified - - -  
 15916803 - Herbals\Mitragynine - Product  
 Substitution Issue;Cerebral Thrombosis;Cerebral Haemorrhage  
 Serious Life Threatening;Required Intervention;Other Outcomes Male  
 24-JAN-2019 05-FEB-2019 Direct 54 YR Not Specified  
 Fda-Ctu Not Specified Not Specified - - 05-  
 FEB-2019 US Not Specified - - -  
 15956746 - Herbals\Mitragynine Back Pain;Drug  
 Dependence Cerebral Mass Effect;Headache;Vomiting;Mental Status  
 Changes;Disorientation;Cerebral Haemorrhage Serious Life  
 Threatening;Required Intervention;Hospitalized Male 24-JAN-2019  
 01-FEB-2019 Direct 54 YR Not Specified Fda-Ctu  
 Healthcare Professional Health Professional - - 01-  
 FEB-2019 US Not Specified - - -  
 15883288 -  
 Alprazolam;Clonazepam;Cocaine;Fentanyl;Diphenhydramine;Herbals\Mitragynine Product Used For Unknown Indication Toxicity To Various Agents;Cardio-Respiratory Arrest Serious Died Male 2017

29-JAN-2019 Expedited 31 YR Not Specified Endo  
 Healthcare Professional Not Specified - 07-JAN-2019  
 29-JAN-2019 US Not Specified US-ENDO  
 PHARMACEUTICALS INC-2019-100837 "Gummin, David D; Mowry, James B;  
 Spyker, Daniel A; Brooks, Daniel E; Osterthaler, Krista M; Banner,  
 William. 2017 Annual Report of the American Association of Poison  
 Control Centers' National Poison Data System. Clinical Toxicology.  
 2018;prepub:1-203" -

15867698 "Butalbital, Acetaminophen, And Caffeine;Heroin"  
 Morphine;Diamorphine;Codeine;Herbals\Mitragynine;Alprazolam;Acetaminop  
 hen\Butalbital\Caffeine Product Used For Unknown Indication  
 Toxicity To Various Agents Serious Died Female 2017 25-  
 JAN-2019 Expedited 28 YR Not Specified Novast  
 Healthcare Professional Not Specified - 14-JAN-2019 25-  
 JAN-2019 US Not Specified "US-NOVAST LABORATORIES, LTD-  
 US-2019NOV000010" "Fagiola M, Hahn T, Avella J. Screening of  
 Novel Psychoactive Substances in Postmortem Matrices by Liquid  
 Chromatography-Tandem Mass Spectrometry (LC-MS-MS). J-Anal-Toxicol.  
 2018;42(8):562-569" -

15861486 - Herbals\Mitragynine;Fentanyl -  
 Accidental Death;Overdose Serious Died Male 14-SEP-2018  
 23-JAN-2019 Direct 32 YR Not Specified Fda-Ctu Not  
 Specified Not Specified Codeine;Cannabis Sativa Flowering  
 Top;Clonazepam - 23-JAN-2019 US Not Specified -

15852553 Methadone Methadone  
 Hydrochloride;Morphine;Meperidine;Phentermine;Herbals\Mitragynine  
 Product Used For Unknown Indication Vomiting;Toxicity To  
 Various Agents;Respiration Abnormal;Death Serious Died;Other  
 Outcomes Male 2017 22-JAN-2019 Expedited 41 YR  
 Not Specified Aurobindo Healthcare Professional Not  
 Specified - 07-JAN-2019 22-JAN-2019 US Not  
 Specified US-AUROBINDO-AUR-APL-2019-002815 "Fagiola M,  
 Hahn T, Avella J, et,al.. Screening of Novel Psychoactive Substances  
 in Postmortem Matrices by Liquid Chromatography-Tandem Mass  
 Spectrometry (LC-MS-MS).. Journal of Analytical Toxicology. 2018;42  
 (8):562-69" -

15851501 -  
 Codeine;Morphine;Herbals\Mitragynine;Diamorphine;Alprazolam;Butalbital  
 Product Used For Unknown Indication Unresponsive To  
 Stimuli;Toxicity To Various Agents;Drug Abuse Serious Died;Other  
 Outcomes Female 2017 22-JAN-2019 Expedited 28 YR  
 Not Specified Aurobindo Healthcare Professional Not  
 Specified - 07-JAN-2019 22-JAN-2019 US Not  
 Specified US-AUROBINDO-AUR-APL-2019-002816 "Fagiola M,  
 Hahn T, Avella J, et,al.. Screening of Novel Psychoactive Substances  
 in Postmortem Matrices by Liquid Chromatography-Tandem Mass  
 Spectrometry (LC-MS-MS).. Journal of Analytical Toxicology. 2018;42  
 (8):562-59" -

15847213 -  
Herbals\Mitragynine;Citalopram;Caffeine;Mirtazapine Product Used  
For Unknown Indication Cardio-Respiratory Arrest;Intentional Product  
Use Issue Serious Hospitalized;Died;Other Outcomes Male  
- 21-JAN-2019 Expedited 32 YR Not Specified  
Apotex Healthcare Professional Not Specified - 09-  
JAN-2019 21-JAN-2019 US Not Specified US-  
APOTEX-2019AP006448 "Gummin DD, Mowry JB, Spyker DA, Brooks DE,  
Osterthaler KM, Banner W.. 2017 Annual Report of the American  
Association of Poison Control Centers' National Poison Data System  
(NPDS): 35th Annual Report. Doi.org/10.1080/15563650.2018.1533727.  
Clinical Toxicology. 2018;1-203" -

15845706 -  
Quetiapine;Herbals\Mitragynine;Cyclobenzaprine;Tramadol Product Used  
For Unknown Indication Drug Abuse;Cardio-Respiratory Arrest  
Serious Other Outcomes;Hospitalized;Died Male - 20-  
JAN-2019 Expedited 31 YR Not Specified Apotex  
Healthcare Professional Not Specified - 09-JAN-2019 20-  
JAN-2019 US Not Specified US-  
APOTEX-2019AP006442 "Gummin DD, Mowry JB, Spyker DA, Brooks DE,  
Osterthaler KM, Banner W.. 2017 Annual Report of the American  
Association of Poison Control Centers' National Poison Data System  
(NPDS): 35th Annual Report. Doi.org/10.1080/15563650.2018.1533727.  
Clinical Toxicology. 2018;1-203" -

15854458 - Herbals\Mitragynine Asthenia  
Feeling Abnormal;Fear Serious Hospitalized;Life Threatening Female  
31-DEC-2018 18-JAN-2019 Direct 33 YR 54 KG Fda-  
Ctu Consumer Consumer  
Cyanocobalamin\Dexpanthenol\Niacinamide\Pyridoxine  
Hydrochloride\Riboflavin 5'-Phosphate Sodium\Thiamine  
Hydrochloride\Vitamin B Complex;Gabapentin;Vitamins;Celexa  
18-JAN-2019 US Not Specified - - -

15842169 -  
Alprazolam;Clonazepam;Fentanyl;Cocaine;Herbals\Mitragynine;Diphenhydramine Product Used For Unknown Indication Death;Cardio-Respiratory Arrest Serious Hospitalized;Other Outcomes;Died  
Male - 18-JAN-2019 Expedited 31 YR Not Specified  
Apotex Healthcare Professional Not Specified -  
09-JAN-2019 18-JAN-2019 US Not Specified US-  
APOTEX-2019AP005521 "Gummin DD, Mowry JB, Spyker DA, Brooks DE,  
Osterthaler KM, Banner W.. 2017 Annual Report of the American  
Association of Poison Control Centers' National Poison Data System  
(NPDS): 35th Annual Report. Doi.org/10.1080/15563650.2018.1533727.  
Clinical Toxicology. 2018;1-203" -

15856852 - Herbals\Mitragynine Anxiety;Pain  
Seizure;Treatment Noncompliance Serious Hospitalized;Other Outcomes  
Female 22-JUL-2018 17-JAN-2019 Direct 33 YR 51 KG  
Fda-Ctu Healthcare Professional Health Professional  
Cannabis Sativa Subsp. Indica Top - 17-JAN-2019 US  
Not Specified - - -

15838083           Methadone           Methadone  
Hydrochloride;Meperidine;Herbals\Mitragynine;Morphine  
Sulfate;Phentermine Hydrochloride           Product Used For Unknown  
Indication           Drug Interaction;Toxicity To Various Agents  
Serious Died        Male        -        17-JAN-2019        Expedited        41 YR  
                    Not Specified   Lannett Healthcare Professional Not Specified  
                    -        07-JAN-2019        17-JAN-2019        US        Not Specified  
                    "US-LANNETT COMPANY, INC.-US-2019LAN000070"        "Fagiola M,  
Hahn T, Avella J.. Screening of Novel Psychoactive Substances in  
Postmortem Matrices by Liquid Chromatography-Tandem Mass Spectrometry  
(LC-MS-MS).. J-Anal-Toxicol. 2018;42(8):562-569"        -  
15837565           -           Herbals\Mitragynine;Amphetamine  
Sulfate\Dextroamphetamine           Attention Deficit Hyperactivity  
Disorder;Pain        Heart Rate Increased;Balance  
Disorder;Mydriasis;Logorrhea;Erythema;Pupillary Reflex  
Impaired;Dysarthria;Blood Pressure Increased;Muscle  
Twitching;Tremor;Hyperreflexia;Muscle Rigidity;Drug Abuse;Impaired  
Driving Ability;Speech Disorder;Restlessness        Serious Other Outcomes  
                    Female        -        17-JAN-2019        Expedited        37 YR        Not  
Specified           Mylan        Healthcare Professional Not Specified        Celexa  
                    08-JAN-2019        17-JAN-2019        US        Not Specified        US-  
MYLANLABS-2019M1002863 Wright TH. Suspected Driving Under the  
Influence Case Involving Mitragynine. J-Anal-Toxicol 2018;42(7):e65-e68.        -  
15836548           -           Fentanyl;Herbals\Mitragynine        Product Used  
For Unknown Indication        Drug Abuse        Serious Other Outcomes;Died  
                    Female        -        17-JAN-2019        Non-Expedited        60 YR        Not  
Specified           Apotex        Healthcare Professional Not Specified        -  
                    09-JAN-2019        17-JAN-2019        US        Not Specified        US-  
APOTEX-2019AP005802        "Gummin DD, Mowry JB, Spyker DA, Brooks DE,  
Osterthaler KM, Banner W.. 2017 Annual Report of the American  
Association of Poison Control Centers' National Poison Data System  
(NPDS): 35th Annual Report. Doi.org/10.1080/15563650.2018.1533727.  
Clinical Toxicology. 2018;1-203"        -  
15836209           -           Fentanyl;Herbals\Mitragynine        Product Used  
For Unknown Indication        Drug Abuse        Serious Died        Female        2017  
                    17-JAN-2019        Expedited        60 YR        Not Specified        Insys  
                    Healthcare Professional Not Specified        -        03-JAN-2019  
                    17-JAN-2019        US        Not Specified        "US-INSYS  
THERAPEUTICS, INC-INS201901-000232"        -        -  
15831424           -           Alprazolam;Diphenhydramine;Clonazepam;Fentanyl;Herbals\Mitragynine;Cocaine  
Product Used For Unknown Indication        Incorrect Route Of  
Product Administration;Cardio-Respiratory Arrest        Serious Died  
                    Male        2017        16-JAN-2019        Expedited        31 YR        Not  
Specified           Insys        Healthcare Professional Not Specified        -  
                    03-JAN-2019        16-JAN-2019        US        Not Specified        "US-  
INSYS THERAPEUTICS, INC-INS201901-000129"        -        -  
15812850           -           Herbals\Mitragynine        Depression;Pain  
Malaise;Product Use In Unapproved Indication;Product Advertising Issue

Non-Serious      Non-Serious      Male      -      11-JAN-2019  
 Direct    30 YR    Not Specified    Fda-Ctu Not Specified    Not  
 Specified    -      -      11-JAN-2019      US      Not Specified  
 -      -      -  
 15808461      -      Fentanyl  
 Citrate;Cocaine;Clonazepam;Alprazolam;Herbals\Mitragynine;Diphenhydramine Hydrochloride      -      Death;Respiratory Arrest;Cardiac Arrest      Serious Died      Male      2017      10-JAN-2019      Expedited  
 31 YR      Not Specified      Pfizer      Healthcare Professional Not Specified      -      04-JAN-2019      10-JAN-2019      US      Not Specified      US-PFIZER INC-2019008954      "Gummin, D.. 2017 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 35th Annual Report. CLINICAL TOXICOLOGY. 2018;10.1080/15563650.2018.1533727" -  
 15805707      -      Quetiapine;Herbals\Mitragynine      Product Used For Unknown Indication Seizure;Tongue Haemorrhage;Hyperthermia;Drug Interaction;Discharge;Toxicity To Various Agents      Serious Other Outcomes;Died;Life Threatening Not Specified      -      10-JAN-2019      Expedited      Not Specified      Not Specified      Macleods Healthcare Professional Not Specified      Valproic Acid      27-DEC-2018      10-JAN-2019      US      Not Specified      US-MACLEODS PHARMACEUTICALS US LTD-MAC2018019464      "Hughes RL.. Fatal combination of mitragynine and quetiapine - a case report with discussion of a potential herb-drug interaction.. Journal Forensic Science, Medicine and Pathology. 2018" -  
 15728141      -      Herbals\Mitragynine;Quetiapine      Product Used For Unknown Indication Hyperthermia;Seizure;Drug Interaction;Toxicity To Various Agents      Serious Other Outcomes;Died      Male      -      05-JAN-2019      Expedited      27 YR      Not Specified      Accord Healthcare Professional Not Specified      Valproic Acid      27-DEC-2018      17-DEC-2018      US      Not Specified      US-ACCORD-095899      Hughes RL. Fatal combination of mitragynine and quetiapine - a case report with discussion of a potential herb-drug interaction. Forensic Sci Med Pathol. 2018 Nov 29. -  
 15726843      -      Quetiapine;Herbals\Mitragynine      Product Used For Unknown Indication Seizure;Toxicity To Various Agents;Drug Interaction;Hyperthermia;Tongue Haemorrhage;Discharge      Serious Life Threatening;Other Outcomes;Died Male      -      05-JAN-2019      Expedited      27 YR      Not Specified      Aurobindo Healthcare Professional      Not Specified      Valproic Acid      27-DEC-2018      17-DEC-2018      US      Not Specified      US-AUROBINDO-AUR-APL-2018-060149      Hughes RL.. Fatal combination of mitragynine and quetiapine - a case report with discussion of a potential herb-drug interaction.. Forensic Sci Med Pathol.. 2018 -  
 15789740      -      Herbals\Mitragynine;Quetiapine      Product Used For Unknown Indication Drug Interaction;Toxicity To Various Agents;Seizure;Tongue Haemorrhage;Hyperthermia;Discharge      Serious Other Outcomes;Life Threatening;Died      Male      -      04-JAN-2019      Expedited      27 YR      Not Specified      Hikma Healthcare Professional Not Specified      Valproic Acid      27-DEC-2018

04-JAN-2019 US Not Specified US-HIKMA  
PHARMACEUTICALS USA INC.-US-H14001-18-09231 - -  
15788815 - Quetiapine;Herbals\Mitragynine Product Used  
For Unknown Indication Hyperthermia;Toxicity To Various Agents;Drug  
Interaction;Tongue Haemorrhage;Discharge;Seizure Serious Other  
Outcomes;Died;Life Threatening Male - 04-JAN-2019  
Expedited 27 YR Not Specified Torrent Healthcare  
Professional Not Specified Valproic Acid 27-DEC-2018 04-  
JAN-2019 US Not Specified US-TORRENT-00007388 -  
-  
15790380 - Herbals\Mitragynine Drug  
Detoxification;Drug Withdrawal Syndrome Cold  
Sweat;Hypoaesthesia;Palpitations;Product Use Complaint;Cardiac  
Flutter;Chest Pain;Product Packaging Issue Serious Other Outcomes  
Female 02-JAN-2019 03-JAN-2019 Direct 28 YR 66.6  
KG Fda-Ctu Consumer Consumer Advil;Methadone -  
03-JAN-2019 US Y - - -  
15781686 - Herbals\Mitragynine - Loss Of  
Consciousness;Dependence;Seizure Serious Life  
Threatening;Hospitalized Female 30-DEC-2018 31-DEC-2018  
Direct 32 YR 56 KG Fda-Ctu Healthcare Professional Health  
Professional Disulfiram;Vortioxetine  
Hydrobromide;Pregabalin;Gabapentin;Diazepam;Carbamazepine -  
31-DEC-2018 US Not Specified - - -  
15776230 - Quetiapine Fumarate;Herbals\Mitragynine  
Product Used For Unknown Indication Pyrexia;Herbal  
Interaction;Inhibitory Drug Interaction;Toxicity To Various  
Agents;Seizure Serious Died;Other Outcomes Male - 31-  
DEC-2018 Expedited 27 YR Not Specified Apotex  
Healthcare Professional Not Specified Valproic Acid 21-DEC-2018  
31-DEC-2018 US Not Specified US-APOTEX-2018AP028355  
"Hughes RL. Fatal combination of mitragynine and quetiapine—a  
case report with discussion of a potential herb-drug interaction. DOI:  
10.1007/s12024-018-0049-9. Forensic Science, Medicine and Pathology.  
2018" -  
15773913 -  
Herbals\Mitragynine;Alcohol;Diphenhydramine;Bupropion;Dextromethorphan  
Product Used For Unknown Indication Drug Abuse;Cardiac  
Arrest;Respiratory Arrest Serious Life Threatening;Died;Other  
Outcomes Male - 29-DEC-2018 Expedited 27 YR  
Not Specified Aurobindo Healthcare Professional Not  
Specified - 14-DEC-2018 29-DEC-2018 US Not  
Specified US-AUROBINDO-AUR-APL-2018-061555 "Gummin DD,  
Mowry JB, Spyker DA, Brooks DE, Fraser MO, Banner W.. 2016 Annual  
Report of the American Association of Poison Control Centers' National  
Poison Data System (NPDS):34th Annual Report. Clinical Toxicology.  
2017;55(10):1072ñ1254" -  
15773700 -  
Herbals\Mitragynine;Alcohol;Acetaminophen\Hydrochloride Diphenhydramine  
Product Used For Unknown Indication Intentional

Product Misuse Serious Other Outcomes;Died Female - 29-  
DEC-2018 Expedited 53 YR Not Specified Aurobindo  
Healthcare Professional Not Specified - 14-DEC-2018  
29-DEC-2018 US Not Specified US-AUROBINDO-AUR-  
APL-2018-063425 "Gummin DD, Mowry JB, Spyker DA, Brooks DE, Fraser MO,  
Banner W.. 2016 Annual Report of the American Association of Poison  
Control Centers' National Poison Data System (NPDS):34th Annual  
Report. Clinical Toxicology. 2017;55(10):1072ñ1254" -  
15768330 Methadone Methadone  
Hydrochloride;Phentermine;Herbals\Mitragynine;Meperidine;Morphine  
Product Used For Unknown Indication Respiration  
Abnormal;Toxicity To Various Agents;Vomiting Serious Died Male  
- 27-DEC-2018 Expedited 41 YR Not Specified  
Sandoz Healthcare Professional Not Specified - 24-  
DEC-2018 27-DEC-2018 US Not Specified  
PHHY2018US194459 "Fagiola M, Hahn T, Avella J. Screening of  
Novel Psychoactive Substances in Postmortem Matrices by Liquid  
Chromatography-Tandem Mass Spectrometry (LC-MS-MS). JOURNAL OF  
ANALYTICAL TOXICOLOGY. 2018;42:562-9" -  
15768328 - Codeine;Morphine;Diacetylmorphine  
Hydrochloride;Herbals\Mitragynine;Alprazolam;Butalbital Product Used  
For Unknown Indication Unresponsive To Stimuli;Toxicity To Various  
Agents Serious Died Female - 27-DEC-2018 Expedited  
28 YR Not Specified Sandoz Healthcare Professional Not  
Specified - 24-DEC-2018 27-DEC-2018 US Not  
Specified PHHY2018US194478 "Fagiola M, Hahn T, Avella J.  
Screening of Novel Psychoactive Substances in Postmortem Matrices by  
Liquid Chromatography-Tandem Mass Spectrometry (LC-MS-MS). JOURNAL OF  
ANALYTICAL TOXICOLOGY. 2018;42:562-9" -  
15764127 - Herbals\Mitragynine;Diphenhydramine  
Product Used For Unknown Indication Completed Suicide  
Serious Other Outcomes;Died Female - 27-DEC-2018  
Expedited 38 YR Not Specified Aurobindo Healthcare  
Professional Not Specified - 14-DEC-2018 27-DEC-2018  
US Not Specified US-AUROBINDO-AUR-APL-2018-060672  
"Gummin DD, Mowry JB, Spyker DA, Brooks DE, Fraser MO, Banner  
W.. 2016 Annual Report of the American Association of Poison Control  
Centers' National Poison Data System (NPDS):34th Annual Report.  
Clinical Toxicology. 2017;55(10):1072ñ1254" -  
15765187 - Herbals\Mitragynine;Alprazolam -  
Toxicity To Various Agents Serious Died Female 24-APR-2018  
26-DEC-2018 Direct 43 YR Not Specified Fda-Ctu Not  
Specified Not Specified - - 26-DEC-2018 US  
Not Specified - - -  
15750330 Heroin  
Diamorphine;Butalbital;Herbals\Mitragynine;Alprazolam Product Used  
For Unknown Indication Unresponsive To Stimuli;Death;Toxicity To  
Various Agents Serious Died;Other Outcomes Female - 21-  
DEC-2018 Expedited 28 YR Not Specified Apotex  
Healthcare Professional Not Specified - 10-DEC-2018 21-

DEC-2018 US Not Specified US-  
 APOTEX-2018AP027493 "Fagiola M, Hahn T, Avella J. Screening of  
 Novel Psychoactive Substances in Postmortem Matrices by Liquid  
 Chromatography-Tandem Mass Spectrometry (LC-MS-MS). Journal of  
 Analytical Toxicology. 2018;42 (8):562 – 569" –  
 15735523 – Quetiapine Fumarate;Herbals\Mitragynine  
 Product Used For Unknown Indication Seizure;Toxicity To Various  
 Agents;Drug Interaction;Hyperthermia Serious Other Outcomes;Died  
 Male – 21-DEC-2018 Expedited 27 YR Not  
 Specified Alkem Healthcare Professional Not Specified  
 Valproic Acid 07-DEC-2018 18-DEC-2018 US Not Specified  
 US-ALKEM LABORATORIES LIMITED-US-  
 ALKEM-2018-11093 "Hughes RL.. Fatal combination of Mitragynine  
 and Quetiapine – a case report with discussion of a potential herb-  
 drug interaction.. Forensic Science, Medicine and Pathology.  
 2018;UNK:1-4" –  
 15748896 – Herbals\Mitragynine  
 Anxiety;Depression;Pain Weight Decreased;Decreased  
 Appetite;Arthralgia;Tremor;Anxiety;Night Sweats;Depression;Bone  
 Pain;Withdrawal Syndrome Serious Other Outcomes Female 13-  
 DEC-2018 19-DEC-2018 Direct 52 YR Not Specified Fda-  
 Ctu Consumer Consumer  
 Gabapentin;Sertraline;Trazodone – 19-DEC-2018 US Not  
 Specified – – –  
 15735652 – Herbals\Mitragynine Affective  
 Disorder;Asthenia;Cognitive Disorder;Disturbance In Attention  
 Cardiac Death Serious Died Male 09-NOV-2018 18-DEC-2018  
 Direct 33 YR 72.57 KG Fda-Ctu Not Specified Not  
 Specified – – – 18-DEC-2018 US Not Specified  
 – – –  
 15744592 – Herbals\Mitragynine Product Used For  
 Unknown Indication International Normalised Ratio Increased;Blood  
 Urine Present;Bleeding Time Prolonged Serious Life  
 Threatening;Hospitalized Male 26-NOV-2018 17-DEC-2018  
 Direct 50 YR 98.5 KG Fda-Ctu Healthcare Professional Health  
 Professional Lisinopril;Testosterone;Levothyroxine – 17-  
 DEC-2018 US Not Specified – – –  
 15734067 – Herbals\Mitragynine – Pneumonia  
 Haemophilus;Toxicity To Various Agents Serious Died Male 02-  
 MAY-2017 17-DEC-2018 Direct 64 YR Not Specified Fda-  
 Ctu Healthcare Professional Health Professional – – –  
 17-DEC-2018 US Not Specified – – –  
 15734060 – Herbals\Mitragynine;Oxycodone –  
 Toxicity To Various Agents;Breast Cancer Metastatic;Drug Screen  
 Positive Serious Died Female 31-OCT-2017 17-DEC-2018  
 Direct 50 YR Not Specified Fda-Ctu Healthcare  
 Professional Health Professional  
 Hydrocodone;Ephedrine;Amitriptyline – 17-DEC-2018 US  
 Not Specified – – –  
 15734028 – Herbals\Mitragynine – Toxicity To

Various Agents;Accidental Death Serious Died Male 01-NOV-2018  
 17-DEC-2018 Direct 27 YR Not Specified Fda-Ctu Not  
 Specified Not Specified Bupropion - 17-DEC-2018  
 US Not Specified - - -

15723428 - Herbals\Mitragynine;Paroxetine -  
 Toxicity To Various Agents;Accidental Death Serious Died Male  
 22-APR-2018 14-DEC-2018 Direct 36 YR Not Specified  
 Fda-Ctu Not Specified Not Specified - - 14-  
 DEC-2018 US Not Specified - - -

15716888 - Herbals\Mitragynine Affective  
 Disorder;Asthenia;Disturbance In Attention Cardiac Death;Toxicity  
 To Various Agents Serious Died Male 09-NOV-2018 12-  
 DEC-2018 Direct 33 YR 72.57 KG Fda-Ctu Not Specified  
 Not Specified - - 12-DEC-2018 US Not  
 Specified - - -

15704628 - Herbals\Mitragynine - Toxicity To  
 Various Agents;Accidental Death Serious Died Male 08-JAN-2017  
 10-DEC-2018 Direct 29 YR Not Specified Fda-Ctu Not  
 Specified Not Specified

Hydroxyzine;Temazepam;Olanzapine;Cannabis Sativa Subsp. Indica  
 Top;Sertraline;Clonazepam - 10-DEC-2018 US Not  
 Specified - - -

15704622 - Herbals\Mitragynine;Oxycodone -  
 Toxicity To Various Agents;Accidental Death Serious Died Female  
 29-MAR-2016 10-DEC-2018 Direct 53 YR Not Specified  
 Fda-Ctu Not Specified Not Specified

Fluoxetine;Pseudoephedrine. - 10-DEC-2018 US Not  
 Specified - - -

15704619 - Herbals\Mitragynine;U-47700 -  
 Overdose;Accidental Death Serious Died Male 29-FEB-2016  
 10-DEC-2018 Direct 25 YR Not Specified Fda-Ctu Not  
 Specified Not Specified - - 10-DEC-2018 US  
 Not Specified - - -

15704002 - Herbals\Mitragynine -  
 Asphyxia;Toxicity To Various Agents;Accidental Death Serious Died  
 Male 08-NOV-2016 10-DEC-2018 Direct 27 YR Not  
 Specified Fda-Ctu Not Specified Not Specified

Diphenhydramine;Tramadol;Guaifenesin;Oxycodone;Topiramate;Promethazine  
 ;Dextromethorphan - 10-DEC-2018 US Not Specified

- - -

15703871 - Herbals\Mitragynine;Citalopram -  
 Alcohol Poisoning;Accidental Death;Toxicity To Various Agents  
 Serious Died Male 12-NOV-2016 10-DEC-2018 Direct 24 YR  
 Not Specified Fda-Ctu Not Specified Not Specified -  
 - 10-DEC-2018 US Not Specified - -

- -

15703855 - Herbals\Mitragynine;Oxycodone -  
 Accidental Death;Toxicity To Various Agents;Alcohol Poisoning  
 Serious Died Male 24-FEB-2018 10-DEC-2018 Direct 32 YR  
 Not Specified Fda-Ctu Not Specified Not Specified -

-        10-DEC-2018     US     Not Specified     -     -  
 -  
 15703850     -     Herbals\Mitragynine;Oxycodone     -  
 Toxicity To Various Agents;Alcohol Poisoning;Accidental Death  
 Serious Died     Male     04-NOV-2017     10-DEC-2018     Direct     26 YR  
 Not Specified     Fda-Ctu Not Specified     Not Specified     -  
 -        10-DEC-2018     US     Not Specified     -     -  
 -  
 15703751     -     Herbals\Mitragynine     -     Accidental  
 Death;Toxicity To Various Agents     Serious Died     Male     23-  
 JUL-2018     10-DEC-2018     Direct     29 YR     Not Specified     Fda-  
 Ctu     Not Specified     Not Specified     Bupropion;Diphenhydramine  
 -        10-DEC-2018     US     Not Specified     -     -  
 -  
 15703747     -     Herbals\Mitragynine     -     Toxicity To  
 Various Agents;Accidental Death     Serious Died     Male     11-AUG-2017  
 10-DEC-2018     Direct     33 YR     Not Specified     Fda-Ctu Not  
 Specified     Not Specified     -     -     10-DEC-2018     US  
 Not Specified     -     -     -  
 15703716     -     Herbals\Mitragynine     -     Toxicity To  
 Various Agents;Accidental Death     Serious Died     Male     11-JUL-2016  
 07-DEC-2018     Direct     30 YR     Not Specified     Fda-Ctu Not  
 Specified     Not Specified  
 Bupropion;Hydroxyzine;Diazepam;Gabapentin;Naltrexone;Clonidine     -  
 07-DEC-2018     US     Not Specified     -     -     -  
 15680525     -     Herbals\Mitragynine     Substance Use     Liver  
 Function Test Increased;Cholecystitis     Serious Hospitalized;Other  
 Outcomes     Male     -     28-NOV-2018     Direct     35 YR     70 KG  
 Fda-Ctu Healthcare Professional Health Professional     -  
 -        28-NOV-2018     US     Not Specified     -     -  
 -  
 15665505     -     Herbals\Mitragynine     -     Overdose  
 Serious Died     Male     02-NOV-2018     27-NOV-2018     Direct  
 32 YR     67.5 KG     Fda-Ctu Not Specified     Not Specified     -  
 -        27-NOV-2018     US     Not Specified     -     -  
 -  
 15665400     -     Herbals\Mitragynine     Pain     Anxiety;Extra  
 Dose Administered;Tremor;Hypertension     Serious Other Outcomes     Female  
 -        27-NOV-2018     Direct     70 YR     Not Specified     Fda-  
 Ctu     Healthcare Professional Health Professional     -     -  
 27-NOV-2018     US     Not Specified     -     -     -  
 15660102     -     Diphenhydramine;Herbals\Mitragynine     -  
 Toxicity To Various Agents;Seizure     Serious Died     Female  
 14-AUG-2017     26-NOV-2018     Direct     33 YR     Not Specified  
 Fda-Ctu Not Specified     Not Specified     -     -     26-  
 NOV-2018     US     Not Specified     -     -     -  
 15660099     -     Alprazolam;Herbals\Mitragynine     -  
 Toxicity To Various Agents     Serious Died     Male     02-JAN-2018  
 26-NOV-2018     Direct     27 YR     Not Specified     Fda-Ctu Not  
 Specified     Not Specified     -     -     26-NOV-2018     US

Not Specified - - - -  
 15660097 - Herbals\Mitragynine - Toxicity To  
 Various Agents Serious Died Male 11-DEC-2017 26-NOV-2018  
     Direct 36 YR Not Specified Fda-Ctu Not Specified Not  
 Specified - - 26-NOV-2018 US Not Specified  
     - - -  
 15656009 - Herbals\Mitragynine;Oxymorphone -  
 Toxicity To Various Agents Serious Died Male 14-MAY-2015  
     23-NOV-2018 Direct 52 YR Not Specified Fda-Ctu Not  
 Specified Not Specified - - 23-NOV-2018 US  
     Not Specified - - -  
 15656003 Hydroxyzine Hydroxyzine  
 Hydrochloride;Herbals\Mitragynine;Clonazepam - Toxicity To  
 Various Agents Serious Died Male 27-OCT-2018 23-NOV-2018  
     Direct 39 YR Not Specified Fda-Ctu Not Specified Not  
 Specified - - 23-NOV-2018 US Not Specified  
     - - -  
 15643589 - Herbals\Mitragynine - Accidental  
 Death;Toxicity To Various Agents Serious Died Male 28-  
     FEB-2018 21-NOV-2018 Direct 50 YR Not Specified Fda-  
 Ctu Not Specified Not Specified - - 21-NOV-2018  
     US Not Specified - - -  
 15643588 Pseudoephedrine. Pseudoephedrine  
 Hydrochloride;Herbals\Mitragynine - Poisoning;Accidental  
 Death;Renal Artery Perforation Serious Died Male 01-OCT-2018  
     21-NOV-2018 Direct 38 YR Not Specified Fda-Ctu Not  
 Specified Not Specified - - 21-NOV-2018 US  
     Not Specified - - -  
 15643582 - Herbals\Mitragynine - Accidental  
 Death;Toxicity To Various Agents Serious Died Male 21-  
     SEP-2016 21-NOV-2018 Direct 29 YR Not Specified Fda-  
 Ctu Not Specified Not Specified - - 21-NOV-2018  
     US Not Specified - - -  
 15642453 - Herbals\Mitragynine - Product  
 Complaint;Recalled Product;Gastroenteritis Salmonella Non-Serious  
     Non-Serious Not Specified 09-APR-2018 20-NOV-2018  
     Direct Not Specified Not Specified Fda-Ctu Not Specified  
     Not Specified - - 20-NOV-2018 US Not  
 Specified - - -  
 15638164 - Herbals\Mitragynine Product Used For  
 Unknown Indication Occupational Problem Environmental;Product  
 Counterfeit;Seizure Serious Hospitalized Female 28-MAY-1997  
     19-NOV-2018 Direct 21 YR 58.5 KG Fda-Ctu Consumer  
     Consumer - - 19-NOV-2018 US Not  
 Specified - - Yes  
 15612598 - Herbals\Mitragynine - Death  
 Serious Died Not Specified 2017 13-NOV-2018 Direct 32 YR  
     Not Specified Fda-Ctu Not Specified Not Specified -  
     - 13-NOV-2018 US Not Specified - -  
     -

15612592 - Herbals\Mitragynine - Death  
 Serious Died Male 24-SEP-2017 13-NOV-2018 Direct 32 YR  
     Not Specified Fda-Ctu Not Specified Not Specified -  
     - 13-NOV-2018 US Not Specified - -  
     -

15612590 - Herbals\Mitragynine - Death  
 Serious Died Male 23-JUL-2016 13-NOV-2018 Direct 40 YR  
     Not Specified Fda-Ctu Not Specified Not Specified -  
     - 13-NOV-2018 US Not Specified - -  
     -

15600806 - Herbals\Mitragynine -  
     Diarrhoea;Dehydration;Palpitations;Unevaluable Event;Vomiting Non-  
 Serious Non-Serious Not Specified AUG-2018 08-NOV-2018  
     Direct Not Specified Not Specified Fda-Ctu Not Specified  
     Not Specified - - 08-NOV-2018 US Not  
     Specified - - -

15599665 - Herbals\Mitragynine Depression  
     Maternal Drugs Affecting Foetus;Drug Withdrawal Syndrome Neonatal  
     Serious Hospitalized Female 09-JUL-2018 08-NOV-2018  
     Direct 1 DAY 3.53 KG Fda-Ctu Healthcare Professional Health  
     Professional - - 08-NOV-2018 US Not Specified  
     - - -

15580732 - Herbals\Mitragynine  
     Anxiety;Depression;Intervertebral Disc Protrusion;Post-Traumatic  
     Stress Disorder Hypophagia;Vomiting;Hyperhidrosis;Diarrhoea  
 Serious Other Outcomes Male 25-OCT-2018 03-NOV-2018 Direct  
     28 YR 72 KG Fda-Ctu Consumer Consumer -  
     - 03-NOV-2018 US Not Specified - -  
     -

15561348 - Herbals\Mitragynine - Malaise;Acute  
     Kidney Injury;Hepatic Failure;Pneumonia;Pain;Respiratory  
     Failure;Hepatic Enzyme Increased;Fatigue Serious Life  
     Threatening;Disabled;Hospitalized Male 21-OCT-2018 26-  
     OCT-2018 Direct 45 YR 90 KG Fda-Ctu Consumer  
     Consumer Vicks Dayquil;Vicks Nyquil - 26-0CT-2018  
     US Not Specified - - -

15549931 - Herbals\Mitragynine - Death  
 Serious Died Female 26-JUN-2015 25-OCT-2018 Direct 43 YR  
     Not Specified Fda-Ctu Not Specified Not Specified -  
     - 25-OCT-2018 US Not Specified - -  
     -

15555676 - Herbals\Mitragynine Anxiety;Insomnia  
     Nausea;Panic Reaction;Hyperhidrosis;Mood Altered;Withdrawal  
     Syndrome;Depressed Level Of Consciousness;Irritability;Confusional  
     State;Restlessness;Asthenia;Anhedonia;Diarrhoea Serious Other Outcomes  
     Male 15-OCT-2018 24-OCT-2018 Direct 39 YR 70.2  
     KG Fda-Ctu Consumer Consumer - - 24-  
     OCT-2018 US Not Specified - - -  
 15549873 - Herbals\Mitragynine - Death  
 Serious Died Female - 24-OCT-2018 Direct 53 YR Not

Specified Fda-Ctu Not Specified Not Specified - - -
 24-OCT-2018 US Not Specified - - -
 15546727 - Herbals\Mitragynine - - Death
 Serious Died Female - 24-OCT-2018 Direct 45 YR Not
 Specified Fda-Ctu Not Specified Not Specified - - -
 24-OCT-2018 US Not Specified - - -
 15546722 - Herbals\Mitragynine - - Death
 Serious Died Male - 24-OCT-2018 Direct 34 YR Not
 Specified Fda-Ctu Not Specified Not Specified - - -
 24-OCT-2018 US Not Specified - - -
 15546706 - Herbals\Mitragynine - - Death
 Serious Died Male 10-MAY-2018 24-OCT-2018 Direct 31 YR
 Not Specified Fda-Ctu Not Specified Not Specified - -
 - 24-OCT-2018 US Not Specified - - -
 -
 15546705 - Herbals\Mitragynine - - Death
 Serious Died Female 26-FEB-2018 24-OCT-2018 Direct 34 YR
 Not Specified Fda-Ctu Not Specified Not Specified - -
 - 24-OCT-2018 US Not Specified - - -
 -
 15526393 - Fentanyl Citrate;Diphenhydramine
 Hydrochloride;Herbals\Mitragynine - Homicide;Euphoric
 Mood;Road Traffic Accident Serious Other Outcomes Male -
 23-OCT-2018 Expedited Not Specified Not Specified
 Pfizer Consumer Not Specified
 Gabapentin;Neurontin;Lexapro;Percocet 17-OCT-2018 18-OCT-2018
 US Not Specified US-PFIZER INC-2018424071 -
 -
 15517591 - Herbals\Mitragynine - Personality
 Change;Drug Dependence;Hyperhidrosis;Agitation;Thinking
 Abnormal;Diarrhoea;Vomiting;Irritability;Tremor;Withdrawal
 Syndrome;Cold Sweat Non-Serious Non-Serious Male -
 18-OCT-2018 Direct 39 YR 81.65 KG Fda-Ctu
 Consumer Not Specified - - 18-OCT-2018 US
 Not Specified - - -
 15492732 - Herbals\Mitragynine Product Used For
 Unknown Indication Death Serious Died Not Specified 26-
 AUG-2018 07-OCT-2018 Direct Not Specified Not Specified
 Fda-Ctu Consumer Consumer - - 07-
 OCT-2018 US Not Specified - - -
 15468345 - Herbals\Mitragynine Pain Accidental
 Death;Unresponsive To Stimuli;Toxicity To Various Agents
 Serious Died Male 26-MAR-2017 05-OCT-2018 Direct 38 YR
 92.53 KG Fda-Ctu Healthcare Professional Health
 Professional - - 05-OCT-2018 US Not Specified
 - - -
 15460471 - Herbals\Mitragynine Pain
 Anxiety;Adjustment Disorder With Depressed Mood Serious Disabled
 Female - 03-OCT-2018 Direct 62 YR 103.5 KG
 Fda-Ctu Consumer Consumer

Calcium;Inderal;Synthroid	-	-	03-OCT-2018	US	Not	
Specified	-	-	Yes			
15418902	-	Herbals\Mitragynine	-	Death		
Serious Died	Female	-	24-SEP-2018	Direct	55 YR	Not
Specified	Fda-Ctu	Not Specified	Not Specified	-	-	
	24-SEP-2018	US	Not Specified	-	-	-
15418898	-	Herbals\Mitragynine	-	Death		
Serious Died	Male	-	24-SEP-2018	Direct	33 YR	Not
Specified	Fda-Ctu	Not Specified	Not Specified	-	-	
	24-SEP-2018	US	Not Specified	-	-	-
15418894	-	Herbals\Mitragynine	-	Death		
Serious Died	Male	-	24-SEP-2018	Direct	32 YR	Not
Specified	Fda-Ctu	Not Specified	Not Specified	-	-	
	24-SEP-2018	US	Not Specified	-	-	-
15418899	-	Herbals\Mitragynine	-	Death		
Serious Died	Female	-	24-SEP-2018	Direct	49 YR	Not
Specified	Fda-Ctu	Not Specified	Not Specified	-	-	
	24-SEP-2018	US	Not Specified	-	-	-
15418807	-	Herbals\Mitragynine	-	Death		
Serious Died	Male	-	24-SEP-2018	Direct	34 YR	Not
Specified	Fda-Ctu	Not Specified	Not Specified	-	-	
	24-SEP-2018	US	Not Specified	-	-	-
15418798	-	Herbals\Mitragynine	-	Death		
Serious Died	Female	-	24-SEP-2018	Direct	29 YR	Not
Specified	Fda-Ctu	Not Specified	Not Specified	-	-	
	24-SEP-2018	US	Not Specified	-	-	-
15418792	-	Herbals\Mitragynine	-	Death		
Serious Died	Female	-	24-SEP-2018	Direct	37 YR	Not
Specified	Fda-Ctu	Not Specified	Not Specified	-	-	
	24-SEP-2018	US	Not Specified	-	-	-
15418787	-	Herbals\Mitragynine	-	Death		
Serious Died	Male	-	24-SEP-2018	Direct	27 YR	Not
Specified	Fda-Ctu	Not Specified	Not Specified	-	-	
	24-SEP-2018	US	Not Specified	-	-	-
15418653	-	Herbals\Mitragynine	-	Death		
Serious Died	Male	-	24-SEP-2018	Direct	35 YR	Not
Specified	Fda-Ctu	Not Specified	Not Specified	-	-	
	24-SEP-2018	US	Not Specified	-	-	-
15418646	-	Herbals\Mitragynine	-	Death		
Serious Died	Male	-	24-SEP-2018	Direct	47 YR	Not
Specified	Fda-Ctu	Not Specified	Not Specified	-	-	
	24-SEP-2018	US	Not Specified	-	-	-
15418633	-	Herbals\Mitragynine	-	Death		
Serious Died	Male	-	24-SEP-2018	Direct	56 YR	Not
Specified	Fda-Ctu	Not Specified	Not Specified	-	-	
	24-SEP-2018	US	Not Specified	-	-	-
15418628	-	Herbals\Mitragynine	-	Death		
Serious Died	Female	-	24-SEP-2018	Direct	32 YR	Not
Specified	Fda-Ctu	Not Specified	Not Specified	-	-	
	24-SEP-2018	US	Not Specified	-	-	-

15418625 - Herbals\Mitragynine - Death  
 Serious Died Male - 24-SEP-2018 Direct 59 YR Not  
 Specified Fda-Ctu Not Specified Not Specified - - -  
 24-SEP-2018 US Not Specified - - -  
 15418624 - Herbals\Mitragynine - Death  
 Serious Died Male - 24-SEP-2018 Direct 28 YR Not  
 Specified Fda-Ctu Not Specified Not Specified - - -  
 24-SEP-2018 US Not Specified - - -  
 15418621 - Herbals\Mitragynine - Death  
 Serious Died Male - 24-SEP-2018 Direct 36 YR Not  
 Specified Fda-Ctu Not Specified Not Specified - - -  
 24-SEP-2018 US Not Specified - - -  
 15418618 - Herbals\Mitragynine - Death  
 Serious Died Male - 24-SEP-2018 Direct 31 YR Not  
 Specified Fda-Ctu Not Specified Not Specified - - -  
 24-SEP-2018 US Not Specified - - -  
 15418514 - Herbals\Mitragynine - Death  
 Serious Died Male - 24-SEP-2018 Direct 42 YR Not  
 Specified Fda-Ctu Not Specified Not Specified - - -  
 24-SEP-2018 US Not Specified - - -  
 15419200 - Herbals\Mitragynine Pain;Withdrawal  
 Syndrome Pain;Apathy;Drug Dependence;Feeling  
 Abnormal;Unemployment;Loss Of Personal Independence In Daily  
 Activities Serious Hospitalized Female 14-JUN-2018 20-  
 SEP-2018 Direct 39 YR 76.5 KG Fda-Ctu Consumer  
 Consumer - - 20-SEP-2018 US Not Specified  
 - - -  
 15367091 Diflucan  
 Fluconazole;Nystatin;Herbals\Mitragynine - Klebsiella  
 Test Positive;Culture Urine Positive;Bladder Disorder Serious Other  
 Outcomes Female 01-AUG-2018 10-SEP-2018 Direct 73 YR  
 Not Specified Fda-Ctu Not Specified Not Specified -  
 - 10-SEP-2018 US Not Specified - - -  
 -  
 15373449 - Herbals\Mitragynine Pain Management  
 Aspartate Aminotransferase Increased;Overdose;Liver Function Test  
 Increased;Alanine Aminotransferase Increased;Blood Alcohol  
 Abnormal;Blood Alkaline Phosphatase Increased Serious  
 Hospitalized;Other Outcomes Female 27-AUG-2018 09-SEP-2018  
 Direct 54 YR 75 KG Fda-Ctu Healthcare Professional Health  
 Professional - - 09-SEP-2018 US Not Specified  
 - - -  
 15357076 - Herbals\Mitragynine Substance Use  
 Psychotic Disorder Serious Other Outcomes;Hospitalized;Disabled  
 Female 10-MAR-2018 04-SEP-2018 Direct 19 YR 49.5  
 KG Fda-Ctu Consumer Consumer - - -  
 SEP-2018 US Y - - -  
 15338188 -  
 Lamotrigine;Quetiapine;Paroxetine;Herbals\Mitragynine Product Used  
 For Unknown Indication Death Serious Died Not Specified -

31-AUG-2018 Expedited Not Specified Not Specified  
 Apotex Healthcare Professional Not Specified - 20-  
 JUL-2018 31-AUG-2018 US Not Specified US-  
 APOTEX-2018AP019264 "Noori M, Hendrickson R, Hatten B.. Kratom:  
 Natural painkiller or herbal enemy?. Clinical Toxicology.  
 2018;56(6):574" -

15346850 - Herbals\Mitragynine Drug Dependence  
 Circulatory Collapse;Fall Serious Died;Life Threatening Male  
 14-AUG-2018 30-AUG-2018 Direct 33 YR 112.5 KG  
 Fda-Ctu Consumer Consumer Lasix;Amitriptyline  
 - 30-AUG-2018 US Not Specified - - -

15339133 - Herbals\Mitragynine Anxiety  
 Fall;Seizure;Fatigue;Cerebral Haemorrhage;Incoherent;Vomiting;Head  
 Injury Serious Life Threatening Male 27-AUG-2018 30-  
 AUG-2018 Direct 22 YR 77.11 KG Fda-Ctu Consumer  
 Not Specified - - - 30-AUG-2018 US Not Specified

15338870 - Herbals\Mitragynine Anxiety  
 Tremor;Withdrawal Syndrome;Cerebral Haemorrhage;Seizure;Head Injury  
 Serious Life Threatening;Hospitalized Male 27-AUG-2018  
 29-AUG-2018 Direct 22 YR 76.5 KG Fda-Ctu Consumer  
 Consumer Prozac - 29-AUG-2018 US Not Specified

15334061 - Herbals\Mitragynine Anxiety;Sleep Disorder  
 Therapy Alcohol Use;Intentional Product Use Issue Serious Died  
 Male 23-NOV-2017 29-AUG-2018 Direct 22 YR 68.04  
 KG Fda-Ctu Consumer Consumer - - 29-  
 AUG-2018 US Not Specified - - -

15346316 - Herbals\Mitragynine - Hepatic  
 Failure;Malaise;Drug Abuse;Staphylococcal Infection Serious  
 Hospitalized;Life Threatening Male AUG-2018 28-AUG-2018  
 Direct 24 YR Not Specified Fda-Ctu Not Specified Not  
 Specified - - 28-AUG-2018 US Not Specified

15346315 - Herbals\Mitragynine Pain Yellow  
 Skin;Drug Dependence;Drug Abuse;Generalised Tonic-Clonic  
 Seizure;Weight Decreased;Withdrawal Syndrome;Brief Resolved  
 Unexplained Event Serious Life Threatening;Disabled Male  
 10-MAY-2018 28-AUG-2018 Direct 35 YR 74.84 KG  
 Fda-Ctu Healthcare Professional Health Professional -  
 - 28-AUG-2018 US Not Specified - -

15305997 - Herbals\Mitragynine - Death  
 Serious Died Male 19-JUN-2018 21-AUG-2018 Direct 36 YR  
 Not Specified Fda-Ctu Not Specified Not Specified -  
 - 21-AUG-2018 US Not Specified - -

15289168 -  
 Lamotrigine;Herbals\Mitragynine;Quetiapine;Paroxetine Product Used

For Unknown Indication Death Serious Died Not Specified -
 17-AUG-2018 Expedited Not Specified Not Specified
 Sciegen Healthcare Professional Not Specified - 09-
 AUG-2018 17-AUG-2018 US Not Specified US-SCIEGEN
 PHARMACEUTICALS INC-2018SCILIT00549 "Monica Noori, Robert
 Hendrickson, Benjamin Hatten et al.. Kratom: Natural painkiller or
 herbal enemy?.. Clinical Toxicology. 122" -
 15468186 - Herbals\Mitragynine - Death
 Serious Died Male 12-MAR-2018 16-AUG-2018 Direct 28 YR
 Not Specified Fda-Ctu Not Specified Not Specified -
 - 16-AUG-2018 US Not Specified -
 -
 15459453 - Herbals\Mitragynine - Death
 Serious Died Male - 16-AUG-2018 Direct 47 YR Not
 Specified Fda-Ctu Not Specified Not Specified -
 16-AUG-2018 US Not Specified -
 15456552 - Herbals\Mitragynine - Death
 Serious Died Male 08-APR-2018 16-AUG-2018 Direct 28 YR
 Not Specified Fda-Ctu Not Specified Not Specified -
 - 16-AUG-2018 US Not Specified -
 -
 15456548 - Herbals\Mitragynine - Death
 Serious Died Male 01-JUN-2018 16-AUG-2018 Direct 26 YR
 Not Specified Fda-Ctu Not Specified Not Specified -
 - 16-AUG-2018 US Not Specified -
 -
 15456483 - Herbals\Mitragynine - Death
 Serious Died Male 03-JUN-2017 16-AUG-2018 Direct 31 YR
 Not Specified Fda-Ctu Not Specified Not Specified -
 - 16-AUG-2018 US Not Specified -
 -
 15456479 - Herbals\Mitragynine - Death
 Serious Died Male 25-JAN-2018 16-AUG-2018 Direct 22 YR
 Not Specified Fda-Ctu Not Specified Not Specified -
 - 16-AUG-2018 US Not Specified -
 -
 15456169 - Herbals\Mitragynine - Death
 Serious Died Male 29-DEC-2017 16-AUG-2018 Direct 26 YR
 Not Specified Fda-Ctu Not Specified Not Specified -
 - 16-AUG-2018 US Not Specified -
 -
 15456106 - Herbals\Mitragynine - Death
 Serious Died Male 03-OCT-2016 16-AUG-2018 Direct 60 YR
 Not Specified Fda-Ctu Not Specified Not Specified -
 - 16-AUG-2018 US Not Specified -
 -
 15456105 - Herbals\Mitragynine - Death
 Serious Died Male 02-MAY-2017 16-AUG-2018 Direct 20 YR
 Not Specified Fda-Ctu Not Specified Not Specified -
 - 16-AUG-2018 US Not Specified -

15456104 - Herbals\Mitragynine - Death  
 Serious Died Male 08-MAR-2017 16-AUG-2018 Direct 34 YR  
     Not Specified Fda-Ctu Not Specified Not Specified -  
     - 16-AUG-2018 US Not Specified - -  
 -  
 15456060 - Herbals\Mitragynine - Death  
 Serious Died Male 30-OCT-2017 16-AUG-2018 Direct 20 YR  
     Not Specified Fda-Ctu Not Specified Not Specified -  
     - 16-AUG-2018 US Not Specified - -  
 -  
 15456052 - Herbals\Mitragynine - Death  
 Serious Died Male 11-JAN-2018 16-AUG-2018 Direct 38 YR  
     Not Specified Fda-Ctu Not Specified Not Specified -  
     - 16-AUG-2018 US Not Specified - -  
 -  
 15456051 - Herbals\Mitragynine - Death  
 Serious Died Male 07-JUL-2017 16-AUG-2018 Direct 24 YR  
     Not Specified Fda-Ctu Not Specified Not Specified -  
     - 16-AUG-2018 US Not Specified - -  
 -  
 15456041 - Herbals\Mitragynine - Sudden  
     Death;Hypertension;Death;Toxicity To Various Agents Serious Died  
         Male 30-APR-2018 16-AUG-2018 Direct 37 YR Not  
         Specified Fda-Ctu Not Specified Not Specified - -  
         16-AUG-2018 US Not Specified - - -  
 15456031 - Herbals\Mitragynine - Death  
 Serious Died Female 05-APR-2018 16-AUG-2018 Direct 31 YR  
     Not Specified Fda-Ctu Not Specified Not Specified -  
     - 16-AUG-2018 US Not Specified - -  
 -  
 15455971 - Herbals\Mitragynine - Death  
 Serious Died Male 19-JAN-2018 16-AUG-2018 Direct 22 YR  
     Not Specified Fda-Ctu Not Specified Not Specified -  
     - 16-AUG-2018 US Not Specified - -  
 -  
 15455966 - Herbals\Mitragynine - Death  
 Serious Died Male 27-JUN-2018 16-AUG-2018 Direct 25 YR  
     Not Specified Fda-Ctu Not Specified Health Professional  
     - - 16-AUG-2018 US Not Specified - -  
 -  
 15455961 - Herbals\Mitragynine - Death  
 Serious Died Male 25-APR-2018 16-AUG-2018 Direct 30 YR  
     Not Specified Fda-Ctu Not Specified Not Specified -  
     - 16-AUG-2018 US Not Specified - -  
 -  
 15455955 - Herbals\Mitragynine - Death  
 Serious Died Male 23-JAN-2018 16-AUG-2018 Direct 39 YR  
     Not Specified Fda-Ctu Not Specified Not Specified -  
     - 16-AUG-2018 US Not Specified - -

15455883 - Herbals\Mitragynine - Death  
 Serious Died Female 09-NOV-2017 16-AUG-2018 Direct 50 YR  
     Not Specified Fda-Ctu Not Specified Not Specified -  
     - 16-AUG-2018 US Not Specified - -  
 -  
 15455877 - Herbals\Mitragynine - Death  
 Serious Died Male 13-APR-2018 16-AUG-2018 Direct 34 YR  
     Not Specified Fda-Ctu Not Specified Not Specified -  
     - 16-AUG-2018 US Not Specified - -  
 -  
 15455816 - Herbals\Mitragynine - Death  
 Serious Died Male 07-OCT-2017 16-AUG-2018 Direct 35 YR  
     Not Specified Fda-Ctu Not Specified Not Specified -  
     - 16-AUG-2018 US Not Specified - -  
 -  
 15454944 - Herbals\Mitragynine - Death  
 Serious Died Female 05-APR-2018 16-AUG-2018 Direct 31 YR  
     Not Specified Fda-Ctu Not Specified Not Specified -  
     - 16-AUG-2018 US Not Specified - -  
 -  
 15454932 - Herbals\Mitragynine - Death  
 Serious Died Male 25-APR-2018 16-AUG-2018 Direct 30 YR  
     Not Specified Fda-Ctu Not Specified Not Specified -  
     - 16-AUG-2018 US Not Specified - -  
 -  
 15454852 - Herbals\Mitragynine - Fall;Toxicity  
 To Various Agents Serious Died Male 30-APR-2018 16-  
 AUG-2018 Direct 37 YR Not Specified Fda-Ctu Not Specified  
     Not Specified - - 16-AUG-2018 US Not  
     Specified - - -  
 15454794 - Herbals\Mitragynine - Death  
 Serious Died Male - 16-AUG-2018 Direct 34 YR Not  
     Specified Fda-Ctu Not Specified Not Specified - -  
     16-AUG-2018 US Not Specified - -  
 15454777 - Herbals\Mitragynine - Death  
 Serious Died Female 09-NOV-2017 16-AUG-2018 Direct 50 YR  
     Not Specified Fda-Ctu Not Specified Not Specified -  
     - 16-AUG-2018 US Not Specified - -  
 -  
 15454755 - Herbals\Mitragynine - Death  
 Serious Died Male 27-JUN-2018 16-AUG-2018 Direct 25 YR  
     Not Specified Fda-Ctu Not Specified Health Professional  
     - - 16-AUG-2018 US Not Specified -  
     - -  
 15287064 - Herbals\Mitragynine Therapy Cessation  
     Mobility Decreased;Vertigo;Visual Impairment;Dizziness;Feeling  
 Abnormal Serious Other Outcomes Female 28-JUL-2018 14-  
 AUG-2018 Direct 30 YR 78.12 KG Fda-Ctu Consumer  
     Consumer - - 14-AUG-2018 US Y

- - -  
 15306341 - Herbals\Mitragynine Drug Dependence  
 Pain;Vomiting;Hyperhidrosis;Dehydration;Drug  
 Dependence;Anxiety;Restless Legs Syndrome;Drug Withdrawal  
 Syndrome;Constipation;Depression;Acne;Agitation Serious Disabled  
 Male 07-AUG-2018 10-AUG-2018 Direct 34 YR 99 KG  
 Fda-Ctu Consumer Consumer Wellbutrin;Buspirone  
 Hydrochloride;Effexor - 10-AUG-2018 US Y -  
 - Yes

15275951 - Herbals\Mitragynine - Generalised  
 Tonic-Clonic Seizure Serious Other Outcomes;Disabled;Life  
 Threatening Female 05-AUG-2018 10-AUG-2018 Direct 32 YR  
 58.5 KG Fda-Ctu Consumer Consumer - - -  
 10-AUG-2018 US Not Specified - - -  
 15216665 - Herbals\Mitragynine Anxiety;Depression  
 Delusion;Drug Dependence;Psychotic Disorder;Hallucination  
 Serious Hospitalized Male 27-JUL-2018 27-JUL-2018  
 Direct 26 YR 69.75 KG Fda-Ctu Consumer  
 Consumer - - 27-JUL-2018 US Not Specified  
 - - Yes

15195288 -  
 Lamotrigine;Herbals\Mitragynine;Quetiapine;Paroxetine Product Used  
 For Unknown Indication Death Serious Other Outcomes;Died Not  
 Specified - 25-JUL-2018 Expedited Not Specified  
 Not Specified Glaxosmithkline Healthcare Professional Not  
 Specified - 20-JUL-2018 25-JUL-2018 US Not  
 Specified US-GLAXOSMITHKLINE-US2018132304 "Noori M, Hendrickson  
 R, Hatten B. Kratom: Natural painkiller or herbal enemy?. Clinical  
 Toxicology. 2018;56(6):574. DOI: 10.1080/15563650.2018.1457818."

-  
 15191858 - Herbals\Mitragynine - Physical  
 Product Label Issue;Diarrhoea Serious Other Outcomes Not Specified  
 12-JUL-2018 24-JUL-2018 Direct Not Specified Not  
 Specified Fda-Ctu Consumer Consumer - - -  
 24-JUL-2018 US Not Specified - - -

15169793 - Herbals\Mitragynine Pain Death  
 Serious Died Male 03-FEB-2018 18-JUL-2018 Direct 46 YR  
 108 KG Fda-Ctu Consumer Consumer - - -  
 18-JUL-2018 US Y - - Yes

15125035 - Herbals\Mitragynine -  
 Malaise;Vomiting;Dizziness;Dehydration Serious Disabled Male  
 02-JUL-2018 07-JUL-2018 Direct 26 YR 80.55 KG  
 Fda-Ctu Consumer Consumer - - -  
 JUL-2018 US Not Specified - - - 07-

15028581 - Herbals\Mitragynine Anxiety;Depression  
 "Hallucination, Auditory;Disturbance In Attention;Weight  
 Decreased;Psychotic Disorder;Drug Dependence;Asocial  
 Behaviour;Hallucination;Anxiety" Serious Other  
 Outcomes;Hospitalized Male 17-DEC-2017 18-JUN-2018 Direct  
 25 YR 72 KG Fda-Ctu Consumer Consumer - -

-        18-JUN-2018     US     Not Specified    -     -

-        15017057     -     Herbals\Mitragynine    -     Toxicity To  
 Various Agents;Dilatation Ventricular;Dilatation  
 Atrial;Cardiomegaly;Cardiac Disorder;Coronary Artery Stenosis  
 Serious Died    Male    -    15-JUN-2018    Direct    38 YR    Not  
 Specified    Fda-Ctu Not Specified    Not Specified    -    -  
 15-JUN-2018    US    Not Specified    -    -    -

15017050     -     Herbals\Mitragynine    -     Seizure  
 Serious Other Outcomes    Male    -    15-JUN-2018    Direct    19 YR  
 Not Specified    Fda-Ctu Not Specified    Not Specified    -  
 -        15-JUN-2018     US     Not Specified    -    -  
 -

15011391     -     Herbals\Mitragynine    Drug Withdrawal  
 Syndrome     Anxiety;Drug Withdrawal Syndrome;Suicidal  
 Ideation;Drug Dependence    Non-Serious    Non-Serious    Male  
 08-JUN-2018    13-JUN-2018    Direct    34 YR    56.25 KG  
 Fda-Ctu Consumer    Consumer    -    -    13-  
 JUN-2018        US    Not Specified    -    -    -

14995024     -     Herbals\Mitragynine    -     Aspartate  
 Aminotransferase Increased;Blood Creatinine;Alanine Aminotransferase  
 Increased;Multi-Organ Disorder;Somnolence;Obesity;Sepsis;Respiratory  
 Failure;Liver Injury;Obstructive Sleep Apnoea  
 Syndrome;Ischaemia;Respiratory Depression;Hypotension;Blood Potassium  
 Increased;Hypoxia;Oxygen Saturation Decreased;Respiratory  
 Acidosis;Dyspnoea;Acute Kidney Injury;Irritability;Cyanosis  
 Serious Hospitalized    Male    -    08-JUN-2018    Direct    43 YR  
 Not Specified    Fda-Ctu Not Specified    Health Professional  
 -        08-JUN-2018     US     Not Specified    -  
 -

14972899     -     Herbals\Mitragynine    -     Vomiting;Job  
 Dissatisfaction;Abdominal Pain Upper;Vision Blurred;Visual  
 Impairment;Loss Of Personal Independence In Daily  
 Activities;Migraine;Abdominal Distension;Loss Of Consciousness  
 Serious Other Outcomes    Female    22-APR-2018    04-JUN-2018    Direct  
 39 YR    49.9 KG    Fda-Ctu Consumer    Consumer    -  
 -        04-JUN-2018     US     Not Specified    -    -  
 -

14955172     Alcohol (Alcohol)  
 Alcohol;Dextromethorphan;U-47700;Diphenhydramine;Herbals\Mitragynine;B  
 upropion     -     Drug Abuse;Toxicity To Various Agents  
 Serious Died    Not Specified    -    31-MAY-2018    Expedited  
 Not Specified    Not Specified    Cipla Healthcare  
 Professional    Not Specified    -    17-MAY-2018    31-MAY-2018  
 US    Not Specified    US-CIPLA  
 LTD.-2018US18723     "Gummin DD, Mowry JB, Spyker DA, Brooks DE,  
 Fraser MO, Banner W. 2016 Annual Report of the American Association of  
 Poison Control Centers' National Poison Data System (NPDS): 34th  
 Annual Report. Clinical toxicology. 2017;1 to 181"    -  
 14933993     -     Herbals\Mitragynine    -     Toxicity To

Various Agents Serious Died Male - 23-MAY-2018 Direct  
 26 YR Not Specified Fda-Ctu Healthcare Professional Health  
 Professional - - 23-MAY-2018 US Not Specified  
 - - -  
 14930211 - Herbals\Mitragynine - Alcohol  
 Use;Headache Serious Died Female 19-MAY-2018 22-MAY-2018  
 Direct 38 YR 61.2 KG Fda-Ctu Healthcare Professional Health  
 Professional Alcohol - 22-MAY-2018 US Not Specified  
 - - Yes  
 14923707 - Herbals\Mitragynine -  
 Gastroenteritis Salmonella;Diarrhoea;Abdominal Pain Upper;Recalled  
 Product Administered;Nausea Non-Serious Non-Serious Not  
 Specified 09-APR-2018 22-MAY-2018 Direct Not Specified  
 Not Specified Fda-Ctu Not Specified Not Specified -  
 - 22-MAY-2018 US Not Specified - -  
 -  
 14920117 - Herbals\Mitragynine - Unresponsive  
 To Stimuli;Alcohol Use;Headache Serious Hospitalized;Life  
 Threatening;Disabled Not Specified 19-MAY-2018 19-MAY-2018  
 Direct 38 YR 61.2 KG Fda-Ctu Healthcare Professional Health  
 Professional - - 19-MAY-2018 US Not Specified  
 - - Yes  
 14895829 - Herbals\Mitragynine - Drug  
 Dependence Non-Serious Non-Serious Not Specified -  
 15-MAY-2018 Direct Not Specified Not Specified Fda-  
 Ctu Healthcare Professional Health Professional - -  
 15-MAY-2018 US Not Specified - - -  
 14909154 - Herbals\Mitragynine - Death  
 Serious Died Male 11-JAN-2018 14-MAY-2018 Direct 41 YR  
 98.1 KG Fda-Ctu Consumer Consumer Sertraline  
 Hydrochloride - 14-MAY-2018 US Not Specified -  
 - -  
 14892289 - Herbals\Mitragynine Stress  
 Vomiting;Headache;Muscle Spasms;Product  
 Contamination;Pyrexia;Diarrhoea;Chills Serious Disabled Male  
 07-MAY-2018 09-MAY-2018 Direct 34 YR 85.5 KG Fda-  
 Ctu Consumer Consumer Fish Oil;Vitamins -  
 09-MAY-2018 US Not Specified - - -  
 14892273 - Herbals\Mitragynine Pain Management  
 Gastroenteritis Salmonella Serious Hospitalized Male 06-  
 MAY-2018 08-MAY-2018 Direct 41 YR Not Specified Fda-  
 Ctu Consumer Consumer - - 08-MAY-2018  
 US Not Specified - - -  
 14875716 - Herbals\Mitragynine - Death  
 Serious Died Male 11-JAN-2018 08-MAY-2018 Direct 41 YR  
 98.1 KG Fda-Ctu Consumer Consumer Sertraline  
 Hydrochloride - 08-MAY-2018 US Not Specified -  
 - -  
 14842070 - Herbals\Mitragynine - Cardiac  
 Arrest;Acute Myocardial Infarction;Ventricular Fibrillation

Serious Life Threatening;Other Outcomes;Hospitalized;Disabled Female  
 23-APR-2018 01-MAY-2018 Direct 29 YR 106 KG Fda-Ctu Healthcare Professional Health Professional  
 Ibuprofen;Xanax - 01-MAY-2018 US Not Specified -

14820210 - Herbals\Mitragynine Pain Escherichia  
 Infection;Illness;Product Contamination Microbial Serious  
 Disabled Female 19-APR-2018 26-APR-2018 Direct 31 YR  
 65.25 KG Fda-Ctu Consumer Consumer  
 Synthroid - 26-APR-2018 US Y - -

14801101 - Herbals\Mitragynine Stress Drug  
 Dependence Serious Other Outcomes Female 01-APR-2018 22-  
 APR-2018 Direct 39 YR Not Specified Fda-Ctu Consumer  
 Consumer - - -

14354167 - 3-  
 Methoxyphencyclidine;Paroxetine;Herbals\Mitragynine;Bupropion;Delorazepam Product Used For Unknown Indication Toxicity To Various Agents;Substance Abuse;Unresponsive To Stimuli Serious Other Outcomes;Died Male - 22-APR-2018 Expedited 21 YR  
 Not Specified Apotex Healthcare Professional Not Specified  
 - 14-MAR-2018 05-JAN-2018 US Not Specified  
 US-APOTEX-2018AP005109 "Mitchell-Mata C, Thomas B, Peterson B, Couper F.. Two fatal intoxications involving 3-methoxyphencyclidine. doi: 10.1093/jat/bkx048. Journal of Analytical Toxicology. 2017;41(6):503-507" -

14784298 - Herbals\Mitragynine -  
 Vomiting;Chills;Pain;Muscle Spasms;Nausea;Illness;Diarrhoea Non-Serious  
 Serious Non-Serious Male 13-APR-2018 20-APR-2018 Direct  
 50 YR Not Specified Fda-Ctu Consumer Consumer  
 - - 20-APR-2018 US Not Specified -

14784877 - Herbals\Mitragynine Anxiety;Arthralgia  
 Abdominal Pain Upper;Diarrhoea;Muscle Spasms;Impaired Work Ability Serious Other Outcomes Male 31-MAR-2018 18-APR-2018  
 Direct 42 YR 92.25 KG Fda-Ctu Consumer  
 Consumer Imodium;Tums;Pepto-Bismol;Ibuprofen;Duloxetine -  
 18-APR-2018 US Y - - -

14769203 - Herbals\Mitragynine - Death  
 Serious Died Male 05-FEB-2018 17-APR-2018 Direct 19 YR  
 Not Specified Fda-Ctu Not Specified Not Specified -  
 - 17-APR-2018 US Not Specified -

14764524 - Herbals\Mitragynine Pain Feeling  
 Abnormal;Gastroenteritis Salmonella;Pyrexia;Hot  
 Flush;Chills;Vomiting;Weight Decreased;Constipation;Night  
 Sweats;Decreased Appetite;Near Death Experience;Tremor Serious Other  
 Outcomes;Hospitalized;Disabled Male 07-MAR-2018 15-APR-2018  
 Direct 25 YR 54 KG Fda-Ctu Consumer Consumer

Excedrin;Tylenol	-	15-APR-2018	US	Not Specified
Specified	-	Yes		
14759510	-	Alcohol;Herbals\Mitragynine	-	
Dialysis;Seizure;Brain Death;Brain Injury;Product Complaint;Myocardial Infarction;Corneal Reflex Decreased;Alcohol Poisoning;Brain Oedema;Blood Methanol	Increased	Serious	Hospitalized;Died	Male
03-APR-2018	13-APR-2018	Direct	32 YR	Not Specified
Fda-Ctu	Not Specified	Not Specified	-	-
14753635	-	Herbals\Mitragynine	-	
Vomiting;Abdominal Discomfort	Non-Serious	Non-Serious	Non-Serious	Not Specified
Specified	29-MAR-2018	12-APR-2018	Direct	Not Specified
Not Specified	Fda-Ctu	Consumer	Not Specified	-
-	12-APR-2018	US	Not Specified	-
-				
14751053	-	Herbals\Mitragynine	-	Nausea;Colitis
Ulcerative;Drug Ineffective;Abdominal Pain;Diarrhoea				
Haemorrhagic;Mouth Ulceration;Vomiting;Physical Product Label Issue;Diarrhoea;Oedema	Peripheral;Pyrexia	Serious	Required	
Intervention;Hospitalized	Female	DEC-2017	11-APR-2018	
Direct	49 YR	Not Specified	Fda-Ctu	Consumer
Specified	-	-	11-APR-2018	US
-	-	-		Not Specified
14753471	-	Herbals\Mitragynine	Drug Withdrawal	
Syndrome;Pain	Chest Pain	Serious	Died	Male
10-APR-2018	Direct	63 YR	56.7 KG	Fda-Ctu
Consumer	Flomax	-	10-APR-2018	US
Specified	-	-		Not Specified
14727666	-	Herbals\Mitragynine	-	Drug Dependence
Dependence;Weight Decreased;Influenza Like Illness		Serious	Other	
Outcomes	Male	-	05-APR-2018	Direct
Not Specified	Fda-Ctu	Consumer	Consumer	-
-	05-APR-2018	US	Not Specified	-
-				
14820204	-	Herbals\Mitragynine	-	
Diarrhoea;Recalled Product Administered;Illness;Gastritis				Non-Serious
Specified	Non-Serious	Female	-	03-APR-2018
Not Specified	Not Specified	Fda-Ctu	Consumer	Direct
-	-	03-APR-2018	US	Not Specified
-	-	-		-
14715448	-	Herbals\Mitragynine	-	Abdominal Pain
Upper;Diarrhoea	Non-Serious	Non-Serious	Male	-
APR-2018	Direct	43 YR	83.25 KG	Fda-Ctu
Consumer	-	-	03-APR-2018	US
Specified	-	-		Not Specified
14708204	-	Herbals\Mitragynine	-	
Myalgia;Recalled Product Administered;Salmonellosis				Non-Serious
Non-Serious	Not Specified	16-NOV-2017	02-APR-2018	
Direct	Not Specified	Not Specified	Fda-Ctu	Consumer
Not Specified	-	-	02-APR-2018	US
				Not Specified

Specified	-	-	-				
14699565	-	Herbals\Mitragynine		Back Pain			
Diarrhoea;Abdominal Discomfort	Serious	Other Outcomes	Male	15-			
FEB-2018	29-MAR-2018	Direct	37 MTH	119.25 KG	Fda-		
Ctu Consumer	Consumer	Advil	-	29-MAR-2018			
US Y	-	-	-				
14699508	-	Herbals\Mitragynine		Attention Deficit			
Hyperactivity Disorder	Drug Dependence	Serious	Other Outcomes	Male			
-	29-MAR-2018	Direct	24 YR	Not Specified	Fda-		
Ctu Consumer	Consumer	-	-	29-MAR-2018			
US Not Specified	-	-	-				
14690808	-	Herbals\Mitragynine	-	Toxicity To			
Various Agents;Accidental Death	Serious	Died	Male	-	28-		
MAR-2018	Direct	Not Specified	Not Specified	Fda-Ctu	Not		
Specified	Not Specified	-	-	28-MAR-2018	US		
Not Specified	-	-	-				
14690805	-	Herbals\Mitragynine	-	Death			
Serious Died	Male	-	28-MAR-2018	Direct	25 YR	Not	
Specified	Fda-Ctu	Not Specified	Not Specified	-	-		
-	28-MAR-2018	US	Not Specified	-	-	-	
14690798	-	Herbals\Mitragynine	-	Death			
Serious Died	Male	-	28-MAR-2018	Direct	38 YR	Not	
Specified	Fda-Ctu	Not Specified	Not Specified	-	-		
-	28-MAR-2018	US	Not Specified	-	-	-	
14690795	-	Herbals\Mitragynine	-	Toxicity To			
Various Agents;Accidental Death	Serious	Died	Male	-	28-		
MAR-2018	Direct	40 YR	Not Specified	Fda-Ctu	Not Specified		
Specified	Not Specified	-	-	28-MAR-2018	US	Not	
Specified	-	-	-				
14690788	-	Herbals\Mitragynine	-	Death			
Serious Died	Male	-	28-MAR-2018	Direct	33 YR	Not	
Specified	Fda-Ctu	Not Specified	Not Specified	-	-		
-	28-MAR-2018	US	Not Specified	-	-	-	
14690779	-	Herbals\Mitragynine	-	Death			
Serious Died	Male	-	28-MAR-2018	Direct	36 YR	Not	
Specified	Fda-Ctu	Not Specified	Not Specified	-	-		
-	28-MAR-2018	US	Not Specified	-	-	-	
14690723	-	Herbals\Mitragynine	-	Death			
Serious Died	Male	-	28-MAR-2018	Direct	23 YR	Not	
Specified	Fda-Ctu	Not Specified	Not Specified	-	-		
-	28-MAR-2018	US	Not Specified	-	-	-	
14690718	-	Herbals\Mitragynine	-	Accidental			
Death;Toxicity To Various Agents	Serious	Died	Not Specified				
-	28-MAR-2018	Direct	26 YR	Not Specified	Fda-		
Ctu Not Specified	Not Specified	-	-	28-MAR-2018			
US Not Specified	-	-	-				
14690713	-	Herbals\Mitragynine	-	Toxicity To			
Various Agents;Accidental Death	Serious	Died	Not Specified	-			
MAR-2018	Direct	30 YR	Not Specified	Fda-Ctu	Not		
Specified	Not Specified	-	-	28-MAR-2018	US		

Not Specified - - - -  
 14689578 Zoloft Sertraline Hydrochloride;Herbals\Mitragynine  
 Anxiety Drug Level Increased;Product Label Issue  
 Serious Died Male 22-APR-2016 27-MAR-2018 Direct 22 YR  
 103.5 KG Fda-Ctu Consumer Consumer -  
 - 27-MAR-2018 US Not Specified - -  
 -  
 14679126 - Herbals\Mitragynine Hypertension  
 Pallor;Intentional Product Misuse;Loss Of Consciousness;Respiratory  
 Rate Decreased;Blood Pressure Decreased;Hyperhidrosis Serious Other  
 Outcomes Male - 23-MAR-2018 Direct 37 YR Not  
 Specified Fda-Ctu Consumer Consumer - -  
 23-MAR-2018 US Not Specified - - -  
 14674127 - Herbals\Mitragynine Anxiety;Depression  
 Drug Abuser;Restless Legs  
 Syndrome;Formication;Rhinorrhoea;Lacrimation Increased;Withdrawal  
 Syndrome;Yawning Serious Other Outcomes Female 22-MAR-2018  
 22-MAR-2018 Direct 35 YR 52.2 KG Fda-Ctu Consumer  
 Consumer Abilify;Wellbutrin;Topamax - 22-  
 MAR-2018 US Not Specified - - Yes  
 14665135 - Herbals\Mitragynine Analgesic Therapy  
 Pain;Headache;Gastrointestinal Disorder;Feeding  
 Disorder;Pyrexia;Abdominal Pain Upper;Flatulence;Nausea Non-Serious  
 Non-Serious Female 15-MAR-2018 19-MAR-2018 Direct  
 60 YR 90 KG Fda-Ctu Consumer Consumer  
 Unspecified Ingredient - 19-MAR-2018 US Not Specified  
 - - -  
 14664687 - Herbals\Mitragynine - Drug  
 Dependence Serious Other Outcomes Male 01-JAN-2018 19-  
 MAR-2018 Direct 34 YR 58.5 KG Fda-Ctu Healthcare  
 Professional Health Professional - - 19-MAR-2018  
 US Not Specified - - -  
 14659699 - Herbals\Mitragynine - Product Label  
 Issue;Vertigo;Nausea;Euphoric Mood Serious Other Outcomes Female  
 16-MAR-2018 19-MAR-2018 Direct 48 YR 61.23 KG  
 Fda-Ctu Consumer Consumer - - 19-  
 MAR-2018 US Y - - -  
 14648750 - Herbals\Mitragynine -  
 Incoherent;Fall;Gait Disturbance;Alcohol Use;Product Use Issue  
 Serious Life Threatening Not Specified 19-FEB-2018 16-  
 MAR-2018 Direct 28 YR Not Specified Fda-Ctu Consumer  
 Consumer - - 16-MAR-2018 US Not  
 Specified - - -  
 14637209 - Herbals\Mitragynine Drug Abuse  
 Toxicity To Various Agents Serious Died Male 13-MAR-2017  
 14-MAR-2018 Direct 31 YR 67.13 KG Fda-Ctu  
 Healthcare Professional Health Professional Gabapentin;Heroin  
 - 14-MAR-2018 US Not Specified - -  
 -  
 14637202 - Herbals\Mitragynine Drug Abuse

Alcohol Use;Accidental Death;Toxicity To Various Agents Serious Died  
Male 27-MAY-2014 14-MAR-2018 Direct 24 YR 73.48  
KG Fda-Ctu Healthcare Professional Health Professional  
Venlafaxine;Mirtazapine - 14-MAR-2018 US Not Specified  
- - -  
14637201 - Herbals\Mitragynine Drug Diversion;Product  
Used For Unknown Indication Accidental Death;Toxicity To Various  
Agents Serious Died Male 08-MAR-2015 14-MAR-2018 Direct  
22 YR 88 KG Fda-Ctu Healthcare Professional Health  
Professional - - 14-MAR-2018 US Not Specified  
- - -  
14637183 - Herbals\Mitragynine Drug Diversion;Product  
Used For Unknown Indication Accidental Death;Toxicity To Various  
Agents Serious Died Male 23-APR-2015 14-MAR-2018 Direct  
31 YR 89.81 KG Fda-Ctu Healthcare Professional Health  
Professional Ibuprofen - 14-MAR-2018 US Not  
Specified - - -  
14637163 - Herbals\Mitragynine Drug Diversion;Product  
Used For Unknown Indication Accidental Death;Toxicity To Various  
Agents Serious Died Male 06-JUL-2015 14-MAR-2018 Direct  
45 YR 68.49 KG Fda-Ctu Healthcare Professional Health  
Professional Lisinopril;Lamotrigine;Atenolol - 14-MAR-2018  
US Not Specified - - -  
14637157 - Herbals\Mitragynine Product Used For  
Unknown Indication Toxicity To Various Agents Serious Died  
Male 19-JUL-2015 14-MAR-2018 Direct 23 YR 75.75  
KG Fda-Ctu Healthcare Professional Health Professional -  
- 14-MAR-2018 US Not Specified - -  
-  
14637152 - Herbals\Mitragynine Product Used For  
Unknown Indication Toxicity To Various Agents Serious Died  
Male 03-JUN-2016 14-MAR-2018 Direct 30 YR 73.03  
KG Fda-Ctu Healthcare Professional Health Professional  
Alprazolam;Citalopram;Zolpidem - 14-MAR-2018 US Not  
Specified - - -  
14637146 - Herbals\Mitragynine Product Used For  
Unknown Indication Toxicity To Various Agents Serious Died  
Female 16-JAN-2017 14-MAR-2018 Direct 25 YR 53.98  
KG Fda-Ctu Healthcare Professional Health Professional  
Alprazolam;Sertraline - 14-MAR-2018 US Not Specified  
- - -  
14637050 - Herbals\Mitragynine Drug Diversion;Product  
Used For Unknown Indication Toxicity To Various Agents  
Serious Died Male 10-MAR-2017 14-MAR-2018 Direct 34 YR  
76.66 KG Fda-Ctu Healthcare Professional Health  
Professional Pregabalin;Oxycodone - 14-MAR-2018 US  
Not Specified - - -  
14635754 - Herbals\Mitragynine Drug Withdrawal  
Maintenance Therapy;Pain Restless Legs Syndrome;Loss Of  
Employment;Impaired Quality Of Life;Anger;Drug Withdrawal

Syndrome;Insomnia;Drug Ineffective;Anxiety;Feeling Abnormal;Depressed Mood;Drug Dependence Non-Serious Non-Serious Male -  
 13-MAR-2018 Direct 26 YR 68.04 KG Fda-Ctu  
 Consumer Consumer Herbals\Withania Somnifera  
 Root;Herbals - 13-MAR-2018 US Not Specified -  
 - -  
 14613817 - Herbals\Mitragynine Drug Rehabilitation  
 Seizure;Drug Dependence;Asthenia;Panic Attack Serious  
 Hospitalized;Required Intervention Male 08-JAN-2016 08-  
 MAR-2018 Direct 32 YR 86.18 KG Fda-Ctu Consumer  
 Consumer - - 08-MAR-2018 US Not  
 Specified - - -  
 14577749 - Herbals\Mitragynine Drug Withdrawal  
 Maintenance Therapy Toxicologic Test Abnormal;Toxicity To Various  
 Agents Serious Died Male 05-FEB-2018 26-FEB-2018 Direct  
 19 YR 72 KG Fda-Ctu Consumer Consumer Prozac  
 - 26-FEB-2018 US Not Specified - -  
 -  
 14566812 - Herbals\Mitragynine Anxiety Euphoric  
 Mood;Behaviour Disorder;Personality Change Serious Hospitalized  
 Male 17-NOV-2017 22-FEB-2018 Direct 42 YR 72 KG  
 Fda-Ctu Consumer Consumer Escitalopram -  
 22-FEB-2018 US Not Specified - - Yes  
 14554687 - Benzodiazepine;Herbals\Mitragynine -  
 Haemodynamic Instability;Cardio-Respiratory Arrest;Pneumonia  
 Aspiration;Substance Abuse;Body Temperature Decreased;Metabolic  
 Acidosis Serious Died Female - 20-FEB-2018 Direct  
 29 YR Not Specified Fda-Ctu Not Specified Not Specified  
 - - 20-FEB-2018 US Not Specified -  
 -  
 14554625 - Herbals\Mitragynine;Diphenhydramine -  
 Therapy Non-Responder;Seizure;Cardiac Arrest Serious Died  
 Female - 20-FEB-2018 Direct 38 YR Not Specified  
 Fda-Ctu Not Specified Not Specified - - 20-  
 FEB-2018 US Not Specified - - -  
 14554619 - Herbals\Mitragynine -  
 Rhabdomyolysis;Hypothermia;Alanine Aminotransferase  
 Increased;Electroencephalogram Abnormal;Aspartate Aminotransferase  
 Increased;Blood Creatine Phosphokinase Increased;Areflexia  
 Serious Died Male - 20-FEB-2018 Direct 22 YR Not  
 Specified Fda-Ctu Not Specified Not Specified - -  
 20-FEB-2018 US Not Specified - - -  
 14554618 - Herbals\Mitragynine - Completed  
 Suicide Serious Died Male 16-JUL-2014 20-FEB-2018 Direct  
 20 YR 73.94 KG Fda-Ctu Healthcare Professional Health  
 Professional - - 20-FEB-2018 US Not Specified  
 - - -  
 14554565 Acetaminophen And Diphenhydramine Hydrochloride  
 Acetaminophen\Hydrochloride;Herbals\Mitragynine;Alcohol -  
 Hydrochloride;Herbals\Mitragynine;Alcohol -

Coagulopathy;Hypotension;Respiratory Failure;Encephalopathy;Sepsis;Treatment Failure;Renal Failure;Acute Hepatic Failure Serious Died Female - 20-FEB-2018 Direct  
 53 YR Not Specified Fda-Ctu Not Specified Not Specified  
 - - 20-FEB-2018 US Not Specified -  
 - -  
 14553550 - Herbals\Mitragynine - Vaginal  
 Haemorrhage;Abnormal Uterine Bleeding;Nausea Non-Serious Non-Serious  
 Serious Female - 14-FEB-2018 Direct Not Specified Not Specified  
 Specified Fda-Ctu Consumer Consumer - -  
 14-FEB-2018 US Not Specified - - -  
 14553541 - Herbals\Mitragynine - Abnormal  
 Uterine Bleeding Non-Serious Non-Serious Female -  
 14-FEB-2018 Direct Not Specified Not Specified Fda-  
 Ctu Consumer Consumer - - 14-FEB-2018  
 US Not Specified - - -  
 14553247 - Herbals\Mitragynine Pain Drug  
 Intolerance;Withdrawal Syndrome;Marital Problem;Socioeconomic  
 Precarity;Pain Serious Disabled;Hospitalized Male 03-OCT-2017  
 11-FEB-2018 Direct Not Specified 99 KG Fda-Ctu  
 Consumer Consumer Wellbutrin;Lexapro - 11-  
 FEB-2018 US Not Specified - - Yes  
 14510268 - Herbals\Mitragynine - Drug  
 Dependence Serious Other Outcomes;Required Intervention Male  
 - 08-FEB-2018 Direct 34 YR Not Specified Fda-  
 Ctu Not Specified Health Professional - - 08-  
 FEB-2018 US Not Specified - - -  
 14510227 - Herbals\Mitragynine Back Disorder Drug  
 Dependence Serious Life Threatening;Disabled;Other Outcomes  
 Male - 08-FEB-2018 Direct 34 YR Not Specified  
 Fda-Ctu Consumer Consumer Unspecified Ingredient  
 - 08-FEB-2018 US Not Specified - - -  
 Yes  
 14510073 - Herbals\Mitragynine Back Pain  
 Aspiration Serious Died Male 19-JAN-2014 07-FEB-2018  
 Direct Not Specified 54 KG Fda-Ctu Consumer  
 Consumer - - 07-FEB-2018 US Not Specified  
 - -  
 14501662 - Herbals\Mitragynine Substance Use  
 Mydriasis;Seizure Serious Life Threatening;Hospitalized Not  
 Specified 03-FEB-2018 06-FEB-2018 Direct 17 YR Not  
 Specified Fda-Ctu Healthcare Professional Health Professional  
 - - 06-FEB-2018 US Not Specified -  
 - -  
 14449343 Bupropion Hydrochloride Xl Bupropion  
 Hydrochloride;Dextromethorphan;Alcohol;U-47700;Diphenhydramine;Herbals  
 \Mitragynine Product Used For Unknown Indication Cardio-  
 Respiratory Arrest;Drug Abuse Serious Died Male - 27-  
 JAN-2018 Expedited 27 YR Not Specified Endo  
 Healthcare Professional Not Specified - 02-JAN-2018 27-

JAN-2018 US Not Specified US-ENDO PHARMACEUTICALS  
INC-2018-013940 "Gummin D D, Mowry J B, Spyker D A, Brooks D E, Fraser  
M O, Banner W.. 2016 Annual Report of the American Association of  
Poison Control Centers' National Poison Data System (NPDS): 34th  
Annual Report. Clinical Toxicology. 2017;55 (10):1072-1254" -  
14379566 - 3-  
Methoxyphencyclidine;Delorazepam;Bupropion;Herbals\Mitragynine;Paroxet  
ine Product Used For Unknown Indication Toxicity To Various  
Agents Serious Other Outcomes;Died Male - 12-JAN-2018  
Expedited 21 YR Not Specified Lupin Healthcare  
Professional Not Specified - 29-DEC-2017 12-JAN-2018  
US Not Specified US-LUPIN PHARMACEUTICALS  
INC.-2017-07801 "Mitchell-Mata C, Thomas B, Peterson B, Couper F. Two  
fatal intoxications involving 3-methoxyphencyclidine.. Journal of  
Analytical Toxicology. 2017;41(6):503-507" -  
14379276 - Paroxetine;3-  
Methoxyphencyclidine;Bupropion;Herbals\Mitragynine;Delorazepam  
Product Used For Unknown Indication Toxicity To Various Agents  
Serious Died;Other Outcomes;Life Threatening Male -  
12-JAN-2018 Expedited 21 YR Not Specified  
Ranbaxy Healthcare Professional Not Specified - 29-DEC-2017  
12-JAN-2018 US Not Specified US-SUN PHARMACEUTICAL  
INDUSTRIES LTD-2017US-159563 "Mitchell-Mata C, Thomas B, Peterson  
B, Couper F. Two fatal intoxications involving 3-methoxyphencyclidine.  
J Anal Toxicol. 2017;41(6):503-507" -  
14378666 -  
Phencyclidine;Bupropion;Delorazepam;Herbals\Mitragynine;Paroxetine  
Product Used For Unknown Indication Toxicity To Various  
Agents Serious Other Outcomes;Died;Life Threatening Male -  
12-JAN-2018 Expedited 21 YR Not Specified  
Aurobindo Healthcare Professional Not Specified - 29-  
DEC-2017 12-JAN-2018 US Not Specified US-AUROBINDO-  
AUR-APL-2018-001673 "Mitchell-Mata C, Thomas B, Peterson B, Couper  
F.. Two fatal intoxications involving 3-methoxyphencyclidine. Journal  
of Analytical Toxicology.. 2017;41(6):503-7" -  
14378661 - 3-  
Methoxyphencyclidine;Bupropion;Paroxetine;Delorazepam;Herbals\Mitragyn  
ine;Alcohol - Toxicity To Various Agents;Unresponsive To  
Stimuli Serious Other Outcomes;Died Not Specified - 12-  
JAN-2018 Expedited Not Specified Not Specified Cipla  
Healthcare Professional Not Specified - 29-DEC-2017  
12-JAN-2018 US Not Specified US-CIPLA  
LTD.-2018US00778 "Mitchell-Mata C, Thomas B, Peterson B, Couper  
F.. Two fatal intoxications involving 3-methoxyphencyclidine. Journal  
of Analytical Toxicology. 2017;41(6):503-507" -  
14367521 - Herbals\Mitragynine Anxiety Hepatotoxicity  
Serious Life Threatening Male 18-DEC-2017 05-  
JAN-2018 Direct 25 YR Not Specified Fda-Ctu Healthcare  
Professional Health Professional - - 05-JAN-2018  
US Not Specified - -

14359491 -  
Herbals\Mitragynine;Bupropion;Delorazepam;Paroxetine Product Used  
For Unknown Indication Toxicity To Various Agents Serious  
Died;Life Threatening;Other Outcomes Male - 05-JAN-2018  
Expedited 21 YR Not Specified Bausch And Lomb  
Healthcare Professional Not Specified - 29-DEC-2017 05-  
JAN-2018 US Not Specified US-BAUSCH-BL-2018-000058  
- -

14355797 -  
Bupropion;Paroxetine;Herbals\Mitragynine;Phencyclidine;Delorazepam Product Used For Unknown Indication Toxicity To Various  
Agents Serious Died;Life Threatening Male - 05-JAN-2018  
Expedited 21 YR Not Specified Sandoz Healthcare  
Professional Not Specified - 02-JAN-2018 05-JAN-2018  
US Not Specified PHHY2017US197643 "Mitchell-Mata  
C, Thomas B, Peterson B, Couper F. Two fatal intoxications involving  
3-methoxyphencyclidine. JOURNAL OF ANALYTICAL TOXICOLOGY.  
2017;41(6):503-507" -

13934406 - Paroxetine;Herbals\Mitragynine;Delorazepam;3-  
Methoxyphencyclidine;Alcohol;Bupropion Completed Suicide  
Toxicity To Various Agents Serious Died Male - 05-  
JAN-2018 Expedited 21 YR Not Specified Alvogen  
Healthcare Professional Not Specified - 29-DEC-2017 05-  
SEP-2017 US Not Specified US-ALVOGEN-2017-ALVOGEN-093372  
"Mitchell-Mata C, Thomas B, Peterson B, Couper F. Two Fatal  
Intoxications Involving 3-Methoxyphencyclidine. J Anal Toxicol. 2017  
Jul 1;41(6):503-507." -

14351639 - Herbals\Mitragynine;3-  
Methoxyphencyclidine;Delorazepam;Paroxetine;Bupropion Product Used  
For Unknown Indication Toxicity To Various Agents Serious Other  
Outcomes;Died;Life Threatening Male - 04-JAN-2018  
Expedited 21 YR Not Specified Glaxosmithkline Healthcare  
Professional Not Specified - 22-DEC-2017 04-JAN-2018  
US Not Specified US-GLAXOSMITHKLINE-  
US2018000016 "Mitchell-Mata C, Thomas B, Peterson B, Couper F. Two  
fatal intoxications involving 3-methoxyphencyclidine. Journal of  
Analytical Toxicology. 2017;41(6):503-507; doi: 10.1093/jat/bkx048"  
-

14347379 - Herbals\Mitragynine Neuropathy Peripheral  
Mental Status Changes;Hepatic  
Failure;Lethargy;Coma;Jaundice;Seizure Serious Died;Hospitalized  
Male 02-JAN-2018 02-JAN-2018 Direct 46 YR 93 KG  
Fda-Ctu Healthcare Professional Health Professional  
Metoprolol;Lisinopril - 02-JAN-2018 US Not Specified  
- - -

14347378 - Herbals\Mitragynine Pain Drug  
Dependence Serious Other Outcomes Male - 02-JAN-2018  
Direct 30 YR 65.25 KG Fda-Ctu Consumer  
Consumer Suboxone - 02-JAN-2018 US Not  
Specified - - -

14345738 - Herbals\Mitragynine Muscle Relaxant  
 Therapy Toxicity To Various Agents;Chromaturia;Liver  
 Injury;Jaundice;Pruritus Serious Hospitalized Male 18-  
 DEC-2017 02-JAN-2018 Direct 35 YR 82 KG Fda-Ctu  
 Healthcare Professional Health Professional - - 02-  
 JAN-2018 US Not Specified - - -  
 14345719 - Herbals\Mitragynine Product Used For  
 Unknown Indication Malaise;Near Death Experience;Accidental  
 Overdose;Drug Screen Positive;Opiates Positive Serious Hospitalized  
 Female 02-OCT-2017 02-JAN-2018 Direct 45 YR 45.36  
 KG Fda-Ctu Not Specified Not Specified - - 02-  
 JAN-2018 US Not Specified - - -  
 14343116 - Herbals\Mitragynine Substance Use  
 Withdrawal Syndrome;Loss Of Employment;Impaired Work  
 Ability;Restlessness;Socioeconomic Precarity;Insomnia;Suicidal  
 Ideation;Depression;Nausea;Drug Dependence Serious Other  
 Outcomes;Disabled Male 05-DEC-2015 31-DEC-2017 Direct  
 33 YR 86.4 KG Fda-Ctu Consumer Consumer  
 Parnate - 31-DEC-2017 US Not Specified - - -  
 -  
 14331847 - Herbals\Mitragynine Pain Socioeconomic  
 Precarity;Impaired Work Ability;Drug Dependence;Seizure Serious  
 Hospitalized Male 27-OCT-2017 27-DEC-2017 Direct 31 YR  
 53.55 KG Fda-Ctu Consumer Consumer  
 Seroquel;Xanax - 27-DEC-2017 US Not Specified -  
 -  
 14291011 - Herbals\Mitragynine - Death  
 Serious Died Male - 15-DEC-2017 Direct Not Specified  
 Not Specified Fda-Ctu Consumer Consumer -  
 - 15-DEC-2017 Not Specified Not Specified -  
 -  
 14291010 - Herbals\Mitragynine - Death  
 Serious Died Male 06-AUG-2017 15-DEC-2017 Direct Not  
 Specified Not Specified Fda-Ctu Not Specified Not Specified  
 - - 15-DEC-2017 Not Specified Not Specified Not Specified  
 - - -  
 14290383 -  
 Bupropion;Alcohol;Diphenhydramine;Herbals\Mitragynine;Dextromethorphan  
 Product Used For Unknown Indication Intentional Product  
 Misuse;Death Serious Died Male - 15-DEC-2017  
 Expedited 27 YR Not Specified Alvogen Healthcare  
 Professional Not Specified - 30-NOV-2017 15-DEC-2017  
 US Not Specified US-ALVOGEN-2017-  
 ALVOGEN-094441 "Gummin DD, Mowry JB, Spyker DA, Brooks DE, Fraser MO,  
 Banner W. 2016 Annual Report of the American Association of Poison  
 Control Centers' National Poison Data System (NPDS): 34th Annual  
 Report. Clin Toxicol (Phila). 2017 Dec; 55(10):1072-1252." -  
 14258558 - Herbals\Mitragynine Pain Agitation;Drug  
 Withdrawal Syndrome;Anxiety;Physical Assault;Hostility;Drug Dependence  
 Non-Serious Non-Serious Male 01-MAR-2016 05-

DEC-2017 Direct 24 YR 90 KG Fda-Ctu Consumer  
 Consumer Unspecified Ingredient;Celexa - 05-DEC-2017  
 US Not Specified - - -  
 14212085 - Herbals\Mitragynine Arthralgia;Depression  
 "Loss Of Personal Independence In Daily Activities;Vomiting;Hallucination, Auditory;Yellow Skin;Drug Withdrawal Syndrome;Nausea;Crying;Drug Abuse;Tremor;Nasopharyngitis;Nightmare" Serious Other Outcomes Male  
 09-MAR-2016 21-NOV-2017 Direct 46 YR 81 KG Fda-  
 Ctu Consumer Consumer - - 21-NOV-2017  
 US Not Specified - - -  
 14204882 - Herbals\Mitragynine Anxiety Brain  
 Death;Respiratory Arrest;Drug Dependence;Pulse Absent;Overdose;Marital Problem;Generalised Tonic-Clonic Seizure Serious  
 Died;Hospitalized Male 14-DEC-2013 18-NOV-2017 Direct  
 36 YR 99 KG Fda-Ctu Consumer Consumer  
 Lamictal - 18-NOV-2017 US Not Specified -  
 - -  
 14194942 - Herbals\Mitragynine - Eye  
 Contusion;Haemorrhage;Scar;Fall;Panic Reaction;Skin Laceration;Somnambulism;Sleep Terror Serious Other Outcomes Female  
 02-JUN-2016 15-NOV-2017 Direct 40 YR 58.5 KG Fda-  
 Ctu Consumer Consumer - - 15-NOV-2017  
 US Not Specified - - -  
 14190720 - Herbals\Mitragynine Drug Dependence  
 Overdose Serious Died Male 26-DEC-2016 14-NOV-2017  
 Direct 22 YR Not Specified Fda-Ctu Consumer  
 Consumer Xanax;Unspecified Ingredient - 14-NOV-2017  
 US Not Specified - - -  
 14180919 - Herbals\Mitragynine Product Used For  
 Unknown Indication Jaundice;Lethargy;Hepatic Enzyme Increased  
 Serious Hospitalized;Other Outcomes Male 07-NOV-2017  
 08-NOV-2017 Direct 26 YR Not Specified Fda-Ctu  
 Healthcare Professional Health Professional - - 08-  
 NOV-2017 US Not Specified - - -  
 14157394 - Herbals\Mitragynine Anxiety;Depression  
 Generalised Tonic-Clonic Seizure Serious Other  
 Outcomes;Hospitalized;Life Threatening Male 26-OCT-2017 01-  
 NOV-2017 Direct 35 YR 54 KG Fda-Ctu Consumer  
 Consumer Lamictal;Keppra;Melatonin - 01-NOV-2017  
 US Not Specified - - -  
 14037602 - Herbals\Mitragynine - Sudden  
 Death;Toxicity To Various Agents Serious Died Male 08-  
 MAY-2017 03-OCT-2017 Direct 39 YR 77.85 KG Fda-  
 Ctu Consumer Consumer - - 03-OCT-2017  
 US Not Specified - - -  
 13929400 Contrave Bupropion Hydrochloride\Naltrexone Hydrochloride;Herbals\Mitragynine Product Used For Unknown  
 Indication Drug Interaction;Withdrawal Syndrome Serious  
 Hospitalized Not Specified 04-MAY-2017 01-SEP-2017

Expedited Not Specified Not Specified Orexigen Therapeutics  
Consumer Not Specified - 18-AUG-2017 01-  
SEP-2017 US Not Specified "US-OREXIGEN THERAPEUTICS,  
INC.-2025430" -  
13516276 - Herbals\Mitragynine;Quinine;Loperamide  
Product Used For Unknown Indication Drug Abuse;Drug  
Interaction;Accidental Overdose Serious Died;Other Outcomes Not  
Specified - 05-MAY-2017 Expedited 33 YR Not  
Specified Ranbaxy Healthcare Professional Not Specified -  
20-APR-2017 05-MAY-2017 US Not Specified US-SUN  
PHARMACEUTICAL INDUSTRIES LTD-2017US-139633 "Bishop-Freeman SC,  
Feaster MS, Beal J, Miller A, Hargrove RL, Brower JO et al.  
Loperamide-related deaths in North Carolina. J Anal Toxicol.  
2016;40(8):677-686" -  
13513333 - Loperamide;Herbals\Mitragynine Product Used  
For Unknown Indication Drug Interaction;Accidental Overdose;Drug  
Abuse Serious Died;Other Outcomes Male - 04-MAY-2017  
Expedited 24 YR Not Specified Ranbaxy Healthcare  
Professional Not Specified Tramadol 20-APR-2017 04-  
MAY-2017 US Not Specified US-SUN PHARMACEUTICAL  
INDUSTRIES LTD-2017US-139677 "Bishop-Freeman SC, Feaster MS, Beal  
J, Miller A, Hargrove RL, Brower JO et al. Loperamide-related deaths  
in North Carolina. J Anal Toxicol. 2016;40(8):677-686" -  
13513320 Propranolol Propranolol  
Hydrochloride;Herbals\Mitragynine;Citalopram;Quinine;Loperamide  
Product Used For Unknown Indication Drug Abuse;Drug  
Interaction;Accidental Overdose Serious Other Outcomes;Died Not  
Specified - 04-MAY-2017 Expedited 37 YR Not  
Specified Ranbaxy Healthcare Professional Not Specified -  
20-APR-2017 04-MAY-2017 US Not Specified US-SUN  
PHARMACEUTICAL INDUSTRIES LTD-2017US-139634 "Bishop-Freeman SC,  
Feaster MS, Beal J, Miller A, Hargrove RL, Brower JO et al.  
Loperamide-related deaths in North Carolina. J Anal Toxicol.  
2016;40(8):677-686" -  
13407030 Fluoxetine Pregabalin;Fluoxetine  
Hydrochloride;Lorazepam;Pipamperone;Olanzapine;Quetiapine;Herbals\Mitr  
agynine;Triazolam;Etizolam Product Used For Unknown Indication  
Haematoma;Pulmonary Oedema;Loss Of  
Consciousness;Aspiration;Overdose;Fall;Humerus Fracture Serious Other  
Outcomes;Died Not Specified - 16-APR-2017 Expedited  
Not Specified Not Specified Mylan Healthcare  
Professional Not Specified - 05-APR-2017 05-APR-2017  
DE Not Specified DE-  
MYLANLABS-2017M1021108 "Domingo O, Roider G, Stover A, Graw M,  
Musshoff F, Sachs H, et al. Mitragynine concentrations in two  
fatalities. Forensic-Sci-Int 2017;271:e1-e7." -  
13421666 Fluoxetine Fluoxetine  
Hydrochloride;Olanzapine;Triazolam;Lorazepam;Quetiapine;Pipamperone;Et  
izolam;Herbals\Mitragynine;Pregabalin Product Used For Unknown  
Indication;Substance Use Loss Of Consciousness;Aspiration

Serious Died Male - 10-APR-2017 Expedited  
 22 YR Not Specified Sandoz Healthcare Professional Not  
 Specified - 28-MAR-2017 10-APR-2017 DE Not  
 Specified PHHY2017DE051635 "Domingo O, Roider G, Stover  
 A, Graw M, Musshoff F, Sachs H, et al.. Mitragynine concentrations in  
 two fatalities. FORENSIC SCIENCE INTERNATIONAL. 2017;271:e1-e7" -  
 13395314 Remeron;Nucynta Tapentadol  
 Hydrochloride;Mirtazapine;Herbals\Mitragynine  
 Depression;Insomnia;Intervertebral Disc Protrusion Serotonin  
 Syndrome;Bedridden;Contraindication To Medical Treatment  
 Serious Life Threatening;Other Outcomes Male 28-MAR-2017 01-  
 APR-2017 Direct 42 YR 84.6 KG Fda-Ctu Consumer  
 Consumer Adderall;Dalmane;Trazodone;Clonazepam;Aspirin -  
 01-APR-2017 US Not Specified - - -  
 13080823 Propranolol Propranolol  
 Hydrochloride;Quinine;Herbals\Mitragynine;Loperamide;Citalopram  
 Product Used For Unknown Indication Drug Interaction;Accidental  
 Overdose;Toxicity To Various Agents Serious Died Not Specified  
 - 03-JAN-2017 Expedited 37 YR Not Specified  
 Lupin Healthcare Professional Not Specified - 20-  
 DEC-2016 03-JAN-2017 US Not Specified US-LUPIN  
 PHARMACEUTICALS INC.-2017-00017 - -  
 13079564 - Quinine;Herbals\Mitragynine;Loperamide  
 Product Used For Unknown Indication Drug Interaction;Accidental  
 Overdose;Toxicity To Various Agents Serious Died Not Specified  
 - 03-JAN-2017 Expedited 33 YR Not Specified  
 Lupin Healthcare Professional Not Specified - 20-  
 DEC-2016 03-JAN-2017 US Not Specified US-LUPIN  
 PHARMACEUTICALS INC.-2017-00016 - -  
 13078751 Propranolol Propranolol  
 Hydrochloride;Citalopram;Quinidine;Quinine  
 Sulfate;Herbals\Mitragynine;Loperamide - Toxicity To Various  
 Agents;Accidental Overdose;Drug Interaction;Drug Abuse Serious Died  
 Not Specified - 02-JAN-2017 Expedited 37 YR  
 Not Specified Teva Healthcare Professional Not Specified  
 - 26-DEC-2016 02-JAN-2017 US Not Specified  
 US-TEVA-725444USA "Bishop-Freeman SC, Feaster MS, Beal  
 J, Miller A, Hargrove RL, Brower JO, et al. Loperamide-related deaths  
 in North Carolina. J-Anal-Toxicol 2016;40(8):677-686." -  
 13078750 - Herbals\Mitragynine;Loperamide;Quinine  
 Sulfate;Quinidine - Drug Interaction;Toxicity To Various  
 Agents;Drug Abuse;Accidental Overdose Serious Died Not Specified  
 - 02-JAN-2017 Expedited 33 YR Not Specified  
 Teva Healthcare Professional Not Specified - 26-  
 DEC-2016 02-JAN-2017 US Not Specified US-  
 TEVA-725443USA "Bishop-Freeman SC, Feaster MS, Beal J, Miller A,  
 Hargrove RL, Brower JO, et al. Loperamide-related deaths in North  
 Carolina. J-Anal-Toxicol 2016;40(8):677-686." -  
 13068630 Propranolol Propranolol  
 Hydrochloride;Loperamide;Citalopram;Quinine;Herbals\Mitragynine;Quinid

ine Product Used For Unknown Indication Drug  
Interaction;Toxicity To Various Agents;Accidental Overdose;Drug Abuse  
Serious Died Not Specified - 28-DEC-2016  
Expedited Not Specified Not Specified Mylan Healthcare  
Professional Not Specified - 15-DEC-2016 28-DEC-2016  
US Not Specified US-

MYLANLABS-2016M1057167 "Bishop-Freeman SC, Feaster MS, Beal J, Miller A, Hargrove RL, Brower JO, et al. Loperamide-related deaths in North Carolina. J-Anal-Toxicol 2016;40(8):677-686." -

13066348 Imodium Loperamide  
Hydrochloride;Quinidine;Herbals\Mitragynine Product Used For  
Unknown Indication Drug Interaction;Toxicity To Various Agents  
Serious Died Not Specified - 27-DEC-2016  
Expedited 33 YR Not Specified Sandoz Healthcare  
Professional Not Specified - 15-DEC-2016 27-DEC-2016  
US Not Specified PHHY2016US175737 "Bishop-  
Freeman SC, Feaster MS, beal J, Miller A, Hargrove RL, Brower JO, et  
al. Loperamide-related deaths in North Carolina.. JOURNAL OF  
ANALYTICAL TOXICOLOGY. 2016;40(8):677-86" -

13066343 Imodium Herbals\Mitragynine;Tramadol;Loperamide  
Hydrochloride Product Used For Unknown Indication Toxicity To  
Various Agents Serious Died Male - 27-DEC-2016  
Expedited 24 YR Not Specified Sandoz Healthcare  
Professional Not Specified - 15-DEC-2016 27-DEC-2016  
US Not Specified PHHY2016US175730 "Bishop-  
Freeman SC, Feaster MS, beal J, Miller A, Hargrove RL, Brower JO, et  
al. Loperamide-related deaths in North Carolina.. JOURNAL OF  
ANALYTICAL TOXICOLOGY. 2016;40(8):677-86" -

13066333 Propranolol;Imodium Quinidine;Loperamide  
Hydrochloride;Citalopram;Propranolol Hydrochloride;Herbals\Mitragynine  
Product Used For Unknown Indication Toxicity To Various  
Agents;Drug Interaction Serious Died Not Specified - 27-  
DEC-2016 Expedited 37 YR Not Specified Sandoz  
Healthcare Professional Not Specified - 15-DEC-2016 27-  
DEC-2016 US Not Specified

PHHY2016US175739 "Bishop-Freeman SC, Feaster MS, beal J, Miller  
A, Hargrove RL, Brower JO, et al. Loperamide-related deaths in North  
Carolina.. JOURNAL OF ANALYTICAL TOXICOLOGY. 2016;40(8):677-86" -

13059371 - Herbals\Mitragynine;Loperamide Product Used  
For Unknown Indication Drug Abuse;Drug Interaction;Accidental  
Overdose;Toxicity To Various Agents Serious Died Not Specified  
- 23-DEC-2016 Expedited Not Specified Not  
Specified Mylan Healthcare Professional Not Specified  
Tramadol 15-DEC-2016 23-DEC-2016 US Not Specified  
US-MYLANLABS-2016M1057231 "Bishop-Freeman SC, Feaster  
MS, Beal J, Miller A, Hargrove RL, Brower JO, et al. Loperamide-  
related deaths in North Carolina. J-Anal-Toxicol 2016;40(8):677-686."  
-

12851019 -  
Quinidine;Quinine;Loperamide;Herbals\Mitragynine Drug

Abuse;Product Used For Unknown Indication      Drug Abuse;Accidental  
 Overdose;Drug Interaction      Serious Died      Not Specified      -  
     18-OCT-2016      Expedited      33 YR      Not Specified  
 Johnson And Johnson      Healthcare Professional      Not Specified      -  
     11-OCT-2016      17-OCT-2016      US      Not Specified      US-  
 JNJFOC-20161010814      "Bishop-Freeman SC, Feaster MS, Beal J, Miller  
 A, Hargrove RL, Brower JO, et al. Loperamide-Related Deaths in North  
 Carolina. Journal of Analytical Toxicology 2016;40(8):677-686."      -  
 12850992      Propranolol      Propranolol Hydrochloride;Cannabis  
 Sativa Subsp. Indica  
 Top;Citalopram;Quinine;Loperamide;Herbals\Mitragynine      Drug  
 Abuse;Product Use Issue;Product Used For Unknown Indication      Drug  
 Abuse;Drug Interaction;Accidental Overdose      Serious Died      Not  
 Specified      -      17-OCT-2016      Expedited      37 YR      Not  
 Specified      Johnson And Johnson      Healthcare Professional      Not  
 Specified      -      11-OCT-2016      17-OCT-2016      US      Not  
 Specified      US-JNJFOC-20161010815      "Bishop-Freeman SC, Feaster  
 MS, Beal J, Miller A, Hargrove RL, Brower JO, et al. Loperamide-  
 Related Deaths in North Carolina. Journal of Analytical Toxicology  
 2016;40(8):677-686."      -  
 12850962      -      Herbals\Mitragynine;Tramadol;Loperamide      Drug  
 Abuse;Product Used For Unknown Indication      Drug Interaction;Drug  
 Abuse;Accidental Overdose;Cardiomegaly      Serious Died      Male      -  
     17-OCT-2016      Expedited      24 YR      Not Specified  
 Johnson And Johnson      Healthcare Professional      Not Specified      -  
     11-OCT-2016      17-OCT-2016      US      Not Specified      US-  
 JNJFOC-20161010807      "Bishop-Freeman SC, Feaster MS, Beal J, Miller  
 A, Hargrove RL, Brower JO, et al. Loperamide-Related Deaths in North  
 Carolina. Journal of Analytical Toxicology 2016;40(8):677-686."      -  
 12639594      Fluoxetine;Trazodone      Trazodone  
 Hydrochloride;Cannabis Sativa Subsp. Indica  
 Top;Morphine;Gabapentin;Fluoxetine Hydrochloride;Herbals\Mitragynine  
     -      Cough;Arteriosclerosis Coronary  
 Artery;Nephrosclerosis;Pulmonary Infarction;Hepatic Steatosis;Deep  
 Vein Thrombosis;Pneumonia;Pulmonary Embolism;Unresponsive To  
 Stimuli;Toxicity To Various Agents;Dilated Cardiomyopathy  
 Serious Died      Male      16-JUN-2015      09-AUG-2016      Direct      43 YR  
     Not Specified      -      Healthcare Professional Health  
 Professional      -      -      09-AUG-2016      Not Specified      Not  
 Specified      -      -      -  
 12639579      Methadone      Methadone  
 Hydrochloride;Herbals\Mitragynine;Alprazolam      -      Accidental  
 Death;Toxicity To Various Agents;Respiratory Arrest;Unresponsive To  
 Stimuli;Scar;Puncture Site Reaction      Serious Died      Male      08-  
 MAR-2015      09-AUG-2016      Direct      22 YR      Not Specified      -  
     Healthcare Professional Health Professional      -      -  
     09-AUG-2016      Not Specified      Not Specified      -      -  
     -  
 12639556      Zolpidem      Zolpidem  
 Tartrate;Herbals\Mitragynine;Alcohol;Quetiapine      -

Haemorrhage;Toxicity To Various Agents;Completed  
 Suicide;Asphyxia;Wound;Fracture Serious Died Male 14-SEP-2015  
 09-AUG-2016 Direct 19 YR Not Specified -  
 Healthcare Professional Health Professional - - 09-  
 AUG-2016 Not Specified Not Specified - - -  
 12639421 -  
 Clonazepam;Herbals\Mitragynine;Alprazolam;Fentanyl - Oedema  
 Peripheral;Left Ventricular Hypertrophy;Urinary Retention;Pulmonary  
 Congestion;Toxicity To Various Agents;Respiratory Arrest;Accidental  
 Death;Drug Screen Positive Serious Died Male 23-APR-2015  
 09-AUG-2016 Direct 31 YR Not Specified -  
 Healthcare Professional Health Professional - - 09-  
 AUG-2016 Not Specified Not Specified - - -  
 12639365 Venlafaxine Venlafaxine  
 Hydrochloride;Alcohol;Diphenhydramine;Mirtazapine;Herbals\Mitragynine  
 - Unresponsive To Stimuli;Depression;Toxicity To Various  
 Agents;Pulmonary Oedema;Fatigue;Urinary Retention;Accidental Death  
 Serious Died Male 27-MAY-2014 09-AUG-2016 Direct  
 24 YR Not Specified - Healthcare Professional Not  
 Specified - - 09-AUG-2016 Not Specified Not  
 Specified - - -  
 12639332 -  
 Morphine;Alcohol;Herbals\Mitragynine;Citalopram;Demoxepam;Alprazolam;C  
 hlordiazepoxide;Nordazepam - Toxicity To Various  
 Agents;Alcohol Poisoning;Accidental Death;Injury Associated With  
 Device Serious Died Male 19-JUL-2015 09-AUG-2016 Direct  
 23 YR Not Specified - Healthcare Professional Not  
 Specified - - 09-AUG-2016 Not Specified Not  
 Specified - - -  
 12639316 - Herbals\Mitragynine;Citalopram;Alcohol -  
     Traumatic Lung Injury;Aortic Injury;Chest  
 Injury;Alcoholism;Gun Shot Wound;Homicide;Suicidal Ideation  
 Serious Died Male 27-MAR-2015 09-AUG-2016 Direct 55 YR  
     Not Specified - Healthcare Professional Not Specified  
     - - 09-AUG-2016 Not Specified Not Specified  
     - - -  
 12639302 - Herbals\Mitragynine;Carbamazepine -  
     Pulmonary Congestion;Toxicity To Various Agents;Substance  
 Abuse;Accidental Death;Blood Alcohol Increased;Pulmonary Oedema  
 Serious Died Male 02-JUL-2015 09-AUG-2016 Direct 45 YR  
     Not Specified - Healthcare Professional Not Specified  
     - - 09-AUG-2016 Not Specified Not Specified  
     - - -  
 12561455 Venlafaxine Alcohol;Diphenhydramine;Venlafaxine  
 Hydrochloride;Herbals\Mitragynine;Mirtazapine - Urinary  
 Retention;Toxicity To Various Agents;Drug Interaction;Pulmonary  
 Oedema;Unresponsive To Stimuli;Vomiting;Pulmonary Congestion  
 Serious Died Male MAR-2015 15-JUL-2016 Expedited  
 24 YR Not Specified Osmotica Healthcare  
 Professional Not Specified Loperamide;Omeprazole 30-JUN-2016

15-JUL-2016 US Not Specified US-  
 OSMOTICA\_PHARMACEUTICAL\_US\_LLCLLC-POI0573201600030 - -  
 11771645 - Buprenorphine;Herbals\Mitragynine  
 Product Used For Unknown Indication Wrong Product  
 Administered;Drug Screen Negative Serious Other Outcomes Male  
 26-OCT-2015 23-NOV-2015 Direct 42 YR 153 LB -  
 Consumer Consumer  
 Hydrocodone;Gabapentin;Propranolol - 23-NOV-2015 Not  
 Specified Y - - -  
 11157587 - Venlafaxine  
 Hydrochloride;Mirtazapine;Diphenhydramine;Herbals\Mitragynine;Alcohol  
     Antidepressant Therapy Accidental Death;Pulmonary  
 Congestion;Vomiting;Blood Ethanol Increased;Pulmonary Oedema;Urinary  
 Retention;Unresponsive To Stimuli;Toxicity To Various Agents  
 Serious Died Male - 01-JUN-2015 Expedited 24 YR  
     Not Specified Sanofi Healthcare Professional "Health  
 Professional ,Literature" - 20-MAY-2015 01-JUN-2015  
     Not Specified Not Specified 2015SA070635 - -  
 10948046 - Paroxetine;Herbals\Mitragynine;Lamotrigine  
     - Pulmonary Infarction;Hypoxic-Ischaemic  
 Encephalopathy;Toxicity To Various Agents;Brain Death;Pulmonary  
 Embolism;Thrombosis;Brain Stem Haemorrhage Serious Other  
 Outcomes;Died Not Specified - 24-MAR-2015 Expedited  
     Not Specified Not Specified Cipla Healthcare  
 Professional Not Specified - 13-MAR-2015 24-MAR-2015  
     US Not Specified US-CIPLA LTD.-2015US02218 "Mowry  
 J.B., Spyker D.A., Cantilena L.R., Mcmillan N, Ford M. 2013Annual  
 Report of the American Association of Poison Control Centers National  
 Poison Data System (NPDS): 31st Annual Report. Clinical Toxicology.  
 2014;52:1032-1283" -  
 10861525 Venlafaxine Diphenhydramine  
 Hydrochloride;Venlafaxine  
 Hydrochloride;Mirtazapine;Omeprazole;Herbals\Mitragynine;Alcohol  
     Product Used For Unknown Indication Pulmonary  
 Oedema;Toxicity To Various Agents;Urinary Retention Serious Died  
     Male - 03-MAR-2015 Expedited 24 YR Not  
 Specified Mcneil Healthcare Professional Not Specified  
 Loperamide 26-FEB-2015 24-FEB-2015 US Not Specified  
     US-JNJFOC-20150213670 "McIntyre IM, Trochta A, Stolberg S,  
 Campman SC. Mitragynine kratom related fatality: a case report with  
 postmortem concentrations. Journal of Analytical Toxicology  
 2015;39(2):152-155." -  
 10884035 - Herbals\Mitragynine;Paroxetine;Lamotrigine  
     Product Used For Unknown Indication Brain Injury;Oxygen  
 Saturation Decreased;Pulmonary Infarction;Poisoning;International  
 Normalised Ratio Increased;Apnoea;Cardiac Arrest;Brain Death;Drug  
 Abuse;Tachycardia;Fall;Venous Thrombosis;Generalised Tonic-Clonic  
 Seizure;Toxicity To Various Agents;Brain Stem Haemorrhage;Hypoxic-  
 Ischaemic Encephalopathy;Unresponsive To Stimuli;Mydriasis;Brain  
 Oedema;Pulmonary Embolism Serious Died Male 2013 26-

FEB-2015 Expedited 36 YR Not Specified Arbor Pharmaceuticals Healthcare Professional "Health Professional ,Literature" - 09-FEB-2015 26-FEB-2015 Not Specified Not Specified ABR\_02013\_2015 - -

10867680 Venlafaxine Hcl Venlafaxine Hydrochloride;Mirtazapine;Herbals\Mitragynine;Diphenhydramine - Pulmonary Congestion;Accidental Overdose;Toxicity To Various Agents Serious Hospitalized;Died Male - 26-FEB-2015 Expedited 24 YR Not Specified Pfizer Healthcare Professional Not Specified Omeprazole 18-FEB-2015 25-FEB-2015 US Not Specified US-PFIZER INC-2015064762 "McIntyre I M.. Mitragynine ""Kratom' Related Fatality: A Case Report with Postmortem Concentrations. Journal of Analytical Toxicology. 2015;39 (2):152-155" -

10712257 - Herbals\Mitragynine;Paroxetine;Lamotrigine Product Used For Unknown Indication Drug Abuse;Death;Cardio-Respiratory Arrest;Tachycardia;Generalised Tonic-Clonic Seizure;Pulmonary Embolism;Hypoxic-Ischaemic Encephalopathy;Brain Stem Haemorrhage;Pulmonary Infarction;Brain Injury Serious Died;Hospitalized;Other Outcomes Male 2013 11-FEB-2015 Expedited 36 YR Not Specified Par Healthcare Professional Not Specified - 02-FEB-2015 14-JAN-2015 US Not Specified "US-PAR PHARMACEUTICAL, INC-2015SCPR009593" "Mowry J.B., Spyker D.A., Cantilena JR L.R., Mcmillan N., Ford M.. 2013 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 31st Annual Report. Clinical Toxicology. 2014;52 (10):1032-1283" -

10733773 - Lamotrigine;Paroxetine Hydrochloride;Herbals\Mitragynine Product Used For Unknown Indication Brain Oedema;Pulmonary Embolism;Brain Stem Haemorrhage;Cardiac Arrest;Hypoxic-Ischaemic Encephalopathy;Thrombosis;Tachycardia;Apnoeic Attack;Generalised Tonic-Clonic Seizure;Drug Abuse;Brain Injury;Pulse Absent Serious Other Outcomes;Hospitalized;Died Male - 05-FEB-2015 Expedited 36 YR Not Specified Apotex Healthcare Professional Not Specified - 21-JAN-2015 23-JAN-2015 US Not Specified US-APOTEX-2015AP005445 "Mowry JB; Spyker DA, Cantilena Jr. LR, McMillan N, Ford M. 2013 Annual Report of the American Association of Poison Control Centers í National Poison Data System (NPDS):31st Annual Report. CLINICAL TOXICOLOGY. 2014;52:1032-1283" -

10708286 - Diphenhydramine Hydrochloride;Herbals\Mitragynine Back Pain;Drug Abuse Toxicity To Various Agents;Bladder Dilatation;Vomiting;Drug Level Increased;Pulmonary Oedema;Pulmonary Congestion Serious Other Outcomes;Died Male - 13-JAN-2015 Expedited 17 YR Not Specified Bayer Healthcare Professional Not Specified Dextromethorphan;Clonazepam;Temazepam 05-JAN-2015 13-JAN-2015 US Not Specified US-

BAYER-2015-000978 "Neerman, M.F., Frost, R.E., Deking, J.. A Drug Fatality Involving Kratom. Journal of forensic sciences. 2013;58 (S1):S278-S279" -

10698706 Venlafaxine Venlafaxine Hydrochloride;Mirtazapine;Alcohol;Diphenhydramine Hydrochloride;Herbals\Mitragynine Depression Pulmonary Oedema;Toxicity To Various Agents;Vomiting;Feeling Cold;Unresponsive To Stimuli;Urinary Retention;Pulmonary Congestion Serious Other Outcomes;Died Male - 09-JAN-2015 Expedited 24 YR Not Specified Bayer Healthcare Professional Not Specified Omeprazole 08-JAN-2015 08-JAN-2015 US Not Specified US-BAYER-2014-191469 "McIntyre IM, Trochta A, Stolberg S, Campman SC. Mitragynine 'Kratom' Related Fatality: A Case Report with Postmortem Concentrations. Journal of Analytical Toxicology. 2014;0:1-4" -

9823195 Oxycontin;Dilaudid Herbals\Mitragynine;Hydromorphone Hydrochloride;Oxycodone Hydrochloride Pain Substance Abuse;Drug Withdrawal Syndrome Serious Other Outcomes Male - 16-JAN-2014 Expedited 43 YR Not Specified Purdue Consumer Not Specified - 30-SEP-2013 16-JAN-2014 US Not Specified US-NAPPUNDI-USA-2013-0107060 -

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8132531 - Tramadol Hydrochloride;Cannabis Sativa Seed\Herbals;Alprazolam;Herbals\Mitragynine;Citalopram Hydrobromide Toxicity To Various Agents Pulmonary Oedema;Respiratory Depression;Overdose;Toxicity To Various Agents;Drug Level Increased;Brain Oedema Serious Died;Hospitalized Male - 25-AUG-2011 Expedited 32 YR Not Specified Actavis Elizabeth Healthcare Professional "Health Professional ,Literature,Foreign" - 09-AUG-2011 25-AUG-2011 25-AUG-2011 Not Specified Not Specified 2011MA011582 -

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8124494 - Tramadol Hydrochloride;Alprazolam;Herbals\Mitragynine;Alcohol Toxicity To Various Agents Toxicity To Various Agents;Pulmonary Congestion Serious Other Outcomes;Died Male - 25-AUG-2011 Expedited 22 YR Not Specified Actavis Elizabeth Healthcare Professional "Health Professional ,Literature,Foreign" - 09-AUG-2011 25-AUG-2011 Not Specified Not Specified 2011MA011579 - -

8124388 - Herbals\Mitragynine;Cannabis Sativa Seed\Herbals;Tramadol Hydrochloride;Amphetamine;Alprazolam Accidental Overdose Toxicity To Various Agents Serious Died;Other Outcomes Male - 25-AUG-2011 Expedited 24 YR Not Specified Actavis Elizabeth Healthcare Professional "Health Professional ,Literature,Foreign" - 09-AUG-2011 25-AUG-2011 Not Specified Not Specified 2011MA011581 - -

8121566 - Unspecified Ingredient;Venlafaxine Hydrochloride;Trimeprazine Tartrate;Tramadol

Hydrochloride;Herbals\Mitragynine                   Toxicity To Various Agents  
Pulmonary Congestion;Toxicity To Various Agents;Pulmonary  
Oedema      Serious Other Outcomes;Died      Male    -      24-AUG-2011  
Expedited      35 YR    Not Specified    Actavis Totowa  
Healthcare Professional "Health Professional ,Literature,Foreign"  
-                09-AUG-2011      24-AUG-2011      Not Specified    Not  
Specified      2011MA011586      -      -  
8121559 -      Zopiclone;Herbals\Mitragynine;Venlafaxine  
Hydrochloride;Unspecified Ingredient;Tramadol      Toxicity To Various  
Agents      Respiratory Depression;Cardiac Arrest;Loss Of  
Consciousness;Accidental Overdose;Toxicity To Various Agents;Pulmonary  
Congestion      Serious Life Threatening;Hospitalized;Died      Female  
-                24-AUG-2011      Expedited      25 YR    Not Specified  
Actavis Totowa      Healthcare Professional "Health  
Professional ,Literature,Foreign"      -      09-AUG-2011      24-  
AUG-2011      Not Specified      Not Specified      2011MA011587      -  
-  
8121551 -      Olanzapine;Diazepam;Nordazepam;Amphetamine;Tramadol  
Hydrochloride;Antipyrine;Fluoxetine  
Hydrochloride;Pregabalin;Norfluoxetine;Herbals\Mitragynine  
Toxicity To Various Agents      Cardiac Arrest;Hepatic  
Steatosis;Pulmonary Congestion;Toxicity To Various Agents;Loss Of  
Consciousness      Serious Died;Other Outcomes      Female    -      24-  
AUG-2011      Expedited      30 YR    Not Specified    Actavis  
Elizabeth      Healthcare Professional "Health  
Professional ,Literature,Foreign"      -      09-AUG-2011      24-  
AUG-2011      Not Specified      Not Specified      2011MA011583      -  
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8121536 Venlafaxine      Tramadol Hydrochloride;Venlafaxine  
Hydrochloride;Diazepam;Mirtazapine;Nordazepam;Buprenorphine;Herbals\Mi  
tragynine;Trimeprazine Tartrate Toxicity To Various Agents  
Cardiac Arrest;Brain Oedema;Toxicity To Various Agents;Loss Of  
Consciousness;Pulmonary Oedema      Serious Died;Other Outcomes      Male  
-                24-AUG-2011      Expedited      27 YR    Not Specified  
Actavis Elizabeth      Healthcare Professional "Health  
Professional ,Literature,Foreign"      -      09-AUG-2011      24-  
AUG-2011      Not Specified      Not Specified      2011MA011584      -  
-  
8083892 Venlafaxine      Venlafaxine  
Hydrochloride;Buprenorphine;Herbals\Mitragynine;Diazepam;Tramadol  
Hydrochloride;Trimeprazine Tartrate;Mirtazapine Product Used For  
Unknown Indication      Pulmonary Oedema;Brain Oedema;Accidental  
Death;Overdose      Serious Died      Male    -      02-AUG-2011  
Expedited      27 YR    Not Specified    Schering Plough Healthcare  
Professional      "Health Professional ,Literature,Foreign"      -  
27-JUL-2011      02-AUG-2011      Not Specified    Not Specified  
2011SP035503      -      -  
7900650 Promethazine      Herbals\Mitragynine;Promethazine  
Hydrochloride;Propylhexedrine;Acetaminophen;Morphine Hydrochloride  
-                Toxicity To Various Agents;Drug Screen Positive

Serious Died;Other Outcomes      Male      -      15-APR-2011  
Expedited      20 YR      Not Specified      Roxane      Healthcare  
Professional      Health Professional      -      08-APR-2011      15-  
APR-2011      US      Not Specified      "US-ROXANE LABORATORIES,  
INC.-2011-R0-00495R0"      -      -  
6959961 -      Hydromorphone  
Hydrochloride;Modafinil;Herbals\Mitragynine      Dependence;Drug  
Withdrawal Syndrome;Hypervigilance;Pain;Thoracic Outlet Syndrome  
Drug Withdrawal Syndrome;Drug Abuse;Stress;Generalised Tonic-  
Clonic Seizure;Incorrect Route Of Product Administration;Drug  
Tolerance Increased      Serious Hospitalized;Other Outcomes      Male  
-      03-APR-2009      Expedited      43 YR      Not Specified  
Roxane      Healthcare Professional Health Professional  
Buprenorphine\Naloxone      30-MAR-2009      03-APR-2009      US      Not  
Specified      "US-ROXANE LABORATORIES, INC.-2009-R0-00301R0"      -  
-  
6669537 -      Modafinil;Herbals\Mitragynine      Drug Withdrawal  
Syndrome;Somnolence      Somnolence;Heart Rate Increased;Drug  
Withdrawal Syndrome;Miosis;Generalised Tonic-Clonic Seizure  
Serious Hospitalized      Male      -      03-JUN-2008      Expedited  
43 YR      Not Specified      Cephalon      Healthcare  
Professional      "Health Professional ,Literature"      -      21-  
MAY-2008      03-JUN-2008      Not Specified      Not Specified  
US023600      -      -