

Enforcement Report - Details for Event ID 68705

Event Detail

Event ID	68705
Product Type	Food
Status	Ongoing
Recalling Firm	Nuevotanicals
City	Fort Worth
State	TX
Country	US
Voluntary/Mandated	Voluntary: Firm Initiated
Recall Initiation Date	2014-07-01
Initial Firm Notification of Consignee or Public	Letter
Distribution Pattern	Alabama, Arizona, California, Florida, Illinois, Nevada, New York, Ohio, Oklahoma, Oregon, Texas, and Virginia.

Product Detail

Product Description	Code Info	Classification	Reason for Recall	Product Quantity	Recall Number
Enhanced Leaf Powder in Ziploc-type freezer bags in 500 g increments, no product label; Bulk Raw (non-extracted) Kratom Leaf Powder in Ziploc-type freezer bags in 500 g increments, no product label.	All products manufactured since 6/1/2011	Class II	This products contain Kratom.	71 kg	F-2417-2015
Max powder in Ziploc-type freezer bags in 500 g increments, no product label	All products manufactured since 6/1/2011	Class II	This products contain Kratom.	326 kg	F-2416-2015
Green Malay/MDI bulk in 1 gallon plastic jugs, no product label	All products manufactured since 6/1/2011	Class II	This products contain Kratom.	77 kg	F-2415-2015
Kr80m Max2 All-Natural Extraction, Formulation, and Distribution by NUEVOtanicals, LLC Fort Worth, TX 76112, 2 tablets; Kr80m Max5 All-Natural Extraction, Formulation, and Distribution by NUEVOtanicals, LLC Fort Worth, TX 76112, 5 tablets; Kr80m Max10 All-Natural Extraction, Formulation, and Distribution by NUEVOtanicals, LLC. Fort Worth, TX 76112, 10 tablets; Tablets are packed in a round, clear plastic screw-on lid container. Dosage is "1 tablet after a meal", each tablet is "4.20 g Maeng Da leaf equiv".	All products manufactured since 6/1/2011	Class II	This products contain Kratom.	2,066 units	F-2414-2015

Enforcement Reports - Recall Information for Food

Recall information is posted in the Enforcement Reports once the products are classified. When an FDA-regulated product is either defective or potentially harmful, recalling that product—removing it from the market or correcting the problem—is the most effective means for protecting the public.

Recalls are almost always voluntary, meaning a company discovers a problem and recalls a product on its own. Other times a company recalls a product after FDA raises concerns. Only in rare cases will FDA request or order a recall. But in every case, FDA's role is to oversee a company's strategy, classify the recalled products according to the level of hazard involved, and assess the adequacy of the recall.

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PRODUCT VIEW

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Product Description	Code Info	Classification	Reason For Recall	Recalling Firm	Distribution Pattern (Event Location)	Event Details
Kratom (Kr8om) Maeng Da Thai Alkaloid Suspension Oil in 150 mg	All products manufactured since 6/1/2011	Class II	These products contain Kratom	Nuevotanicals	Alabama, Arizona, California, Florida, Illinois, Nevada, New York, Ohio, Oklahoma, Oregon, Texas, and Virginia.	Details
Bizcocho de Queso (Cheese Cake) 10oz	Expiration Date: 8/8/2014 to 11/19/2014	Class I	FDA inspection disclosed product labels with undeclared	AYAA Popcorn Manufacturing Co	Product distributed to local Supermax Supermarket Stores	Details
Rugby Poly Vitamin Liquid, 50ml	UPC: 05368-45080 Lot: 20701407	Class II	Packaging label does not match individual product label. Outside packaging may have incorrect Lot/Exp and product identity.	Pharmatech LLC	NY, IL, TX, UT, MN, AL, CO, CA, WA, VA, MA, AZ, GA, KY, HI, OH, NC, MI, FL, PA, MO, MS, VT, ND, IN, NH, NJ, OR, TN, OK, NE, WI, MO, CT, LA, SC, AR, PR	Details
Carrot Cake 3 oz, 10 oz. and 14 oz.	Expiration Date: 8/8/2014 to 11/19/2014	Class I	FDA inspection disclosed product labels with undeclared milk	AYAA Popcorn Manufacturing Co	All located within CA. No foreign distribution.	Details
Corn Cake 10 oz and 14 oz	Expiration Date: 8/8/2014 to 11/19/2014	Class I	FDA inspection disclosed product labels with undeclared milk.	AYAA Popcorn Manufacturing Co	nationwide to retailers and consumers	Details
Sugar Free Carrot Cake 2 oz	Expiration Date: 8/8/2014 to 11/19/2014	Class I	FDA inspection disclosed product labels with undeclared milk.	AYAA Popcorn Manufacturing Co	651 stores of 1 consignee located in CA (San Diego and Los Angeles area only). No distribution to other states or foreign countries.	Details
Carrot Cake 3 oz, 10 oz. and 14 oz.	Expiration Date: 8/8/2014 to 11/19/2014	Class I	FDA inspection disclosed product labels with undeclared milk	AYAA Popcorn Manufacturing Co	distributed in Montana and Washington.	Details
Corn Cake 10 oz and 14 oz	Expiration Date: 8/8/2014 to 11/19/2014	Class I	FDA inspection disclosed product labels with undeclared milk.	AYAA Popcorn Manufacturing Co	All located within CA. No foreign distribution.	Details
Sugar Free Carrot Cake 2 oz	Expiration Date: 8/8/2014 to 11/19/2014	Class I	FDA inspection disclosed product labels with undeclared milk.	AYAA Popcorn Manufacturing Co	distributed in Montana and Washington.	Details
Carrot Cake 3 oz, 10 oz. and 14 oz.	Expiration Date: 8/8/2014 to 11/19/2014	Class I	FDA inspection disclosed product labels with undeclared milk	AYAA Popcorn Manufacturing Co	All located within CA. No foreign distribution.	Details
Corn Cake 10 oz and 14 oz	Expiration Date: 8/8/2014 to 11/19/2014	Class I	FDA inspection disclosed product labels with undeclared milk.	AYAA Popcorn Manufacturing Co	All located within CA. No foreign distribution.	Details