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
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
- Sulfoaildenafil
- Sulfosildenafil
- Hydroxythiohomosildenafil

Xzen Platinum:
- Tadalafil: >300mg/capsule
Tainted Sexual Enhancement Products – Something New
Tainted Weight Loss Products—Undeclared Ingredients

- Sibutramine
  - Previously approved in Meridia
  - Removed from the market in 2010
    - Seizure/cardiovascular risks
  - Schedule IV Controlled Substance
Tainted Weight Loss Products—Undeclared Ingredients

= lorcanerain

= 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

Products to treat:
- Chronic Pain
- Diabetes
- Hypertension
- High Cholesterol
- Hypothyroidism

Pro ArthMax
- Diclofenac
- Ibuprofen
- Naproxen
- Indomethacin
- Chlorzoxazone
- Nefopam

Diexi
- Metformin

Hydravax
- Triamterene

U-Prosta
- Terazosin
Public Notification: A1 Slim contains hidden drug ingredients

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, 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.
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
  – 17α-methyl-etioallocholan-2-ene-17β-ol
  – 4-hydroxyandrostenedione (4-OHA)
  – 5α-androstano[3,2-c]pyrazole-3-one-17β-ol-THP-ether
  – Androsta-1,4-dien-3,17-dione
  – 17α-methyl-4-chloro-androsta-1,4-diene-3β,17β-diol
  – 2α,3α-epithio-17α-methyl-17β-hydroxy-5α-etioallocholane
• Anabolic steroids and their analogues;
• Aromatase inhibitors – estrogen blockers
Enforcement Challenges

THE FDA INSPECTOR IS COMING

SHOW HIM "ALL" OUR DOCUMENTS
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
Various Sellers/Supply Chains

• One product could be collected from different sellers and tested multiple times
• Which one is tainted?
“Authentic” Tainted Products

Authentic Products:
1. Laser mark “MZT” on the softgel.
2. It feels knaggy when touching laser mark “MZT”

Special Note:
The softgel with laser mark is safe; non-toxicity can be taken safely

Fake Products:
1. No laser mark “MZT” on the softgel.
2. Mimeograph “MZT” on the soft gel, which can be removed by alcohol or other liquid.

Caution: Fake products are harmful for your health.

All-Natural Herbal Formula
Supports Active Lifestyle
100% Authentic

Anti-counterfeit

Bee pollen Capsule

Supports Active Lifestyle
100% Authentic
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

- 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

2015: Stanley Brower of Brower Enterprises indicted
“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.

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.

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.
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
Beware of Products Promising Miracle Weight Loss

This year, I’m going to lose some weight...

If you find yourself making this common New Year’s resolution, know that many so-called “miracle” weight loss supplements and foods (including teas and cleanses) 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 harmful active ingredients that make a product effective against a specific disease contained in prescription drugs, such as medications that went in drugs that have been removed from the market or that are not intended for the product’s labeled use.

In addition, many beehive products marketed as dietary supplements with claims to treat a variety of disease, including obesity, allergies, high blood pressure and high cholesterol. Because dietary supplements are unregulated, they may contain harmful substances.

When people buy these claimed weight loss supplements, they are unknowingly taking one or more ingredients containing stimulants, the active ingredient found in Phentermine, a prescription drug used for the treatment of depression and other conditions. Another product contained an interferon, a powerful hormone (paracetamol) that can have serious side-effects and should be used under the supervision of a health care professional.

Many of these products are imported, unlabeled, and heavily promoted on social media. Some can also be found on sale in

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

• [website link]
Resources

• Health Fraud Scams: www.fda.gov/healthfraud

• Reporting a Tainted Product: 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
    • https://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm
Resources

• MedWatch: 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
Thank you!