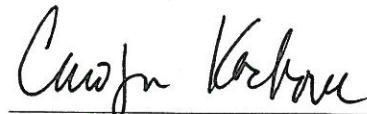


CERTIFICATE

Pursuant to the provisions of Rule 44 of the Federal Rules of Civil Procedure, I hereby certify that Domenic J. Veneziano, Director, Division of Import Operations and Policy, Office of Regulatory Affairs, United States Food and Drug Administration, whose declaration is attached, has custody of official records of the United States Food and Drug Administration.

In witness whereof, I have, pursuant to the provision of Title 42, United States Code, Section 3505, and FDA Staff Manual Guide 1410.23(1)(a)(6)(ii), hereto set my hand and caused the seal of the Department of Health and Human Services to be affixed this 11 day of May, 2009.



Carolyn Kachovec, Director
Division of Dockets Management
Office of Management Programs
Office of Management
Food and Drug Administration

By direction of the Secretary of
Health and Human Services

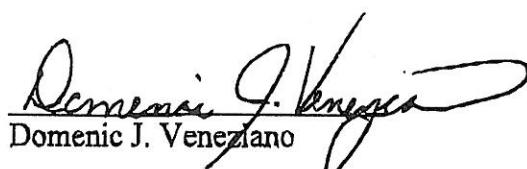
DECLARATION OF DOMENIC J. VENEZIANO

Domenic J. Veneziano declares as follows:

1. I am the Director, Division of Import Operations and Policy, Office of Regulatory Affairs, United States Food and Drug Administration (FDA).
2. In this capacity, I have custody of official records of FDA relating to import alerts.
3. Attached is a copy of an index to documents related to FDA's addition of electronic cigarettes manufactured by Shenzhen Kanger Technology Co Lt, Desonic Industrial, Loong Totem Science & Technology, to Import Alert 66-41. In addition, my office consulted with FDA's Center for Drug Evaluation and Research regarding these determinations.
4. Copies of the documents referenced in paragraph 3 above are part of the official records of FDA.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on MAY 1, 2009.


Domenic J. Veneziano

Smoking Everywhere, Inc.
Import Alert 66-41
Index to Administrative Record

Document Date	Description	Bates Number
5/8/2009	Import Alert 66-41	000001-000091
undated	Web content: Crown Seven Hydro - Electronic Smoking Device	000092-000107
undated	Crown Seven Photos	000108-000112
undated	Fifty-One User Manual	000113-000128
undated	Fifty-One Atomizer User Manual	000129-000135
undated	Label of cartridge box	000136
undated	Mini-Pipe User Manual	000137-000147
undated	Smoke Fifty-One advertising	000148
undated	Smoke Fifty-One Card Front and Back	000149-000150
undated	Smoke Fifty-One Sales Sheet	000151
undated	Photo of pipe	000152
3/4/2009	Importer Entry Form	000153-000156
3/6/2009- 3/13/2009	Email exchange between FDA and Importer regarding a determination of the regulatory status of product	000157-000163
3/10/2009	Email from Importer to Carrier attaching legal information and advertising material	000164
3/13/2009	Importer Entry Form	000165-000178
3/23/2009	Email from Merril Racke to Kevin Budich (cc: Andrew Seaborn, John Verbeten, and Steven Branch) regarding detention of another electronic cigarette	000179

IA #66-41 - 5/11/07 REVISION OF IMPORT ALERT #66-41 "DETENTION WITHOUT PHYSICAL EXAMINATION OF UNAPPROVED NEW DRUGS PROMOTED IN THE U.S." ATTACHMENT A REVISED 4/21/09, ATTACHMENT B REVISED 1/23/07

NOTE: The revision dated 5/10/2007 adds a charge for misbranded drugs. Relevant edits are bracketed by asterisks (***) .

TYPE OF ALERT: Detention Without Physical Examination (DWPE)

(Note: This import alert contains guidance to FDA field personnel only. It does not establish any requirements, or create any rights or obligations on FDA or on regulated entities.)

PRODUCT: Unapproved new drugs, *** Misbranded drugs ***

PRODUCT

CODE: See attachment

PROBLEM: Unapproved drugs *** and/or misbranded drugs *** promoted in the U.S.

OASIS

CHARGE CODE: UNAPPROVED, *** MISBRANDED ***

PAF: AAP (Approvals)

PAC: 56008H
63001

SHIPPER: See attachment

REFERENCE: Regulatory Procedures Manual Chapter 9, Subchapter "Coverage of Personal Importations" issued 2/11/89. (Note: This subchapter, previously designated as RPM 9-71, was issued to consolidate guidance that previously existed in RPM Chapters: 9-71, "Mail Importations" and Chapter 9-72, "Coverage of Importations Contained in Personal Baggage," and the Pilot Guidance for Release of Mail Importation dated July 29, 1988.)

Compliance Policy Guide (CPG) 120.500 (formerly 7150.10) gives extensive background on health fraud, and the indirect risks of relying on unproven remedies. Health fraud has been defined by the agency as the promotion of unproven medical products.

IA 000001

CHARGE: "The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be a new drug within the meaning of Section 201(p) without an effective new drug application (NDA) [Unapproved New Drug, Section 505(a)]".

*** When unaccompanied by labeling which makes drug claims, but other evidence attributable to the manufacturer, owner, or consignee exists which establishes the product's intended use as a drug, charge:

"The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be a drug within the meaning of Section 201(g) and it lacks adequate directions for use. [Misbranded, Section 502(f)(1)]. ***

RECOMMENDING

OFFICE: Division of Import Operations and Policy (HFC-170)
*** Center For Drug Evaluation and Research, Office of
Compliance (HFD-300) ***

REASON FOR

ALERT: Media reports concerning FDA's guidance for release of importations for personal use have inaccurately suggested that any unapproved drug may be imported through the mail for personal use. The pilot guidance and subsequent Regulatory Procedures Manual Subchapter, "Coverage of Personal Importations," that issued is much more restrictive than reported. The RPM subchapter provides guidance for use in those instances in which field personnel determine that the exercise of discretion regarding the admissibility of an unapproved drug might be appropriate. The guidance is by its very terms discretionary, and does not provide anyone with a right to import any drug.

The guidance provides that release of an unapproved drug for personal use may be appropriate if, among other considerations, the drug is intended for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means, and it is not considered to represent an unreasonable risk. The guidance is intended to apply only to: (1) persons who have received treatment in a foreign country with an unapproved drug which is not available in the United States, and who, upon returning to the United States, have imported the drug for their personal use in an effort to continue the treatment started abroad; and (2) persons who have made

IA 000002

their own arrangements for obtaining an unapproved drug from foreign sources, when the drug has not been promoted in the United States.

When there is evidence of promotion of unapproved drugs to persons in the United States, the products should be considered for detention. Evidence of promotion may consist of solicitations for mail orders, press releases, advertising materials, and other public announcements that are directed to persons residing in the U.S.

The subchapter of the RPM on coverage of personal importations provides guidance for FDA personnel on when it is appropriate to recommend import alerts involving unapproved products likely to be imported for personal use. Such recommendations are appropriate when an unapproved product represent a health fraud, as defined in CPG 120.500 or an unapproved foreign product is promoted for mail-order shipments. Thus, the field may recommend detain without physical examination when an unapproved *** and/or misbranded *** product poses either a direct health risk or indirect health risk.

GUIDANCE: Districts may detain without physical examination any Unapproved *** and/or misbranded drug *** listed in the attachment.

Districts may also detain without physical examination any other unapproved *** and/or misbranded *** drug that fails to meet the discretionary release criteria in the RPM. *** Contact CDER Import-Export Team before detaining any OTC product that appears to only meet the misbranding criteria and would therefore be detained on misbranding charges exclusively. *** When detained products appear to meet these criteria are not listed in the attachment, districts should forward documentation to DIOP for consideration for inclusion in this alert.

SPECIAL NOTE: Districts should continue to enforce, as appropriate, related import alerts restricting fraudulent, dangerous and commercial unapproved *** and/or misbranded *** drug importations.

FOI: No purging required.

KEYWORDS: New drugs, unapproved new drugs, *** misbranded drugs ***

IA 000003

PREPARED BY: DIOP, Operations and Policy SDWG: HFC-172, (301) 443-6553
 *** Center For Drug Evaluation and Research, Office of
 Compliance (HFD-300) ***

DATE LOADED

INTO FIARS: May , 2007

ATTACHMENT A TO IMPORT ALERT #66-41 4/21/09

*** Unapproved and/or misbranded new drugs that may be subject to DWPE ***

Although Gamma Hydroxybutyrate (GHB) has been identified as an unapproved new drug and covered in this import alert, effective March 13, 2000, GHB was classified as a Schedule I Controlled Substance and under DEA authorization. Therefore, entries of GHB, or its analogue GBL should be returned to Customs for appropriate disposition. (GBL and related substances can be treated as controlled substance analogues, and as Schedule I Controlled Substances, if intended for human consumption).

Manufacturer	Product/Product Codes
Chempropack BV	"G-Spot"
Donker Duyvisweg 45	65V50 and 65V51
Dordrecht, 3316 BL, Netherlands	GPI = VI
FEI# 3002854125	3/30/00

Products shipped by the following firms were found to contain the drugs glyburide and phenformin, which are used to treat diabetes. These products, being promoted as dietary supplements claiming to contain only natural Chinese herbal ingredients, are available through mail order and can be purchased by telephone or via the Internet. These products are being recalled under a Class I recall as a health hazard.

PRODUCT	SOURCE	COUNTRY
Ayurvedic Fair and Lovely Cream	Hindustan Lever Ltd.	India
53L[][]03	Dag No 21 of 122 F.s. grant	
11/3/06	Mouza-tingra	
	Doomdooma Industrial Estate, Off Nh-37	
Ayurvedic Fairness Cream	Mumbai, India	
53L[][]03	FEI# 3004356927	
11/3/06		
All Products	Harbin Dong Fang International	China
GPI = DR	Trading Corp.	
GPI = VI	No. 68 Dong Feng St. Dist. Harbin	
2/24/00	Aphin, China	
	FEI# 3002158294	

IA 000004

All Products China Hua Yang Technology & Trade China
 GPI = DR Corp.
 GPI = VI No. 13, South Xin Hua St., He Ping Men
 2/24/00 Beijing 10052, China
 FEI# 1000280039

PRODUCT	SOURCE	COUNTRY
"Alpecin Special"	Continental Cosmetics, Ltd.	Canada
Vitamin Hair	390 Millway Ave.	
Lotion	Concord, Ontario, L4K 3V8 (Shipper)	
	Canada	
	MID #XOCONCOS390CON	
	Alcina Bielefeld (Manufacturer)	Germany
	MID #DEALCBIE	
	Alcina Cosmetic Belus BVBA/SPRL Spaoi s.r.l. GE, Italia Italy (Distributor)	
	MID #ITALCCOSGEN	
	Alcina Cosmetic Nederland B V (Distributor)	Netherlands
	MID #NLALCCOSUNK	
Calfcart (calf cartilage cream) 8/19/94	Atto gram Corp. 12295 Hwy 50, RR #3 Bolton, Ontario MID# CAATTCOR1229BOL	Canada
PRODUCT	SOURCE	COUNTRY
"Crino Pouss"	Altesse Cosmetique, Inc.	Canada
Capillary Serum with Placenta	BP452BR Montreal, Que. Canada H2S 3M3 Canada MID #XQALT COS452MON	

Buffalo district recently detained two hair lotions products which were labeled with claims of anti-hair loss. The district detained the products based on violation of 21 CFR 310.527(b) in that the products were represented

IA 000005

as external hair loss prevention lotions which is regarded as a new drug within the meaning of section 201(p) for which a new drug application (NDA) under section 505 is required for marketing.

The shipments were commercial size entries which appeared to be for distribution and sale in the U.S.

Dextran Sulfate Polydex Pharmaceuticals, Ltd. Canada

"Formula 101" Manufacturer: China
"Beijing Zhangguang" General Factory of
Hair Regrowth Liniment Beijing Zhangguang Hair
Regrowth Liniment 725, Area 7, Jim Song Xi,
Chagyang, Beijing, China

Shipper: Canada
International
Health Organization
(aka - R&R International)
Cornwall, Ontario, Canada

Kamagra (Sildenafil 100 mg. oral tablet) 65PD[]02 04/4/03 Ajanta Pharma Limited 318 Linking Road Mumbai, India FEI #1000446587 India

	Promoter/Distributor	Canada
Life Crystals, oral 32 oz.	Dr. Ravi Devgan	
5 cc I.V. Chondriana,	Life Crystals, (dba: The Total Wellness Center	
6 cc I.V.	42 Redpath Avenue	
Immumostim LV047	Toronto, Ontario, Canada, M4S 2J6	
	MID# XORAVDEG42TOR	

METBAL

Metabolic Balance
vitamin Metabolic balancing
serum used for a verity of
conditions such as cancer,
diabetes, lupus, etc.

IA 000006

AND

PRODUCT	SOURCE	COUNTRY
Organotherapy-	The Total Wellness Center	Canada
(Live Cell	21219 Woodbine Avenue	
Fractions Therapy)	R.R. 1, Queensville, Ontario	
Shark cartilage)	LOG 1R0	
CAR-T-Cell	Canada	
Natcell M - mesenchyme	MID# XOTOTWEL2121QUE	
Natcell C- cerebrum		
Natcell T - thymus		

AND

Distributor

NaturPharm Inc.
Address Unknown

AND

Promoter

Dr. George Merkl, President Canada
Consumer Health Organization
of Canada
250 Sheppard Avenue
Willowdale, Ontario,
M2N 5S9, Canada

AND

Distributor

Life Crystals	Dr. Villalpando	Mexico
	Address Unknown	

(Note: Some or all of the above identified products are perhaps being shipped by the shippers/distributors/promoters so identified)

All the above products are reported to be used in a treatment regimen promoted by The Total Wellness Centers, one of which is operated by Dr. Ravi Devgan.

IA 000007

Available literature promotes the procedure as effective for the treatment of AIDS, Epstein Barr Virus and cancer, by cleansing the blood. A video tape, entitled "New Frontiers in Molecular Biology Life Crystal Capturing the Sun" promotes use of these products and is narrated by Dr. Merkl, who is also the President of ^

^.

Cancer treatment - Drogueria Samuel Hahneman Colombia
(Product purportedly Fundacion Palcossio
made from extracts of Carrera 42 E. NO. 88-20
turkey-buzzard Barranquilla, Colombia
(vulture) and
reinforced with 333
anticancer plants.

All Drugs International Products West Germany
7000 Stuttgart 1

*Adrenal cortex All All
extract

PRODUCT SOURCE COUNTRY

*(It should be noted that these products are also covered under Import Alert #66-08 "Drug Products Containing Adrenal Cortex Extract or Adrenal Cortex Injection".)

*Adrenal cortex All All Injection

All Drugs Interlab, Luzerner Str. 28 Switzerland
CH-6330-CHAM-2G
Interlab, Serco Ex Via
Cantonale 42, CH-6948
Porza-Lugano

Interlab, Newport, England England
Pagnell, Bucks MK 16 8AA

All Drugs Pharmaceutical International Mexico

Artrilan Tablets Offenbach Mexicana Mexico
(contains prednisone,
salicylamide, and
meprobamate)

IA 000008

Zone Generators	All	All
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Polyerga HorFerVit West Germany
 Pharma GMBH
 Hormone Fermente
 Vitamine
 Wehdestrabe 16
 D-2900 Oldenburg,
 West Germany

Zellen Live Cell Zellen Cell Pharmaceuticals Mexico
 Therapy (and all (10/22/92)
 other products) Tijuana, B.C. Mexico
 C.P. 22000

Zellyn Cell Research Oxygenesis Live Cell Therapy Bermuda
 P.O. Box HM 1120 (and all other products) (4/21/94)
 Hamilton, HMEX Bermuda
 MID# BMZELCEL1120HAM

Energy Complex A.G.E.S. Distribuidora Mexico
 Apartado Postal No. 2603
 Tijuana, B. C., Mexico
 C.P. 22000
 ID# MXAGEDIS2603TIJ

Nutri-Mail Mexico
 Apartado Postal No. 8-F 6/19/96
 Tijuana, B.C., Mexico 22540
 MID# MXNUT8TIJ

Note: Product may also be shipped from Inter-Medica of Tijuana, B.C., Mexico. This firm was identified for similar promotion in Bulletin IB#66-08, 10/26/87, for Neutralizer G.H, a weight loss product.

PRODUCT	SOURCE	COUNTRY
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Beta-Interferon	CORNE,S.A. de C.V.	Mexico
(Trade name FRONE TM)	Rio San Lorenzo No. 623	
(Alternate names-	Col. Puentes del Valle	
Rebif (TM)	Garza Garcia, Nuevo Leon	
R-FRONE)	66220, Mexico	

Manufacturer:

Serono Laboratories

IA 000009

Mexico

SAN-DO received promotional literature for the purchase of the above referenced product. The literature identifies the product for the treatment of Multiple Sclerosis and implies it is similar to the approved Interferon beta-1b approved for use in the U.S.

The product is shipped via UPS upon receipt of a doctor's prescription. The shipment includes FRONE TM 3,000,000 U.I. with dilutent, etc. for \$200. Information from the manufacturer of the approved Beta-Interferon to be sold in the U.S., indicates this product appears to be half the strength of the U.S. recommended therapeutic dose.

MIN-DO received promotional literature for the purchase of the above referenced product from A.G.E.S. Distribuidora, Mexico. The literature identifies the product as a "sexual breakthrough"; "potential benefits are: Immediate energy and vigor, Reverses impotence in men of any age, ***"; "from limp, standstill impotence to virility in as little as 48 hours"; etc.

Discretionary release of unapproved drug products promoted to individuals in the U.S. is unacceptable under the Personal Importation Guidance of Regulatory Procedures Manual Chapter 9-71.

All Drugs	A. Werner & Co. P.O. Box 615 111 21 Prague 1 Czechoslovakia MID #: CSWERCO615PRA	Czechoslovakia 9/23/93
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All products	Lenex Labs Wavecrest House West Bay St. P.O. Box N-8174 Nassau, Bahamas
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U.S. Distributor:
Alpha Omega Labs
Box 291
Fort Benton, Montana 59442

Boston District received promotional literature and mail order solicitation for drugs from Alpha Omega Labs. The materials accompanied a letter from Lenex Labs, in which Lenex stated that Alpha Omega would service orders on Lenex's former products. The firms offer a variety of products, including cancer inhibitors, weight loss products, and treatment for toxic bowel symptoms.

IA 000010

PRODUCT	SOURCE	COUNTRY
*** All Drug Products	Gero Vita International 2255 B Queen Street East, Suite 820 4/6/95 Toronto, Ontario M4E 1G3 Canada MID# XOGERVIT2255TOR FEI# 1000327472	Canada Updated 8/18/97

Gero Vita International (may be doing business as)
 Life Force Laboratories 12/5/97
 2255 B Queen Street East, Suite 820
 Toronto, Ontario M4E 1G3
 Canada
 FEI# 3001190383

Gero Vita Laboratories 11/4/97
 130A Denison Street
 Markham, Ontario, Canada L3R 1B6
 FEI# 30001146884

***NOTE: Gero Vita Laboratories is currently listed on the attachment to import alert 66-41 for their promotion and distribution of "Prostata". Evidence has been provided to FDA which indicates the firm is also promoting and distributing to individuals in the U.S. numerous other drug products (including but not limited to: GH3 (enhances memory); Testerex (enhances sexual vitality); SOD Complex (fights disease causing free-radicals); Medi-Zyme N (anti-inflammatory); Serezac (helps alleviate depression); Lung Support Formula (moistens lungs & breaks up sputum; strengthens kidneys); Vita Potencia (protects heart health; helps control stress); ACF 223 (reduces risk of heart disease, cancer);etc.) which would be considered unapproved new drugs.

Gero Vita Laboratories 2/14/00
 4936 Yonge Street
 Toronto, Ontario, Canada M2N 6S3
 FEI# 3002084064

Quantrol I	Quantrol Research Institute	Dominican
Quantrol II	Ave. Sarasota Edificio	Republic
(or CanCell)	EmbaJador Edif. E, 8-I	12/22/95
(May be invoiced as Santo Domingo 99999 water)	Dominican Republic	
PRODUCT CODE: 62I99 aka Quantrol Agency or Quantum Research		

INTERNATIONAL TRADE Live Cell Therapy	Mexico
---------------------------------------	--------

IA 000011

Apartado Postal No. 81 GPI=DR

2/9/96

Admon. de Correos Mesa De Otay
Mexico CP 22500
MID:MXINTTRA81ADM
FEI:1000481446

Information submitted to DIOP by ATL-DO indicates the above firm is soliciting individuals to purchase Live Cell Therapy. The product is currently on import alert from other shippers and under the name of Zellen Live Cell Therapy. The Live Cell Therapy is being promoted for numerous medical conditions, including aging problems, lack of energy, impotency, diabetes, degenerative brain disease, etc. Promotion is usually accompanied by a MEMO FROM DR. HANZ BYRON PREMATURE AGING SPECIALIST, HOLISTIC HEALTH CENTER LONDON, ENGLAND, ZURICH, SWITZERLAND.

OTC-TRANSDERMAL PATCHES ALL

ALL

FOR WEIGHT CONTROL

8/6/96

There has been an increase in the promotional advertising for OTC transdermal patch products claiming they are effective for weight control. Health Fraud Bulletin #13, dated February 3, 1989, regards OTC transdermal patch drug products as unapproved new drugs and misbranded drugs, because of the method of administration. (DRND/MLLM) (Product Code-66V[][]99)

(Note: Nicotine transdermal patch drug products are now acceptable for OTC marketing via approved NDAs)

(Note: One firm in Canada has been identified as currently promoting such patches-United Research Center, 1414 Place Bonaventure, Montreal, Quebec, Canada, H5A 1H3 (FEI #1000595188, MID #XQUNIRES1414MON) under the name of "The Svelt Patch")

PRODUCT	SOURCE	COUNTRY
All over-the-counter (OTC) vaginal contraceptive drug products (including contraceptive sponges) NOT labeled for "immediate use" (immediate use = less than one hour prior to intercourse) and not the subject of an approved new drug application (NDA).	65X[][]01, 65X[][]02, 65X[][]03, 65X[][]04, 65X[][]99	6/16/97

Liquid Deprenyl Citrate Discovery Experimental and Mexico

IA 000012

(Finished product) Development Mexico, N.A. 7/1/97
Juan Carrisco no. 13
GPI = DR Tijuana, B.C., Mexico
FEI# 3000326275

AND

Deprenyl (bases and salts) All Sources All Countries
(common name = selegilene) 62J[[]99, 66Y[[]99 7/21/97
or similar anti-parkinson products

Ephedrine Hydrochloride Tablets Sun Labs. Ltd. Canada
60C[[]22 1700-1700 McLeod Road 9/16/97
Niagara Falls, Ontario, Canada
L2G 7K3
FEI# 3000928033

ALL IAS Ltd. Great Britain
P.O. Box 2995 10/17/97
Muswell Hill
London N10 2NA
Great Britain
FEI #3001047710

aka: Int'l Antiaging Systems
P.O. Box 337
Guernsey, Channel Islands
Great Britain

Super Concentrated Aloe Vera WLA 132 The Wolfe Clinic Canada
C-Max 5 Scotsville Road 12/17/97
Coral Calcium & Coral Calcium Gold Strathlorne, Nova Scotia
Cesium Calcium FEI# 3001109438
PRO-MAX PRODUCT CODE: 66V[[]99
Pak-of-Life

ANTI-AGING PILL (Multitabs) Conseils De Sante, S.A. Switzerland
PRODUCT CODE: 66V[[]99 P.O. Box 331 1/27/98
1211 Geneva 12
Switzerland
FEI# 3001366101

This product contains deprenyl, vinpocetin, ergoloid mesylates (hydergine),

IA 000013

procaine HCl, and hematoporphyrin.

OSMOPAK PLUS (Manufacturer - per label) Canada
 61MBJ11 Laboratoire Charton Laboratories 3/26/98
 Division Herdt & Charton Inc.
 9393 Louis H. Lafontaine
 Montreal, Quebec, Canada
 FEI# 1000541169

PRODUCT	SOURCE	COUNTRY
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(Shipper)
 Distribution Rapiflex
 759 Marie-Victorin
 St. Bruno, Quebec, Canada
 FEI# 3001019316

This product is used as a drawing salve for the inflammation of subcutaneous tissues.

BM Oral Solution, Xiehe Group Co., Ltd. China (Mainland)
 and any product 19-A-8 Sanhac Street 4/1/98
 containing the Shenyang, Liaoning
 ingredient China (Mainland)
 Staphylococcin FEI #3001281354

Prescription Vitality Health Products Thailand
 Drugs: C/O Nimit Pharmacy 8/13/98
 Dexfenfluramine944 Rama 4 Road
 Medroxyprogesterone Bangkok
 Premarin Thailand
 66V[][]99 FEI #3001715829

QUINICRINE HYDROCHLORIDE ALL FOREIGN All
 FINISHED PRODUCT/ALL MANUFACTURERS 8/25/98
 FORMS-TABLETS,
 (CAPSULES, LIQUID, ETC./
 (NOT BULK/RAW MATERIAL)
 PRODUCT CODE-60W[][]34

Dermopura Acneiche Revivre Cosmetiques C.R.B. spa Italy
 Treatment against Acne & Via Vallina Orticella, 34 12/3/98
 scarring.(Product maybe 31030 Borsio Del Grappa (TV), Italy
 entered as a Cosmetic under FEI #1000484992

IA 000014

PC(53LC-03) As a drug treatment it may be entered as PC 64X--07 or 99 (acne drug products) or as 66V--99 (Miscel. Patent Medicines)

NOTE: CDER has determined this product is being marketed over the internet and promoted for use as a treatment against "acne and scarring". The active ingredients listed include "azelaic acid". That ingredient offered as an OTC acne treatment, is a new drug, requiring an NDA to obtain marketing authorization and should not be promoted as an OTC product. This product also appears to be in violation of the final rule (21 CFR section 333.301) covering acne products. Questions regarding this product or other similar products should be addressed to Constance E. Bulawka, OTC Compliance Branch, Division of Drug Labeling and Nonprescription Drug Compliance, HFD-312, 301-594-1065.

PLEASE ADD THE ABOVE FIRM/PRODUCT TO THE ATTACHMENT OF IMPORT ALERT #66-41.

PRODUCT	SOURCE	COUNTRY
Serotril Sciences, International 125 A - 1030 Denman Street Suite 100 Vancouver, B.C. V6G 2M6 Canada FEI# 3002597084	"Serotril" Active Ingredient is Hypericum perforatum which is St. John's Wort - 2/9/99 54Y--64 54Y--99	

NOTE: CDER has determined that this product is being promoted as an alternative to prescription drugs such as Fen-Phen and Imipramine and is intended to treat obesity and depression and claims to correct the "biochemical cause of weight loss". The product is described as an MAO inhibitor. MAO inhibitors are a class of antidepressant drugs which can pose health risks to patients if certain dietary restrictions are not observed during therapy.

PRODUCT/PRODUCT CODE	SOURCE
GAMMA-BUTYROLACTONE (GBL) (SYNONYMS FOR GBL) 2 (3H)-FURANONE DIHYDRO BUTYROLACTONE 4-BUTYROLACTONE DIHYDRO-2 (3H)-FURANONE 4-BUTANOLIDE 2 (3H)-FURANONE	65V--51 (SEDATIVE) ALL 3/19/99

IA 000015

DIHYDRO
TETRAHYDRO-2-FURANONE
BUTYROLACTONE

1, 4-BUTANEDIOL/65V--52 (SEDATIVE) ALL

(Note: FDA has identified GBL products labeled as: Renewtrient; Revivarant or Revivarant G; Blue Nitro or Blue Niro Vitality; GH Revitalizer; PRO-G; Gamma G and Remforce. This list should not be considered all-inclusive.)

GAMMA HYDROXYBUTYRATE (GHB) /65V--50 ALL

(SYNONYMS FOR GHB)

SODIUM GAMMAHYDROXYBUTYRATE (NaGHB)
POTASSIUM GAMMAHYDROXYBUTYRATE (KGHB)

GAMMA HYDROXYBUTRIC ACID

SODIUM OXYBATE

4-BUTANOLIDE

4-HYDROXYBUTYRIC ACID

4-OHB

ETHYL 4-ACEBUTANOATE

(Note: FDA has identified GHB products labeled as: Alcover; Gamma-OH; Smatomax-PM; Somsanit; Anectamine; Natural Sleep 500, etc. This list should not be considered all-inclusive.)

GBL and GHB also have many street names. Some of the most common are: G; Liquid E or Liquid X; Georgia Home Boy; Great (Grievous) Bodily Harm; Liquid Ecstacy; Scoop; Water.

GBL related products have been associated with reports of at least 55 adverse health effects, including Death. When taken orally, GBL is converted in the body to gamma hydroxybutyrate or GHB. GBL products are sold in liquid and powder form.

GBL and GHB products are promoted with claims to build muscles, improve physical performance, enhance sex, reduce stress and induce sleep. These products are very potent unapproved drugs and powerful hypnotic substances known to produce significant and potentially dangerous sedating effects.

District may detain the above products without physical examination from all sources. FDA is aware these products are being offered for importation using various non-drug claims such as: "wood softener" "bubble bath", etc. Further, GBL is a known ingredient for commercial floor strippers. Never-the-less, unless evidence is provided to the district that supports the product for non-drug use, the product should not be considered for release. These products are also inappropriate for release under FDA's Personal Importation Guidance.

IA 000016

For additional background information on GHB, please refer to import alert 66-60. Questions regarding GBL/GHB can be directed to CDER/Office of Compliance, HFD-310, Bradford Williams, 301-827-7364.

All Products	Meditalent Enterprises Ltd.	Taiwan
GPI = DR	87 Hsin Sheng N Road	8/4/99
GPI = VI	Taipei, Taiwan	11/17/99
FEI# 1000441748		

Meditech Enterprise Co. Ltd.	Taiwan
PO Box 58388	8/4/99
Taipei, Taiwan	11/17/99
FEI# 1000132804	

Firm Product/Product Code
(Note: products may be entering as skin care cosmetics, therefore, we are including the product code "53LC---" (Skin Care Preparations) along with appropriate drug codes:

64L--28 (Fluocinonide)
64L--06 (Betamethasone dipropionate)
64L--99 (Glucocorticoids, n.e.c.)

Pramil Srl Regge Lemon Gel
Milan, Italy .05% Betamethasone dipropionate
FEI # 3002619397 64L--06/53LC
10/15/99

Topvate Cream
.05% Clobetasol Propionate
64L--99/53LC

Movate Cream Esapharma
.05% Clobetasol propionate
64L--99/53LC

Omic Gel Esapharma
.025 g Fluocinonide
64L--28/53LC

Duwin Pharmaceutical and Chemical Co. Ltd. Regge Lemon Gel

IA 000017

38 Denton Street .05% Betamethasone dipropionate
Lagos, Nigeria 64L--06/53LC
FEI #3002558741
10/15/99 Topvate Cream
.05% Clobetasol Propionate
64L--99/53LC

Topsone Gel
.05% Betamethasone dipropionate
64L--06/53LC

Omic Gel Edkeen
.025% Fluocinonide
64L--28/53LC

Topsovate Cream Edkeen
.05% Clobetasone butyrate
64L--99/53LC

M Movate Industries, Inc. Movate Cream - M - 10/15/99
Milan, Italy .050 g Clobetason propionate
FEI #3002823220 64L--99/53LC

Tecmomed s.r.l. Dermo-Gel plus - Techmomed
viale san gimignano, 2 .075% Fluocinonide
Milan, Italy 64L--28/53LC
FEI #3002606542
10/15/99 Neoprosone-Gel Forte
.05% Betamethasone and
.1% Neomycin Sulphate
64L--06/53LC

Lemonvate Cream
.05% Clobetasol propionate
64L--99/53LC

N.P. Italiana srl Top-Gel with Special Sunscreen Agent
Napoli, Italy .025% Fluocinonide
FEI #3002823229 64L--28/53LC - 10/15/99

IA 000018

M.C.A. Medical and Chemical Agency Prosone Gel MCA
Via Parini, 13 .05% Betamethason dipropionate
S. Vittore Olona 64L--06/53LC
Milan, Italy 20028
FEI #1000167943 Top-Gel Plus MCA
10/15/99 .025 g Fluocinonide
64L--28/53LC

Mitchell International Pharmaceuticals Ltd Pro Beta-Zone
Unit 7 Kingston House Estate .05% Betamethasone dipropionate
Portsmouth, Thames Ditton, UK 64L--06/53LC
FEI #1000480864
10/15/99 Beta-Vate
.05% Betamethasone dipropionate
64L--06/53LC

Mercury Top Gel
.05% Fluocinonide
64L--28/53LC

Topsone Gel
.05% Betamethasone dipropionate
64L--06/53LC

Omic Gel Edkeen
.025% Fluocinonide
64L--28/53LC

Topsovate Cream Edkeen
.05% Clobetasone butyrate
64L--99/53LC

Manufacturer:
Glaxo Smith Kline Uk Dermovate Cream
(a.k.a. Glaxo Wellcome Clobetasol propionate
Research & Development) 64L[] [] []
Greenford Road 10/15/99
Greenford, Middlesex, UK UB6 OHE
FEI #3000263379 Update name and product code
9/15/08

Shipper:
Salawu Enterprises Ltd.
10 Onikosi Street
Otta, Nigeria

IA 000019

FEI #3004526255

Laboratoires Mitchell Srl. Dermacare Gel

Paris, France .05% Fluocinonide

FEI #3002823274 64L--28/53LC

distributed by: 10/15/99

Sears Pharmaceuticals & Chemicals Ltd.

Nigeria

FEI #3002823282

Mitchell Cosmetics Srl Regge Lemon Gel

6 Bis Chemin Byron Case .05% Betamethasone dipropionate

Postale 59 64L--06/53LC

Geneva, Switzerland

FEI #3002582140 Omic Gel Plus

10/15/99 0.025 g Fluocinonide and Neomycin

Sulfate 0.05g

64L--28/53LC

Preventac Tablets, PremeTab, Formulex Canada, Inc. Canada

SomaTac, UriTab Caplets 5950 EST Chemin Cote-de-Liesse

60LBA05, 60LAA05 Ville Mont-Royal

54F- - 99, 54A- - 99 Quebec, Canada

5/19/00 FEI # 3002269313

PACKER/SHIPPER:

Ropack Inc.

10801 Mirabeau

Anjou, Quebec H1J 1T7

Canada

FEI # 3002674295

Products shipped by the following firms were found to contain the drug

IA 000020

glyburide, which is used to treat diabetes. These products are, being promoted as dietary supplements & claim to contain only natural Chinese herbal ingredients. They are available through mail order and can be purchased by telephone or via the Internet. These products are being recalled under a Class I recall as a health hazard.

All Products Heilongjiang Provincial Hechang China
GPI = DR Import and Export Co.Ltd.
GPI = VI Harbin, China
6/6/00 FEI# 3002799794

All Products Harbin Zhongshan Diabetes China
GPI = DR Research Institute
GPI = VI Harbin, China
6/6/00 FEI# 3003028087

Calidou Sun Lotion MFG. (per label) Canada
66P- --99 Prodemedis Enr.
6/8/00 St. Hubert, Quebec
Canada
FEI # 3003030473

MFG. (per shipper):

Laboratories Confab, Inc.
4355 Sir Wilfrid Laurier
St. Hubert, Quebec J3Y 3X3
FEI # 1000610344

Catalysis, S.I. Blue Cap Spray Spain
Zurbano 39 Blue Cap Cream 6/29/00
Madrid, Spain 28010 Blue Cap Shampoo
FEI# 3002989319

Product Codes:

Blue Cap Spray (100 ml, 3.33 fl oz): 62SAQ99, 61SAQ01, 61HBQ05,
53E[][]06, 53J[][]02, 53L[][]06
Blue Cap Cream (50 g, 1.6 oz): 62SAJ01, 53E[][]06, 53L[][]03,
53L[][]06
Blue Cap Shampoo (150 ml, 4.99 oz): 61HBL05, 63SAL01, 53E[][]06,
53L[][]06

Mifepristone All All
65J[][][]/ 9/28/00
65D[][][]

IA 000021

FDA has determined that unapproved versions of mifepristone manufactured outside the U.S. are being promoted in this country for use to end pregnancy. Due to the risks to the safety of the user in inadequately controlled settings, mifepristone should be considered inappropriate for release under the Personal Import Guidance. Districts encountering entries of mifepristone should determine whether the importer of record for the article being entered is Danco Laboratories, LLC, New York, New York (distributor of the U.S. approved product) or whether the article is being entered under an IND that is in effect. In such circumstances (when the article is being imported by the distributor of the U.S. approved product or under an IND that is in effect), the article is outside the scope of this guidance.

(Districts should contact CDER for verification of IND status.)

Source	Product/Product Code	Country
M.C.A.	Top-Gel Super	Italy
Medical and Chemical Agency	0,03 g Fluocinonide	2/12/01
Via Parini, 13	64L--28/53LC	
S. Vittore Olona Milan, Italy 20028 FEI #1000167943		
All drug & dietary supplement products	De-Sjamaan Hommelseweg 170	Netherlands 10/7/02
GPI - DR/IND - 54	Arnhem, Netherlands 6821 FEI #3003671336	
All products	ALPHA - Aleppo Pharmaceuticals Industries GPI = DR Baron Street, P.O. Box 517 GPI = VI Aleppo, Syria FEI #3003659034	Syria 11/21/02

The following sources/products have met the criteria for detention without physical examination. Shipments are likely to be encountered through express mail or courier operations.

Certain drugs have special safety restrictions on how they are distributed. These restrictions include distribution limited to facilities (such as hospitals) or physicians with special training or expertise; or requiring certain medical procedures (such as pregnancy or blood testing) if the drug will be used. The following drugs are subject to a restricted distribution program. Due to the serious health risks associated with the use of these drugs with inadequate control, shipments of these drug are inappropriate for release under the personal importation policy. For questions, Districts

IA 000022

should contact Ada Iriaray at the Center of Drug Evaluation and Research, Division of Prescription Drug Compliance and Surveillance, HFD-330 at 301-594-0101.

PRODUCT/PRODUCT CODES	SOURCE	COUNTRY
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Isotretinoin	All	All
64X 11		
12/06/02		

Other names: Accutane, *** Accutane Roche 40, *** Retinoic Acid, 13-cis-, Roaccutane, Isotrex, Accure, Amnesteem, Antibiotrex, Isohexal, Isotrex Eritromicina, Isotrexin, Nimegen, Oratane, Roaccutan, *** Sotret, Claravis ***

*** Somatropin Recombinant All All

64R 23

2/19/04

Other names: Humatropo, Somatropin, Biosynthetic; Growth Hormone Recombinant ***

*** Abarelix All All

60V--99

2/19/04

Other names: Plenaxis ***

Firm My Drugs Canada

Address Jonathan Valicenti, PO Box 370, 1250 University St.
Montreal, Quebec, Canada H3B 3B0

FEI# 3004452174

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^

Firm Pharmacy RX Drugs Inc.

Address 9 Sundown Court, Thornhill, Ontario, Canada L4J 3V4

FEI# 3004452183

^

^

Firm PharmAnabolics

Address Karznik Pretrova, Wroclaw, 5548 Poland

FEI# 3004452189

^

^

Firm Pilot Mound Pharmacy

Address Darcey Mosquin, Box 89, Pilot Mound, MB Canada R0G 1P0

FEI# 3004452193

IA 000023

Firm The U.P.P. Group
Address 74 Perry Drive, Sylvan Lake, Alberta, Canada T4S 1K4
FEI# 3004452206

Firm TAME
Address 404-250 McDermont Avenue, Winnipeg, Manitoba, Canada, R3B 0S5
FEI# 3004452213

Firm The Dispensary
Address NT Lusk, 25 Hipwood St, Brisbane, 4170 Australia
FEI# 3004452215

Firm Liberty Lifestyle Pty Ltd.
Address Managing Director, PO Box 103 Concord West, Sydney, NSW 2138
Australia
FEI# 3004452224

Firm DiscountMeds Online Corp.
Address PO Box 1005, Grand Anse, St. Georges, Grenada
FEI# 3004452230

Firm 1drugstore-online.com
Address 429 Rochor Road, Startech Holding Limited 188452 Singapore
FEI# 3004452234

Firm Punta Internacional de las Americas SA
Address Punta Punta, Costado Este del AutoBanco Nacional, Ave 10
San Jose, 11111 Costa Rica
FEI# 3004452237

Firm DB Group (BHPHARMACY)
Address BLK 820, Yishun Street 81 #06-656, Singapore 760820
FEI# 3004452239

IA 000024

Firm Border Pharmacy
Address 26 Abasolo y Reforma, C.P. 919020 Mexico
FEI# 3004452241
^

Firm My Drugs Canada
Address PO Box 370, 1250 University St., Montreal, Quebec, Canada H3B 3B0
FEI# 3004452242
^

Firm Universal Needs SJ Inc.
Address PO Box 370, 1250 University St., Montreal, Quebec H3B 3B0 Canada
FEI# 3004452246
^

Firm Fraser Valley Online
Address PO Box 435, Abbotsford, British Columbia, Canada V25 5Z5
FEI# 3004452248
^

Firm MedsCorp
Address County Aunan, Blc. 5-6, Office 6b, Nurburger, 27850 Germany
FEI# 3004452249
^

Firm Defining Presence Marketing Group Inc.
Address Universal Needs SJ Inc., PO Box 370, 1250 University Street
Montreal, Quebec, H3B 3B0 Canada
FEI# 3004452254
^

Firm 111 Drugstore.com
Address Unknown Street Address, Singapore
FEI# 3004452260
^

Firm Abas Pharmacy
Address Lakeside Computer Source, Box 136, Camp Morton, MB R0C 0M0, Canada
FEI# 3004452261
^

Firm Adv-Care Pharmacy Inc.
Address Amr Bannis, 50 Heathcote Ave., Toronto, Ontario, Canada M2L1Z1
FEI# 3004452262
^

Firm Rx Resources Inc.

IA 000025

Address Box 11 Group 100 RR2, Lorette R0A 0Y0, Manitoba, Canada
FEI# 3004452266
^ ^

Firm Aptech Inc.
Address Box 1158, Stonewall, Manitoba R0C 2Z0, Canada
FEI# 3004452268
^ ^

Firm LePharmacy Inc.
Address 7310 Mountain Sights Ave., Montreal, QC, Canada H4P 2A6
FEI# 3004452269
^ ^
^ ^

Firm TCE Group Inc.
Address Amr Bannis, 50 Heathcote Ave., Toronto, Ontario, Canada M2L 1Z1
FEI# 3004452278
^ ^

Firm Canada Med Express
Address 330 McCowan Road Suite 1508, Scarborough, Ontario, M1J 3N3 Canada
FEI# 3004452279
^ ^

Firm Arborg Pharmacy
Address 273 Main St, Box 640, Arborg, MB R0C 0A0, Canada
FEI# 3004452283
^ ^

Firm Canamerica Drugs
Address 12 Carina Cove, Winnipeg, MB, Canada R2V 4N8
FEI# 3004452158
^ ^

Firm Canadiansdrugstore.com
Address Martin Bean, 1609-200 Ronald St., Winnipeg, MB,
Canada R3J 3J3
FEI# 3004452159
^ ^

Firm Black Mountain IDA Pharmacy (1979) Ltd.
Address 11-590 Hwy. 33 W., Kelowna, B.C. Canada V1X 6A8
FEI# 3004452167
^ ^

IA 000026

Firm Canada Rx Connection
Address 11 Ayr Blvd., Winnipeg, Manitoba, Canada R3P 0K4
FEI# 3004452169
^

^

Firm Health 2000 Pharmacy
Address 105-6950 Nicholson Rd., North Delta, BC, Canada V4E 1Z7
FEI# 3004217327
^

^

Firm MediMart Pharmacy
Address Paul Emmer, 1511-690 Kenaston Blvd. Winnipeg,
MB, Canada R3N 1Z3
FEI# 3004452182
^

^

Firm Access Meds
Address 46 Parnlet, Newcastle, South Africa
FEI# 3004452185
^

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Firm Pharmacy International
Address 61 King George, Roseau, Dominica
FEI# 3004452192
^

^

Firm Rx2world
Address c/- monarch holdings, PO Box 257, Port Vila, Vanuatu
FEI# 3004452194
^

^

Firm E-pharmacy.net
Address World Pharmacy Supplies, c/-Suite 9, 14 Norton St,
Leichhardt 2040, NSW Australia
FEI# 3004452204
^

^

Firm i-pharmacy
Address PO Box w66, Shop 3, 14-16 Military Rd. Watson's Bay NSW 2030
Australia
FEI# 3004452208
^

^

Firm Planet Drugs Direct Ltd.
Address PO Box 33 893 Takapuna, North Shore City, New Zealand
FEI# 3004051223

^

IA 000027

Firm Hometown Meds
Address Robert Watts, 43 Roslyn Rd, Winnipeg, MB, Canada R3L 0G1
FEI# 3004452214

^
Firm Icanrx.com
Address Contact Media Group, 12840 16th Ave #203, White Rock, BC V4A 1N6
Canada
FEI# 3004452216

^
Firm CANUSA Health Group
Address Doug Burton, 865 Brawley Road West, Ashburn, Ontario,
Canada L1M 1M5
FEI# 3004452226

^
Firm Good Samaritan Rx
Address Dr Morgan Campbell Inc., 124 3185 King George Hwy,
Surrey, BC, Canada V4P 2J9
FEI# 3004452228

^
Firm Pharmawest Pharmacy Ltd.
Address #69-15515-24 Avenue, Surrey, BC, Canada V4A 2J4
FEI# 3004452235

^
Firm Direct Drugs
Address 1569 Orange Street, Winnipeg, Manitoba, Canada R3E 3S2
FEI# 3004452238

^
Firm Pelikon Investments Limited
Address Peter Kraus, Mykinon 1, Nicosia, NO 1065, Cypress
FEI# 3004452302

^
Firm Canadian Pharmacy
Address See Phuket, 12 De Castro Street, Tortola
British Virgin Islands, 12345
FEI# 3004452315

IA 000028

Firm 1Meds
Address Steven King, 21 Marion St., Shorewood 7276, Taiwan
FEI# 3004452316
^ ^

Firm Canada Value Meds
Address Junodis Solutions, 47 Regent Ave., Hamilton, Ontario Canada
L9B 1R4
FEI# 3004452318
^ ^

Firm Americana Meds
Address Kelsie Mercer, 319 South River Road, Elora, Ontario, Canada
NOB 1SO
FEI# 3004452156
^ ^

Firm Online-Pharmacy
Address Online Pharmacy SA, Corrientes 1820, Buenos Aires,
Capital Federal 1108, Argentina
FEI# 3004452322
^ ^

Firm Discount Prescription Drugs Online
Address Liberty Lifestyle Pty Ltd, Barry West, P.O. Box 103 Concord West
Sydney, NSW 2138 Australia
FEI# 3004452329
^ ^

Foreign Websites Selling Accutane or Generic Isotretinoin

(1) Firm: Mac Pharma Network
Address: MAC Pharma Network
No.31, Block S
DHA
Lahore, Punjab 54792
Pakistan
FEI# 3005130603
^ ^

(2) Firm: Drugdelivery.ca
Address: Andrina Owens
Canadian Drug Delivery Inc.
11215 Jasper Ave Suite 601
Edmonton AB T5K 0L5 Canada
1-877-888-3562

IA 000029

FEI# 3005130862

^ ^

(3) Firm: 3a Pharmacy.com & 3amed
Address: Jakob Neubert
(WHITNEY-FERGUSON2 3 AMED.COM)
+45.28804290
Fax: +45.28804290
Aginavej 5
Copenhagen s, Copenhagen s 2300
Denmark

FEI# 3005130835

^ ^

(4) Firm: Pharmanabolics.com
Address: Panacea International Ltd
Copthall, P.B. Box 2331
Roseau, Denmark

FEI# 3005130870

^ ^

(5) Firm: European-Pills.com
Address: Georgios Mitropoulos
(george_mit@hotmail.com)
European Pills
113 Aristomenous St.
Kalamata, None 24100
Greece +30-6944374425

FEI# 3005130887

^ ^

(6) Firm: Hallmark Pharmacy
Address: Hallmark Pharmacy
Organization Address
14 School Lane, Bengali Market
New Delhi
110001
DE
INDIA

FEI# 3005130889

^ ^

(7) Firm: Canada Prescriptions Plus
Address: Canada Prescriptions Plus
11420- 142 Street
Edmonton, Alberta T5M 1V1

IA 000030

Canada
Admin Contact: Cooper, Bill
wbc@canadaprescriptionsplus.com
FEI# 3005130899

^ ^
(8) Firm: Your-Online-Pharmacy.com
Address: Mikalai Markau
Polevaya 3A
Grodno, Belarus
FEI# 3005130944

^ ^
(9) Firm: MedsIndia
Address: Meds India, Ltd (MEDSINDIALTD3-DOM)
20 Macaw Avenue
Belmopan, Belmopan C.A.
Belize
FEI# 3005130954

^ ^
(10) Firm(s): Panacea-Pharmacy.com and/or
MedicaCenter
Address: Karznik
Petrova
Wroclaw, 5548
Poland
Admin Contact: Karznik, David
dkarznik@yahoo.com
FEI# 3004452189

^ ^
Note: These two different firms are operating under the same firm address and
two different website locations.

^ ^
(11) Firm(s): Night and Day Pharmacy.com and/or
Freedompharmacy.com and/or
Globalchemist.com
Address: Monarch Holdings (VTGEEPZWD)
2nd Floor, Windsor House
Lini Highway, P.B. Box 257
Port Vila, Fort Vila 00000
Vanuata
FEI# 3004452194

IA 000031

Note: These three different firms are operating under the same firm address and three different website locations.

(12) Firm: ValuePharmaceuticals.com
Address: Liberty Lifestyle Pty Ltd
Managing Director
PO Box 103 Concord West
Sydney, NSW 2138
Australia
FEI# 3004452329

(13) Firm: Discount Meds
Address: DiscountMeds Online Corp.
(USAMEDICINE4-DOM)
P.O. Box 1005
Grand Anse, St. Georges
Grenada
FEI# 3004452230

(14) Firm: OP Online Pharmacy.cc
Address: Online Pharmacy SA
Corrientes 1820
Buenos Aires, Capital Federal 1108
Argentina
FEI# 3004452322

(15) Firm: The Dispensary.com
Address: NT Lusk
25 Hipwood St.
Brisbane, 4170
Australia
FEI# 3004452215

Website Additions to Import Alert # 66-41 - Foreign Websites Selling Clozaril or Humatropine

(1) Firm: Anabolics-Online
Address: Jarda Pokorny
(ANABOLICS-ONLINE-COM-DOM)
Libusina 37

IA 000032

Praha, 110 00
Czech Republic

FEI# 3005133122

^ ^
(2) Firm: Hormone Boutique
Address: CWP
PO Box 3149, Pasea Estate
Road Town,
Tortola,
British Virgin Isles BV 1000
FEI# 3005133124

^
(3) Firm: Pharmacy-Network
Noprescriptiondrugs.com
Address: Azenith International LLC
Copthall PO Box 2331
Roseau
St. George, Dominica 00152
FEI# 3005133150

Note: These two different firms are operating under the same firm address and two different website locations.

^ ^
(4) Firm: HGH Human Growth Hormone
Address: Laura Vadillo
My Cancun Weddings
laura@my-cancun-weddings.com
Av. Sayil No. 24
Cancun, Quintana Roo 77500
Mexico
FEI# 3005133169

^ ^
(5) Firm: New Age Nutrition
Address: Discount Nutrition S.A.
Sayil
Cancun, Quintana Roo 77500
Mexico
Vadillo Laura director@ discount-human-growth-
hormone.com
St. George, Dominica 00152
FEI# 3005133172

IA 000033

(6) Firm: Bestbuyinjectablehgh.com
Address: BIP Cancun S.A. de C.V. (FGNXPTCWTD)
Calle Azucenas SM.22 M.2, Lote 19
Cancun, ZZ 77500
Mexico
FEI# 3005133178

^(^
(7) Firm: Pharmacy-online.com
Address: Barney Briton
#500, 400 Crowfoot Cresc. NW
Calagary, Alberta T3G 5H6
Canada
FEI# 3005133180

^(^
(8) Firm: Imported Drugs
Address: Canam Shopping Services, Ltd
Suite #243 15-180 Central Road
Dunca, BC V9L-4X3
Canada
FEI# 3005133190

^(^
(9) Firm: 3amed
Address: Jakob Neubert
(WHITNEY-FERGUSON2 3 AMED.COM)
+45.28804290
Fax: +45.28804290
Aginavej 5
Copenhagen s, Copenhagen s 2300
Denmark
FEI# 3005133196

^(^
(10) Firm: 77canadapharmacy.com
Address: Pharmacy Network
Vancouver, BC V2V 1K4
Canada
FEI# 3005133203

PRODUCT	SOURCE	COUNTRY
Sildenafil Citrate	Wallace Service P/L	Canada

IA 000034

Soft Tabs Clive Wallace
(Soft Tabs Viagra) 81 c Marine Parade
65P02 Seacliff, South Australia
5/27/05 Australia
FEI# 3004857162
^ ^

Sildenafil Citrate Medical Compounding Canada
Soft Tabs Software
(Soft Tabs Viagra) Box 421 Arnold Street
65P02 Richmond Hill
5/27/05 Ontario L4C 3R0
Canada
FEI# 3004857167
^ ^

Fentanyl All All
60M 24
12/06/02

Other names: Actiq

PRODUCT/PRODUCT CODE SOURCE COUNTRY

Bosentan All All
60TCA99
12/06/02

Other names: Tracleer

Clozapine All All
65V 13
12/06/02

Other names: Clopine, Clopsine, Clozaril, Elcrit, Froidir, Lanolept, Leponex, Zolapin

Dofetilide All All
63E 32
12/06/02

Other names: Tikosyn

IA 000035

Alosetron Hydrochloride All All
61T 30
12/06/02

Other names: Lotronex

Mifepristone All All
65J 38
12/06/02

Other names: Mifegyne, Mifeprrex

Sodium Oxybate All All
60P--01
65V 50
12/06/02

Other names: Alcover, Anetamin, Gamma-OH, Somsanit, Xyrem

Trovaftloxacin All All
61H 47
12/06/02

Other names: Trovan

Thalidomide All All
65V--40
12/06/02

Other names: Synovir, Thalomid

PRODUCT SOURCE

Ancom Tablets Shanghai Pharmaceutical Industry Corp. (mfg)
GPI=VI 27 Chungshan Road
GPI=DR Shanghai, China
2/12/03 FEI # 3003884699

China National Medicines & Health (shipper)
Products Import & Export Corp.
Shanghai Branch
27 Chungshan Road (E1)
Shanghai, China
FEI # 5534

Tourasia (internet promoter)

IA 000036

246 Sukhumvit Soi 16
 Bangkok, Thailand 10110
 FEI # 3003925496

Charisma Co., Ltd. (internet promoter)
 248/1 Sukhumvit Soi 16
 Bangkok, Thailand 10110
 FEI # 3003925501

Source	Product/Product Code	Country
(manufacturer)	"Busto-Lift" capsules	Italy
Italiani Selex	and cream for growth	04/23/03
20063 Cassina de Pecchi Milano, Italy	enlargement of the Female bust	
FEI # 3003901090	53LC-99	
	66VA-99	
(shipper)	66VB-99	
Luoice Marketing Enterprise No. 7 Off Jalan Bukit Bintang Luala Lumpur, Malaysia		
FEI # 3003901091		

(manufacturer) "Recovery Biostructural Canada
 Biomedica Laboratories, Inc. Medicines" for relief of 4/29/03
 "No Street Address" Chronic pain and
 Vancouver, British Columbia, inflammation
 Canada
 FEI # 3003807448 54FCR99
 (Shipper)
 The Nutraceutical Medicine Co.
 Unit #2, 3006 Boys Road
 Duncan, British Columbia, Canada V9L 6W4
 FEI # 3003056414

Chemon Inc.	"Joint by Joint"	Korea, Republic of
4645 Chung-Ri	Supplement	5/5/03
Kusung-Up, Yougin-Si	GPI - DR/VI	
Kyungki-Do, Korea		
FEI# 3003952905		

Product	Source:	Country:
Sildenafil citrate (generic)	Generic Viagra Bz 5870 Manatee Drive 65P02	Belize
	Button Wood Bay, Belize	

IA 000037

5/23/03

FEI# 3003868410

^

^

All drugs Mr. Vikan Thailand
GPI-DR Carrefour Rama 4 Road
GPI-VI MBE Suite 019
5/23/03 Bangkok, 10110, Thailand
FEI# 3003885661

^

^

Agrumax Bioxem, Inc. Canada
54AGL90 1421 Nobel
8/19/03 Sainte-Julie
Quebec, Canada
FEI# 3003756848

Face Cream Diane de Beaute All
53L[[]][[]/64X[[]][[]] PO Box 11-7599
9/5/03 Beirut, Lebanon
FEI# 3003914273

Charantia Ampalaya Herbcare Corp. Philippines
Food Supplement Herbcare Center, PDC Compound
54E[[]]99 - Tea form Pilar Village, Las Pinas City,
54F[[]]99 - Capsule form Philippines
FEI# 3003865977

and

Herbcare Corp. Philippines
Box 163
Las Pinas City,
Philippines
FEI# 3003659682

Herbal Medicines including Akita Herbal Products Philippines
Gluco-Norm Gold, Corner Volga and Zambensi Streets
Banabooster, Riverside Subdivision Friendship
Cancers Protocol Angeles City, Philippines
54Y- - - FEI #3003977207
66V- - -
11/17/03

IA 000038

Eleotin (and all products from this firm making #1130-4871 Shell Road
GPI = DR

Eastwood Bio-Medical Research Inc. Canada
any drug claims) \

Richmond, B.C. V6X 3Z6
GPI = VI CANADA
61P[][]99 FEI #3001619750
54F[][]99
12/1/03

The product label indicates Eleotin is a supplement, but refers customers to the firm's website www.eastwoodcos.com which claims the product can be used to treat diabetes. The product can also be purchased from the firm's website. The website claims Electin restores the body's own ability to control blood glucose levels and results in long-term molecular level changes to assist the body to recover glucose normalcy.

According to the firm's website, Eastwood Bio-Medical Research Inc. is engaged in the development and commercialization of safe and effective treatment for non-insulin dependent diabetes mellitus and cancer.

Careseng #1 Pegasus Pharmaceuticals Group Inc. Canada
(Capsules & Liquids) 3331 No. 3 Road
66V -- 99 Richmond, British Columbia
1/13/04 Canada
FEI #3004153848

Careseng #2
66V- -99 Dba
3/1/04

Pegasus Natural Supplements, Inc.
Unknown
Richmond, Canada
FEI #3003817323

Pegasus Pharmaceuticals, Inc.
#156 11786 River Rd
Richmond, Canada
FEI #3003114241

Pegasus Pharmaceut
156 11786 River Road
Richmond, Canada
FEI #3003659429

IA 000039

PRODUCT	SOURCE	COUNTRY
All Products 2/6/04	American Style Products BHikaji Cam PL New Delhi, IN FEI: 3004413333	India

The agency received information about an overseas inter
lling counterfeit contraceptive patches that contain no activ
ts. The counterfeit contraceptive patches were promoted as Orth
sdermal patches, Ortho Evra transdermal patches, a Johnson and
Ortho-McNeil Pharmaceutical, Inc. product.. This internet site's c
is www.rxpharmacy.ws.

Ukraine 2/6/04	Nowicky Pharma Margaretenstrasse 7 Vienna, a-1040 FEI: 3000960791	Austria
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UKRAIN is an injectable promoted as an anticancer drug. Districts encountering shipments of this product should contact DIOP using the ORA HQ DIOP EMPLOYEES e-mail for guidance.

PRODUCT/PRODUCT CODE	SOURCE	COUNTRY
All Skin Bleaching and Lightening Lotions, Creams, Soaps and Serum 66[]][[]] 53[]]-[] 3/9/04	Catherine Abbaa 98 Badagry Exp. Way Lagos, Nigeria FEI# 3003407077	Nigeria

Note: products may be entering as skin care cosmetics, therefore, we have included the product code "53[]]-[]" along with the appropriate drug code.

IA 000040

PRODUCT/PRODUCT CODE	SOURCE	COUNTRY
Humatropo 64R[][]23 3/26/04	ALL	ALL

Other names: Somatropin, biosynthetic; Growth Hormone Recombinant

Plenaxis 60V[][]99 3/26/04	ALL	ALL
----------------------------------	-----	-----

Other names: Abarelix

PRODUCT	SOURCE	COUNTRY
Plaquex 3/26/04	All	All

A product used for chelation therapy is represented to be useful in a number of therapeutic conditions. It is called Plaquex. The product comes into the country from the Bahamas using the personal importation policy on the "front" end, however a recently detained package declared the contents to be a nutritional supplement. The company involved in this is called Jeunomed International and it has a Key Biscayne address. Product administration is by IV and requires refrigeration. One 50ml vial is said to contain 2500ml essential Phospholipids as 70% Phosphatidylcholine, 1250mg Deoxycholic acid, 10mg Vitamin E, 10mg Nicotinic acid, 10mg Adenosine triphosphate, 450mg Benzyl alcohol and 120mg Ethanol. Plaquex, is an injectable drug product, and as such, it poses a significant health risk and it is being promoted in the U.S. through the internet ; e.g. <http://www.plaquex.ch/>.

PRODUCT	SOURCE	COUNTRY
V-1, V-4 Magnesium Dietary Supplements GPI=DR 54Y- -99 54B- -08 4/15/04	Jirashataporn Co., Ltd. Thailand 72/2-3 Moo 10 Sukumvit Rd. Chachoengsao, Thailand FEI# 3004375809 Immunitor Manufacturer Co., Ltd. Thailand	

IA 000041

71 Moo 5, Bangpakong Industrial Park
 Chachoengsao, Thailand 24130
 FEI# 3004375808

Avicenna Pharma brand	A.M. Herbs (M) SDN BHD	Malaysia
Dietary supplements:	2-4 Jalan 3/114,	
Cholestmed	Kuchai Business Center	
Glucosure	58200 Kuala Lumpur	
Gastro Balance	Malaysia	
Renalife	FEI# 3004686954	
Livtone		
Respire		

Product Codes: 54Y--99 54F--99

9/1/04

PRODUCT	SOURCES	COUNTRY
Sildenafil Citrate Vee Excel Tablets	Drugs & Pharmaceuticals (P) Ltd	India
65P02	G-16, 3rd Floor	
9/16/04	Preet Vihar, Vikas Marg	
Delhi, India		
FEI# 3004062123		

Vee Excel (V Excel International)
 2, Veer Sawarkar Block
 Triveni Complex
 Madhuban Road, Shakar Pur
 Delhi, India
 FEI# 3003945550

Vee Excel Drugs & Pharmaceutical
 R-23-B, 1/F, Rita Block
 Delhi, India
 FEI# 3004062373

PRODUCT	SOURCES	COUNTRY
Wings Heartdrop Formula	Wings International	CANADA
Herbal Tinture	Marketing Ltd.	

IA 000042

54F[.][]99 6595 Herry Road.
 9/30/04 Vernon, BC
 Canada
 FEI #3004497001

PRODUCT	SOURCES	COUNTRY
"Actra-RX"	Shenyang Changgong Yibao All	
Other names: "Yilishen"	Alcohol Co. Ltd. Under the supervision of	
54- - - -	Shenyand Medicline Research on	
65P- - -02	Biologic Resource	
(Contains prescription strength	126 Changbai Street, Dongling District	
sildenafil by FDA analysis)	Shengyang, Liaoning, China	
11/10/04	FEI: 3003791634	

PRODUCT	SOURCE	COUNTRY
All	IVFMeds	Gibraltar
GPI=DR	Suite 5, Ellicott House	
2/16/05	1/3 Town Range	
	Gibraltar	
	(no FEI)	
All	Bowling Chemist Ltd.	United Kingdom
GPI=DR	7 Wardour Street	
2/16/05	London, W1D 6PE	
	United Kingdom	
	FEI# 1000474709	

Background: Based on accompanying documents, the product appears to be a new drug without an approved application. An internet-based pharmacy, IVFMeds, is reportedly filling orders using certain unapproved foreign versions of Serono fertility products through another UK-based pharmacy called Bowling Chemists Ltd. In addition, after reviewing the firm's website www.ivfmeds.com, it appears that IVFMeds also promotes and offers for sale into the U.S. foreign versions of various other unapproved drug products.

PRODUCT/CODE	SOURCE	COUNTRY
Anthelios XL Crème	La Roche-Posay	France
Ultra Protection UVA 60+SPF	Labatoire Pharmaceutique	

IA 000043

Anthelios XL Lait 86270 La Roche Posay, France
 Ultra Protection UVA 60+SPF FEI# 3003818446
 Antherpos Protection UVA
 SPF 50
 Anthelios XL Fluid Extreme
 Ultra Protection LSF 60
 66P 99
 65L 99
 53L 99
 3/2/05

Background: Based on accompanying documents, the above specified La-Roche-Posay sunscreen products appear to be new drugs without an approved application (NDA). These products contain ingredients that are not permitted in the final rule for Sunscreen Drug Products for Over-The-Counter Human use [21 CFR Part 352]. 505(a) charge.

PRODUCT	SOURCE	COUNTRY
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Bryson Primer # 1	Bryson Garden Remedies	Canada
Cleansing Herbal Formula 1695 Franklin Street		
54FCL99	Vancouver, Canada	
3/21/05	FEI# 3003274380	
SAFI, Blood Purifier	HAMDARD (WAKF) Laboratories	India
54F[[]][[]]	Ghaziabad, India	
3/21/05	FEI# 3004659877	
	2000027663	

Beijing Kowloon Pharmaceutical Stamax Sexual Stimulant	China
Factory	Dietary Supplement
No 1200 Diyang Bldg.	66S[[]]51
Beijing, China	
FEI# 3003880203	
5/16/05	

PRODUCT	SOURCE	COUNTRY
Powder Enlarge Patch	Cybermed Industries	Canada
80L[[]]DQ	204-1010 View Street	
54F[[]]99	Victoria, BC, Canada V8V4V3	
66V[[]]99	FEI# 3003657059	
5/26/05		

Background: Power Enlarge Patch is offered for sale on this firm's Internet site at www.enlargepatch.com. This product is promoted as a transdermal patch that infuses its ingredients directly into the bloodstream, bypassing the

IA 000044

digestive system. Based on its intended uses, Power Enlarge Patch is a drug. As labeled and formulated, this drug is not generally recognized as safe and effective by experts, and is a new drug marketed without an approved new drug application. Furthermore, because this product is a transdermal drug, the method of administration or application suggested in the labeling causes it to be a new drug. See 21 CFR § 310.3(h) (5). Per CDER the appropriate charge is 505(a).

PRODUCT	SOURCE	COUNTRY
ESNATRI brand natural triple estrogen moisturizing cream 53B---- 53L---- 64G---- 6/2/05	ALL	ALL

Based on accompanying documents, Esnatri brand estrogen moisturizing cream appears to be a new drug without an approved application NDA).

^ ^

Product	SOURCE	COUNTRY
All topical "Black Salve" Products 66V[][]99 54E[][]37 54E[][]99 54F[][]99 54Y[][]99 (Black Salve is also known by the following other names: Cansema Black Topical Salve, Cansema Deep Tissue, Cansema w/Lugol's Iodine (topical), Cansema for Cats, Dogs, and Horses, Cansema Tonic I, Cansema Tonic II, Cansema Tonic III, Cansema Capsules, Cansema Suppositories, Bloodroot Paste, C-Herb Paste, CAN-X, Cancerx, H3O, Healing Formula) 6/2/05	ALL	ALL

Background/Reason for Alert: Black salve, also known by the names cited above, has been advertised for use in the cure, mitigation, treatment or prevention of cancer. In addition, various websites promote black salve

IA 000045

products for use in the treatment and cure of cancer, tumors, herpes, venereal diseases, diabetes, lupus, and internal malignancies. Based on its intended uses, this product is a drug. Further, CDER is not aware of any substantial scientific evidence that demonstrates that this product is generally recognized as safe and effective for its labeled uses. Districts may detain without physical examination any product named above, and refuse entry to any black salve product that is labeled or is accompanied by labeling, with claims that it is intended to diagnose, cure, mitigate, treat or prevent a disease.

Product/code:	Source:	Country:
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DIATECH 2000	Pharmatech 2000	Canada
Food Supplement	16508 100 Street	
54F[]99	Edmonton, AB, Canada	
7/25/05	FEI# 3004024126	

PRODUCT	SOURCE	COUNTRY
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Serrapeptase (Serratia Peptidase Enzyme)	Enerex Botanicals Ltd. 8531 Eastlake Drive	Canada
66V[]99	Burnaby,	
54[]99	British Columbia V5A 4T7	
8/23/05	Canada	
	FEI# 3003787333	

Note: product may be entering as a dietary supplement, therefore, we have included the product code "54[]99" along with the appropriate drug code.

The product's accompanying literature indicates Serrapeptase(Serratia Peptidase Enzyme), among other claims, is used to treat arterial blockage in coronary patients" and the product has anti-inflammatory and pain blocking benefits. The firm's website, ^ makes similar claims.

In 1982, Woodward's Gripe Water was promoted for infants including newborns and older children over 12 months of age and labeled for gripes, acidity, flatulence, a quick and gentle way of relieving baby's hiccups, minor tummy upsets and teething. The article contains, among other things, dill oil or dill water, sodium bicarbonate, and 3.67 - 4.69% alcohol. Gripe water has been used in various foreign countries for many years. However, in the United States it is not generally recognized as safe and effective for its intended uses, based on its formula and labeling, and therefore, is considered a new drug which cannot be marketed without an approved New Drug Application. In addition the Center for Drugs Evaluation and Research (CDER) has safety concerns regarding the dill oil or dill water ingredients. A recent OASIS data search indicates that there continue to be importations of gripe water into the U.S. at various ports of entry. Districts should Detain Without Physical Examination shipments labeled as gripe water or other types of water

IA 000046

aqueous products (i.e., dill water, dill oil) which might be labeled with drug claims.

Firm Name and Address: Product/Product Code:

All Gripe Water
8/25/05 66V[] []99
54F[] []99

NOTE: This product was previously subject to Detention Without Physical Examination under Import Alert #66-09. Effective as of the issuance of these notification shipments of gripe water should be detained per Import Alert #66-41, "Unapproved New Drugs Promoted in the U.S."

FIRM NAME AND ADDRESS	PRODUCT/PRODUCT CODE
Inter Medical Lab	Bangkok Slim Weight Loss Program
AKA Inter Medical Clinic	GPI=DR/54-----
24-16 Phahonyothin Rd	I Inter Bangkok Clinic Weight
Loss	Bangkok, Thailand GPI=DR/54-----
9/16/05	FEI# 3003141248

Manufacturer

Gynostemma Pentaphylla	Weimin Medicine Manufactory	China
And Evening Primrose Pills	Unknown Street Address	
54F[] [][]	Beijing	
54H[] [][]	FEI# 3005271572	
54Y[] [][]	Shipper	
GPI=DR		
10/28/05	Yung Sing Enterprises Ltd.	Canada
	279 E. Pender Street	
	Richmond	
	British Columbia	
	FEI# 3002950572	

Herbal Life (or Herbal Life and	ALL Products	Canada
Essence Co.)	GPI = DR	
2416 Main Street, Unit 132	IND - 54	
Vancouver, Canada (BC)		
FEI# 3004136252		
11/25/05		

IA 000047

[Note: This firm is connected to the website ^
that is promoting various products for use as street drug alternatives. The
agency considers any product that is promoted as a street drug alternative to
be an unapproved new drug and a misbranded drug in violation of Sections 505
and 502 of the FFDCA.]

Bioxira Health Technologies,
S.A. de C.V.
Callejon Zaragoza No. 1
Cuajimalpa, Distrito Federal
Mexico
FEI# 3005011306

Bioxira Skin Cream Impregnated Cloth
Bioxira PreventAge 1.0
Bioxira Defining 1.0

12/7/05

PRODUCT	SOURCE	COUNTRY
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Emagrece Sim Dietary Supplement (all Levels)	Fitoterapicos (Fytoterapicos) Rua Estrela Dione 340	All
GPI-DR/54[]][[]][[]] 12/23/05	Riacho das Pedras Contagem, Brazil	
	FEI# 3005061819	

Emagrece Sim Dietary Supplement (all Levels)	Phytotherm Sim Rua Estrela Dione 300	All
GPI-DR/54[]][[]][[]] 12/23/05	Contagem, Brazil	
	FEI# 3005289514	

Herbathin Dietary Supplement (all Levels)	Fitoterapicos (Fytoterapicos) Rua Estrela Dione 340	All
GPI-DR/54[]][[]][[]] 12/23/05	Riacho das Pedras Contagem, Brazil	
	FEI# 3005061819	

Herbathin Dietary Supplement (all Levels)	Phytotherm Sim Rua Estrela Dione 300	All
GPI-DR/54[]][[]][[]] 12/23/05	Contagem, Brazil	
	FEI# 3005289514	

Laboratorio Urena Sa Via Argentina EDF Balmoral Panama City, Panama FEI# 3005274240	Te Diossana 54Y[][]99 31K[][]99 54E[][]99
--	--

IA 000048

1/5/06

NOTE: The label of the herbal product includes the website:

^ ^ This website makes direct reference to treatments for cancer cures as well as treatments for AIDS and diabetes. Additionally, a letter that accompanies the imported product states in Spanish that this product has been used to treat patients with cancer, leukemia, and HIV positive obtaining good results even on those patients with terminal conditions. We are not aware of any substantial scientific evidence that establishes that this product is generally recognized as safe and effective for its intended use. This product is not the subject of an approved new or abbreviated new drug application.

Liver Cleanse	Innercleanse 2000 Inc.	Canada
Lung Cleanse	AKA Herbal Care Direct, Inc.	
Kidney Cleanse	2319 Fairview Street	
Arterial Cleanse	Unit 608	
Anti-Para Parasite Cleanse	Burlington, Ontario	
54I[]99	54B[]99	L7R2E3
54E[]99	54C[]99	FEI# 3002671576
54F[]99	54Y[]99	FEI# 3004011959
66V[]99		

8/11/06

Note: product may be entering as a dietary supplement, therefore, we have included the product code "54[]99" along with the appropriate drug code.

The product labeling for the above products do not make any drug claims however, the firm's website that provides drug related information on the products ^ ^ and their ordering website that also provides drug related information ^ ^ makes claims such as curing kidney infections.

Nature Products	Revivo (Chinese Herb Mix)
Mekong Hill Garden	62V[][]99
Jinghong, Yunnan	54Y[][]99
China	2/1/06
FEI# 3005550994	

NOTE: This product is promoted to treat AIDS/HIV infection and other viral diseases on the firm's website ^ ^.

Beijing Kowloon Pharmaceutical Factory, Rm: 105, No. 3	4EVERON SEXUAL STIMULANT TABLET
Tianzhuzhongjie Shunyi District	(declared as L-arginine
Beijing, China	dietary supplement)
FEI# 3003880203	54C[][]02, 54F[][]29

IA 000049

54Y[] [] 99, 65P[] [] 02
3/29/06

8

PRODUCT	SOURCE	COUNTRY
"Marine Phytoplankton"	Unique Seafarm	Canada
Core Marine Phytoplankton	3145 Headland Rd	
Capsules & Liquid	Nanaimo	
66V--99	Canada	
5/3/06	V9X 1N8	
FEI# 3005095075		

Product/Code:	Source:	Country:
PEB One and PEB Two Capsules (Brand Renutryent) Dietary Supplement	Michelle Gleneuine Av. Canal Marapendi	
66V[] []99	No. 4100/1105, BL1	
5/4/06	Rio de Janiero, Brazil	
	FEI# 3005524067	

FDA has determined that this product contains the undeclared drug ingredients Fenproporex HCl and Chlordiazepoxide HCl.

IA 000050

chedule

he IV Drugs. Fenproporex hydrochloride has been used as an anc

treatment of obesity although the use of stimulants in this
onger

recommended. Chlordiazepoxide is used in the short-term tre
nxiety

disorders, insomnia, muscle spasm, alcohol withdrawal syndr
anesthetic premedication before surgery. The product is lak

e treatment of weight reduction by increasing the metabolism,
anxiety, and inhibiting excessive appetite. Based on its ir

, this product is a drug. There is no substantial scientific eviden

s product is generally recognized as safe and effective for th

s recommended or suggested in its labeling.

Shu Li Foot Pouches	Ion Farms Co	Korea, (South)
80KGX	2f Donggyoung Bd	
5/12/06	Incheon	
	Korea, (South)	
	FEI# 3005463878	

PRODUCT	SOURCE
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Salusil/61H[][]99	Friger & Chemicals Ltd.
-------------------	-------------------------

1 Tetrosil/61H[][]99 P.O. Box 12053 Industrial Area
5/16/06 Hefer, Israel 38800
FEI #: 3003887525

Psorcure Oil	Dr. Shelender Dhawan (Manufacturer)
Psorcure Ointment	1759 Sector 16, Faridabad
Psorcure Capsules	Haryana
Psorclean Tablets	India
Psorcalm Capsules	FEI #3005619744
Immunopsor Drops	
5/25/06	

Psorcure Oil	ECom Consultant (Shipper/Distributor)
--------------	---------------------------------------

) Psorcure Ointment 4 Cobbler Street
Psorcure Capsules Brampton, Ontario L6X 4T4

IA 000051

Psorclean Tablets Canada
Psorcalm Capsules FEI # 2000011553
Immunopsor Drops WWW.Clinicpsoriasis.com
5/25/06 WWW.Psorcure.com

Manufacturer Opto-Pharm Pte Ltd. "Ortho-Eyes" Lubric

ps

13 Tuas Avenue 12 (Labeled as a complement)

Singapore 639035 66V[] [] 99
FEI# 3005320466 54Y[] [] 99
6/1/06

Shipper
AOR Inc./
Advanced Orthomolecular Research
Bay 9, 4101 19 Street N.E.
Calgary, Alberta T2E 6X8
Canada
FEI# 3004288965

Bio-Gulf Sdn Bhd Libidus
24-2 Medan Setia 2 65P[][]02
Plaza Damansara 54Y[][]99
50490 Kuala Lumpur 54F[][]99
Malaysia
FEI# 3004792803
3005314803

NOTE: "Libidus" is promoted on the Internet websites ^
<<< and ^^ and >>> www.biogulf.com <<< as an herbal, male, s

IA 000052

by

CDER's Division of Pharmaceutical Analysis, HFD-920, found t

contain the undeclared chemical "acetildenafil," an analog of

Sildenafil citrate is the active ingredient in Viagra a product

s not by Pfizer for the treatment of erectile dysfunction. "Aceti

the declared as one of the ingredients on the Libidus' product's

pharmacology of this new drug is unknown.

08/25/06 1950 West Broadway

Vancouver, BC V6J 5C2, Canada

Website: www.natropрактика.com

FEI #3005860590

"Green Sun" is promoted on Natropactica's website, www.natrc.com, for

use as an "effective barrier which inhibits the ability of

other STIs (Sexually Transmitted Infections) from replicatir

\of the skin and inhibits their ability to adhere to the skin

\of the skin and inhibits their ability to adhere to the skin.

our own anti-viral gel lube with Carrageenan and other subst

\already working with in the protocol and developed our own

\the following metatag key words are connected with this web

-viral

gel;" "genital herpes;" "Genital Herpes Symptoms;" "varicell

shingles;" "sexually transmitted diseases;" " STD;" "AIDS;"
urable
diseases;" etc.

Based on its intended uses this product is a drug. Further, aware

of any substantial scientific evidence that this product is recognized as safe and effective for the conditions recommended.

LA 000050

d Kingdom

Sweet Cures Waterfall D-Mannose

Any Sweet Cures

36A[] [] 99

101 Foxwood Lane

York, YO24 3LQ

United Kingdom

FEI# 3005724802

09/27/06

Pro Sero Co., Ltd
 7F., No. 122, Section 1,
 Ho-ping West Road
 Taipei, Taiwan, Republic Of China
 FEI# 3003179061

"Pro Sero Plas
 pain relieving patc
 60L[] [] [] []
 79K[] [] GX, 89M
 10/27/06

Swiss Medica, Inc

Essential Oil Neutralizer

a

53 Yonge Street, 3rd Floor 024 Fibromyalgia
 Toronto GPI = DR
 Canada 11/1/06
 FEI# 3004932367

^

^

SOURCE	PRODUCT	COUNTRY
Dragonedge Resources 1207 Jasmine Towers Selangor Malaysia FEI# 3005748500 GPI=CO	Revitapatch (All Natural Detox) Foot Patch GPI=DR GPI=DE	Japan 11/13/06

ough

Malaysia. The product is a combination product as defined in 3.2(e)(1) (the pad is the device portion and the ingredients to the

patch is the drug portion). The product's labeling clearly states that the patch is a detoxifier; and as promoted on the product's website, declaims

improves blood circulation, increases the metabolism, activates

cells, enhances the quality of sleep and aids in the release of

IA 000054

through the skin.

八

1

All Products Catalysis, S.L.
GPI=DR, GPI=VI Macarena 14
12/11/06 Madrid, Spain 28016
FEI # 3002989319
<http://www.catalysisusa.net>

Canada	Coffee	S.A. Wilson
0 Unit #2	Coffee with Enema Kit	2891 Regi
12/ /06	66V[][]99	Bowmanville, Ontario
FEI# 3005507009	Canada L1C 3K6	

PRODUCT	SOURCE	COUNTRY
Ayurvedic Fair and Lovely Cream	Hindustan Lever Ltd.	India
53L[]03	Dag No 21 of 122 F.s.grant	
11/3/06	Mouza-tingra	
Doomdooma Industrial Estate, Off Nh-37		
Ayurvedic Fairness Cream	Mumbai, India	
53L[]03	FEI# 3004356927	
11/3/06		

PRODUCT	SOURCE	COUNTRY
Ranitome/Rani Tonic	Rani Drug House	India
GPI=DR	Nellayi	
54F[][][] 53B[][][]	Thrissur District	
54Y 53E	Kerala, India	

IA 000055

31K[[]][] 53F[][][] FEI# 3005734324

31L[[]][] 53L[][][] ^

31P[[]][] 53J[][][] ^

1/25/07

PRODUCT/PRODUCT CODE	SOURCE	COUNTRY
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Isotretinoin	All	All
64X [] [] 11		2/8/07

Foreign Websites Selling Isotretinoin

Sharpmeds.com

Jose Carlos domain @ sharpmeds.com

Apartado Postal 10-65666

Mexico City, null 425369

Mexico

phone: 52.5542369532

FEI# 3006084927

^

Gold Shield Corporation

23-845 Dakota Street-300

Winnipeg, Manitoba R2M 5M3

Canada

^

^

^<

FEI# 3006076714

VrDrug.com

451 Ladprow Rd

Wangtonglang, Wangtonglang

Bangkok, Bangkok10210

Thailand

^

^<

FEI # 3006076729

Note: The above firm appears to market clozaril (clozapine) as well as isotretinoin.

Medisave.ca

IA 000056

Medisave
1364 Cliveden Ave.
Delta, British Columbia,
Canada V3M 6K2
^
FEI# 3005359913

Heibert Net Inc
Al Wong
8181, 120 A Street, Suite #2
Surrey BC V3W 3P2
Canada
^
^
^
FEI# 3006093160

AnabolicShop
DG (Damian Garel)
damiangarel@gmx.de
Lofgister 34
Bjorntal, 5689
Sweden
69845564
^
FEI# 3006078870

Note: The above firm appears to market various anabolic steroids as well as isotretinoin on its website.

Rx-Pharmacy.cc
Pharm Export
Hornweg 18
Amsterdam, AR 1045
Netherlands
^
FEI# 3006078881

Note: The above site appears to be selling accutane online and includes airmail shipping.

bestonlineforeignpharmacies.com
ExpertInfo, Inc.
Jose Luis Soto
PO Box 2411-0834
Panama City,
Panama

IA 000057

FEI# 3006078947

Note: The above site appears to be a buyer's group.

North Pharmacy Inc
110-165 Kimta Road
Victoria V9A 7T1
Canada

FEI# 3006078952

CanPharm
P.O. Box #88614
Surrey, BC V3W 2P2
Canada

FEI# 3006080166

Newton Pharmacy
1004-7445 132 St
Surrey, BC, Canada
V3W 1J8

FEI# 3005349015

Note: The above (3) firms have the same URL website.

Guillermo Rivera
Chivilcoy 4820
Capital Federal, Buenos Aires 1419
Argentina

FEI# 3006080192

Solaris Worldwide
1364 Cliveden Ave.
Delta, BC V3M 6K2
Canada

FEI# 3006080199

IA 000058

CanadaDrugsOnline.com
1364 Cliveden Ave
Delta, British Columbia
Canada V3M 6K2
^
FEI# 3005335274

Planet Systems, Inc.
John Variss
58 Shirley St., 1st Floor PO Box 88 15670
Nassau, Bahamas
^
FEI# 3006084943

Tangny Enterprises, Inc.
Edificio Banco Aliado
Calle Ricardo Arias, Piso No. 15
Apartado 6443
Panama 5, R. de Panama
^
FEI# 3006084950

Indianmeds4u.com
235/a,
Mumbai 11
INDIA
^
FEI# 3006084980

Indian Meds 4u
B-311, Place, Gaulind Road
Patna(city)
Bihar(province)
INDIA
^
FEI# 3006084999

AAA Webmanagement AG
Aegeristrasse 4
Zug, Kantone Zug 6301
Switzerland
^
FEI# 3006086033

MSAP
144 Richmond Hill Rd
Sumner

IA 000059

Christchurch, Canterbury 8008
U.K.
^
FEI# 3006086041

Onlinepharmashop.com
Cigdem Aksoy
Burj el Arab
King suite
Dubai 6676543
United Arab Emirates
^
FEI# 3006086047

Medesis Pharmacy Inc.
Hooman Tabarsi
7505 Victoria Drive
Vancouver, British Columbia V5P 3Z6
CANADA
^
FEI# 3004619313

Canadacure
7505 Victoria Drive
Vancouver, BC V5P 3Z6
CANADA
^
FEI# 3005917828

Abbott Renuka Pharmacy Ltd.
420 Abbott St.
Vancouver, British Columbia V6B2L1
CANADA
^
FEI# 3003919300

OnlineCanadaMeds
#400-601 6th Street
New Westminster, British Columbia
V3L3C1, Canada
^
FEI# 3006086393

Natsuko Enterprises
362-10-1104 Kamiokuma
Kasuya-machi
Kasuya-Gun, Fukuoka 811-2301

IA 000060

Japan

^ ^

FEI# 3006086773

Farmacia Centrale

Farmamondo

Via Volta 2

Chiasso, Switzerland

^ ^

^ ^

FEI# 3003519143

According to information on the website, the isotretinoin is manufactured by
"Mepha Pharma"

4cnrs-skincare

Santovittorio Holdings Ltd.

PO Box 87-1008

Panama 7,

Panama

^ ^

FEI# 3006086811

RX Trust Pharmacy

Kevin Liang (admin@idig.net)

PO Box 97008

Richmond Main PO

Richmond, British Columbia V6Y 4H4

Canada

^ ^

FEI# 3006086822

Inhousedrugstore dba Inhousepharmacy

Santovittorio Holdings Ltd.

Apartado 6-6305

El Dorado,

Panama

&

P.H.L.

PO Box 337

Port Vila

Vanuatu

^ ^

^ ^

FEI# 3006089036

Pharmacy Network

IA 000061

Azenith International LLC
Copthall PO Box 2331
Roseau
St. George, Dominica 00152
Virgin Islands
^
^
^
FEI# 3006089093

LePharmacy.com
4196864 Canada Inc.
11215 Jasper Ave.
Suite 435
Edmonton AL T5K0L5
Canada
^
^
FEI# 3004452269

MedicineShoppePharmacy
#122, 1959 152 street
White Rock, BC V4A 9E3
Canada
License # L85 Pharmacy
Manager: Chris Lewis
^
^
FEI# 3006090494

Panacea-Pharmacy.com
Gamma Commercial Complex
#47 Rizal Highway cor. Manila Avenue
Subic Bay Freeport, Olongapo City
Philippines
^
^
FEI# 3006090496

Deca-Sustanon.com
Karznik, David
Petrova,
Wroclaw, 5548
Poland
^
^
FEI# 3004452189

Canada Drug Delivery
5765 Turner Road, Suite 233
Nanaimo BC, V9T 6M4
Canada

IA 000062

FEI# 3005268261

Discount Prescription Drugs Online
Domain Discreet
P.O. Box 278
Yarmouth, N8 B5A 4B2
CANADA

FEI# 3006090568

Pharmawest Pharmacy Ltd
Unit #101 20560 56th Ave
Langley, BC, Canada
V3A 3Y8

FEI# 3004036103

My-drugs.ca
P.O. Box 370
1250 University Street
Montreal, Quebec H3B 3BO
Canada

FEI# 3004452174

PRODUCT/PRODUCT CODE	SOURCE	COUNTRY
Clozapine 65V[[]]13	All	All 2/8/07

Other names: Clopine, Clopsine, Clozaril, Elcrit, Froidir, Lanolept, Leponex, Lozapin, Zolapin

Foreign Websites/Firms Marketing Clozapine

Direct-RX Meds
Direct RX Meds
58
Xanthi 67100
Greece

IA 000063

FEI# 3006090653

onlinesolution4u.com

Easystore4u

Ravi Jain

10/12/ Modul Town

Ludhiana PU, 56632

India

FEI# 3006091360

Nice Price Pharmacy

2n Flr. Windsor House

Port Vila, Vanuatu

FEI# 3006091381

Healthy Choice Pharmacy.COM INC

PO Box 457

Port Vila

VANUATU

FEI# 3006091391

VrDrug.com

VrDrug.com

451 Ladprow Rd

Wangtonglang, Wangtonglang

Bangkok, Bangkok10210

Thailand

FEI# 3006076729

Note: The above firm appears to market clozapine as well as isotretinoin.

PRODUCT	SOURCE	COUNTRY
Bamboo Crystal Foot Plaster	Beijing Golden Herb &	China
GPI: DR	Health Co., Ltd.	
GPI: DE	205, Huixin Building	
GPI: CO	Beijing University of	
3/7/07	Chemical Technology	
	15, Sanhuanbei Road,	
	Beijing 100029	
	China	
	FEI# 3005888678	

IA 000064

Chinky Enterprises
2-4 Prat Avenue
3/F Kundamal House
Kowloon, Hong Kong
FEI# 3005866578

Although Bamboo Crystal Foot Plaster/Patches are manufactured in China, they are shipped through either China or Hong Kong. The product is a combination product as defined under 21 CFR 3.2(e)(1) (the pad is the device portion and the ingredients absorbed into the pad make up the drug portion). The product's labeling declares Bamboo Crystal Foot Plaster is a detoxifier; and as promoted on the product's website, ^ declares Bamboo Crystal Foot Plaster helps with constipation, eliminates swollen veins, helps with menstrual cramps, reduces joint pain, reduces swelling, helps with fatigue, enhances sleep as well as aid in the release of toxins through the skin.

TR Networks Limited "Kinohimitsu detox patches"
50 MacPherson Road, #09-01 66V--99
Singapore 4/6/07
FEI # 3004126810
Web site: ^

NETD Active Nutra Trading Company Blue Steel
No. 15 Yongjiang Rd. Dietary Supplement
Beilun, NETD 54Y--99
Ningbo, 315800 4/13/07
China
FEI# 2000021726
2000032670

Hindustan Lever Ltd. Fair and Lovely Cream
Unit-2, Tinsukia 786 151, Assam M.L. 53L--03
No. C-10M/2003 53L--06
Mumbai, India 4/16/07
FEI# 3006115474

Herbal Hair Regrowth Radico India
Shampoo and Serum 39-A Type-D 4/18/07
53E[][]06 HSIDC Industrial Estate
66V[][]99 88/17, Sector 31
4/9/2007 Faridabad, Haryana, India
FEI# 3001224283

IA 000065

Qinghai Qingzang Resource Zang Wang Shen Bao
Special Medical Co., Ltd. Capsules
809 Shunda Building No. 188 54F--99
Shunyi Road 4/26/07
Shanghai, China
FEI# 3006109242

This product is promoted on the Internet and sold at retail as a dietary supplement for natural male enhancement. FDA analysis found tadalafil in this product. Tadalafil is the active ingredient in the FDA approved drug Cialis.

PRODUCT	SOURCE	COUNTRY
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(MANUFACTURER)

Han Palace	Unifier Sdn Bhd	Malaysia
Capsules	Lot 7.13, 7th Floor	7/6/07
66V[]99	Imbi Plaza, Jalan Imbi	
54Y[]99	55100 Kuala Lumpur	
54F[]99	FEI# 3004805836	

(SHIPPER)

V-Shine Marketing Sdn Bhd	Malaysia
Lot 7.13, 7th Floor	7/6/07
Imbi Plaza, Jalan Imbi	
55100 Kuala Lumpur	
FEI# 3005435032	

This product was invoiced as a dietary supplement and found to contain Acetildenafil, an analogue of an erectile dysfunction prescription drug, sildenafil.

PRODUCT	SOURCE
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Corvalol	Farmak Jsc
Korvalol	63 Frunze Street
Corvalolum	Kiev, Ukraine
54F--99 (mis-declared product code)	FEI #3006146593
61M--31 (correct product code)	
8/24/2007	

Detentions of this product should use the 502(f)(1) misbranding charge.

FDA has determined that the Corvalol product contains undeclared Phenobarbital. The agency is aware that the product is being sold Over the

IA 000066

Counter (OTC) in Eastern European American communities for the treatment of angina, chest pains, and as a sedative. This product is not approved for OTC use in the U.S. FDA previously issued a health hazard alert for Corvalol on July 28, 1997.

PRODUCT/ Product Code	SOURCE	COUNTRY
Curaderm-BEC5 Cream	All ("BEC5 Curaderm") 62 I [] [] [] [] 64X [] [] [] [] 64X [] [] 06	All The following website on the internet are selling Curaderm-BEC5 Cream ("BEC5 Curaderm") as a skin cream that is a therapy for skin cancer.
IAS, c/o Les Autelets Suite I, Sark Gy9 0SF United Kingdom		United Kingdom
FEI#:	3006417641	8/30/07
Dr. Calmez Ltd PKF House, Lini Highway Port Vila, Sheffa 1212 Vanuatu, South Pacific		Vanuatu
FEI # 3006417672		8/30/07
Postal Address: Dr. Calmez Limited P.O. Box 7095 Port Vila, Efate Island, Shefa Province Vanuatu, South Pacific		Vanuatu
FEIs#:3006417654		8/30/07
WallCann IP Pty Ltd Drew Canning ^ 81c Marine Parade Seacliff South Australia Australia 5049		Australia
^	^<	
^	^	

IA 000067

FEI#: 3006417663

8/30/07

Biogenesis Laboratories Order Form South Africa
 P.O. Box 48119
 Kommetjie 7976
 South Africa

^ ^<
 FEI#: 3006417666 8/30/07

PRODUCT	SOURCE
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The Chlamydia Treatment Cream 53L[]03, 66V[]99 09/12/07	Apis Skin Care Cream Ltd. 68 Aylesford Street St. Albans Christchurch, New Zealand FEI# 3004630781
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Apis Skin Care Cream 219 Tuam Street Christchurch, New Zealand FEI# 3005530915

The Chlamydia Treatment Cream product is sold and promoted on the internet for the treatment of Chlamydia. [www.chlamydia-cream.com] Based on its intended uses, this product is a drug. Further, CDER is not aware of any substantial scientific evidence that this product is generally recognized as safe and effective for the conditions recommend or suggested in its labeling.

PRODUCT/	SOURCE	COUNTRY
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Product Code

Website for Nu Eyes:

"Nu-Eyes" &	Website Registrant:	Seychelles
"Can-C Eyedrops"	Bionational Pharmaceuticals	9/12/07
55RP12	POB 998, 1st Floor, Office 14	
66[]V	Trinity House	
54[]Y	Victoria, Mahe	
55QP58	Seychelles	

^ ^
 FEI# 3006434908

Website Contact Address:	United Kingdom
Bionational Ltd.	9/12/07
Unit 34 Uplandside,	
Manor Road	

IA 000068

Clopton,
Woodbridge IP 13 6SH
United Kingdom
FEI# 3005459508

Can-C Eye drops
Website registrant: United Kingdom
Pharm-Assay International Limited 9/12/07
The Gemini Building
Houghton Hall Park
Dunstable, Beds LU5 5GB
United Kingdom
Admin/Tec Contact: Damien Trevatt
^ ^
^ ^
^ ^
^ ^
^ ^
FEI # 3004104373

Website registrant: United Kingdom
I.A.S. Limited 9/12/07
c/o Les Autelets
Suite I, VA GY9 OSF
United Kingdom
^ ^
FEI # 3006435049

Website Contact Address: United Kingdom
IAS 9/12/07
Les Autelets
PO Box 6
Sark GY9 OSF
Great Britain
FEI# 3006417641

License Holder:
International Antiaging Systems United Kingdom
PIL Gemini Building 9/12/07
Houghton Hall Park
Beds LU5 5GB
England 01582
FEI# 3006435366

PRODUCT

SOURCE

IA 000069

Virus Sin Health Industrias Biologicas
Plus Combination Sin Fin S.A. DE C.V.
Dietary Supplement Calle de Edzna No. 106
54H[][]06 Colonia Independencia
9/13/07 Delgado Benito Juarez
C.P. 03630, Mexico D.F.
Mexico
FEI# 3004483676

This product which was entered as a dietary supplement was labeled to contain "caustic liquid rayon" and was found to have a very basic pH. There are also multiple drug claims for the product on the firm's website.

PRODUCT	SOURCE
Jiaoli Miraculous Cream,	Harbin Gelidai Cosmetics Company Ltd.
Day and Night Whitening	No. 69 Erdao Street
53L[][]03, 53L[][]99	Nanyuan, China
66[][][]	FEI# 3005419167
09/14/07	
	Website: ^ ^
	Administrative contact/Registrant:
	Nellie Era Saa
	37 Pearl St. Donna Juana
	Subdv. Rosario
	Pasig City, Philippines 1609

Note: Product has been found to contain Mercury, which can constitute a health hazard. Additionally the website promotes and sells this product for drug use. There is no substantial scientific evidence that this product is generally recognized as safe and effective for the conditions recommended or suggested in its labeling.

PRODUCT/PRODUCT CODE	FIRM NAME AND ADDRESS
Diabe Cinn Capsules	OTC Pharma International BV
54Y--99	Edisonweg 22
66V--99	NL 4207, Gorinchem
10/9/07	Netherlands
	FEI# 3004188169

This product is expressly labeled for People with Type II diabetes for

IA 000070

treating the characteristic signs and symptoms
(lowering blood sugar and increasing insulin sensitivity) of this
disease.

PRODUCT SOURCE

Spirulina Tablets	Spirulina International BV
54A--99	Edisonweg 22
54Y--01	NL-4200, Gorinchem
10/9/07	Netherlands
	FEI# 3002781920

This product's labeling includes structure, function or disease claims including speeding up recovery from illness. Also one of the directions for use involves topical application which takes it out of the dietary supplement classification for that use.

PRODUCT SOURCE

Trim-Caps	Ercorlat E.I.R.L.
Dietary Supplement	Alfredo Salazar 228
54F--99	Miraflores
11/20/07	Lima, Peru
	FEI #3005185816

This product is sold at retail as a dietary supplement containing papaya extract, garlic and other ingredients. FDA analysis found furosemide in this product. Furosemide is the active ingredient in the FDA approved drug Lasix and twenty-nine other drug products.

PRODUCT SOURCE COUNTRY

Nivea Good-bye	O'Will Corporation	Japan
Cellulite Patch	2-13-12, Hirakawa-cho,	
53[[]][[]]	Chiyoda-ku	
66V[[]]99	Tokyo 1020093	
12/5/07	FEI# 3005438433	

REASON FOR ALERT: Product has been previously submitted for import misdeclared and product coded [53LF[]06] as a moisturizing cosmetic. The

IA 000071

product labeling states "Continuous Release Diffusion continue" and that the product "continuously releases one of its ingredients into the fatty tissue of the skin."

The OTC monograph system does not include "timed release" or "sustained release" drug products, a dosage form that is designed to release the ingredients over a prolonged period of time. All products in timed release dosage form are new drugs requiring approved applications [see 21 CFR 310.502(a) (14)].

PRODUCT	SOURCE	COUNTRY
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Block & White	Sara Lee Philippines, Inc.	Philippines
Papaya Whitening	Insular Life Corporate Centre	
Lotion	Filivest Corporate City	
53L[]06	Alabang, Muntinlupa City	
66V[]99	Philippines	
1/3/08	FEI# 3003995293	

Block & White		
Radiance Lotion SPF10		
53L[]06		
66V[]99		
1/3/08		

Block & White		
Ultima Skin Perfecting		
Whitener		
53L[]06		
66V[]99		
1/3/08		

REASON FOR ALERT: The Block & White skin creams are unapproved new drugs based upon their skin bleaching claims and are also misbranded for failure to bear an ingredient statement.

PRODUCT	SOURCE	COUNTRY
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Progesterone Creme	Matol Botanical International Ltd,	Canada
65J[]31	290 Labrosse Avenue, Pointe-Claire,	
2/6/08	Quebec, Canada	
	FEI# 3003478937	

Allgesic Dietary Supplement	Advanced Orthomolecular Research,	Canada
	9-4101 19th Street NE, Calgary,	

IA 000072

54A[][]03 Canada
 54Y[][]99 FEI# 3004288965
 2/6/08

PRODUCT	SOURCE	COUNTRY
Kalawalla Herbal Supplement	Organic Hope	Honduras
Immuno C Food Supplement	Casa 5 Block B	
66V[][]99	Tegucigalpa	
54F[][]99	Honduras	
3/13/08	FEI# 3006350612	

Kalawalla Herbal Supplement	Chemical Manufacturing	Honduras
Immuno C Food Supplement	and Exporting Company	
66V[][]99	Km. 8 Desvio Cantarranas	
54F[][]99	Tegucigalpa, Honduras	
3/13/08	FEI# 3004279042	

Diabetin (Ampoules)	Laboratoire Manuves,	Canada
61PBL99	880 Selkirk, Pointe-claire, QC,	
54F[][]45	Canada	
3/13/08	FEI# 3006603941	

Manufacturer listed on the label Canada		
Diabetin (Ampoules)	Pharmavigor,	
61PBL99	11750 Av 4e, Montreal, QC,	
54F[][]45	Canada	
3/13/08	FEI# 3003420847	

Hiruval 35 Cream	Vimex Pharma Inc,	Canada
63V[][]99	21951 Vanneck Rd,	
3/13/08	Ilderton, ON,	
	Canada	
	FEI# 3003463724	
^	^	

PRODUCT	SOURCE	COUNTRY
Dietary Supplement	Spc Inc,	Canada
Restless Legs	2446 Bank Street Suite 424,	
54Y[][]99	Ottawa, ONTARIO, Canada	
3/27/08	FEI# 3006658197	

Seigen Lactobacillus A.L.A. Corporation,	Japan
Fermented Extracts 651 No, Tokyo,	

IA 000073

66V[] []99 Japan
 3/27/08 FEI# 3003535254

PRODUCT	SOURCE	COUNTRY
KPC-25 Capsules	Taian Zhongxin Lingzhi Technology	China
Optimum Female Enhancer	and Development Co., Ltd.	
54F[] []99	Peitianmen Street	
54Y[] []99	New and High-Tech Development Zone	
4/7/08	China	
	FEI# 2000034470	
KPC-25 Capsules		

Optimum Male Enhancer	Taian Zhongxin Lingzhi Technology	China
54F[] []99	and Development Co., Ltd.	
54Y[] []99	North of Road No. 5	
4/7/08	High and New Development Zone	
	Taian, CN-37, 271000	
	China	
	FEI# 3005380922	

These products are promoted as dietary supplements for male and female sexual enhancement. FDA analyses found sildenafil in these products. Sildenafil is the active ingredient in the FDA approved drug Viagra.

PRODUCT	SOURCE	COUNTRY
Neurofosfaton	Combisa Laboratorios	El Salvador
Infantile Syrup	428 Carret A San Marcos	
54Y[] []99	San Salvador, El Salvador	
54A[] []03	FEI# 3005069146	
4/17/08		

PRODUCT	SOURCE	COUNTRY
Nattokinase	Advanced Orthomolecular Research,	Canada
54Y[] []99	9-4101 19 Street NE,	
5/28/08	Calgary, Canada	
	FEI# 3004288965	

IA 000074

PRODUCT/PRODUCT CODE:

FIRM NAME AND ADDRESS:

COUNTRY:

Super Shanghai/Strong
Testis Capsules
54F--99
54Y--99
5/28/08

Beijing Jianyang Health Product Co., Ltd.
Liren Street
Beijing, China
FEI# 2000025150

Shanghai Ultra/Shanghai
Ultra X Capsules
54F--99
54Y--99
5/28/08

Xuan Zhan Jin Xing
Yuan Hutian Developing Area
Huaihua City
Hunan Province
China
FEI #3006296075

Lady Shanghai Capsules
54F--99
54Y--99
5/28/08

Shanghai Regular/
Chaojimengnan Tablets
54F--99
54Y--99
5/28/08

Dan Wu Xin Xing
Yuan Hutian Developing Area
Huaihua City
Hunan Province
China
FEI# 3006597012

Li Xiang Jin Xing
Yuan Hutian Developing Area
Huaihua City
Hunan Province
China
FEI# 3006597021

These products are promoted as dietary supplements for men and women. FDA analyses found sildenafil and tadalafil in these products. Sildenafil is the active ingredient in the FDA approved drug Viagra. Tadalafil is the active ingredient in the FDA approved drug Cialis. These drugs are only approved to treat erectile dysfunction (ED) as indicated in the FDA approved drug applications.

IA 000075

PRODUCT	SOURCE	COUNTRY
Intrauterine Device, SMB Corporation of India [IUD] Copper T; All models 85H[][]DT 65J[][]36 5/28/08	13, 33, 34, 35, 36 Prem Industrial Estate, Subhash Road, Jogeshwari (East) Mumbai 400060 FEI# 3005135560	India

REASON FOR ALERT: IUDs for the purpose of contraception are regulated as medical devices; however, IUDs for the purpose of contraception that incorporate heavy metals, such as copper, drugs, or other active substances are regulated as drugs. The SMB IUDs are new drugs requiring approved applications [see 21 CFR 310.502].

PRODUCT	SOURCE	COUNTRY
REVLIMID (lenalidomide) 61C[][]03 5/29/08	All	All

REASON FOR ALERT: Revlimid may only be marketed and used under a restricted distribution program approved by FDA because of the potential for birth defects resulting from exposure of this product to a developing fetus. Under the restricted distribution program, only prescribers and pharmacists registered with the program are able to prescribe and dispense the product. In addition, Revlimid must only be dispensed to patients who are registered and meet all the conditions of the risk management plan. CDER has learned that overseas pharmacies may be importing this product into the U.S. directly to U.S. citizens.

Shipments of Revlimid are inappropriate for release under the personal importation policy.

PRODUCT	SOURCE	COUNTRY
Roberts Medicated Soap 66V[][]99 7/3/08	Edward Cook and Company 8 Salisbury Square London, United Kingdom FEI# 3002480794	United Kingdom

IA 000076

REASON FOR ALERT: The term "Medicated" and the active ingredient, "potassium mercuric iodide solution," on the labeling represents and suggests that the product is intended for "drug" use(s). The immediate container label also identifies the product for removing unsightly pimples, spots, dandruff, scurf and other parasites, left free of infection, prevents sickness from spreading, and stops any irritation. These are "drug" claims under 201(g)(1) which defines a drug as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals "

Crusader	Elliot Irving Ltd.	United Kingdom
Medicated	9 Newton Place	
Soap	Glasgow, United Kingdom	
66V[]99	FEI# 3000227446	

7/3/08

REASON FOR ALERT: The term "medicated" and the active ingredient, "potassium mercuric iodide solution," on the labeling represents and suggests that the product is intended for "drug" use(s). These are "drug" claims under 201(g)(1) which defines a drug as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals "

PRODUCT	SOURCE	COUNTRY
Cell Pro Line	Omnimedica Ag.	Switzerland
Nasal Spray &	Laettenstrawwe 27	
Oral Tablets	Schileren, Switzerland	
66V[]99	FEI# 3006487532	

7/3/08 ^ ^

REASON FOR ALERT: The labeling as well as internet includes drug claims that this product "relieves migraine, extremely powerful anti-inflammatory allergy headaches and related symptoms", therefore, this product is a drug under 201(g)(1), which defines a drug as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals "

PRODUCT	SOURCE	COUNTRY
To-to Skin	Smooford International, Ltd.	Nigeria
Soap	To-to Villa, Box 41	
66V[]99	Iperu-Remo, Ogun State, Nigeria	

7/3/08 FEI# 3006761252

REASON FOR ALERT: The labeling on this product makes several disease claims.

IA 000077

On the "Indications/Claims" label it states that the product should be used for ringworm, scabies, and pediculosis capitis, which is a parasitic infection. Thus, this product is a drug under 201(g)(1), which is defined as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals".

PRODUCT	SOURCE	COUNTRY
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Tetmosal	Jagal Pharma Ltd.	Nigeria
Soap	Jagal Road	
66V[][]99	Oregun, Lagos, Nigeria	
7/3/08	FEI# 3003229596	

REASON FOR ALERT: The labeling on this product makes a disease claim. The label states, "use in place of toilet soap for both prevention and treatment of scabies." Thus, this product is a drug under 201(g)(1), which is defined as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals".

PRODUCT	SOURCE	COUNTRY
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Medicated	Pz Industries	Nigeria
Powder	45/47 Town Planning Way	
(Mentholated)	Ilupeju, Nigeria	
66V[][]99	FEI# 3006749033	
7/7/08		

REASON FOR ALERT: The term "Medicated" on the labeling represents and suggests that the product is intended for "drug" use(s). The immediate container label also identifies the product for antiseptic use and to treat prickly heat. These are also "drug" claims under 201(g)(1), which defines a drug as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals".

PRODUCT	SOURCE	COUNTRY
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Albabukum	Copac Nigeria Ltd.	Nigeria
Powder	Plot K6, Apapa-Oshodi Expressway	
(aspirin and	Lagos, Nigeria	
Caffeine	FEI# 3006742008	
66V[][]99		
7/7/08		

REASON FOR ALERT: This product is labeled to contain 100 sachets, each sachet

IA 000078

containing acetylsalicylic acid 760 mg, and caffeine 60 mg. This product is indicated for fast relief of pain, cold, headache and feverishness.

There is yet no final monograph for internal analgesics. However, this and all other internal analgesic OTC drug products are required to bear certain labeling including the drug facts format (21CFR 201.66), the Reye's Syndrome Warning (21CFR 201.314). This product also does not comply with the tamper evident packaging requirements for OTC drugs (21CFR 211.132).

PRODUCT	SOURCE	COUNTRY
Tokpela's Mist [bottled water]	8 Knot Co., Ltd. 3-7-21 Minamisuita, Suita City	Japan
29W[)][02	Osaka, Japan	
29W[)][01	FEI# 3006715094	
29Y[)][99		
66V[)][99 7/25/08	8 Knot Co., Ltd. 1339-1 Aza Minami Kawahara Yasuikawa, Shin Asahi-cho Takashima, Japan FEI# 3005369655	Japan

REASON FOR ALERT: A pamphlet accompanying the product claims:

- "Tokpela's Mist eliminates ROS* (Reactive Oxygen Species) is believed to cause conditions including cancer, high blood pressure, diabetes, kidney disease "
- "Tokpela's Mist makes stressed erythrocytes "Red Blood Cells" (RBC's) more flexible. RBC's ... can then effortlessly pass smoothly through our capillaries . RBC's accordingly can quickly carry oxygen to our extremities ."

Although "Tokpela's Mist (Miracle Water)" appears to be sold as a food, in that its label bears a Nutrition Facts panel, the above claims cause the product to be a new drug.

PRODUCT	SOURCE	COUNTRY
Piccan Teething Remedy 66V[)][99 08/22/08	Ipcra Laboratories Ltd. 48 Kandavli Ind. Estate Kandivli (West)	India

IA 000079

Mumbai, India
FEI # 3003335665

The combination of paracetamol (acetaminophen) and diphenhydramine has not been evaluated under the OTC Drug Review for use in relieving children's teething pain and associated troubles. The labeling contains structure/function claims, such as using the product to relieve children's teething pains, making this product a drug under 201(g)(1) of the FFDCA. Further, we are not aware that this drug is generally recognized as safe and effective for its labeled uses. Consequently, this drug appears to be a new drug.

PRODUCT	SOURCE	COUNTRY
PainNot Patch 60L[][]99 9/3/08	Shantou Wuhuan Pharmaceutical Co Ltd. Fujian Road, Longxin District Shantou City, Guangdong Province China FEI# 3005354975	China

NOTE: Claims of "Pain Relieving Patch For temporary relief of minor aches & pains Works in 10 minutes to relieve pain " and "Relieves pain from arthritis, back, bursitis, carpal tunnel, tendonitis, sprains, strains, and more " were found during review of labeling for the product and the internet website for the initial distributor, Suarez Corporation. Also, review of the formulation found that it did not match the Tentative Final Monograph for OTC External Analgesics.

PRODUCT/PRODUCT CODE:	FIRM NAME AND ADDRESS:	COUNTRY:
Phyto Shape Capsules 54F[][][] 54Y[][][] 9/16/08	Etumax Corporation Sdn Bhd. No. 102 Jalan Gasing Seksyen 5, Petaling Jaya 46000 Selangor Malaysia FEI# 3005109004 3006357520 3006375686 3006380113	MALAYSIA
Etumax Tongkat Ali Power Plus 54Y[][][] 54F[][][] 11/12/08		

IA 000080

This product is promoted as dietary supplement for weight loss. FDA analysis found rimonabant in this product. Rimonabant is the active ingredient in Zimulti. Zimulti is an anti obesity drug not approved in the United States.

This product was found to contain undeclared Sildenafil, an erectile dysfunction prescription drug.

PRODUCT	SOURCE	COUNTRY
---------	--------	---------

Medicated Powder (mentholated)	PZ Nigeria Limited (aka Pz Industries)	Nigeria
"Robb Ointment"	45/47 Town Planning Way	
66V[[]][[]]	Ilupeju, Nigeria	
9/16/08	FEI# 3006742009	

NOTE: Labeling on the product does not differentiate between active and inactive ingredients and the listed ingredients are not recognized as approved active ingredients for nasal decongestion under the monograph.

PRODUCT	SOURCE	COUNTRY
---------	--------	---------

Manufacturer:		
Ashton & Parsons	Glaxo Smith Kline	Nigeria
Matricaria	Nig Plc Igbesa Road	
66V[[]][[]]	Agbara, Nigeria	
9/16/08	FEI# 3006742011	

Shipper:		
Salawu Enterprises Ltd.	10 Onikosi Street	Nigeria
	Otta, Nigeria	
	FEI# 3004526255	

NOTE: The product is labeled to contain tincture of matricaria, is indicated for teething and slight stomachic upsets during infancy, and FDA is not aware that the product is generally recognized as safe and effective for its labeled uses.

Jiangxi Gaoan Tea Co., Ltd.	Healing Collection 4 Tea 9/24/08 31K[[]]99
Qiao Bei Road,	54E[[]]99

IA 000081

Gao An City, 66V[] []99
 Jiangxi, China (Mainland)
 FEI# 3004273888 Diabetic Choice Tea 11/12/08
 31K[] []99

REASON FOR ALERT: Labeling of this herbal product makes drug claims related to the mitigation of cholesterol, diabetes and high blood pressure thus causing the product to be a new drug for which no approval is in effect.

NOTE: Product may be entering as a dietary supplement, therefore, we have included the product code "54E[] []99" along with the appropriate drug code "66V[] []99" and the product code used in the entry for which this firm was added "31K[] []99."

PRODUCT	SOURCE	
"Chinese Love Stone"	Tsang Fook Kee Medicine Co.	9/29/08
"Rock Hard"	5, G/F, Ko Shing Street	
"Black Stone"	Hong Kong	
"Stud 100"	FEI# 1000231335	
GPI=DR		
GPI=VI		
54Y[] []99		
54F[] []99		
66V[] []99		

Note: Product has been found to contain the toxin Bufotenine, which is classified by DEA as a Schedule 1 drug.

PRODUCT	SOURCE
Pop Face Polish (AHA)	Pop Inc.
53L[] []03	Unknown Street Address
GPI=DR	Bangkok, Thailand
11/12/08	FEI# 3006948477

PRODUCT	SOURCE
Acne Solutions	Herbal Solutions Health, S.A. de C.V.
Herbal Capsules	Jesus Garcia No. 388-B Zona Centro
54E[] []99, 54F[] []99	Irapuato, Mexico 36500
54Y[] []99, 66V[] []99	FEI# 3006484715

IA 000082

GPI=DR
11/12/08

Clear and Balance	Herbal Solutions Health, S.A. de C.V.
Facial Gel	Jesus Garcia No. 388-B Zona Centro
GPI=DR	Irapuato, Mexico 36500
11/12/08	FEI# 3006484715

PRODUCT	SOURCE
Neutrotone Cream 64L[][]67 11/12/08	Orange Drugs Ltd. 66/68 Town Planning Way Ilupeju Lagos, Nigeria FEI# 3006755325

PRODUCT	SOURCE
CiCi Natural Herbal Capsules GPI=VI GPI=DR 11/12/08	Beijing Yin Han Health Products Manufactory Inc. Wang Xin Zhuang Zhen Le Yuan Lu 29 Hao Ping Gu District Beijing, China FEI # 3006531677

This product was found to contain an undeclared drug called aminotaladafil, an analog of taladafil, an erectile dysfunction prescription drug.

PRODUCT	SOURCE
Uptrol Dietary Supplement aka Uptrol Male- Enhancement Formula GPI=VI GPI=DR 11/12/08	Natural Health Products Office 8 The Village Dubai, United Arab Emirates FEI# 3005114054

This product was found to contain an undeclared drug called taladafil, an erectile dysfunction prescription drug.

IA 000083

PRODUCT	SOURCE
Maxi-Peel Exfoliant 53L[]03 66V[]99 11/18/08	Splash Corporation 17F Lazaro Street Canumay West Valenzuela City, Philippines FEI# 3004096041
PRODUCT	SOURCE
Aloe Vera Cream (Clobetasol Propionate) GPI=DR 11/18/08	Vitus Pharm Co. Unknown Street Address Milan, Italy FEI# 3002939833
PRODUCT	SOURCE
Sulpher Ointment GPI=DR 11/19/08	Associated Pharm/Food & Chemical Ltd. Eziama Industrial Estate Lagos, Nigeria FEI# 3006804324
Aboniki Balm GPI=DR 11/19/08	Global Industries Nigeria Ltd. 41 Egbon Street Ugowo, Benin City, Nigeria FEI# 3006780965
Detox Foot Patch GPI=DR 11/19/08	Sanzi Cosmetics (dba Guangzhou Sanzi Cosmetics) 5 Pine Park New City, Guangzhou, China FEI# 3006850529
Li Da Dai Hua Slimming Capsules GPI=VI GPI=DR 12/1/08	Kunming Dali Industry & Trade Co., Ltd. No. 372, West Renmin Road Kunming, Yunnan, China FEI #2000033137

This product was found to contain an undeclared drug called Sibutramine, the active ingredient in the FDA approved anti-obesity drug Meridia.

PRODUCT/PRODUCT CODE: FIRM NAME/ADDRESS: Country:

IA 000084

"Good Night"	Paragom Metal Inc.	China
Male Erection &	No. 69 Dongfang Rd.	
Performance Enhancer	Tower A Etan Plaza	
54[[]][[]]	Pudong, Shanghai, China	
2/10/09	FEI# 3007044504	

NOTE: This product is promoted on the Internet and sold at retail as a dietary supplement for natural male enhancement. FDA analysis found tadalafil in this product. Tadalafil is the active ingredient in the FDA approved drug Cialis.

PRODUCT	SOURCE	COUNTRY
Tetmosol Medicated Soap (81 gm bar)	FCC Fragrances, Cosmetics & Consulting	Switzerland
Labeling states "Made in England"	10 Chemin Des Orlons, CH-1860 Aigle,	
66V[[]]99	Switzerland	
2/13/09	FEI# 3005755019	

PRODUCT/PRODUCT CODE:	FIRM NAME/ADDRESS:	Country:
Slimming Capsules	Beijing Lidameizi S&T Development Co., Ltd.	China
GPI=VI	Room 1001, Building D,	
GPI=DR	Yonghe Plaza, 28 East St.	
2/18/09	Beijing, China	
	FEI# 3007101828	

This product was found to contain an undeclared drug called Sibutramine, the active ingredient in the FDA approved anti-obesity drug Meridia.

PRODUCT/PRODUCT CODE:	FIRM NAME/ADDRESS:	Country:
Electronic Cigarettes and Shenzhen Kanger Technology Co Lt	4th Bldg 3rd Industrial Zone	China
Electronic Cigarette Components	Shajing Town Shenzhen	
66B[[]]44	China	
66B[[]]99	FEI #3007420742	
77EPN		
77KCO		

IA 000085

89MZx

91DLC

3/30/09

PRODUCT/PRODUCT CODE: FIRM NAME/ADDRESS: Country:

Electronic Cigarettes and Desonic Industrial CHINA

Electronic Cigarette Components 11 Bl Shiao 2nd In

66B[]44 Shenzhen, China

66B[]99 FEI# 3007137400

77EPN

77KCO

89MZx

91DLC

4/6/09

PRODUCT/PRODUCT CODE: FIRM NAME/ADDRESS: Country:

Electronic Cigarettes and Loong Totem Science CHINA

Electronic Cigarette Components & Technology

66B[]44 2 F, Pingan Bldg

66B[]99 Gangkou Road 1

77EPN Jiangmen City

77KCO Guangdong Province

89MZx China

91DLC FEI #3007474573

4/7/09 #3007467475

PRODUCT SOURCE COUNTRY

Fitness Essence 999 Sanjiu Enterprises Group CHINA

54Y--99 1028 Beihuan Road, Shenzhen

54F--99 Shenzhen, China 518029

4/21/09 FEI# 3005167350

ATTACHMENT (B) TO IMPORT ALERT #66-41 1/23/07

IA 000086

Unapproved New Drugs That May Be Subject to DWPE

***ATTACHMENT B: "AYURVEDIC DRUGS"

PRODUCTS: Ayurvedic, a/k/a: Pushpapdhanwa, etc.

PRODUCT CODE: New Product Code for Ayurvedics TBD

54F[][]99

54Y[][]99

PROBLEM: Unapproved drugs

PAC: AAP

PAF: 56008H

COUNTRIES: All

MANUFACTURER/SHIPPER: All Firms and Products Listed

CHARGES: For finished products that appear to be intended for use as drugs: "The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to be a new drug under the meaning of section 201(p) without an effective new drug application, as required by section 505. [Unapproved new drug, section 505(a)]"

REASON FOR ALERT: A number of ayurvedic drugs may present a serious health hazard to the user because they may contain heavy metals such as lead, mercury, and arsenic. Heavy metals pose a particular health risk because they may accumulate in vital organs. For example, arsenic poisoning can cause nausea, abdominal pain, vomiting, severe diarrhea, neuropathy, dermatitis, heart abnormalities, kidney or liver damage, and reduced motor nerve function. Lead poisoning can cause fatigue, irritability, insomnia, nerve disorders, muscle and joint pain, memory and concentration problems, dizziness, seizures, and coma. Mercury poisoning can cause fatigue, headache, muscle weakness, joint pain, tremors, irritability, concentration problems, slowed sensory and motor nerve function, and reduced mental function. Children are particularly at risk from the toxic effects of heavy metals.

IA 000087

BACKGROUND:

A December 15, 2004, article published in the Journal of the American Medical Association (JAMA) reports that of 70 ayurvedic drugs sampled and tested, 14 (20%) were found to contain potentially harmful levels of lead, mercury, and/or arsenic. These products were produced in South Asia and were purchased in South Asian grocery stores located in Boston, Massachusetts. In July 2005, Health Canada tested a number of ayurvedic products available in the Canadian market and determined that they contained high levels of lead, mercury, and/or arsenic. In August 2005, the Department of Health, City and County of San Francisco, tested a number of ayurvedic products that had been consumed by an individual who suffered severe lead poisoning and found that the products contained elevated levels of lead. In 2003, the Santa Clara County Department of Health, in California, tested Pushpadhanwa, an ayurvedic product that was associated with two incidents of injury, and found the product contained high levels (8%) of lead.

GUIDANCE:

Most imported ayurvedic products are marketed as drugs. Some ayurvedic products are imported as dietary supplements. These products are distinguishable by the fact that their labels contain the statements "Dietary Supplement" and the disclaimer required for dietary supplements. Districts encountering ayurvedic products labeled as dietary supplements should consult with CFSAN for guidance.

All ayurvedic drug products subject to this Import Alert are intended for ingestion, are labeled in English and Hindi, or totally in Hindi. Under the Federal Food, Drug, and Cosmetic Act (Act), a drug is an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. 21 U.S.C. § 321(g)(1)(B). A drug is likewise an article (other than food) intended to affect the structure or any function of the body. 21 U.S.C. § 321(g)(1)(C). Ayurvedic products that are not dietary supplements can still be drugs if they do not bear disease claims but are intended to affect the structure or any function of the body. Drugs that contain heavy metals (other than minor unavoidable trace amounts found in some drugs) are not generally recognized as safe and effective for any indication. Therefore, these products are "new drugs" within the meaning of section

IA 000088

201(p) of the Act. Since these products are not the subject of an approved new drug application (NDA), their importation into the United States violates section 505(a) of the Act. The products listed in the attachment are the ayurvedic products that were tested and found to contain heavy metals as described above. Districts may detain without physical examination any shipments of the finished ayurvedic drugs listed in the attachment. Discretionary release of these products under the Personal Importation guidance of Chapter 9 of the Regulatory Procedures Manual (RPM) may not be appropriate.

KEYWORDS: Ayurvedic; Bal Chamcha; Bala Guti; Bala Sogathi; Balgutti Kesaria; Gesari; Karela; Maha Sudarshan Churna; Mahalakshmi Vilas Ras; Swarnna Mahayograj Guggulu; Navratna Rasa; Safi; Shilajit; Pushpadhanwa;

Ayurvedic Drugs That Have Been Found To Contain Heavy Metals

PRODUCT: MANUFACTURER:

Bal Chamcha Jalaran
62 Midc Area
India
FEI# 3003440655

Bala Guti The Zandu Pharmaceutical Works
Maha Sudarshan Churna Ltd., GIDC, Plot No.82, Uapi
Gujarat, India
FEI# 3005378718

Bala Sogathi, Navjeevan Ayurvedic
515/17, Manlana Azad
Nallbazaar, Mumbai, India
FEI# 3005378729

Balgutti Kesaria Kesari Ayurvedic Pharmacy
Abrama, VIA Vedchha
Gujarat, India
FEI# 3005378744

"Diabet Guard" Granules The Himalaya Drug Company India
"Himalaya Diabecon" Makali, Tumkur Road

IA 000089

54Y[] [] 99 Bangalore, Karnataka
54F[] [] 99 India
 FEI # 3004259394 1/23/07
 FEI # 3004681347

Goodcare Pharma Pvt. Ltd. India
1, Gupta Lane
Calcutta, West Bengal
India
FEI # 3005383147 1/23/07

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Gautam Global Also DBA Botanika India
34 Old Cannought Place
Dehradun
India
FEI # 3003507632 1/23/07

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Rave Overseas Pvt. Ltd India
P O Box No. 611, GPO
Indore
India
FEI # 3006074168 1/23/07

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Gesari Harinarayan Pharmacy
India
FEI# 3005378957

HSY 103 Harbhajan Singh Yogi & Sons,
Chandigarh, India
FEI# 3005378967

Herbal Ayurvedic Medicine Shree Baidyanath Ayurved Bhawan Ltd
62QBY99 Gwalior Road, Jahansi
8/25/06 India
FEI# 3003175278

Karela The Himalaya Drug Company
Makali, Bangalore, India
FEI# 3002535359

Maha Sudarshan Churna Dabur India Limited
 P.O. Daburgram, Bihar
 New Delhi, India
 Zandu, India;

IA 000090

FEI# 3003618623

Mahalakshmi Vilas Ras with gold Ayurved Bhawan Limited
Gwalior Road
Jhansi, India
FEI# 3003199854

Majayograj Guggulu w/silver & Baidyanath Aywued
Makardhwaj Jhansi, India
Swarna Mahayograj Guggulu with gold FEI# 3004149275

Navratna Rasa Unjha Ayurvedic Pharmacy
India
FEI# 3005379055

Pushpadhanwa tablets Shree Dhootapapeshwar Ltd.
135 Nanubhai Desai Road
Mumbai, India
FEI# 3002945659

Safi, Blood Purifier Hamdard (WAKF) Laboratories
B/1-2 111 Industrial Area
Ghaziabad, India
FEI# 3004659877
2000027663

Hamdard Laboratories
Hamdard, Pakistan
FEI# 3005339043

Shilajit Syncom Formulations Limited
Factory: 256-257, Sector 1,
Pithampur (Dhar), Caves Road,
Andher, Mumbai, India
FEI# 3005379096

IA 000091

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What Is A Crown7 Electronic Smoking Device?

Electronic cigarettes, also called an e-cigarette (or e-smokes) is a electric version of a cigarette, providing small amounts of nicotine with each inhalation. But, instead of unhealthy smoke dispersing from the cigarette, harmless water vapor is dispersed through the machine. And the best thing about the new smoking alternative from Crown7 is that you can enjoy anywhere you wish, **even indoors!** We are proud to be the top provider of electric cigarettes, electric cigars, and electric pipes and accessories! Browse our selection of smokeless cigarettes today! Start Shopping.



Electronic Cigarettes | The All New **HYDRO** From Crown7

Crown7 offers you the first alternative to smoking that will satisfy your nicotine urges and cravings without having to light up. And now for the first time we are proud to introduce THE HYDRO electronic cigarette.

The new HYDRO is the same size as a traditional 100 length cigarette but does not contain any tar or carcinogens. 100% redesigned from the traditional "Art Deco Tube," this sexy sleek design is what our customers have been asking for, and now it has arrived.

Each cartridge is the equivalent to 10 cigarettes and we offer Regular, Menthol and 5 colorful flavors including Watermelon, Strawberry, Grape, Vanilla, and Cherry.

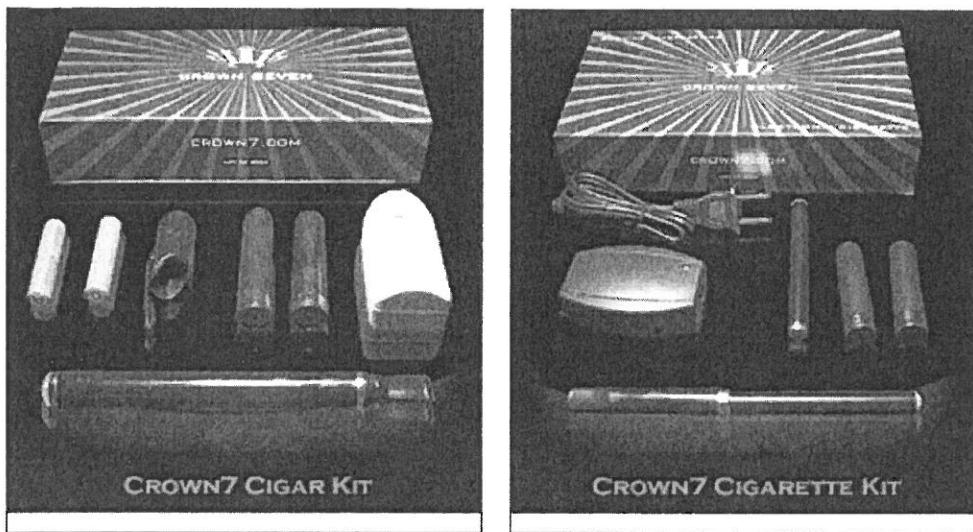
Crown7 has gone to great lengths to make ensure our electronic cigarettes are the very best products available on the market. After hundreds of test designs and extensive travel to ensure we are providing the highest quality products, we have officially launched *The Future Of Smoking, The Crown Seven HYDRO.*

Electric Cigarettes, Cigars, And Pipe Refills

At Crown7, we are constantly developing new and innovative products to satisfy our growing consumer base. Not only do we provide the HYDRO (same size as a traditional 100 cigarette), but we also offer the traditional Art Deco Tube electric cigarette as well as the Crown7 Cigar. All of our products are online today with individual items as well as all-in-one kits available for purchase.

With various flavor such as Vanilla Bean, Cherry, and Double Orange to choose from, this is the first smokeless cigarette you will actually enjoy to smoke!

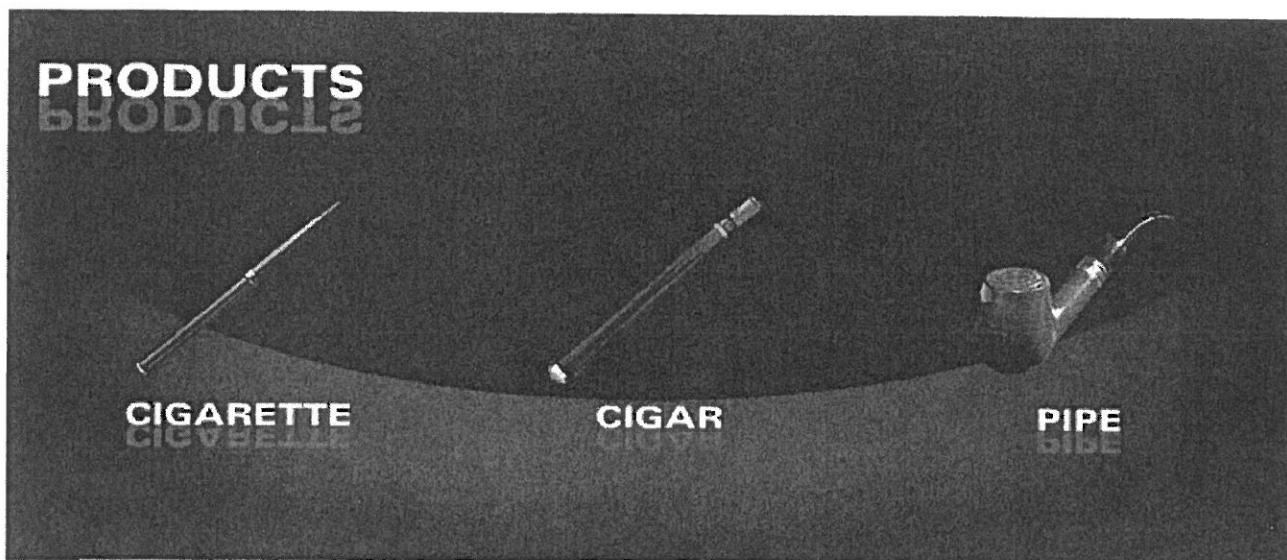
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- Mani
- Ropl



What Restrictions Will I Have With Crown7?

No longer will you need to smoke 'outside' or in 'reserved' smoking areas. Use Crown7 electronic cigarettes anywhere you wish!

Traditional cigarettes commonly contain tobacco, nicotine, glue and paper, when ignited, along with hundred of additives (our research has shown up to 599 additives), according to the Centers for Disease Control, harm nearly every organ of the body, and cause cancer, and cardiovascular and respiratory disease. No longer are all of these an issue with the introduction of Crown7 electronic cigarettes.

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Select The Product Of Choice Above Or Read Below To Learn More:

A Crown7 is the perfect alternative for any smoker

- Use Crown7 in Any Situation Where Smoking is Prohibited - Our Product is Non-Offensive
- Rechargeable Battery for Endless Hours of Enjoyment and Smoking Pleasure
- No Offensive Smoke... Only a Harmless Vapor is Emitted
- Perfect Solution to Smoking in a Casino or Pool Hall - Prevents Noxious Odors by Never Creating Them
- Sophisticated Design, Sleek Art Deco Look & Feel
- No Residual Clothing or Room Odor... Now that's a Real Benefit!
- Battery Operated, Simple to Manipulate in all Situations Where Smoking Cigarettes has been Prohibited
- Replaceable Filter Cartridges



Features

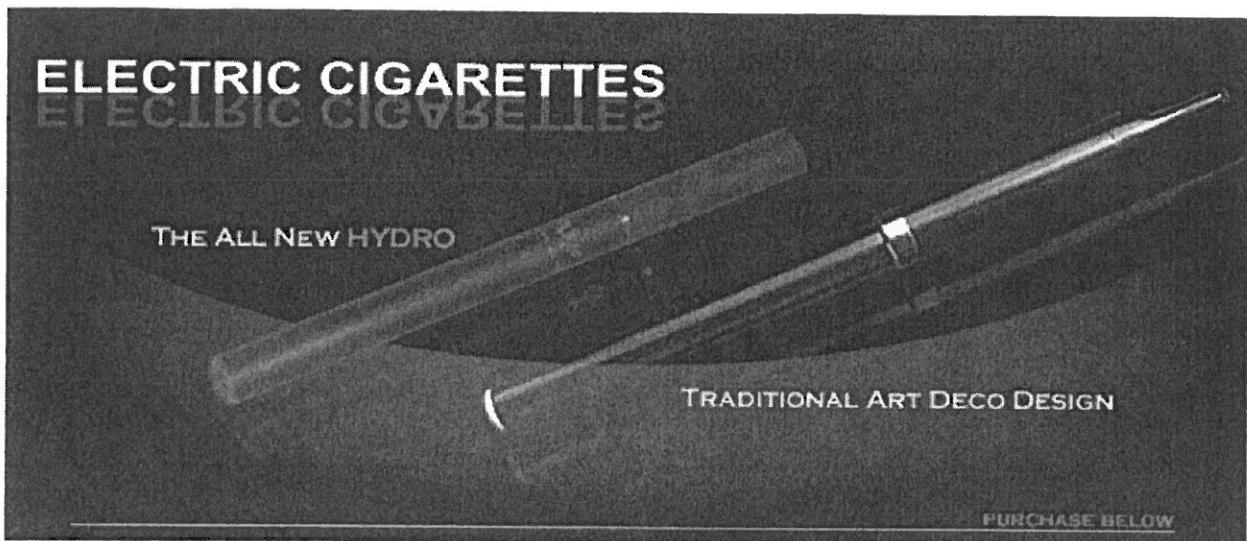
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- Odor.

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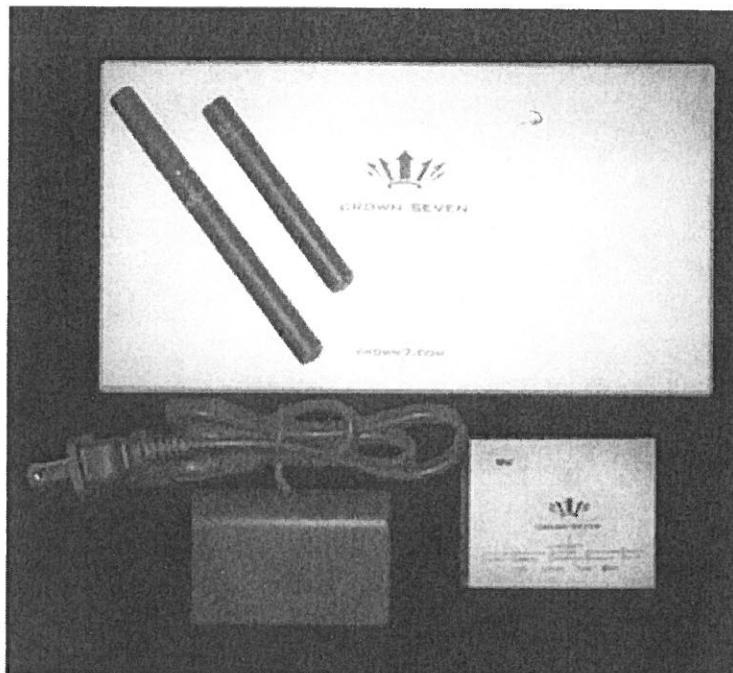
- Battery Operated, Simple to Manipulate in all Situations
- Replaceable Filter Cartridges

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Crown7 HYDRO KIT



Price: \$79.95
Shipping Weight: 1.00 pound

Contents Include:

- * Crown7 HYDRO Unit
- * Battery Recharger
- * Two Lithium Batteries
- * One pack of 5 regular flavor, zero strength Filters.
- * Complete Instructions

Crown7 HYDRO ASSORTED FLAVOR CARTRIDGES



Features

- Use C
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- No Re
- Odor.

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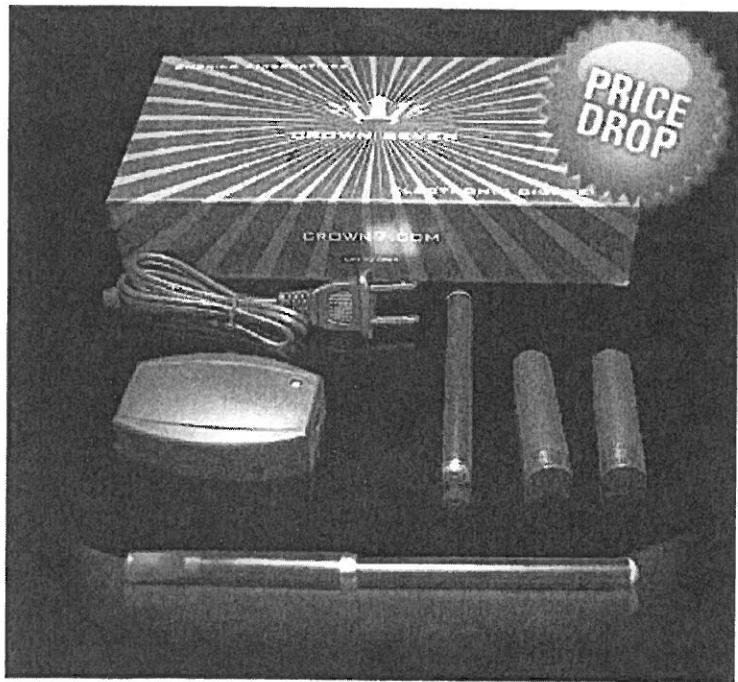
Price: \$9.95

Each Box Contains One High Strength of Each of the Following Flavors:

- * Watermelon
- * Strawberry
- * Grape
- * Vanilla
- * Cherry

- * Battc Mani
- * Repl

Crown7 TRADITIONAL CIGARETTE KIT



Price: \$79.95

Shipping Weight: 1.00 pounds

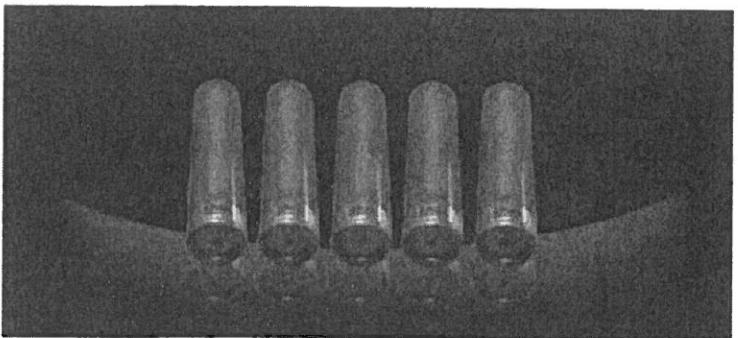
Contents Include:

- * Crown7 Unit
- * Battery Recharger
- * Two Lithium Batteries
- * Two Replacement Filters
- * Complete Instructions
- * Handsome Case

Complete Cigarette Starter Kit Includes:

- * Crown7 Cigarette Unit
- * 2 Batteries & Charger
- * 2 Replacement Cartridges

Crown7 TRADITIONAL CIGARETTE CARTRIDGES



Contents Include...

- * Crown7 Replacement Cartridges 5-pack for Cigarette Style Unit

Please Check for each Product(s) Unique Cartridge Requirements.

Each cartridge is the equivalent to 2

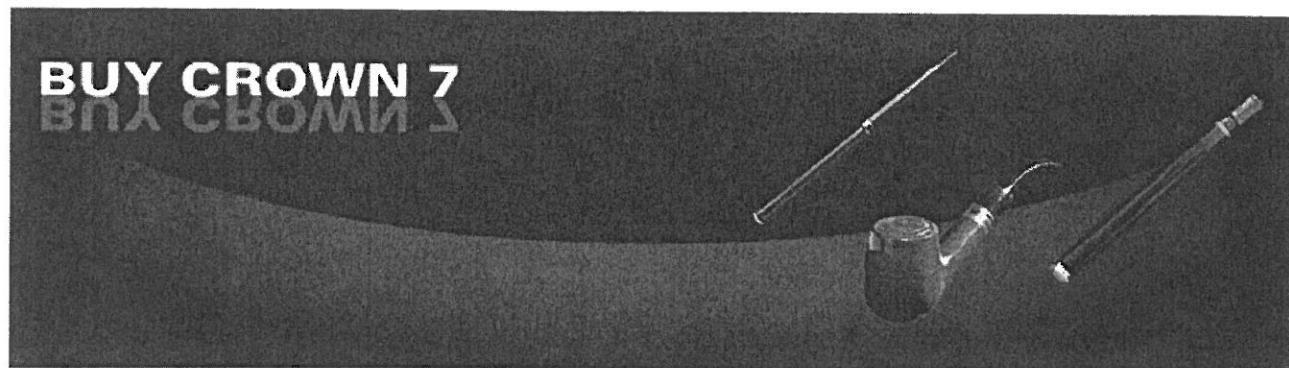
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packs of cigarettes



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**Buy your Crown7 and accessories here.**

Choosing a product will take you to the PayPal shopping cart. If you want to add more to your cart, return to this window and select your items. They will add to those already in the cart.

Cigarette, Cigar and Pipe are marked in color. Be sure to buy the proper accessories for your Crown7.

Please direct any questions to support@crown7.com or
Crown7
PO BOX 14257
Scottsdale, AZ 85267

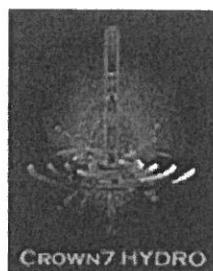
All USA
Tracking
when ord
your add
ordering.

Crown7 HYDRO Cigarette Kit

Price: \$79.95 - (U.S.A.)



Quantity: 1

**Crown7 Traditional Cigarette Kit**

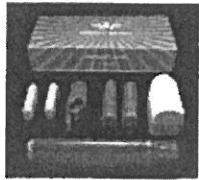
Price: \$79.95 - (U.S.A.)



Quantity: 1

Crown7 Cigar Kit

Price: \$54.95 - (U.S.A.)



Quantity: 1

PayPal
Add To Cart

HYDRO Cigarette Cartridges (HYDRO ONLY)

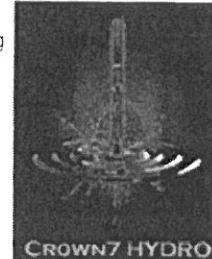
Price: \$10.00 - Per 5-Pack

* Assorted 5-Pack only available in High Strength, and includes 5 of our best selling flavors, including; Watermelon, Strawberry, Grape, Vanilla, & Cherry.

Quantity: 1

High Select Nicotine Strength

Regular Select Nicotine Flavor



PayPal
Add To Cart

Cigarette Replacement Cartridges (Traditional Cigarettes Only)

Price: \$10.00 - Per 5-Pack - Nicotine

Each cartridge is the equivalent to 2 packs of cigarettes

Select Quantity: 1

High Select Nicotine Strength

Regular Select Nicotine Flavor



PayPal
Add To Cart

Cigar Replacement Cartridges

Price: \$10.00 - Per 5-Pack - Nicotine

Each cartridge is the equivalent to 2 packs of cigarettes

Select Quantity: 1

High Select Nicotine Strength

Regular Select Nicotine Flavor



PayPal

Add To Cart

Pipe Replacement Cartridges

Price: \$10.00 - Per 5-Pack - Nicotine

Each cartridge is the equivalent to 2 packs of cigarettes

Select Quantity: 1

High

Select Nicotine Strength

Regular

Select Nicotine Flavor

PayPal

Add To Cart

Crown7 Cigarette Car Charger



Price: \$19.95

PayPal

Add To Cart

Quantity: 1

Crown7 Cigar Car Charger



Price: \$19.95

PayPal

Add To Cart

Quantity: 1

Crown7 Lanyard



Price: \$2.00

PayPal

Add To Cart

Quantity: 1

Crown7 Cigarette Atomizer



Price: \$9.95

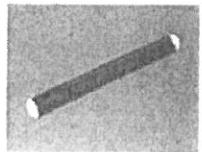
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Quantity: 1

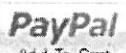
Crown7 Cigarette Battery

IA 000101



Price: \$9.95

Quantity:



Please review our return policy and privacy policy.

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IA 000102

FAQ**How Does It Work?**

Crown7 performs similarly to traditional smoking. It looks, feels and tastes like a cigarette and delivers all the pleasures of smoking, without all the problems. The secret to what makes Crown7 better than traditional smoking is what is inside this revolutionary new product.

The non-flammable Crown7 is driven by modern microelectronic technology, a small rechargeable battery and a unique, safe replaceable cartridge containing water, propylene glycol, nicotine, and a scent that emulates a tobacco flavor.

When using Crown7, the act of inhaling or smoking it produces the tactile and craving satisfactions traditional smokers seek, and triggers a vaporizing process that releases a simulated smoke that is actually a vapor mist that harmlessly evaporates into the air within a few seconds.

[back to top](#)

What Is In Crown7 Compared To Cigarettes?

The number of ingredients in Crown7 and the outcome of those ingredients when used are vastly different than those found in traditional cigarettes and cigars.

Crown7 contains only water, propylene glycol, nicotine, and a scent that emulates a tobacco flavor. None of these ingredients are considered cancer-causing agents. The Food and Drug Administration deems propylene glycol safe. Nicotine itself is not believed to have toxicological effects, offers some therapeutic uses and can be found in pepper, tomato, eggplant and potato.

Cigarettes and cigars commonly contain tobacco, nicotine, glue and paper, which when ignited, along with hundred of additives (our research has shown up to 599 additives), according to the Centers for Disease Control, harm nearly every organ of the body, and cause cancer, and cardiovascular and respiratory disease.

[back to top](#)

What Is Propylene Glycol?

Propylene glycol is a commonly used organic compound that is recognized as generally safe by the Food and Drug

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Administration. It is used in food coloring, and flavoring, as an additive to keep food, medicines and cosmetics moist, and in machines that simulate smoke as well as an ingredient in toothpaste and mouthwash. In Crown7, propylene glycol functions to provide the vapor mist that looks like smoke and to suspend flavor.

[back to top](#)

- Baltic
- Mani
- Repl.

What Is Nicotine?

Nicotine is an alkaloid found in certain plants, predominantly tobacco, and in much lower quantities in tomatoes, potatoes, eggplant and green peppers. When absorbed in small amounts, whether from cigarettes, cigars or Crown7, nicotine can cause stimulation, a feeling of relaxation, calmness, and alertness. The effects of nicotine can last from minutes to hours.

The carcinogenic properties of nicotine in a standalone form (i.e., separated from smoking or chewing tobacco) have not been evaluated by the International Agency for Research on Cancer. However current available literature indicates that nicotine in standalone form does not promote the development of cancer in healthy tissue and has no mutagenic properties.

[back to top](#)

Is Crown7 Approved As A Smoke Cessation Device?

Crown7 has never been proven to be a smoking cessation device and is not sold or marketed as such. Crown7 is an alternative to smoking that offers reduced health risk, freedom to smoke anywhere, social inclusion versus isolation, no first or second hand smoke, virtually odor-free smoking, non-flammability, convenience, and lower cost than traditional smoking.

[back to top](#)

How Long Does Each Cartridge Last?

The equivalent to 1 1/2 to 2 PACKS of cigarettes, depending on your smoking habits.

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Do You Use Crown7 Like A Regular Cigarette?

No, Use your Crown7 when you feel the craving for a cigarette-a few puffs and you craving will be satisfied.

[back to top](#)

Is Crown7 Approved By The FDA?

The Alcohol and Tobacco Trade Bureau (TTB) and the Food and Drug Administration (FDA) have formally stated that Crown7 is not a product that warrants the involvement or oversight of either government entity. The FDA notes that Crown7 do not fit the classification of products it governs. The TTB (Tobacco and Taxation Bureau, formerly the ATF, Alcohol Tobacco and Firearms) has formally determined that the TTB has no regulatory interest in Crown7 because it does not contain tobacco.

[back to top](#)

Does Crown7 Taste Like A Cigarette?

Crown7 taste similar to light cigarettes and cigars, yet the odor is barely noticeable, unlike regular cigarettes and cigars.

Where Can You Use Crown7?

Crown7 is non-flammable and contains no tobacco, it is not smoking and its use is not prohibited by law. Restaurants, bars, your work place and your car are all acceptable.

"If they have no tobacco in them, as we've heard they don't, they would be allowed, simply because they would fall outside the regulation of what the law includes,"

- Don Harrington with the Arizona Department of Health Services.

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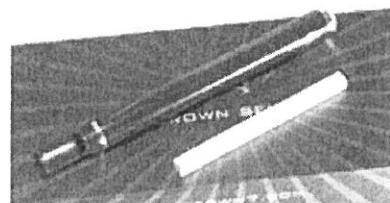
What Flavors Are Available?

Regular, Menthol, Vanilla Bean, Espresso, Untamed Cherry, Strawberry, Juicy Grape, Double Orange. More coming in '09!!

[back to top](#)

How Big Is The Crown7?

Take a look at these photos comparing the Crown7 devices to a regular cigarette.



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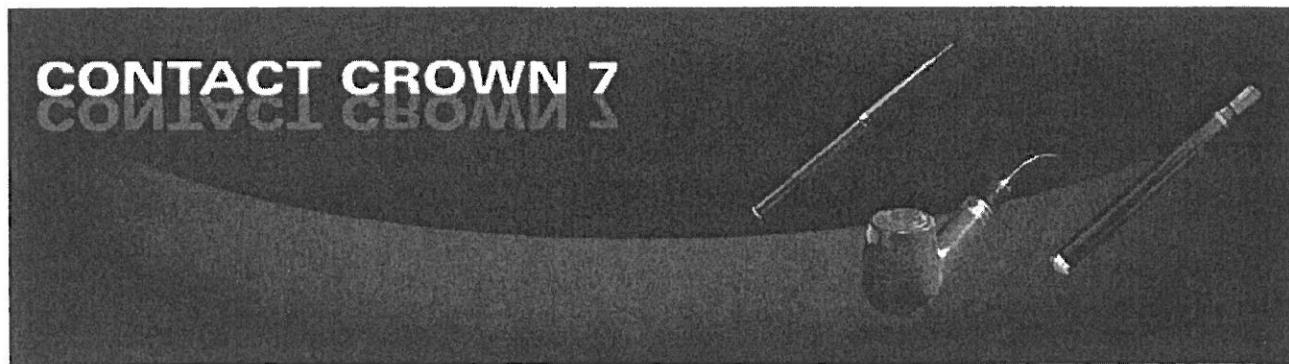
PRODUCTS

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FAQ

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CONTACT US



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Last Name *

Company

Email *

Address

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State

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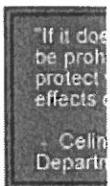
Phone

How did you find our site

How can we help you? Please indicate which service or products that you need.



* Please enter the security code from the image above:

Crown7
PO BOX 14257

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IA 000106

- Battery Operated. Simple to Manipulate in all Situations
- Replaceable Filter Cartridges

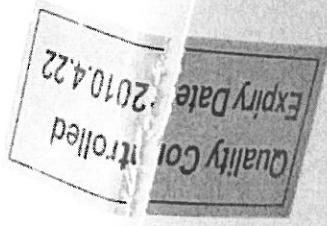
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Atomized cartridge

F.D.A.





CROWN SEVEN

ASSORTED FLAVORS []

- VANILLA BEAN UNTAMED CHERRY
 ESPRESSO STRAWBERRY
 JUICY GRAPE DOUBLE ORANGE
 BURSTING MELON GREEN TEA
 CREAMSICLE GINSING

- HIGH MEDIUM LOW
 NONE

Ingredients of the Cigarette
Nicotine (1mg, 1mg, or 0mg)
Tobacco, Nicotine, Propylene Glycol and water
Flavor essence, Propylene Glycol and water

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CROWN7.COM

CROWN SEVEN


High
E-Cartridge

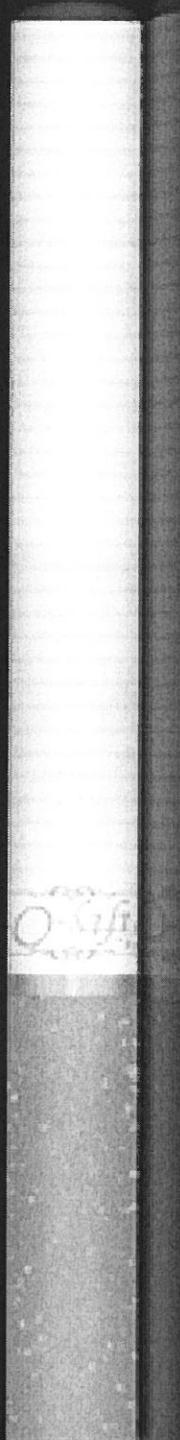
ORANGE GREEN TEA
SICLE GINSING
 NONE

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User Manual

Smok-On-OneTM

Smoke Anywhere USA, Inc.



The Premiere Electronic Smoking Device
IA 0000113

FIFTY-ONE™ AUTOMIZER USER MANUAL

- This User's Manual must be carefully reviewed before commencing use of the Fifty-One™ product.
- Please keep this manual in good condition for possible reference in future.
- Warning prompts:
- *Health protection:* As a reminder, the Fifty-One™ is programmed to have the front end indicator lamp continuously flash 10 times if you are over-using the product in a short period of time, based upon 4.5 second intervals;
- *Battery protection:* When the battery begins to run down, the front indicator lamp will continuously flash 20 times. When this happens, you should immediately stop using the battery and recharge.

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II.	<i>Safety Information</i>	4
III.	<i>Product Introduction</i>	5
IV.	<i>Directions for the Use of the Fifty-One™ Atomizer</i>	7
V.	<i>Directions for the Use of the AC Charger</i>	8
VI.	<i>Service & Maintenance</i>	9
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IA 000115

I. PRODUCT COMPONENTS

*Electronic
Smoking Device*



Charger

IA 000116

III. SAFETY INFORMATION

In order to safely and effectively use the "Fifty-One™ Atomizer" and its supporting accessories, please read through the following information very carefully and follow the standard operating procedures strictly.

III. PRODUCT INFORMATION

Certain studies suggest that nicotine may cause addiction in certain users. Should such dependency result, stopping use of the Fifty-One™ Atomizer may cause discomfort and other potentially injurious effects. There have also been certain studies that nicotine may be particularly dangerous to users if used in excess amounts or if ingested or otherwise consumed accidentally or contrary to instructions for use.

The "Fifty One™ Atomizer" is different from the tobacco cigarette in several ways such as being:

- Non-flammable, without the danger of over 4,000 chemical substances produced by the tobacco cigarette, like carbon monoxide;
- Less harmful to others and the environment, without producing the danger of "second-hand smoke";
- Usable in most places where smoking is not permitted, although all local signs and establishment requirements and procedures should be adhered to and complied with.

IV. DIRECTIONS FOR THE USE OF AC CHARGER

To charge the special lithium battery in the "Fifty-One™ Atomizer, simply screw the battery into the provided charger. Approximately Four hours later, the battery will be fully charged and the indicator light will turn from red to green. When charge is complete the battery should be removed and disengaged from the charger's power supply.

The Atomizer is now again ready for use.

- The charger should never be used outdoors or in a damp environment.*



Charging with common charger

V. DIRECTIONS FOR THE USE OF FIFTY-ONE ATOMIZER

1. Installation method

Step 1: Unpack the cartridge, and remove the plastic cap(s);

Step 2: Screw the cartridge into the "Fifty One™ Atomizer" battery body.

Step 3: The unit is now ready for use.

2. Stand-by mode: The Fifty One™ will be in standby mode once a Cartridge is attached. For best results Cartridge should be used within two weeks of affixing to the battery.

3. Operating mode: Upon inhalation of the Cartridge, the indicator light will turn "on" and the product is now operating. Atomization of the nicotine will stop when inhalation stops and the product will return to its stand-by mode. It is time to change or recharge the battery when the indicator light begins to flash or dim.

4. When the indicating lamp continuously flashes 10 times this is a reminder and warning that you may be over using the product.

continued

5. The microcomputer in the Fifty-One™ is programmed with an automatic self cleaning function. After approximately 1500 inhales, the indication light at the front of the atomizer body will shine continuously for 8 seconds, which indicates that the computer controlled program is automatically carrying out product cleaning.



IA 000121

VI. SERVICE & MAINTENANCE

The maintenance and repair of the product shall be conducted by the customer service department of the company only. The company takes no responsibility for any loss caused by abnormal use or intentional or careless damage.

VII. WARNINGS

- Collisions should be avoided so that the Fifty-One™ Atomizer does not activate and to avoid damage to the unit.
- The charger unit should not be used outdoors or in a damp environment. Do not use this product in or near water – for example, a bathtub, kitchen sink, laundry tub, or a swimming pool – and the like.
- Avoid storing Fifty-One™ Atomizer and cartridges in high temperatures.
- Keep the Fifty-One™ Atomizer and its accessories out of children's reach; the Fifty-One™ Atomizer should not be used by anyone under the age of 18.
- Be advised that nicotine is addictive. Fifty-One products have not been evaluated by the US FDA. They are not intended to be drug products that diagnose, treat, cure or mitigate any disease or condition. Do not use these products if: you are under the legal smoking age in your state, if you are a non-smoker, if you have a demonstrated allergy or sensitivity to nicotine or any combination of inhalants, if you are pregnant or breast-feeding or persons with heart disease, diabetes, high blood pressure or asthma.

IA 000123

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- This is an electric product – not a toy. To avoid risk of fire, burns, personal injury and electric shock, it should not be played with or placed where small children can reach or gain access.
- To reduce the risk of fire or electric shock, do not expose the product's AC Adapter to rain or moisture. Do not use the AC Adapter with an extension cord or other adapter plug.
- Do not use attachments that are not recommended by the manufacturer.
- This product should be charged only from the supplied AC Adapter.
- Do not use product for other than its intended use.
- Unplug atomizer and charger when leaving the house, when retiring for the night or if left unattended.
- Do not place near gas or electric heaters, fireplaces, candles or other similar sources of heat.
- Do not cover, mix, combine or otherwise use the Fifty-One™ Atomizer with any products, materials or accessories other than those provided exclusively to users by and from the manufacturer.

IA 000124

- Certain studies suggest that nicotine may cause addiction in certain users. Should such dependency result, stopping use of the Fifty-One™ Atomizer may cause discomfort and other potentially injurious effects. There have also been certain studies that indicate that nicotine may be particularly dangerous to users if used in excess amounts or if ingested or otherwise consumed accidentally or contrary to instructions for use.
- Keep product in horizontal position when in operation to prevent consuming or ingesting of liquid contained in the Atomizer.
- Do not pierce through the battery with a nail or other edge tool.
- In case of peculiar smell, heat generation, discoloration, distortion or any abnormality of battery during the process of charging, cut off the power supply, take the battery out of the device or charger and do not use the battery.
- Please protect your mucous membrane from direct contact with the simulation smoke liquid contained in the product's cartridge.

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a product by Smoke Anywhere USA, Inc.

1-888-SMOKE-51

www.Smoke51.com

IA 000128

FIFTY-ONE™ ATOMIZER USER MANUAL

● This User's Manual must be carefully reviewed before commencing use of the Fifty-One™ product.

● Please keep this manual in good condition for possible reference in future.

◆ Warning prompts:

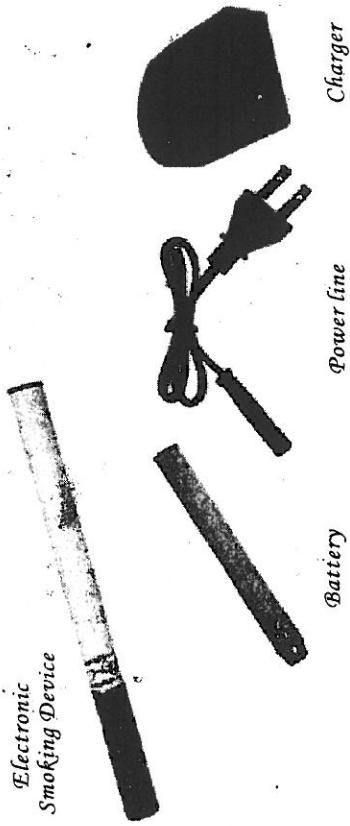
● **Health protection:** As a reminder, the Fifty-One™ is programmed to have the front end indicator lamp continuously flash 10 times if you are over-using the product in a short period of time, based upon 45 second intervals;

● **Battery protection:** When the battery begins to run down, the front indicator lamp will continuously flash 20 times. When this happens, you should immediately stop using the battery and recharge.

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I. PRODUCT COMPONENTS



IA 000130

3

II. SAFETY INFORMATION

In order to safely and effectively use the "Fifty-One™ Atomizer" and its supporting accessories, please read through the following information very carefully and follow the standard operating procedures strictly.

III. PRODUCT INFORMATION

Certain studies suggest that nicotine may cause addiction in users. Should such dependency result, stopping use of the Fifty-One™ Atomizer may cause discomfort and other potentially injurious effects. There have also been certain studies that nicotine may be particularly dangerous to users if used in excess amounts or if ingested or otherwise consumed accidentally or contrary to instructions for use.

The "Fifty One™ Atomizer" is different from the tobacco cigarette in several ways such as being:

1. Non-flammable, without the danger of over 4,000 chemical substance produced by the tobacco cigarette, like carbon monoxide;
2. Less harmful to others and the environment, without producing the danger of "second-hand smoke";
3. Usable in most places where smoking is not permitted, although all local signs and establishment requirements and procedures should be adhered to and complied with.

IV. DIRECTIONS FOR THE USE OF AC CHARGER

To charge the special lithium battery in the "Fifty-One™ Atomizer, simply screw the battery into the provided charger. Approximately Four hours later, the battery will be fully charged and the indicator light will turn from red to green. When charge is complete the battery should be removed and disengaged from the charger's power supply.

The Atomizer is now again ready for use.

The charger should never be used outdoors or in a damp environment.

Charging with common charger



V. DIRECTIONS FOR THE USE OF FIFTY-ONE ATOMIZER

1. Installation method
Step 1: Unpack the cartridge, and remove the plastic cap(s);
Step 2: Screw the cartridge into the "Fifty One™ Atomizer" battery body.

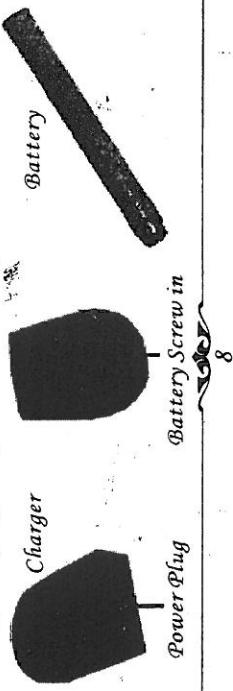
Step 3: The unit is now ready for use.

2. Stand-by mode: The Fifty One™ will be in standby mode once a Cart is attached. For best results Cartidge should be used within two we of affixing to the battery.
3. Operating mode: Upon inhalation of the Cartridge, the indicator lig will turn "on" and the product is now operating. Atomization o the nicotine will stop when inhalation stops and the product will re to its stand-by mode. It is time to change or recharge the battery wi the indicator light begins to flash or dim.

- Note: When the battery is charging, indicative light will light up. Once full power, indicative light will become dim and stop charge automatically.
4. When the indicating lamp continuously flashes 10 times this is a reminder and warning that you may be over using the product.
5. The microcomputer in the Fifty-One™ is programmed with an automatic self-cleaning function. After approximately 1500 inhales, the indicative light at the front of the atomizer body will shine continuously for 8 seconds, which indicates that the computer controlled program is automatically carrying out product cleaning.

VI. SERVICE & MAINTENANCE

The maintenance and repair of the product shall be conducted by the customer service department of the company only. The company shall have no responsibility for any loss caused by abnormal use or intentional or careless damage.



VII. WARNINGS

- Collisions should be avoided so that the Fifty-One™ Atomizer does not activate and to avoid damage to the unit.
- The charger unit should not be used outdoors or in a damp environment.
- Do not use this product in or near water - for example, a bathtub, kitchen sink, laundry tub, or a swimming pool - and the like.
- Avoid storing Fifty-One™ Atomizer and cartridges in high temperatures.
- Keep the Fifty-One™ Atomizer and its accessories out of children's reach; the Fifty-One™ Atomizer should not be used by anyone under the age of 18.
- Be advised that nicotine is addictive. Fifty-One products have not been evaluated by the US FDA. They are not intended to be drug products that diagnose, treat, cure or mitigate any disease or condition. Do not use these products if: you are under the legal smoking age in your state, if you are a non-smoker, if you have a demonstrated allergy or sensitivity to nicotine or any combination of inhalants, if you are pregnant or breast-feeding or persons with heart disease, diabetes, high blood pressure or asthma.

10

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- This is an electric product - not a toy. To avoid risk of fire, burns, personal injury and electric shock, it should not be played with or placed where small children can reach or gain access.
- To reduce the risk of fire or electric shock, do not expose the product's AC Adapter to rain or moisture. Do not use the AC Adapter with an extension cord or other adapter plug.
- Do not use attachments that are not recommended by the manufacturer.
- Do not use attachments that are not charged only from the supplied AC Adapter.
- This product should be charged only from the supplied AC Adapter.
- Do not use product for other than its intended use.
- Unplug atomizer and charger when leaving the house, when retiring for the night or if left unattended.
- Do not place near gas or electric heaters, fireplaces, candles or other similar sources of heat.
- Do not cover, mix, combine or otherwise use the Fifty-One™ Atomizer with any products, materials or accessories other than those provided exclusively to users by and from the manufacturer.

IA 000134

- Certain studies suggest that nicotine may cause addiction in certain users. Should such dependency result, stopping use of the Fifty-One™ Atomizer may cause discomfort and other potentially injurious effects.
- There have also been certain studies that indicate that nicotine may be particularly dangerous to users if used in excess amounts or if ingested or otherwise consumed accidentally or contrary to instructions for use.
- Keep product in horizontal position when in operation to prevent consuming or ingesting of liquid contained in the Atomizer.

● Do not pierce through the battery with a nail or other edge tool.

● In case of peculiar smell, heat generation, discoloration, distortion or any abnormality of battery during the process of charging, cut off the power supply, take the battery out of the device or charger and do not use the battery.

● Please protect your mucous membrane from direct contact with the simulation smoke liquid contained in the product's cartridge.

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BOX CONTAINING CARTRIGES

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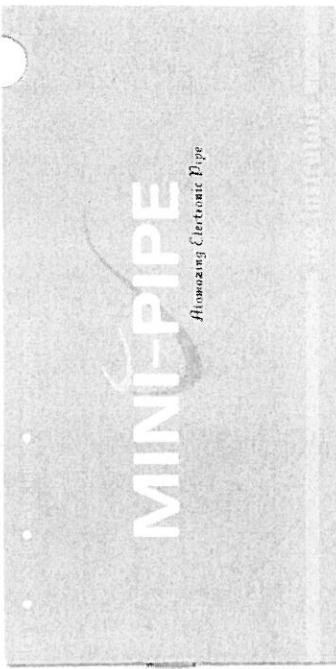
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Electronic Cigarette

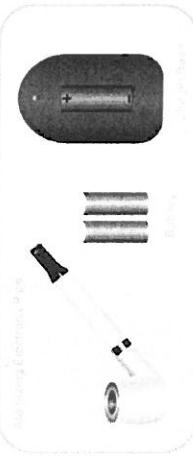
Atomized cartridge

IA 000136



IA 000137

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The usage of tobacco has been raising concerns relating to its harmfulness to human health. The World Health Organization (WHO) had called upon related countries and passed an agreement of The Framework Convention on Tobacco Control after four years' discussions. The spokesperson of WHO reported that smoking caused the death of 4.9 million people every year. The figure might go up to as much as 10 million annually with in the next 20 years. Meanwhile, he also pointed out that the second hand smoke also has serious harmlessness to non-smokers, especially women and children. In view of such circumstances, there appears numbers of manufacturers to research and exploit it for non-harmful smoking substitute. The worldwide competition of research and development of nonflammable smoking substitutes is severe. However, they are starting the ultimate goal to create the best for human beings.

Recent research studies have proved that more than 4000 constituents in the smoke, and with hundreds of them may cause lung cancer, pneumoconiosis, amyotrophy, asthma, oral cancer, throat cancer, and cardiac system diseases. The scientists of Shenzhen Kangen Technology Co., Ltd had broken through all the technological obstacles and invented atomizing electronic pipe. The brand has been registered and protected by the international

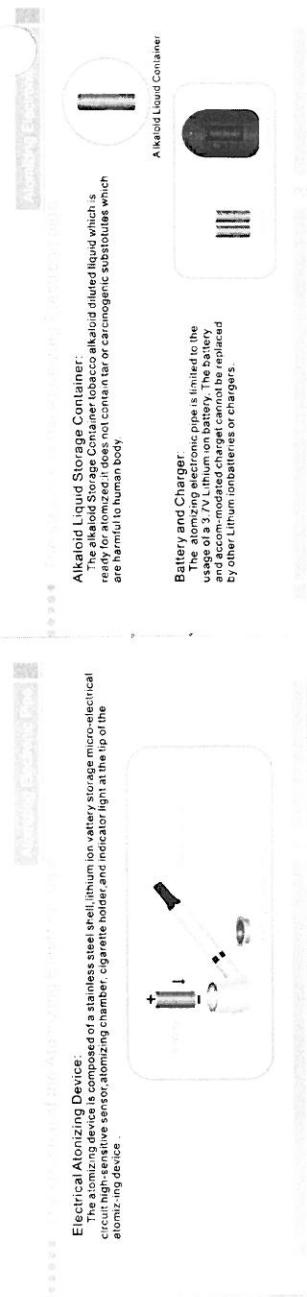
Patent

Patent. The microelectronic control technology and supercritical atomizing method applied to atomizing electronic pipe in extract the high purified tobacco alkaloid liquid, and then atomized into smoke mist. Tobacco alkaloid liquid contains tobacco alkaloid, tobacco essence and normal hot additive. The invention brings us a revolution in the human smoking history. This product not only marked a milestone but also brought good news to all the smokers and those who want to quit smoking. There is no doubt that tobacco damages human health although it had not yet been considered so seriously when it was discovered. We believe that the atomizing electronic pipe can be helpful to those who want to find a way to quit smoking.

The atomizing electronic pipe is a nonflammable atomizing electronic pipe which performs and carries the similar functions and features as the ordinary pipe. It produces a refreshing, heating and bulls the smokers' addiction through the delivery of the sense of satisfaction and relaxation. Besides, the product also carries the functions as a smoke-quitting substitute. The major differences between the atomizing electronic pipe and ordinary pipe are as follows:

1. No tar or other harmful constituents in human body, hence contains no carcinogenic compounds during sminton.
2. No ignition required, hence will not lead to the production of more than 4000 constituents form chemical reaction.
3. No "Second hand smoke" or environmental pollution.
4. No possibility to cause fire. It can be used safety at fire prevention area.
5. According to the smoke-quitting proposal, the target of quitting smoke can be reached non-painfully in a short period of time.

1. No tobacco or ignition. Do not contain tar or other carcinogenic and harmful constituents NO ignition, hence it will not cause any fire disasters.
2. With humanized architecture, simulate the temperature of the emitting smoke between 40°C-50°C.
3. No environmental pollution. The emitted smoke is the atomized mist from tobacco alkali and liquid, hence no harmful second hand smoke.
4. Barrier of the electromagnetic wave. No electromagnetic radiation is allowed.
5. Contains highly purified medical grade tobacco alkaloid and associate with the design of Nicotine Replacement Therapy realize the aim to quit smoking non-painfully.
6. The economic cost of one container is lower than twenty ordinary cigarettes. The special design of the nicotine delivery system can reduce the frequency of smoking and increase the health of smokers.
7. Reduce the frequency of smoking and increase the health of smokers.
8. Recommended temperature range to use this product is set between 5°C and 21°C.
9. Wide areas of application.



Electrical Atomizing Device:
The atomizing device is composed of a stainless steel stainless steel lithium ion battery storage micro-electrical circuit high-sensitive sensor atomizing chamber, cigarette holder and indicator light at the tip of the atomizing device.

Alkaloid Liquid Storage Container:
The alkaloid storage container tobacco alkaloid diluted liquid which is ready for atomized it does not contain tar or carcinogenic substances which are harmful to human body.

Battery and Charger:
The atomizing electronic plate is included in the battery and can be charged by the battery and can be charged by other lithium ion batteries or chargers.



Stand-by Mode.
When the product's instructions, take off the battery storage knob at the top of the pipe to put the lithium ion battery into the battery storage correctly. Please do not use a metal object to connect the positive and negative poles of the battery. Unwrap the atomizing electronic atomizer and liquid container. Pull out the inhaler of the pipe, pull in the liquid storage container with open-side tray in and insert the inhaler, the product will then turn into the stand-by mode.



Operating Electronic Pipe

Functioning Mode.
As soon as the atomizing electronic pipe is inhaled by mouth, the electronic circuit will start to work. The indicator light at the tip of the product will illuminate at the same time. Atomization will stop once the inhaling action ends. When the indicator light is dark obviously, it signifies that the battery should be charged.

Retrieval Operation Mode:

After a product has been used for 20 to 30 days, and with a new atomizing atomizer installed and battery fully charged, it happens that the atomizing quantity reduced evidently, please take out the tobacco alkaloid liquid container. Use a metal object to connect screw with copper pillar; Repath this operation until the indicator light illuminates for ten to twenty seconds. After functions turned, the product can be used normally. However, this operation should not be used frequently.



Precautions:

- Do not place the battery at high temperature area when charging.
- Do not position the battery in reversed polarity direction.
- Do not connect the positive and negative terminal of the battery with metal object in order to prevent short circuit.
- Do not weld the battery directly and pierce with other sharp steel.

Using instructions:

- in case of battery's leakage, batons, and the electrolyte get into the eyes, please do not rub the eyes and wash them with clear water immediately and no to contact for medical treatment.
- If the battery smells burning, charred color deforms or any other unusual case happened during charging, cut off the power supply, and then take away the battery from the device or charger and stop using.

When using the product, if the indicator light becomes dark obviously, the battery should then be charged. If a dark red light appears on the battery, it means the battery has been charged for >4 hours and the red color of the charger's indicator light turns green, take it out and cut off the power supply of the charger.



Using the Battery and Charger can only be used for the Lithium ion battery of the atomizing electronic pipe.

The recommended charger can only be used to charge other battery of similar type.

Please do not attempt to use this charger to charge other battery of similar type.

If the battery is not to be used for a long period of time, take it away from the device or the charger. Keep the battery stored alone in a low temperature and dry area after fully charged.

Warnings: minimal voltage of the battery is 3.7 volts and the maximal rechargeable voltage is 4.2 volts.

1. Ensure the minimal voltage of normal usage is 2.75 volts. There is still tobacco alkaloid liquid in the atomizing alkaloid liquid container, if the atomizing quantity is dropping evidently, then the battery should be charged immediately.

2. The circulatory using frequency of the battery will be no less than 300 times.

4. Only the accommodated battery and charge provided by our company could be used for this product.

5. Verify the polarity of the battery before using, the product must charging.

6. If the battery is not necessary to charge the battery for 12 hours, normal charging time should be 1.5 hours, test less than 3 hours.

7. Atomizing electronic pipe and atomizing tobacco alkaloid liquid should be kept out of reach from children.

8. The nicotine contains in the atomizing tobacco alkaloid liquid should be kept away from oral and nasal cavity.

9. This product is a high technology micro-electrical product. Collision should be avoided.

Atomizing Tobacco Alkaloid Liquid (A.L.I.) is designed according to Nicotine Replacement Therapy (NRT). It helps smokers to quit smoking through the methods which reduce the initial desire. The persons who wish to quit smoking may consider the following steps before:

FOUR STEPS

- Step 1: Starting with the High nicotine oil and use it for six weeks by normal smoking habit;
Step 2: Then switch to the Medium nicotine oil for twelve weeks by normal smoking habit;
Step 3: Then switch to the alternation to the Medium nicotine oil and free nicotine of weeks by normal smoking habit;
Step 4: Finally quit smoking by using the Free nicotine oil for three more weeks.

Appropriate user

1. The people who have been smoking for a long period of time and have hard keeping of smoking.
2. The smoking habits who work in the smokingorden area.
3. The smokers who want to quit smoking can adopt the nicotine reducing method carefully in order to quit smoking in a non-painful way.

Inappropriate User

1. The teenagers.
2. The non-smoking habitants and people who have allergic to nicotine.
3. The patients.
4. The patients who should avoid smoking.

IA 000146

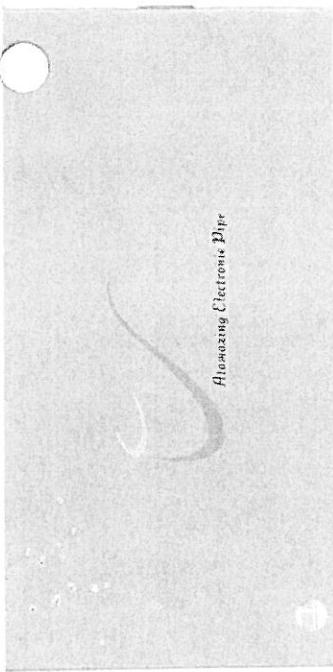
MINI-PIPE

If there are any defects appeared in our product, it should not be handled by non-professionals. The defective product should be returned to our customer service department for repairing (Please refer to the Product Maintenance Card attached with the device for repairing details). If the product defects are caused by human factors instead of normal usage, our company will not be liable for such damages.

The Solutions to the problems:

- 1 When the indicator light becomes dark, please charge a charged battery.
- 2 When the column to atomizing nicotine decreases, please change atomizing alkohol/liquid container or battery.

Atomizing Electronic Pipe



Holographic Electronics Pte Ltd

IA 000147

1-888-SMOKE-51

Fifty-One™

www.Smoke51.com

Join the club and...

Smoke Anywhere!

Even at Surf Expo in the OCCC
Booths 1300N & 1300S



The #1 Premiere
Electronic Smoking Device

No Tar * No Carbon Monoxide * No Pollution * No Flame
IA 000148

No Tobacco... No Tar... No Second Hand Smoke... No Pollution...

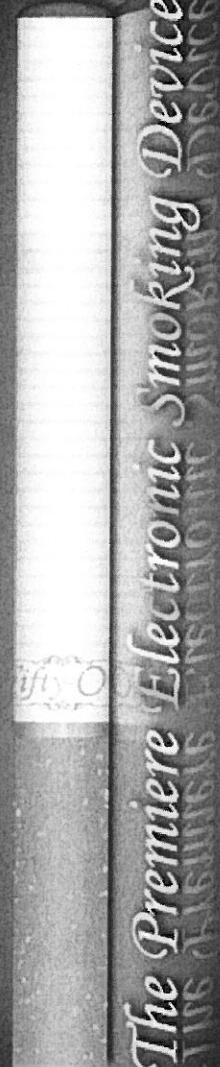
Fifty-One™

www.Smoke51.com

Code: KF51

- (b) (4)
- (b) (4)
- (b) (4)

Smoke Anywhere USA, Inc.



The Premiere Electronic Smoking Device

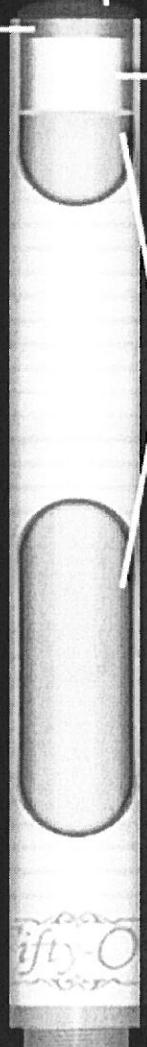
Looks like, Feels like, Tastes like a Cigarette - But it's NOT a Cigarette!

IA 000149

Say No to Second Hand Smoke and Enjoy Your
Smoking Experience Virtually ***Anywhere!***



Operating Mode Sensor



Lithium Ion Battery Smart Chip Controller



Atomization Chamber

IA 000150

Attention: Say No to Second Hand Smoke and Enjoy Your *Smoking* Experience Virtually *Anywhere!*

Looks like a Cigarette...

Feels like a Cigarette...

Tastes like a Cigarette...

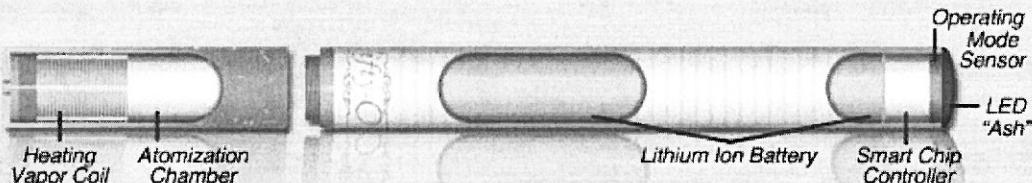
But it's NOT a Cigarette...

1-888-SMOKE-51

Fifty-One™

www.Smoke51.com

Smoke Anywhere USA, Inc. proudly introduces the Fifty-One™ -- a revolutionary electronic smoking device designed as a healthier smoking alternative to traditional tobacco cigarettes. Using advanced technology, the Fifty-One™ allows one the freedom to smoke virtually anywhere, without the flame, ash, tar, or carbon monoxide found in traditional tobacco cigarettes. As the Fifty-One™ is completely free of tobacco, this product likewise does not contain the thousands of harmful chemical compounds and carcinogens typically found in tobacco products. With no offensive second-hand smoke, this smokeless product offers a safer, healthier environment for both the user and the non-smoking community. Simply put, there is no longer a need for anyone to breathe the unwanted, dangerous second-hand smoke produced by traditional tobacco cigarettes.



The Fifty-One™ consists of a two-part unit, including a lithium ion battery and a nicotine cartridge, and it uses high-frequency patented technology to atomize nicotine and produce only a smokeless "vapor". Our cartridges are offered at nicotine levels ranging from 8mg to 0mg, and in a variety of tasteful flavors for a more enjoyable smoking experience.

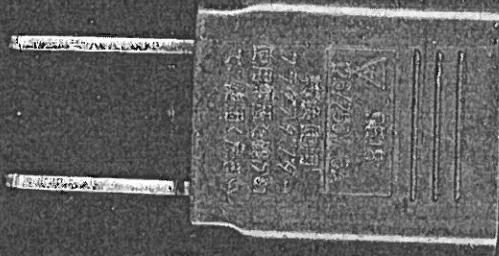
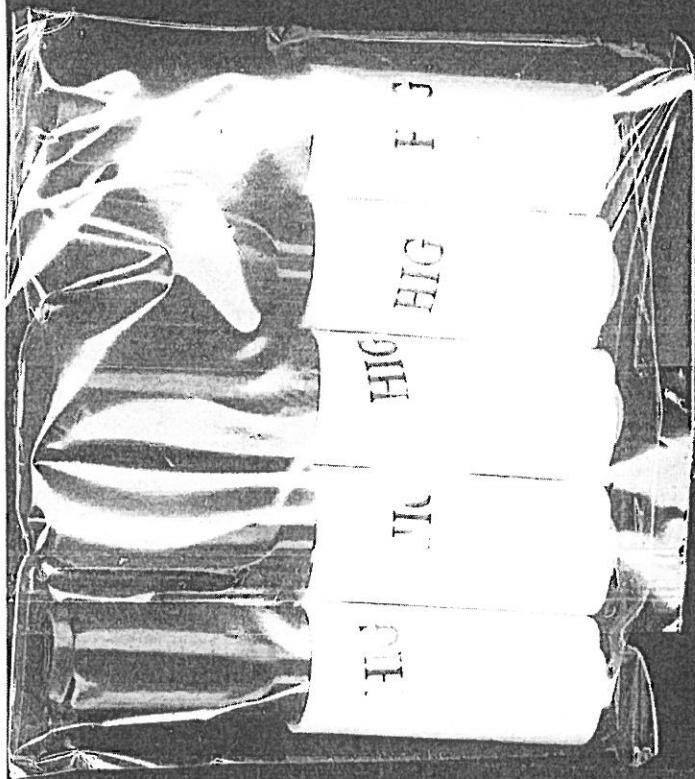
The Fifty-One™ offers all of the nicotine you crave, without the 4,000 plus toxins found in traditional tobacco cigarettes. With countless advantages over traditional cigarettes, this premier electronic smoking device offers both the smoking and non-smoking community a new approach for dealing with the problems associated with harmful second-hand smoking, and allows one to smoke virtually anywhere.

The #1 Premiere Electronic Smoking Device!

Warning: Please note that nicotine is addictive, and Fifty-One™ products have not yet been evaluated by the US Food and Drug Administration. These products are in no way intended to diagnose, treat, cure or mitigate any disease or condition. Refrain from using this product if you are under the legal smoking age in your state, if you are a non-smoker, if you have demonstrated an allergy or sensitivity to nicotine or any combination of inhalants, if you are pregnant or breast-feeding, or if you have heart disease, diabetes, high blood pressure or asthma.

Fifty-One™ is a product of Smoke Anywhere USA, Inc.

IA 000151



IA 000152

ENTRY DATA TAKEN FROM

<input type="checkbox"/> ID Advance Notice	Number (b) (4)
<input type="checkbox"/> Manifest	Date 030409
<input type="checkbox"/> IT Advance Notice	Commercial invoice attached YES

DEPARTMENT OF
HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATIONFiling Date: 03/04/2009
Entered by: [Redacted]Data entry date: 03/04/2009
Entered by: [Redacted](b) 41593771 030409
ENTRY NO. AND DATE

BILL OF LADING NO. (b) (4)	PORT OF LADING: CN	COUNTRY OR ORIGIN CN	PORT OF UNLOADING LOUISVILLE INTL	PORT OF ENTRY LOUISVILLE INTL
BROKERS REF. NO. (b) (4)	C.H. BOX NO.	VALUE OF ENTRY IN U.S. \$ (b) (4)	CONTAINER NO.	IMPORTING VESSEL 5X
FOR THE ACCOUNT OF Consignee SMOKE ANYWHERE 3101 W HALLANDALE BLVD RM STE 10 PEMBROKE PARK FL 33009 U S		IMPORTER OF RECORD (b) (4)	(Name & Address) MANUFACTURER / SHIPPER (Name & Address) (b) (4)	
BROKER (If not same as above)		LOCATION OF LOT (For FDA examination) (b) (4)		DATE AVAIL 030409
Number of items sampled from this entry	Invoice Number	LEAD SAMPLE	PHONE NO.	

3/5 No warehouse scrus

THIS IMPORTATION
MAY PROCEED
Without FDA Examination

This notice does not preclude action should
the merchandise later be found violative

VALID ONLY IF SIGNED

SIGNED _____

FD-45 (Rev. 1-25-85)

(FOR BROKERS USE)
GENERAL DESCRIPTION OF SHIPMENT

QTY.	PACKAGED	ITEMS (Check IND, NTR, FST, AER, or CNT Ind.)
(b) (4)	PCS	LMS 3/4 ELECTRONIC ATOMIZER SAMPLE

IMPORTANT NOTICE — An import shipment must be held intact locally pending further notice from FDA. With the advance notice, or otherwise, Broker or Importer must inform FDA of the following:

1. Earliest date the shipment will be available for sampling.
2. Location in local area of the shipment on that date.
3. Breakdown as shown on the invoice-number and size of units each lot, and \$ value each lot

BROKER: See reverse of last page for instructions on import reporting.

Phone Sheet

CUSTOMER: SMOKE ANYWHERE DATE: 3/4/2009

CONTACT: PHONE:

ENTRY#: (b) 11593771 FAX #:

TRACKING #: (b) (4) LIQUIDATION DATE:

FORMAL/INFORMAL: Informal AB:

COMMENTS

2009-03-04
MFG IS.

(b) (4)

IA 000154

Commercial Invoice

1. 发件公司名称 (Company name) (b) (4)	1. 收件公司名称 (Company name) Smoke Anywhere USA. Inc.
2. 地址 (Address) (b) (4)	2. 地址 (Address) 319 W Hallandale Blvd #100 Pembroke Park, Florida 33099
TEL: (b) (4)	TEL: 786-303-4111
发件人名 (Contact Person): (b) (4)	收件人名 (Contact Person) Kevin

发票号码 Inv. No.	承运人 Carrier
1. 贸易方式 Term of Trade: CIF <input type="checkbox"/> FOB <input type="checkbox"/> CNF <input type="checkbox"/> EXW <input type="checkbox"/> OTHERS <input type="checkbox"/>	
2. 运单号码 Airway Bill No: (b) (4)	日期 DATE:
3. 件数 No. of pieces (b) (4)	Actual/Chargeable WT(kg) ()
4. 体积大小尺寸... 公分 Dimensions:	

详细商品名称 Full Description of goods	数量 No. of Items	单价 USD Items Value	报关总价 USD Total Value For Customs
Electronic atomizer tariff # 8543899795 Material: plastic & stainless steel Atomized product tariff # 3824802800	(b) (4)	(b) (4)	(b) (4)
All item as samples			Total (b) (4) usd

★ 制造商名称和地址 (Name and Address of Manufactory)

★ 此货出口理由 (Reason for Export) Sample

★ 本人认为以上提供的资料属实和正确，货物原产地是 I declare that the above information is true and correct to the best of my knowledge and that the goods are oforigin CHINA

★ 谨代表上述公司 (For an on behalf of the above named company)

签名 Signature (b) (4)

公章 Stamp

(b) (4)

(b) (4)

III. PRODUCT INFORMATION

Certain studies suggest that nicotine may cause addiction in certain users. Should such dependency result, stopping use of the Fifty-One™ Atomizer may cause discomfort and other potentially injurious effects. There have also been certain studies that nicotine may be particularly dangerous to users if used in excess amounts or if ingested or otherwise consumed accidentally or contrary to instructions for use.

The "Fifty One™ Atomizer" is different from the tobacco cigarette in several ways such as being:

1. Non-flammable, without the danger of over 4,000 chemical substances produced by the tobacco cigarette, like carbon monoxide;
2. Less harmful to others and the environment, without producing the danger of "second-hand smoke";
3. Usable in most places where smoking is not permitted, although all local signs and establishment requirements and procedures should be adhered to and complied with.

Ticker, Douglas

From: Budich, Kevin M
Sent: Friday, March 13, 2009 3:52 PM
To: Racke, Merril E
Cc: Verbeten, John E. (ORA); Seaborn, Andrew; Williams, Toniette K; Connelly, Virginia R; Rodriguez, Robert; Huffman, Troy A; Thompson, Teresa C; Rybus, Craig; Levy, Michael; Bormel, Frances Gail; Batista, Huascar R
Subject: FW: Entry number (b) (4)41593771
Attachments: 0903102313.TIF; FW: (b) (4) 41593771; Smoke51_User-Manual.pdf; (b) (4)41593771.pdf

Merril,

I have reviewed the attached labeling and entry documents for Import Entry No (b) 41593771, regarding the product "Fifty-One Atomizer," or "Fifty-One Electronic Cigarette" as it is also named. I have also reviewed the website www.smoke51.com, which is identified in the "User Manual" and on the other labeling that you have provided. According to the labeling and the website, "Fifty-One Atomizer" (or "Fifty-One Electronic Cigarette"), is a nicotine delivery system that is constructed with a rechargeable battery-operated heating element and a replaceable cartridge that contains various chemicals, including nicotine. Nicotine and other chemicals are intended to be volatilized when the user inhales through this product, just as one would when using conventional tobacco-containing cigarettes. In addition, "Fifty-One Atomizer" is intended to heat air as it is drawn through it by the user. This heated air purportedly volatilizes the chemicals contained in the replaceable cartridges. The volatilized chemicals are then inhaled by the user. According to the labeling and the web site, this product is designed to look like and to be used (inhaled) in the same way that a smoker uses conventional cigarettes. And, just like conventional cigarette products, the website states that "Fifty-One Atomizer" (or "Fifty-One Electronic Cigarette") delivers nicotine and other volatilized chemical substances.

The www.smoke51.com website includes the following statements:

"Smoke FIFTY-ONE - Just the Nicotine . . .

10 reasons to quit smoking tobacco and switch to Fifty-One Electronic Cigarette . . . by switching to Fifty-One electronic cigarette, these reasons become irrelevant. Switching to Fifty-One is the easy way out . . .

The Fifty-One will give you your nicotine fix . . .

It's good to quit smoking, I'm all for it. But too many people find it too hard of a task, for these people the Fifty-One electronic cigarette is the best option- best feel, most convenient, best taste, best smoke, best for your health . . .

This revolutionary new way to smoke is called Fifty-One™ electronic cigarette. The electronic cigarette looks like a cigarette and works in a similar way. It gives the smoker the nicotine he craves . . .

Why Switch to Fifty-One Electronic Cigarette? These little gadgets allow you to inhale nicotine without having to deal with the other chemicals that all cigarettes are made of. They're a way to stop smoking and are a great way to get a nicotine fix in a healthier manner . . .

The nicotine cartridges are only \$15 for 5pk [pack] which is equivalent to 10 packs of cigarettes . . .

Unlike a tobacco cigarette, Fifty-One™ delivers only one chemical - nicotine . . .

Here is another email we got from a happy customer join the club by getting your own Fifty-One electronic cigarette.
Nicole,

IA 000157

I just wanted to thank you personally, for all the help you have been. As of 3 weeks this Monday, I have not had a regular cigarette . . . Most importantly, for a smoker of over 20 years your product is absolutely amazing! If it could get me to quit, it could get anyone to quit! I would typically be smoking 1-2 packs a day, and on weekends it could be more as I am out, and bar-hopping . . . Adam, Chief Technology Coordinator . . .

Your body will get the fix it needs and at the same time, your health is not ruined. By using electronic cigarette, you can break the vicious circle that is created by smoking your regular cigarette. You can also stop further nicotine dependency using e-cigarette . . .

When some smokers finally want to quit smoking, they are unable to do so because they have become a victim of nicotine addiction. So, how do we handle these smoking problems? . . . for those who have already given into this habit there is a better smoking alternative. It is called electronic cigarette or electric cigarette. It is a battery operated device that simulates the effects of smoking a real cigarette, including the smoke and flame. It uses an atomizer that is triggered when the smoker inhales, it vaporizes the nicotine fluid present in the cartridge. The electronic cigarette comes in an assortment of Nicotine levels from 0mg to 8mg and flavors including mint, vanilla, chocolate and coffee . . . The cartridge of the e-cigarette has only three ingredients: water, the nicotine you crave, and propylene glycol . . . [m]any people are now opting for E-cigarettes instead of trying to battle with their smoking habit. It is now easier to eliminate the major health risks and still satisfy the nicotine craving . . .

How does the Fifty-One electronic cigarette work? When you inhale, the heating element inside the cartridge atomizes the nicotine solution into a harmless "smoke"-like vapor that you inhale. In the lungs, the nicotine is absorbed quickly, and it satisfies your craving for nicotine . . . The electric cigarette helps curb your smokers cough. In fact, Fifty-One™ can reduce the noticeable respiratory reactions to smoking by a considerable amount . . .

Based on the foregoing, "Fifty-One Atomizer" (or "Fifty-One Electronic Cigarette") and its component parts appear to be intended to affect the structure or function of the body, and to prevent, mitigate, or treat the withdrawal symptoms of nicotine addiction. "Fifty-One Atomizer" (or "Fifty-One Electronic Cigarette") also appears to be drug-device combination products under section 503(g)(1) (21 U.S.C. 353(g)(1)).

Since we are not aware of any data establishing "Fifty-One Atomizer" (or "Fifty-One Electronic Cigarette") as generally recognized among scientific experts as safe and effective for the uses described above and in the labeling, this product appears to be a "new drug," as defined by section 201(p) of the Act (21 U.S.C. 321(p)). "New drugs" require approval of an application filed in accordance with section 505 of the Act (21 U.S.C. 355) to be legally marketed in the United States. "Fifty-One Atomizer" (or "Fifty-One Electronic Cigarette") is not so approved and its marketing in the United States would violate this section of the Act.

"Fifty-One Atomizer" (or "Fifty-One Electronic Cigarette") is also an adulterated device under section 501(f)(1)(B) of the Act (21 U.S.C. 351(f)(1)(B)), because there is no approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act (21 U.S.C. 360e(a)), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act (21 U.S.C. 360j(g)).

Therefore, in accordance with section 801(a) of the Act (21 U.S.C. 381(a)), the marketing of the "Fifty-One Atomizer" (or "Fifty-One Electronic Cigarette") and its component parts appear to violate section **505** of the Act and section **501(f)(1)(B)**, as described above, and we support the District's detention of the referenced import entry citing these violations.

For your information, our assessment of "Fifty-One Atomizer" (or "Fifty-One Electronic Cigarette") and its component parts considered the existing statutes affecting tobacco products, i.e., the Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 15 U.S.C. §§ 1331 et seq., and the Comprehensive Smokeless Tobacco Health Education Act, Pub. L. No. 98-474 (1986), 15 U.S.C. §§ 4401 et seq. Since "Fifty-One Atomizer" (or "Fifty-One Electronic Cigarette") and its component parts do not appear to contain any tobacco leaf or stem, they would not be subject to these statutes.

If you have any questions, or would like to discuss, please let me know.

Kevin

IA 000158

5/7/2009

Kevin M. Budich
Compliance Officer
Food and Drug Administration
CDER/Office of Compliance
Division of New Drugs & Labeling Compliance
OTC Drugs Team
10903 New Hampshire Ave.
WO51-5174
Silver Spring, MD 20993

301-796-3304
kevin.budich@fda.hhs.gov

From: Racker, Merrill E
Sent: Tuesday, March 10, 2009 4:13 PM
To: Seaborn, Andrew; Budich, Kevin M
Cc: Verbeten, John E. (ORA); Williams, Toniette K; Connelly, Virginia R; Rodriguez, Robert; Huffman, Troy A; Rybus, Craig; Thompson, Teresa C
Subject: FW: Entry number (b) 41593771

Kevin

I may have messed this up. The original documents submitted to me where (b) 41593771.pdf with a recommendation for detention based on a label exam "Label examined. Deficiencies noted as follows: potential health issues with the use of the nicotine in an atomized form." This observation was based on the one page of the manual. Instead of asking for more documents I went ahead and set up a detention based on no listing and the product appeared to be an OTC drug nicotine.

the importer has supplied the document "smoke51 User-manual.pdf" the email "FW: (b) 41593771" with attachments of sales literature. The Filer (b) pulled one of the packages and supplied the manual "0903102313.TIF" The Importer is arguing the following points.

Below is the legal information we received & if you notice our intended use is not for smoking cessation & note the corresponding advertising material attached follow the same:

- fda regulates "drugs" largely because they claim to treat a disease or in some other way are intended to affect the body's structure
- while the fda has argued that cigarettes that promote addiction to nicotine promote a change in the body's physiology, to date cigarettes containing nicotine have not been regulated as drugs due to the lack of drug required "intended use" claims
- "cigarettes" by definition do not have to contain nicotine
- "cigarettes" by definition are tobacco products
- what is referred to as an "e-cigarette" is not really a cigarette at all because it does not contain tobacco
- "Tobacco cigarette" manufacturers and importers are subject to a myriad of federal and state regulations
- I would suggest the product not be called a cigarette and that the "claims" made in advertising, etc stay clear of claiming to be any type of treatment or cure for smokers or smoking related maladies -

Merril Racker Ph.D.
Food and Drug Administration
6751 Steger Drive
Cincinnati, OH 45237
Phone 513-679-2700 ext 161

IA 000159

5/7/2009

FAX 513-679-2773
Imports Email ciniimportcomp@fda.hhs.gov
Personal Email merril.racke@fda.hhs.gov

From: (B)(4), (B)(6) [REDACTED]
Sent: Tuesday, March 10, 2009 2:33 PM
To: Racke, Merril E; (B)(4)(b)(6) [REDACTED]
Cc: Huffman, Troy A; Rybus, Craig; Rodriguez, Robert
Subject: RE: Entry number (b) (4) 41593771

Merril,
Please see attached from our hub. They state the box itself has no labeling, but attached is a copy of the manual. Also attached is an email with information and attachments from the consignee.
Thank you,

(b) (4) & (b) (6) [REDACTED]

(b) (4) [REDACTED]
[REDACTED]

ph# (b) (4) & (b) (6)
fax#(b) (4) & (b) (6) [REDACTED]

From: Racke, Merril E [mailto:Merril.Racke@fda.hhs.gov]
Sent: Tuesday, March 10, 2009 2:18 PM
To: (b) (4) & (b) (6) [b] (b) (4) [REDACTED]
Cc: (B)(4)(b)(6) Huffman, Troy A; Rybus, Craig; Rodriguez, Robert
Subject: RE: Entry number (b) 41593771

(b) (4) & (b) (6) [REDACTED]

When the reviewer first did the review he had a copy of what looked like a page from a manual. Please provide me a copy of one of the manuals if they are in the shipment.

Thank you

Merril Racke Ph.D.
Food and Drug Administration
6751 Steger Drive
Cincinnati, OH 45237
Phone 513-679-2700 ext 161
FAX 513-679-2773
Imports Email ciniimportcomp@fda.hhs.gov
Personal Email merril.racke@fda.hhs.gov

IA 000160

5/7/2009

From: (B)(4)(b)(6)
Sent: Tuesday, March 10, 2009 1:13 PM
To: Racker, Merril E; (B)(4)(b)(6)
Subject: RE: Entry number(b) 1593771

Kevin,

I have sent a request for all labeling of the product. Once received I will forward to both parties.
Thank you,

(b) (4) & (b) (6)

(b) (4)

ph# (b) (4) & (b) (6)
fax#(b) (4) & (b) (6)

From: Racker, Merril E [mailto:Merril.Racker@fda.hhs.gov]
Sent: Tuesday, March 10, 2009 12:25 PM

To: kevin

Cc: (b)(4) & (b)(6)

Subject: RE: Entry number(b) 41593771

Kevin

Below is the answer I received from FDA headquarters. Please have (b) (4) submit the labeling for the product.

In order to make a definitive determination of the regulatory status of any product it is necessary that we review a complete description of the product's design, function, its formulation, labeling and promotion (including statements and representations on the Internet), and any other information (e.g., patents) that describe the product's intended uses. In addition, as a matter of policy, we limit communications about the regulatory status of specific marketed products to those responsible for them, and we do not discuss our enforcement actions except with the targets of those actions. Nonetheless, we can make the following general comments:

The "electronic cigarettes" that we have reviewed are drug-device combinations under section 503(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 353(g)(1)) with their "drug" uses, as defined by section 201(g) of the Act (21 U.S.C. § 321(g)), as the primary mode of action. These products contain no tobacco leaf or stem material, but are designed to look like conventional cigarettes. They are intended to be manipulated and used (inhaled) in ways similar to how a smoker manipulates and uses conventional cigarettes. And, like conventional cigarettes, they are intended primarily for the delivery of volatilized chemical substances to affect the body's structures and functions and/or to mitigate or treat the symptoms of nicotine addiction through a chemical or metabolic action on the body. The "electronic cigarettes" that we have reviewed are designed with a rechargeable battery-operated heating element that volatilizes the chemical constituents contained within replaceable cartridges. These cartridges may or may not include nicotine. Thus, the "electronic cigarettes" that we have reviewed are intended for "drug" use. Since we are not aware of any data establishing that such products

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are generally recognized among scientific experts as safe and effective for these "drug" uses, they are "new drugs," as defined by section 201(p) of the Act (21 U.S.C. § 321(p)) requiring approval of an application filed with FDA in accordance with section 505 of the Act (21 U.S.C. § 355) to be legally marketed in the United States. None of these so-called "electronic cigarettes" is covered by an approved NDA. Thus, the marketing of them in the United States is subject to enforcement action.

Furthermore, the "electronic cigarettes" that we have reviewed are not subject to the Federal Cigarette Labeling and Advertising Act (FCLAA), Pub. L. No. 89-92, (15 U.S.C. §§ 1331 et seq), nor are they subject to the Comprehensive Smokeless Tobacco Health Education Act (CSTHEA), Pub. L. No. 98-474 (1986), (15 U.S.C. §§ 4401 et seq). Thus, they do not fit within the regulatory scheme that Congress has established for tobacco products.

FDA has detained and refused several importations of various brands of these "electronic cigarettes" and the agency is continuing to evaluate their regulatory status on a case-by-case basis.

A detailed discussion of the new drug application (NDA) process is available on FDA's Internet Web site at: <http://www.fda.gov/cder/regulatory/applications/default.htm>. The sections of the Act referenced above are also available on FDA's Internet web site at www.fda.gov.

Merril Rache Ph.D.
 Food and Drug Administration
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 Cincinnati, OH 45237
 Phone 513-679-2700 ext 161
 FAX 513-679-2773
 Imports Email cinimportcomp@fda.hhs.gov
 Personal Email merril.rache@fda.hhs.gov

From: (b) (4)
Sent: Monday, March 09, 2009 10:59 AM
To: Rache, Merril E
Cc: '(b) (4)
Subject: Fw: Entry number (b) (4)41593771

Merril,

I went and dug up the emails related to the info we had received for you reference if needed. Not sure if they mean much, but figured they may help.

Look forward to hearing from you,

Kevin

Subject: RE: Smoke Anywhere
 Date: Thu, 20 Mar 2008 14:29:57 +0000

Good morning. This morning I spoke with Ted Ogdahl, Head of fda import operations in Miami....here's his bottom line comments • if its not a food, drink and doesn't cure, treat, diagnose or mitigate any malady, it is not regulated by the fda • the new fda commissioner has publicly stated that he doesn't want the fda to regulate tobacco or nicotine because there would be no way in the world to ever prove these are "safe and effective" as all fda-approved "drugs" must be...accordingly, having them still be legal substances but asking the fda to regulate them as drugs would be impossible and, at least the current commissioner has indicated he doesn't want to go near the issue "with a 10 foot pole"...naturally, congress could always require fda oversight regardless of the obvious problems there would be.

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(b) (4)

[REDACTED]

[REDACTED]

From: [REDACTED]^{(b) (4)}

To: [REDACTED] (b) (4)

Sent: Fri Mar 06 17:31:30 2009

Subject: Entry number [REDACTED] (b) (4) 41593771

(b) (4)

Please see attached FDA Notice of Detention. You will find the FDA Compliance Officer's contact details on page 2, but you can reach him at 513-679-2700 x161 Merril Racke. You will need to reference the entry number. It is listed at the top of both pages top left and is listed as the subject of this email. Please let me know if there is anything I can do to assist.

Thank you,

(b) (4) & (b) (6)

(b) (4)

ph# (b) (4) & (b) (6)
fax#[b] (b) (4) & (b) (6)

IA 000163

5/7/2009

From: (b) (4)

Sent: Tuesday, March 10, 2009 1:17 PM

To: (b) (6)

Cc: (b) (6)

Subject: FW:(b) (4)

Attachments: SMOKE51-CARD-BACK-HR.jpg; SMOKE51-CARD-FRONT (b) (4).jpg;
Smoke51-SalesSheet-011909-F.jpg; SE (b) (4)-101008-REGULAR-SMOKE51-LR.jpg

Dear Christi,

Below is the legal information we received & if you notice our intended use is not for smoking cessation & note the corresponding advertising material attached follow the same:

- fda regulates "drugs" largely because they claim to treat a disease or in some other way are intended to affect the body's structure
- while the fda has argued that cigarettes that promote addiction to nicotine promote a change in the body's physiology, to date cigarettes containing nicotine have not been regulated as drugs due to the lack of drug required "intended use" claims
- "cigarettes" by definition do not have to contain nicotine
- "cigarettes" by definition are tobacco products
- what is referred to as an "e-cigarette" is not really a cigarette at all because it does not contain tobacco
- "Tobacco cigarette" manufacturers and importers are subject to a myriad of federal and state regulations
- I would suggest the product not be called a cigarette and that the "claims" made in advertising, etc stay clear of claiming to be any type of treatment or cure for smokers or smoking related maladies -

(b) (4)

IA 000164

ENTRY DATA TAKEN FROM

DEPARTMENT OF
HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

<input type="checkbox"/> ID Advance Notice	Number (b) (4)
<input type="checkbox"/> Manifest	Date 031309
<input type="checkbox"/> IT Advance Notice	Commercial invoice attached YES

BILL OF LADING NO. (b) (4)	PORT OF LADING HK	COUNTRY OR ORIGIN CN	PORT OF UNLOADING LOUISVILLE INTL	PORT OF ENTRY LOUISVILLE INTL
BROKERS REF. NO. (b) (4)	C/H BOX NO	VALUE OF ENTRY IN U.S.\$ (b) (4)	CONTAINER NO.	IMPORTING VESSEL 5X
FOR THE ACCOUNT OF Consignee (b) (4)		IMPORTER OF RECORD (b) (4)	(Name & Address) MANUFACTURER / SHIPPER (b) (4) (Name & Address)	
		BROKER (If not same as above)		LOCATION OF LOT (For FDA examination) (b) (4)
Number of items sampled from this Entry	Related Sample Numbers	LEAD SAMPLE		DATE AVAIL 031309
				PHONE NO

3618 - DUNS *agent***(b) (4)**

THIS IMPORTATION	
MAY PROCEED Without FDA Examination	
This notice does not preclude action should the merchandise later be found violative.	
VALID ONLY IF SIGNED	
SIGNED _____	FD&R Representative _____ Date _____

(FOR BROKERS USE)

GENERAL DESCRIPTION OF SHIPMENT		
QTY.	PACKAGED	ITEMS (Include FDA Lot No. if applicable)
1	PCS	ATOMIZING DEVICE
<i>663 B 5'44</i>		

IMPORTANT NOTICE — An import shipment must be held intact locally pending further notice from FDA. With the advance notice, or otherwise, Broker or Importer must inform FDA of the following:

1. Earliest date the shipment will be available for sampling.
2. Location in local area of the shipment on that date
3. Breakdown as shown on the invoice-number and size of units each lot, and \$ value each lot

BROKER: See reverse of last page for instructions on import reporting

(b) (4)

INVOICE

CONSIGNEE:

INVOICE NO : (b) (4)

DELIVERY TO : America
DATE : 2009-03-06

(b) (4)

ORDER NO & LINE NO	PART REF NO	DESCRIPTION	QTY (pc)	UNIT PRICE (USD)	TOTAL PRICE (USD)
	KR-808A	GOODS: Atomizing Device Set (U.S Set, include 5 cartridges for free) Atomizing Device Cartridges For KR-808A Set Accessories For Atomizing Device KR-808A Set Atomizer For KR-808A Cases For Atomizing Device Set	(b) (4)	FOB (b) (4)	(b) (4)
		TOTAL			
		FREIGHT			
					(b) (4)

TOTAL: To Door

[Signature]

09.03.11

IA 000166

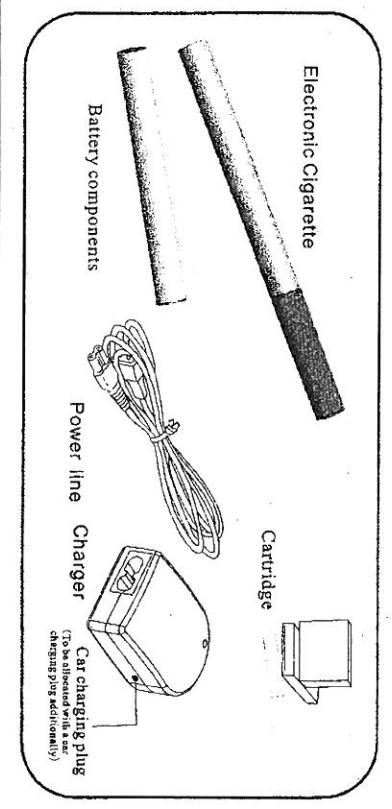
User Manual for Electronic Cigarette

Electronic Cigarette

IA 000167

Product Components

- Congratulations on your beginning to choose a healthy lifestyle. This will also create a healthy and environmental-friendly living space for both you and your family.
- Before you start to use this product, please read this user manual carefully so that its performances can be made best use of and this unit be used in accordance with the requirements herein.
- Please keep this manual properly for future reference.



IA 000168

Catalog

Safety information

01

In order to use "Electronic Cigarette" and its supporting products safely and effectively. Please read through the following information carefully before you start to use, and follow the standard operating procedures strictly.

01

After installing new cartridge and battery components correctly, Electronic cigarette is being to its standby state, Smoking action can be stimulated through sucking the inhaler, old cartridge will have to be replaced by a new one if smoke is reduced. When the power of the dedicated lithium battery is used up, the indicator in front of the cigarette body will flash continuously, At this time, a new dedicated lithium battery assembly will have to be used

04

Please screw the dedicated lithium battery into electronic cigarette's dedicated charger. The charger can work normally with an AC 100V-240V 50/60Hz voltage. To reduce the risk of electric shock, charger should be unplugged from its power source before cleaning it. A charger is forbidden to use outdoors or in a damp environment.

09

Please screw the dedicated lithium battery into electronic cigarette's dedicated charger. The charger can work normally with an AC 100V-240V 50/60Hz voltage. To reduce the risk of electric shock, charger should be unplugged from its power source before cleaning it. A charger is forbidden to use outdoors or in a damp environment.

12

13

15

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Safety Information

Safety information

Do not carry

If you are carrying the "electronic cigarette" with you, please take care of the "electronic cigarette" separately. And any collision or squeeze must be avoided.

"Electronic Cigarette" is a kind of high-tech product and its components are dedicated ones such as cartridge, battery, charger and so on. These components are supplied by manufacturers exclusively. The use of any undedicated components will lead to electronic cigarette's malfunction and the damage of this product.

"Electronic cigarette" will not produce any second-hand smoke to others. It does not cause harm to surrounding people and environment; meanwhile, electronic cigarette does not need to be lit and will not have any fire risk. So it can be used safely in most public places

Do not use it

Please ensure your strict compliance with the relevant laws and regulations of the country or region where you are staying. Be concentrated on driving. And pay attention to road conditions. Do not use "electronic cigarette" while driving and keep your electronic cigarette properly, to avoid any damage to the product caused by collision.

Electronic cigarette should be avoided to use or store, in any hot and/or damp environment.

Do not let children play "electronic cigarette" and its supporting components. Avoid improper operation that may cause damage to this product. "E-cigarette" should be taken care of properly and kept away from children's reach.

When using the "Electronic cigarette", it would be appropriate that the time and frequency of your continuous sucking action should not exceed that of smoking a traditional cigarette in normal times.

Product Introduction

Product Introduction

"Electronic Cigarette"

"Electronic Cigarette" uses advanced microelectronic technology and supercritical physical atomization technology. To atomize the high-purity and exciting nicotine dilution extracted from tobacco into smoke for smokers' sucking and accordingly meet the needs of those smokers. All the nicotine dilution contains nicotine, tobacco flavor and food additives used commonly.

The birth of "Electronic Cigarette" is a revolution of mankind's smoking history. Undoubtedly, its birth brings a gospel to mankind especially the vast smokers and will have extremely far-reaching impact on human being's lifestyle. We believe that "Electronic Cigarette" will certainly be able to eradicate evil tobacco's hazards to human being.

"Electronic Cigarette" is a kind of non-flammable electronic cigarette with similar functions to those of a common cigarette that is to refresh smokers and satisfy their smoking addiction, thus making them happy and relaxed. Electronic cigarette is the best substitute to a common cigarette.

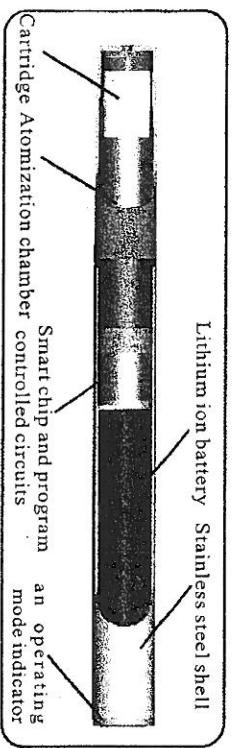
"Electronic Cigarette":

1. Free of tar and other carcinogenic substances harmful to human body;
2. Non-flammable, without the danger of over 4,000 chemical substances produced by the common cigarette;
3. Harmless to others and pollution-free to environment caused by "second-hand smoking";
4. Without the hidden danger of fire accident and can be used in most public places;
5. Wide serviceable range and be able to work normally between -5 degrees to 42 degrees;
6. Humanely designed, similar simulated smoke temperature to body temperature;
7. Shielded electromagnetic, free of electromagnetic radiation;
8. The nicotine content of each liquid container is less than that of 20 ordinary cigarettes. Electronic cigarette is controlled by smart chip in order to let smokers not inhale continuously by this device. It reduces the frequency of use so that smokers can keep health.

“Electronic Cigarette”

Structure of “Electronic Cigarette”

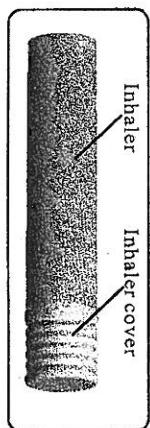
The cigarette body is an integrated structure consisting of stainless steel shell, lithium ion battery assembly, smart chip and program controlled circuits, atomization chamber, cartridge and so on. In the front of it, there exists an operating mode indicator.



The atomization cartridge of an “Electronic Cigarette” is composed of an inhaler and a liquid container. The nicotine dilution to be atomized is stored in this liquid container and is free of ingredients harmful to human body, such as tar and carcinogenic substance.

The inhaler is for one-time-only use.

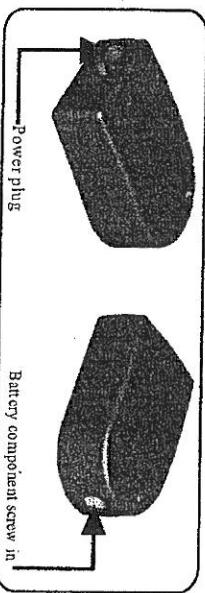
The nicotine content in cartridge is classified into high, medium, low and zero with various tastes to meet the needs of different people.



"Electronic Cigarette"

Charger

"Electronic cigarette" uses a 3.7V special lithium ion battery and the supporting charger is also a special device for this and both battery and charger cannot be substituted by other lithium battery or charger. The input supply voltage of the charger is AC100V~240V 50/60 Hz. It must be paid attention to that whether the rated value of local supply voltage is consistent with that of electronic cigarette's charger.



Power plug

Battery component screw in

Use Methods of "Electronic Cigarette"

Step one:

Step one: unpack the cigarette and remove the inhaler cover of the cartridge.

Step two:

Step two: insert the cartridge into the cigarette body.

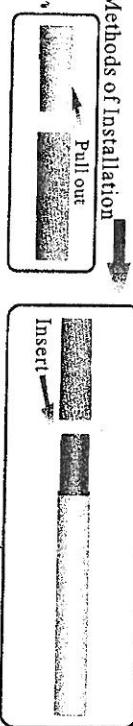
When placing the "Electronic Cigarette" into lips and sucking it, circuit will be activated. And the indicator in front the cigarette body will light up immediately, when inhaling ended, atomization will stop accordingly, and its operating mode changes into standby. The best angle of using this unit is horizontal, and it is not appropriate to use it upwards to prevent any small amount of liquid from flowing into the mouth which may cause stimulation to oral mucositis. The built-in micro-computer controlled programs have self-cleaning function. When accumulated number of "Electronic Cigarette" suction has reached 1,500, the indicator in front of the cigarette body will keep on lighting for 6 seconds, which means that the micro-computer controlled programs are cleaning the unit automatically.

"Electronic Cigarette"

During the use of this unit, If indicator in front of the cigarette body is found to be flashing slowly for consecutive 20 times, it means that the battery may have to be replaced. If you continue to use, the electronic cigarette is not able to work.

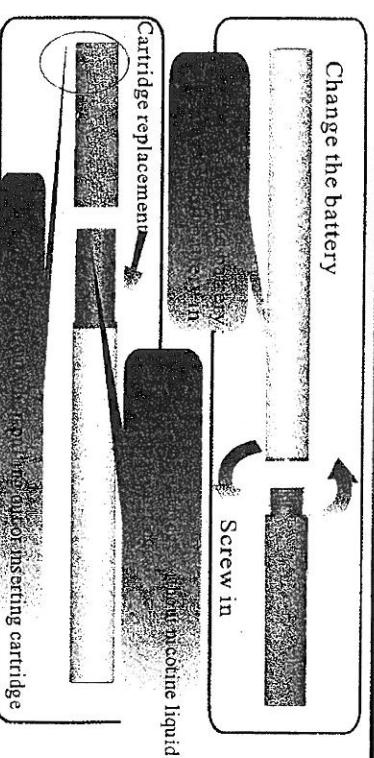
During the use of unit, if smoke is found to be significantly reduced, please replace the cartridge accordingly.

Methods of Installation



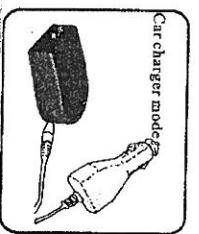
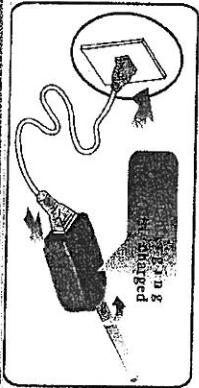
Use Methods

Change the battery



Methods of Charger

During the use of this unit, if indicator in front of the cigarette body is found to be flashing, the accompanying charger or this unit should be used to charge the battery assembly. If you still use it, the electronic cigarette will stop working. When charging, please connect the power cord for the charger and the plug into a socket. Screw the battery into the charger jack for charging 1-2 hours. When the charger indicator will turn from red to green, that means the battery has been fully charged, and please remove the battery and disconnect the power source of the charger accordingly. (The original accessories do not contain the power line of car charger, please buy if you need.)



Cautions

It is prohibited that battery is charged near a high-temp heat source.

It is prohibited that battery is welded directly or pierced by nails or any other sharp objects. If battery is found to be emitting any odor or heat or be discovered or deformed or have any abnormality during charging, please cut off the power source immediately and remove the battery from cigarette body or charger and suspend the use of it.

This charger can only be used to charge electronic cigarette's dedicated lithium ion battery. Do not try to use this charger to charge other kind of battery.

Please keep this "electronic cigarette" and cartridge from the reach of children.

This product can only use the accompanying charger and battery provided by our company. The first charging must be kept for 8 hours and the charging for regular use be kept for 1-2 hours.

Cautions

The nicotine dilution contained in the cartridge of this "electronic cigarette" is prohibited from direct contact with mucositis. No direct entrance to mouth is allowed. It may lead to nicotine dilution by mouth if you used too much suction.

This is a high-tech electronic product and knocking or collision must be avoided.

When sucking it normally, you will hear the slight "ZhiZhi" sound exuded by atomizer. The sound from fever silk atomizing liquid, it is a normal phenomenon. In order to prevent too frequent use of this product, if the cigarette is sucked for consecutive 20 times within one minute, the front indicator will flash for 10 seconds for reminding and electronic cigarette will stop work at the same time. It returns normal after one minute.

If you do not use the electronic cigarette for a long time, please lay the battery and atomizer separately.

Suitability and忌諱

People with long smoking history and suffering from uncomfortable feeling without smoking cigarette.

People working in no-smoking areas for long time but having a habit of smoking

Minors under the age of 18;

People without the habit of smoking;

People allergic to nicotine or any components of inhalants;

Pregnant and breastfeeding women.

Frequently Asked Questions about Electronic Cigarette

Ask: Why does the electronic cigarette have no smoke out when it is used, indicator lights normally and atomizer does work?

Answer: This is because cartridge uses up. It will work normally after replacing new a cartridge.

Ask: When using the electronic cigarette, why does it stop work after indicator flashes for several times?

Answer: The front indicator flashes slowly for 20 times, namely must to replace the battery. If you go on using, the electronic will stop work. After charging the battery it will work normally.

Ask: In the use of electronic cigarette, why does the indicator light and atomizer seem to work after stopping suction actually?

Answer: The electronic cigarette may automatically clean atomizer once in a while so that can guarantee atomizer's atomization effect. If this

Phenomenon occurs frequently in the process of use, that maybe liquid is too much that leads to jam the flow channel. It only needs to remove cartridge, flings the unnecessary liquid with reverse-atomization force.

Then it can uses normally.

Ask: When putting the electronic cigarette on the table or doing outdoor activities with it, I do not suck it. Why does it work itself? Is this dangerous?

Answer: The electronic cigarette is made of extremely sensitive electronic device. Airflow, sound and vibration can activate interior circuit. Please keep away from strong airflow, sound and vibration when it is not used. The electronic cigarette uses low-voltage soft lithium battery-powered. The interior has perfect protection circuit and will not cause danger. However, provided longtime place at the above occasions, will reduce battery's life.

"Customer Inquiry about electronic cigarette"

Ask: Why does the front indicator flash very soon in the use of electronic cigarette? Then it stops work but may use normally after a short time.

Answer: The electronic cigarette's interior has protection circuit. When continuously sucked over than 20 times, it will automatically protect. But it will return normal in one minute.

Cut along the dotted line

For your protection, please complete the following information when you purchase the electronic cigarette. Otherwise, you may not be able to enjoy some warranty and post-sale service.

Customer name:	Telephone:
Address:	
Purchase store:	
Purchase date:	
Invoice No.	

IA 000178

Miller, Andrew R

From: Racke, Merrill E
Sent: Monday, March 23, 2009 7:49 AM
To: Budich, Kevin M
Cc: Seaborn, Andrew; Verbeten, John E. (ORA); Branch, Steven
Subject: (b) 42592525-5

Attachments: (b) 42592525.pdf



(b) 2592525.pdf

Kevin
Another Electronic Cigarette

Manufacturer : (b) (4)

Shipper : (b) (4)

I went ahead and detained the entry based on its similarity to (b) -3567610-3 that we refused earlier. When I looked at the manual it appeared to be the same as the one in (b) -3567610-3 from Mfg: (b) (4).

Merril Racke Ph.D.
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