

# Tainted Products Marketed as Dietary Supplements



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# Overview

- Definition of health fraud
- Tainted products – then and now
- Dietary Supplement Health and Education Act of 1994 (DSHEA)
- Concerns related to tainted products
- Enforcement challenges
- Resources

# FDA Definition of Health Fraud

- The deceptive promotion, advertisement, or sale of products as being effective to diagnose, prevent, cure, treat, or mitigate disease, or to provide a beneficial effect on health, but which have not been scientifically proven safe and effective for such purposes.
- May be deliberate, or done without adequate knowledge or understanding of the product.



# Health Fraud: What are the Risks?

- **Direct health hazard:** product is likely to cause injury, death or other serious adverse effect when used as directed
- **Indirect health hazard:** product poses no direct hazard, but consumer is likely to delay or discontinue appropriate medical treatment by relying on product.



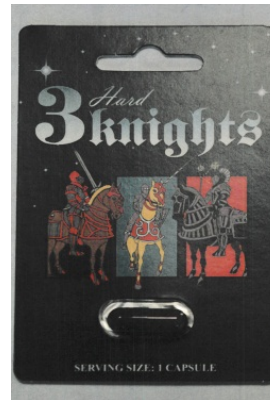
# Tainted Products – Then

- 1865-1906: “Golden age” of American quackery
- 1905 estimate: 50,000 patent medicines
  - Drugs were bought and sold like any other consumer good.
  - Contain dangerous, addictive, misidentified ingredients
  - Alcohol, cocaine, heroin, opium, without restrictions
  - Did not have to disclose ingredients
  - No warnings about misuse
  - Manufacturer not listed



AllPosters

# Tainted Products – Now





# Dietary Supplement Health and Education Act of 1994



- FDA regulates both finished dietary supplement products and dietary ingredients.
- Companies are responsible for evaluating the safety and labeling of their products before marketing
- Dietary supplements are subject to current Good Manufacturing Practices (cGMPs)

# Good Manufacturing Practices

- GMP regulations for dietary supplements published in 2007
- Supplements manufactured in consistent manner and meet quality standards





# Dietary Supplements

Dietary supplements may not contain:

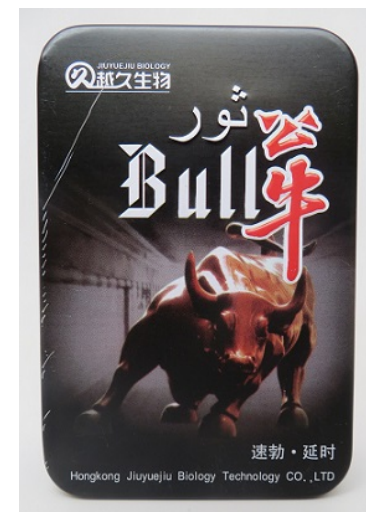
- Banned or controlled substances like sibutramine for weight loss (pulled from U.S. market for cardiovascular complications)  
or
- Bodybuilding drugs like anabolic steroids and their analogues; or aromatase inhibitors – estrogen blockers  
or
- Prescription drugs like sildenafil (Viagra); tadalafil (Cialis); vardenafil (Levitra); or analogs of these drugs;  
or
- Corticosteroids, muscle relaxers, NSAIDs to treat pain or drugs to treat diabetes, hypertension or other conditions.

# Tainted “Dietary Supplements”

- [Tainted Products](#)  
[Marketed as](#)  
[Supplements Database](#)
- Currently >800 products in database
- 42 different APIs identified to date



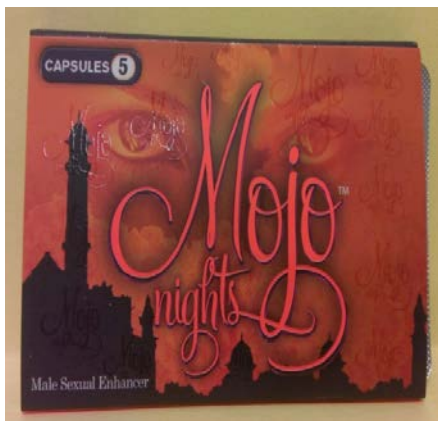
Weight Loss



Sexual Performance

# Dangerous Drug Levels & Combinations for Sexual Enhancement

- May result in dangerous interactions with Rx drugs
- Adulterants often found in high levels of PDE5 inhibitors or combinations of PDE5s or their analogs



### Mojo Nights

- Sildenafil
- Tadalafil
- Vardenafil
- Sulfoildenafilil
- Sulfosildenafilil
- Hydroxythiohomosildenafilil



### Xzen Platinum:

- Tadalafil: >300mg/capsule

# Tainted Sexual Enhancement Products – Something New

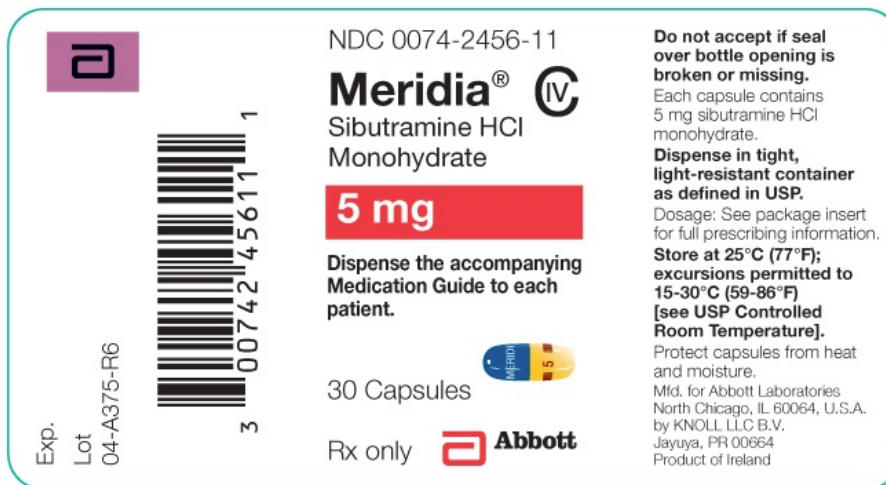






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# Tainted Weight Loss Products- Undeclared Ingredients

- Sibutramine
  - Previously approved in Meridia
  - Removed from the market in 2010
    - Seizure/cardiovascular risks
  - Schedule IV Controlled Substance




 NDC 0074-2456-11  
**Meridia**®   
 Sibutramine HCl  
 Monohydrate  
**5 mg**  
 Dispense the accompanying  
 Medication Guide to each  
 patient.  
 30 Capsules   
 Rx only  **Abbott**

Exp. Lot 04-A375-R6  
 3 00742 45611 1

**Do not accept if seal over bottle opening is broken or missing.**  
 Each capsule contains 5 mg sibutramine HCl monohydrate.  
**Dispense in tight, light-resistant container as defined in USP.**  
 Dosage: See package insert for full prescribing information.  
**Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].**  
 Protect capsules from heat and moisture.  
 Mfd. for Abbott Laboratories North Chicago, IL 60064, U.S.A. by KNOLL LLC B.V. Jayuya, PR 00664 Product of Ireland

# Tainted Weight Loss Products- Undeclared Ingredients



= **lorcaserin**



= **fluoxetine**



# Dangerous Drug Levels & Combinations for Weight Loss

- Bethel 30
  - Sibutramine – 84.2mg/cap
  - Phenolphthalein – 88.9 mg/cap
- [Consent decree](#) – part of DOJ and federal partners Dietary Supplement Enforcement initiative (Nov 2015)

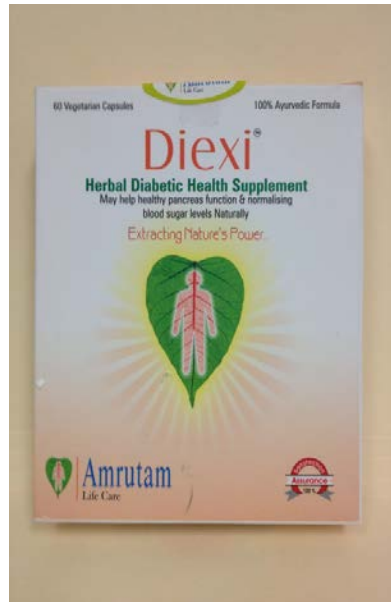


# Other Types of Tainted Products



## Pro ArthMax

- Diclofenac
- Ibuprofen
- Naproxen
- Indomethacin
- Chlorzoxazone
- Nefopam



## Diexi

- Metformin

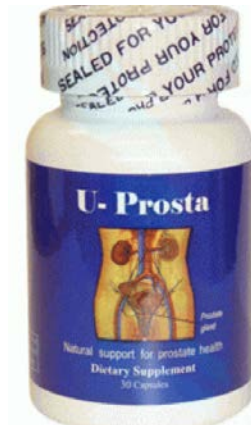
## Products to treat:

- Chronic Pain
- Diabetes
- Hypertension
- High Cholesterol
- Hypothyroidism



## Hydravax

- Triamterene





## U-Prosta

- Terazosin

# Public Notifications

## Medication Health Fraud

### Resources for You

- Sign Up for Email Alerts on Tainted Products Sold as Dietary Supplements 
- Tainted Products That are Marketed as Dietary Supplements RSS Feed 

## Public Notification: A1 Slim contains hidden drug ingredients

 SHARE
  TWEET
  LINKEDIN
  PIN IT
  EMAIL
  PRINT

[10-3-2017] The Food and Drug Administration (FDA) is advising consumers not to purchase or use A1 Slim, a product promoted and sold for weight loss on various websites, including [www.Amazon.com](http://www.Amazon.com), and possibly in some retail stores.

FDA laboratory analysis confirmed that A1 Slim contains sibutramine and phenolphthalein.

Sibutramine is a controlled substance that was removed from the market in October 2010 for safety reasons. This product poses a threat to consumers because sibutramine is known to substantially increase blood pressure and/or heart rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias, or stroke. This product may also interact, in life-threatening ways, with other medications a consumer may be taking.

Phenolphthalein is a chemical that is not an active ingredient in any approved drug in the United States. Studies indicate that it may increase the risk of cancer.

### [Recall Notice](#)

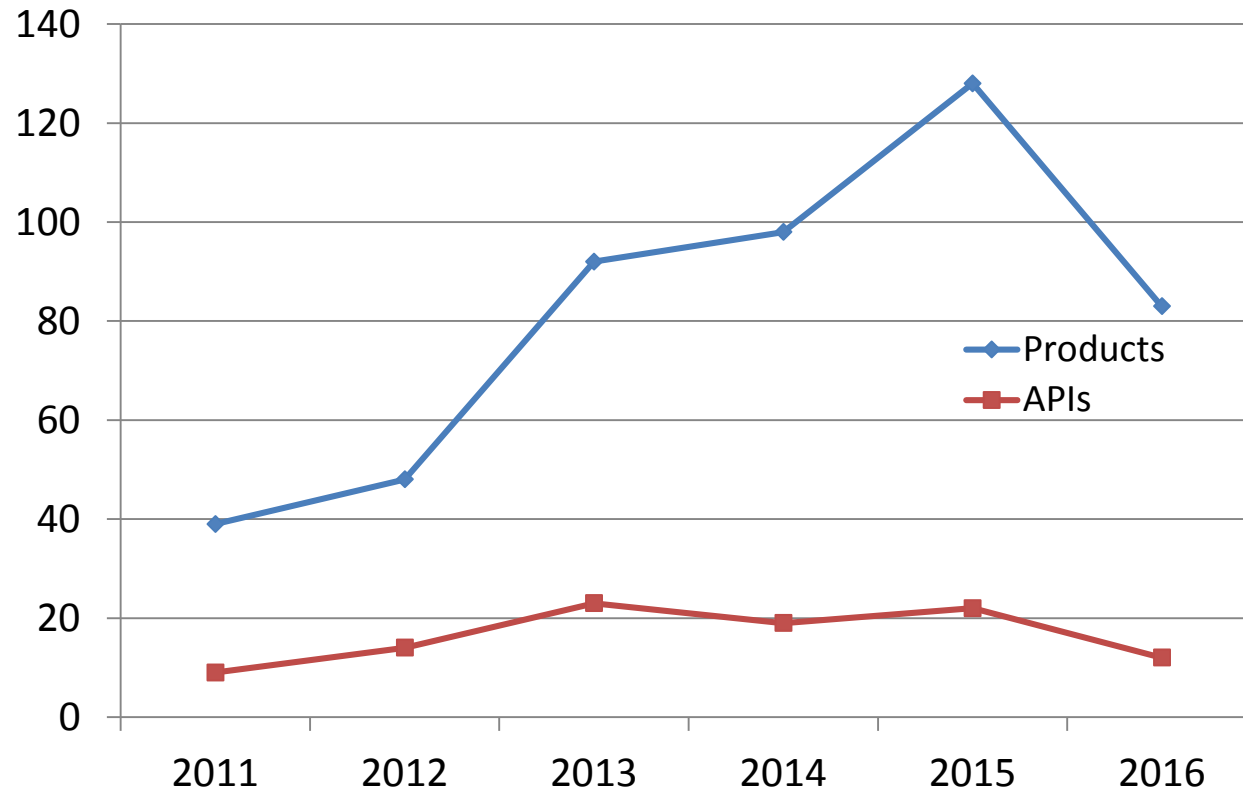
Health care professionals and patients are encouraged to report adverse events or side effects related to the use of this product to FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online [MedWatch Online Voluntary Reporting Form](#), or:
- Download and complete the [form](#), then submit it via fax at 1-800-FDA-0178.

Note: This notification is to inform the public of a growing trend of dietary supplements or conventional foods with hidden drugs and chemicals. These products are typically promoted for sexual enhancement, weight loss, and body building and are often represented as being "all natural." FDA is unable to test and identify all products marketed as dietary supplements that have potentially harmful hidden ingredients. Consumers should exercise caution before purchasing any product in the above categories.



# Products & Active Pharmaceutical Ingredients (APIs) 2011-2016



*Notes the number of products added to the FDA Tainted Product Database and the number of different APIs found in those products*



# Tainted Foods



# Malaysian Coffee - 2017

- FDA warns consumers about health risks of herbal coffee products from Malaysia containing undeclared active pharmaceutical ingredients





# Tainted Cosmetics

- [Skin lighteners and anti-aging creams containing mercury](#)
- [Bentonite Clay cosmetic face mask containing lead](#)
- [FDA Warns Consumers Not to Use Viansilk's "Crema Piel De Seda" \("Silky Skin Cream"\)](#)



Minnesota Dept. of Health  
found this cream to contain  
16,000 ppm mercury



Found to contain lead



Found to contain mercury

# Bodybuilding Products

- Confusing, sometimes made-up names:
  - 19-Norandrosta-4,9-diene-3,17 dione
  - 17 $\alpha$ -methyl-etioallocholan-2-ene-17 $\beta$ -ol
  - 4-hydroxyandrostenedione (4-OHA)
  - 5 $\alpha$ -androstano[3,2-c]pyrazole-3-one-17 $\beta$ -ol-THP-ether
  - Androsta-1,4-dien-3,17-dione
  - 17 $\alpha$ -methyl-4-chloro-androsta-1,4-diene-3 $\beta$ ,17 $\beta$ -diol
  - 2 $\alpha$ ,3 $\alpha$ -epithio-17 $\alpha$ -methyl-17 $\beta$ -hydroxy-5 $\alpha$ -etioallocholane
- Anabolic steroids and their analogues;
- Aromatase inhibitors – estrogen blockers



# Enforcement Challenges



# Unknown Manufacturers and Suppliers



- Distributors - imported products through mail
  - Rapid screening devices to detect presence of active pharmaceutical ingredients
  - Confirmatory lab analysis



# Tainted Products at the International Mail Facility



IMF at JFK Airport, NY



# Tainted Products at the International Mail Facility



IMF at LAX Airport, CA



# Good Manufacturing Practices?



# Widespread Availability of Tainted Products

- Internet – social media & online marketplaces



*"On the Internet, nobody knows you're a dog."*

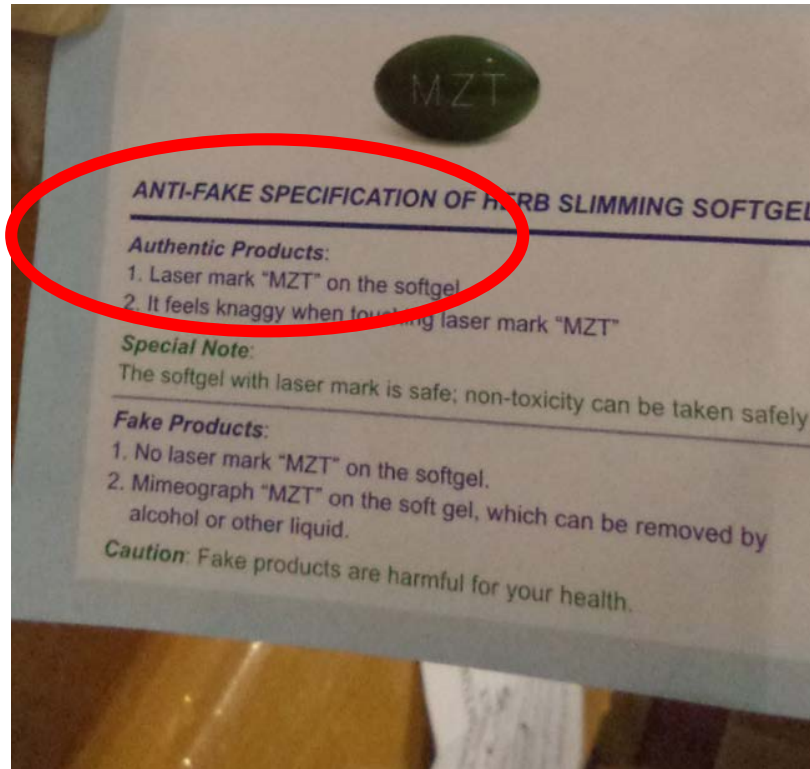


# Various Sellers/Supply Chains

- One product could be collected from different sellers and tested multiple times
- Which one is tainted?



# “Authentic” Tainted Products



# Tainted Products Relabeled Sexual Enhancement



- Xzen Platinum → Xzone Premium after public notification
- Both found to contain over **300mg tadalafil**



# Tainted Products Relabeled Weight Loss



- Bella Vi Insane Amp'd → XCEL
- Found to contain: **sibutramine, phenolphthalein, and fluoxetine**



# Tainted Pain Products Relabeled

## Reumofan → WOW



**2015: Stanley Brower of  
Brower Enterprises indicted**

- Products marketed as supplements claim to treat arthritis, bone cancer, osteoporosis, and more.
- Dozens of serious injuries reported to FDA;
- Contains at least 3 hidden Rx drugs: **dexamethasone, diclofenac, methocarbamol**

# “ Addresses are fake...contacts have simply disappeared.”

## Maker of dangerous pain pills is 'ghost' that can't be found

Alison Young, USA TODAY



A USA TODAY investigation finds that consumers buying Reumofan dietary supplements are trusting their lives to a company that uses fake addresses, lies about ingredients and may not even exist.



(Photo: Alison Young, USA ToDAY)

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GUADALAJARA, Mexico — A Mexican dietary supplement called Reumofan has gained a loyal following in the United States as a "100% natural" treatment for arthritis and joint pain. It's supposedly made by a company called Riger Natural from ingredients such as shark cartilage, white willow and glucosamine, or so the labels say.

### STORY HIGHLIGHTS

- Reumofan dietary supplements contain hidden, dangerous medications
- FDA has received dozens of adverse event reports, including bleeding, strokes and deaths

But consumers who buy Reumofan products are risking dangerous side effects and trusting their lives to a company that uses fake addresses, lies about the ingredients in its products and may not even exist, a USA TODAY investigation has found.

The newspaper set out to find Riger Natural and the people responsible for producing and selling the

# Recalls

- Tainted products almost always a Class I recall
- Almost always voluntary
- FDA oversees company's strategy and assesses adequacy of recall



The FDA announced that Kiriko, LLC is voluntarily recalling all lots of a weight-loss dietary supplement after a laboratory analysis revealed dangerous chemicals and prescription drugs.

The logo for the U.S. Food &amp; Drug Administration (FDA). It consists of a white square containing the letters 'FDA' in blue, followed by the text 'U.S. FOOD &amp; DRUG ADMINISTRATION' in white on a dark blue background.

Kiriko, LLC. Ban hành Quyết định Thu hồi Tự nguyện Toàn Quốc đối với sản phẩm A1 Slim Do có chứa các chất Sibutramine, Phenolphthalein và N-Desmethyl sibutramine Không được Khai báo

# Enforcement Actions

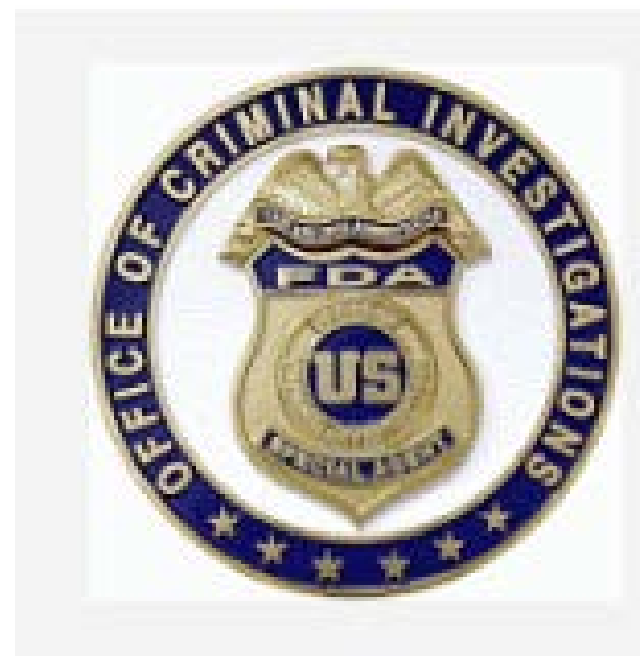
**February 16, 2017: Atlanta Man Convicted of Illegally Importing and Distributing Male Enhancement Products from China**

**April 15, 2015: Owner of Harrisburg Diet Supplement Business Charged with Selling Misbranded Drugs**

**March 26, 2014: Distributor of Dietary Supplements Pleads Guilty in Manhattan Federal Court to Misbranding Weight-Loss Pills**

**March 22, 2017: Diamond Bar Man Pleads Guilty to Smuggling ED Drugs that Were Sold as 'Herbal Enhancement' Products without Prescriptions**

**July 6, 2017: North Olmsted Man Charged with Selling Misbranded Drugs**



# Consumer Outreach

FDA Consumer Health Information  
www.fda.gov/consumer

## Some Bee Pollen Weight Loss Products Are a Dangerous Scam

**P**roducts labeled to contain bee pollen that promise to help you lose weight or reshape your body could actually harm you, warns the Food and Drug Administration (FDA).

Bee pollen is the pollen that bees collect from flowers; it is the food that nourishes bee larvae. But it's not a miracle ingredient, says Garry Coody, R.Ph., FDA's national health fraud coordinator.

Some bee pollen products marketed for weight loss have been found to contain hidden and potentially dangerous ingredients that may be harmful for people who have conditions such as irregular heartbeat, high blood pressure and bipolar disorders (a brain disorder that causes unusual shifts in mood), says Coody.

FDA recently warned consumers to immediately stop using one of these products—Zi Xiu Tang Bee Pollen (<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/saw092163.htm>)—because it contains at least one potentially harmful ingredient that is not listed on the product's label.

Zi Xiu Tang is just one of several bee pollen products that the FDA has found to contain undeclared sibutramine and/or phenolphthalein.



Others include Ultimate Formula, Fat Zero, Bella Vi Amp'd Up, Isane Amp'd Up, Slim Trim U, Infinity, Perfect Body Solution, Asset Extreme, Asset Extreme Plus, Asset Bold and Asset Bee Pollen. All these products marketed for weight loss included bee pollen in the list of ingredients.

The agency has received from consumers and health care professionals more than 50 adverse event reports associated with the use of tainted bee pollen weight loss products. The reports include at least one death, serious cardiac issues, chest pain, heart palpitations,

tachycardia (increased heart rate), increased blood pressure, seizures, suicidal thoughts, anxiety, insomnia and diarrhea.

In addition, many bee pollen weight loss products are marketed as dietary supplements with claims to treat or prevent a variety of diseases and signs or symptoms of disease, including obesity, allergies, high blood pressure and high cholesterol. By law, dietary supplements may not claim to treat or prevent a disease.

"When people buy these tainted bee pollen weight loss products, they are unknowingly taking one or more

1 / FDA Consumer Health Information / U.S. Food and Drug Administration JUNE 2014

FDA Consumer Health Information  
www.fda.gov/consumer

## Beware of Products Promising Miracle Weight Loss

**"T**his year, I'm going to lose some weight."

If you find yourself making this common New Year's resolution, know this: many so-called "miracle" weight loss supplements and foods (including teas and coffees) don't live up to their claims. Worse, they can cause serious harm, say FDA regulators. The agency has found hundreds of products that are marketed as dietary supplements but actually contain hidden active ingredients (components that make a medicine effective against a specific illness) contained in prescription drugs, unsafe ingredients that were in drugs that have been removed from the market, or compounds that have not been adequately studied in humans.

"When the product contains a drug or other ingredient which is not listed as an ingredient we become especially concerned about the safety of the product," says James P. Smith, M.D., an acting deputy director in FDA's Office of Drug Evaluation.

**Tainted Products**

For example, FDA has found weight-loss products tainted with the prescription drug ingredient sibutramine. This ingredient was in an



FDA-approved drug called Meridia, which was removed from the market in October 2010 because it caused heart problems and strokes.

"We've also found weight-loss products marketed as supplements that contain dangerous concoctions of hidden ingredients including active ingredients contained in approved seizure medications, blood pressure medications, and antidepressants," says Jason Humbert, a senior regulatory manager at FDA. Most recently, FDA has found a number of products marketed as dietary

supplements containing fluoxetine, the active ingredient found in Prozac, a prescription drug marketed for the treatment of depression and other conditions. Another product contained triamterene, a powerful diuretic (sometimes known as "water pills") that can have serious side-effects and should only be used under the supervision of a health care professional.

Many of these tainted products are imported, sold online, and heavily promoted on social media sites. Some can also be found on store shelves.

1 / FDA Consumer Health Information / U.S. Food and Drug Administration JANUARY 2015

Bee Pollen Consumer Update also in Chinese:

<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm401795.htm>



# Multilingual Health Fraud Protection Initiative



- “Made in the USA” or “FDA Approved”
- Scammers often target people who prefer to shop at nontraditional places, especially those who have limited English proficiency
- Products advertised in ethnic newspapers, magazines, online, infomercials on radio and TV stations or in ethnic stores, flea markets, and swap meets, which may stock products claiming to be from, for example, Latin America or Asia
- [www.fda.gov/supplementsafety](http://www.fda.gov/supplementsafety)



# Resources

- Health Fraud Scams : [www.fda.gov/healthfraud](http://www.fda.gov/healthfraud)
- Reporting a Tainted Product:  
[TaintedProducts@fda.hhs.gov](mailto:TaintedProducts@fda.hhs.gov)
- Reporting Unlawful Sales of Medical Products on the Internet:
  - <https://www.fda.gov/Safety/ReportaProblem/ucm059315.htm>
- Report Suspected Criminal Activity:
  - [www.fda.gov/oci](http://www.fda.gov/oci)
    - <https://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm>

# Resources

- MedWatch: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)
- Consumer Complaint Coordinators:
  - <https://www.fda.gov/Safety/ReportaProblem/default.htm>
- Multilingual Health Fraud Protection Initiative:  
[www.FDA.gov/SupplementSafety](http://www.FDA.gov/SupplementSafety)



Thank you!