

FDA Drug Topics: Fraudulent Products – Hidden Ingredients and Unproven Claims in Products Marketed as Dietary Supplements



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Objectives

1. Define the health hazards associated with fraudulent products
2. Identify the product categories where tainted products are most commonly found
3. Describe one of the regulatory challenges associated with fraudulent products
4. Summarize how fraudulent products or adverse events related to such products are reported



Overview

- Introduction to Health Fraud
- Tainted “Supplements”
- Labeling
- Enforcement Challenges
- Consumer Outreach
- Resources



Introduction

FDA Definition of Health Fraud

- Compliance Policy Guide 120.500: 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.



Fraud at the Beginning

- 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



Fraud Now



What are the Risks?



Direct Health Hazard

Product is likely to cause injury, death or other serious adverse effect when used as directed



Product poses no direct hazard, but consumer is likely to delay or discontinue appropriate medical treatment by relying on the product



Indirect Health Hazard



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





Tainted “Supplements”

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 “Supplements”

- Tainted Products
Marketed as Dietary
Supplements Database
 - Over 1000 products in the database
 - Over 50 different APIs identified
- Transitioning to the new Health Fraud
Product Database



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



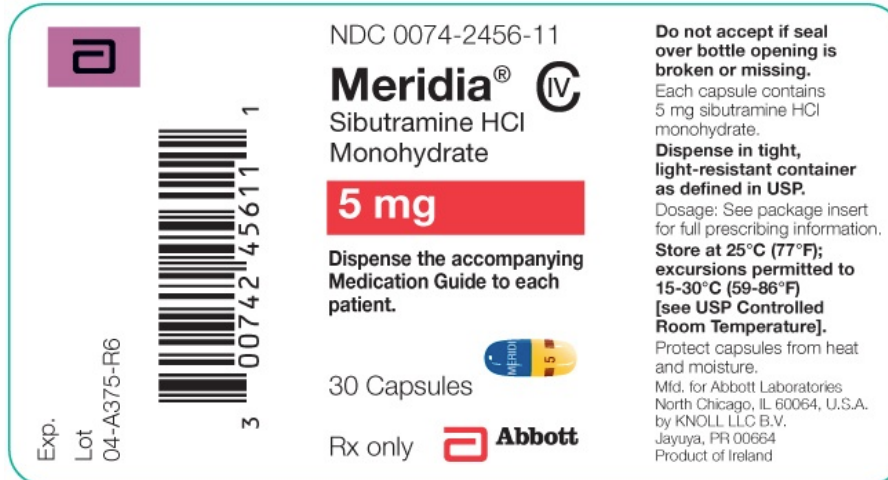
Alpha Male was found to contain aminotadalafil, sulfosildenafil, sulfoildenafil, sildenafil, hydroxythiohomosildenafil, and dimethylsildenafil



Xzen Platinum was found to contain >300mg/capsule of tadalafil


Tainted Weight Loss Products- Undeclared Ingredients


- Sibutramine
 - Previously approved in Meridia
 - Removed from the market in 2010
 - Schedule IV Controlled Substance



Exp. Lot 04-A375-R6


3 00742 45611 1


 NDC 0074-2456-11

Meridia® 
Sibutramine HCl
Monohydrate

5 mg

Dispense the accompanying Medication Guide to each patient.

30 Capsules 

Rx only  **Abbott**

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



Product found to contain
sibutramine and
desisobutylbenzylsibutramine

Tainted Weight Loss Products- Undeclared Ingredients



Lorcaserin

Fluoxetine

DMAA

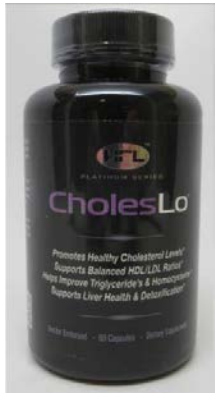


Dangerous Drug Levels & Combinations for Weight Loss

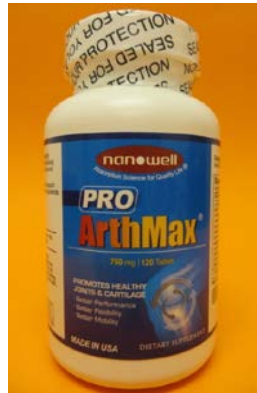
- Bethel 30
 - Sibutramine – 84.2mg/cap
 - Phenolphthalein – 88.9 mg/cap
- [Consent decree](#) – part of DOJ and federal partners Dietary Supplement Enforcement initiative (Nov 2015)



Other Tainted “Supplements”



Lovastatin



Diclofenac

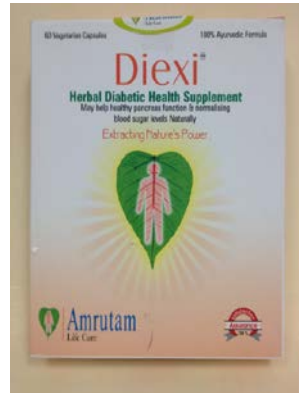
Ibuprofen

Naproxen

Indomethacin

Chlorzoxazone

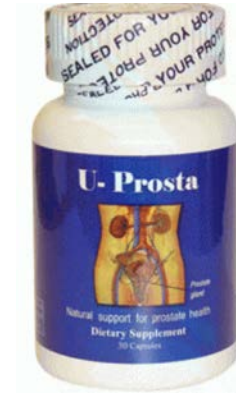
Nefopam



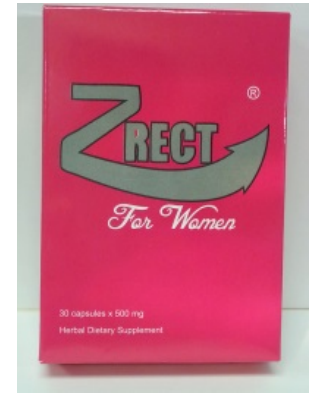
Metformin



Triamterene



Terazosin



Flibanserin

Immediate Public Notifications


Public Notification: X Rated Honey For Men contains hidden drug ingredient

Subscribe to Email Updates | Share | Tweet | LinkedIn | Email | Print

Medication Health Fraud

[7-9-2021] The Food and Drug Administration is advising consumers not to purchase or use X Rated Honey For Men, a product promoted and sold for sexual enhancement on various websites, including www.adameve.com, and possibly in some retail stores.

FDA laboratory analysis confirmed that X Rated Honey For Men contains tadalafil, the active ingredient in the FDA-approved prescription drug Cialis, used to treat erectile dysfunction. FDA's approval of Cialis is restricted to use under the supervision of a licensed health care professional. This undeclared ingredient may interact with nitrates found in some prescription drugs such as nitroglycerin and may lower blood pressure to dangerous levels. People with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates.



Health care professionals and patients should 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 at [MedWatch Online Voluntary Reporting Form](#), or;
- Download and complete the [form](#), then submit it via fax at 1-800-FDA-0178.

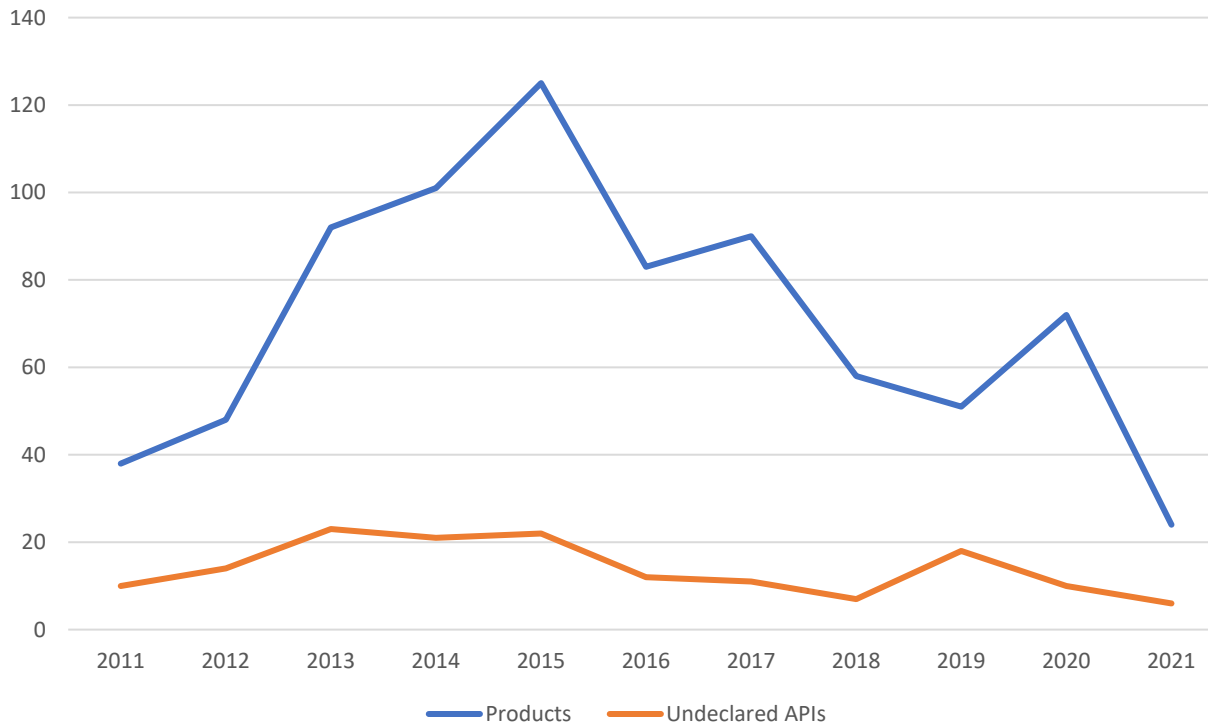
Note: This notification is to inform the public of products marketed as dietary supplements or conventional foods with hidden drug ingredients and chemicals. These products are typically promoted for sexual enhancement, weight loss, or body building and are often represented as being "all natural." FDA 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.

Content current as of: 07/09/2021

Regulated Product(s)
Dietary Supplements
Drugs

Topic(s)
Safety - Issues, Errors, and Problems

“Supplements” and Undeclared APIs



Number of products added to the FDA [Tainted Products Marketed as Dietary Supplements Database](#) and the number of different APIs found in those products

Other Tainted Products





Unproven Claims

Dietary Supplements

- Three categories of permissible claims:
 - nutrient content claims
 - health claims
 - structure/function claims
- Dietary supplements may be considered fraudulent when marketed with claims to prevent, treat, or cure diseases or other health conditions, but are not proven safe and effective for those uses.

Supplements – Opiate Withdrawal

- “#1 Selling Opiate Withdrawal Brand”
- “Safe and effective natural supplements that work to ease many physical symptoms of opiate withdrawal”
- “Break the pain killer habit”
- “Relieve Your Symptoms... addiction, withdrawal, cravings”
- These products are not generally recognized as safe and effective for the referenced uses and therefore FDA considers them “new drugs”



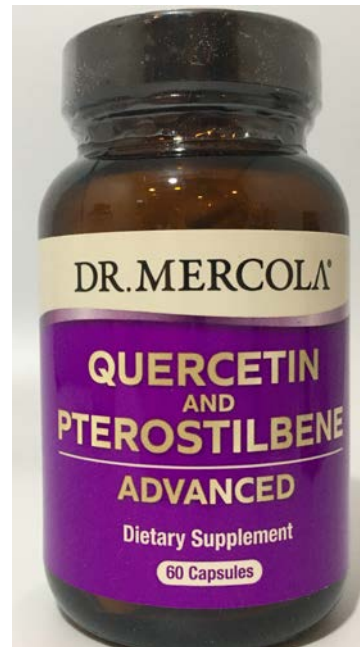
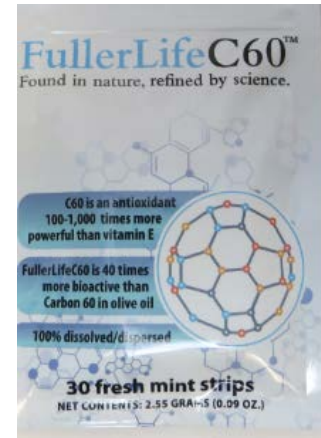
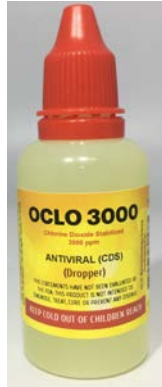
2018 – FDA and FTC take action against companies illegally marketing unapproved products with claims to help with opioid addiction and withdrawal

Ongoing COVID-19 Response: Operation Quack Hack

- Operation Quack Hack was launched in March 2020 to proactively identify and neutralize threats to consumers
- This cross-agency task force manages and coordinates regulatory actions, civil and criminal enforcement to protect consumers from fraudulent medical products during the COVID-19 pandemic



Fraudulent Products – COVID-19



Fraudulent COVID-19 Claims

- Market flooded with various products making unproven claims
- Products are unlawful and put patients at risk

FDA Response

- Conducting ongoing surveillance
- Issued +190 warning letters to firms selling fraudulent COVID-19 products
- Majority of firms stopped selling products or took down claims

Product Examples

- Dietary Supplements
- Bleach
- Colloidal Silver
- Copper
- Honey
- Botanical Oils

Fraudulent COVID-19 Claims

- “When it comes to avoiding coronavirus, there are some herbs that have shown promise. These herbs include: . . . Elderberry”
- “Quercetin was initially found to provide protection against SARS coronavirus in the aftermath of the SARS epidemic ... Now, some doctors are advocating its use against SARS-CoV-2...”
- “Simple Silver (Colloidal Silver) with ionic solubility technology is a dietary supplement that has ionic solubility that may supports the Immune system ability to fight off and kill nasty pathogens that can cause illnesses inside and outside the body such as: CORONAVIRUS (COVID-19) . . . Ideal for dedicated health care professionals working with Covid-19 patients . . .”



Enforcement Challenges

Tainted Products at the International Mail Facility

- 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

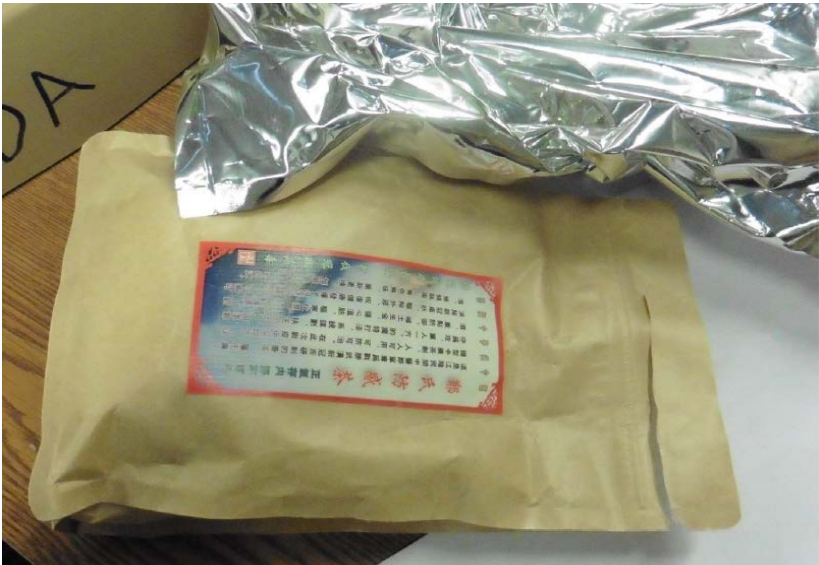


IMF at LAX Airport, CA

Imported COVID-19 Products



“COVID-19 Protection Blend”



Herbal tea claiming to “Fight/overcome Wuhan Corona Virus”

Good Manufacturing Practices?



Widespread Availability of Tainted Products



Warning about Tainted Products Sold through Online Marketplaces

FDA Warns Consumers to Avoid Certain Male Enhancement and Weight Loss Products Sold Through Amazon, eBay and Other Retailers Due to Hidden, Potentially Dangerous Drug Ingredients

Agency Urges Online Marketplaces, Other Websites and Retailers to Stop Selling These Male Enhancement and Weight Loss Products to American Consumers

[f Share](#) [t Tweet](#) [in LinkedIn](#) [✉ Email](#) [🖨 Print](#)

For Immediate Release: December 17, 2020

On July 26, 2021, the FDA issued an [untitled letter](#) to notify Amazon about its distribution of sexual enhancement and weight loss products in violation of the Federal Food, Drug, and Cosmetic Act. The FDA continues to find potentially dangerous products available for purchase and urges stores, websites, and online marketplaces, including Amazon, to stop selling these potentially dangerous products. The FDA will continue to alert the public when products and companies place consumers' health at risk.

[Español](#)

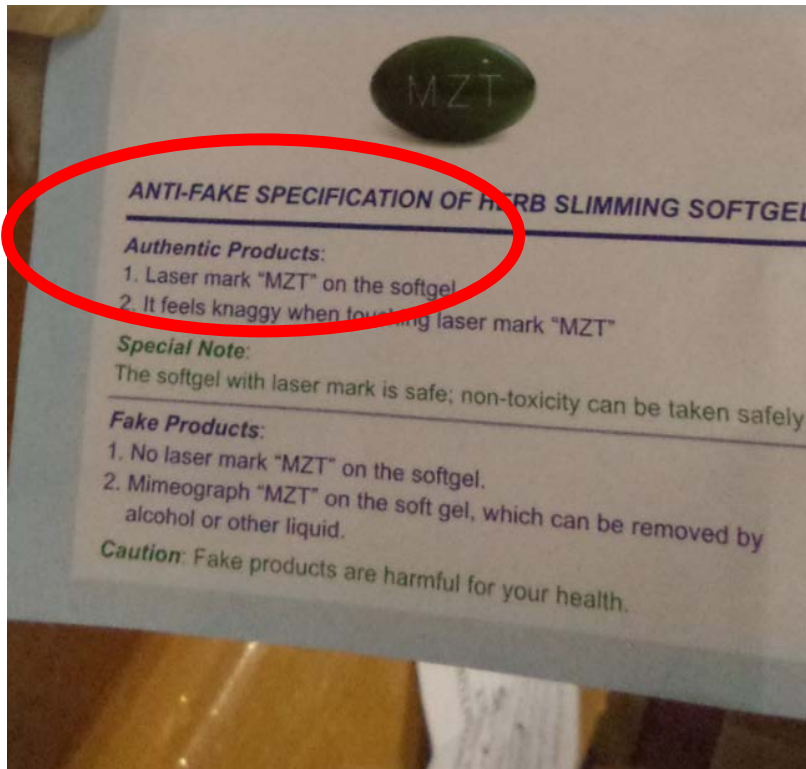
The U.S. Food and Drug Administration is warning consumers not to use nearly 50 [male enhancement](#) or [weight loss](#) products that have been found to contain hidden ingredients and may pose a significant health risk. The FDA purchased these products on Amazon and eBay and agency testing found that the products contain active pharmaceutical ingredients not listed on their labels, including some with ingredients found in prescription drugs. These products may cause potentially serious side effects and may interact with medications or dietary supplements a consumer is taking.

Various Sellers/Supply Chains

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



Various Sellers/Supply Chains



Tainted Products Relabeled – Weight Loss



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

Tainted Products Relabeled – Sexual Enhancement



Since 2007, FDA has identified over 30 products marketed with variations of the name “Rhino” that contained undeclared API(s).



Tainted Products Relabeled – Pain Relief



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**

Reumofan Investigation



NEWS

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

Alison Young USA TODAY

Published 6:06 a.m. ET Sept. 25, 2013 | Updated 11:23 a.m. ET Sept. 27, 2013

Story Highlights

- Reumofan dietary supplements contain hidden dangerous medications
- FDA has received dozens of adverse event reports including bleeding strokes and deaths
- Product labels say Reumofan is made in Mexico by Riger Natural but the company may not exist
- Some Reumofan pills are stamped with an M logo that is the same as one used by Laboratorios Marcel

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.

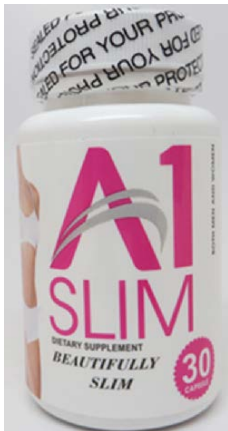
But consumers who buy Reumofan products are risking dangerous side effects and trusting their lives to a company that uses fake addresses, lies about the ingredients in its products and may not even exist, a USA TODAY investigation has found.

The newspaper set out to find Riger Natural and the people responsible for producing and selling the supplement, searching corporation records and visiting addresses in Mexico where it had been listed on the Web as having a lab. Those addresses are fake and there's no evidence the company ever had facilities in the locations. Some Mexican retailers who once distributed the product say their contacts have simply disappeared. Even Mexican health authorities have been unable to track down the company.



Recalls

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



Kiriko, LLC. Issues Voluntary Nationwide Recall of A1 Slim Due to Undeclared Sibutramine, Phenolphthalein and N-Desmethyl Sibutramine

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



Coronavirus (COVID-19) Update: Federal judge enters temporary injunction against Xephyr LLC doing business as N-Ergetics, preventing sale of Colloidal Silver Products for COVID-19

U.S. FDA
@US_FDA

A federal court granted a motion for default judgment & permanent injunction against Xephyr LLC dba N-Ergetics, Derrill Jinks Fussell & Linda Sue Fussell for violating federal law by distributing their colloidal silver products to prevent/treat #COVID19.

District Court orders permanent injunction against companies selling sexual enhancement products containing undisclosed drugs



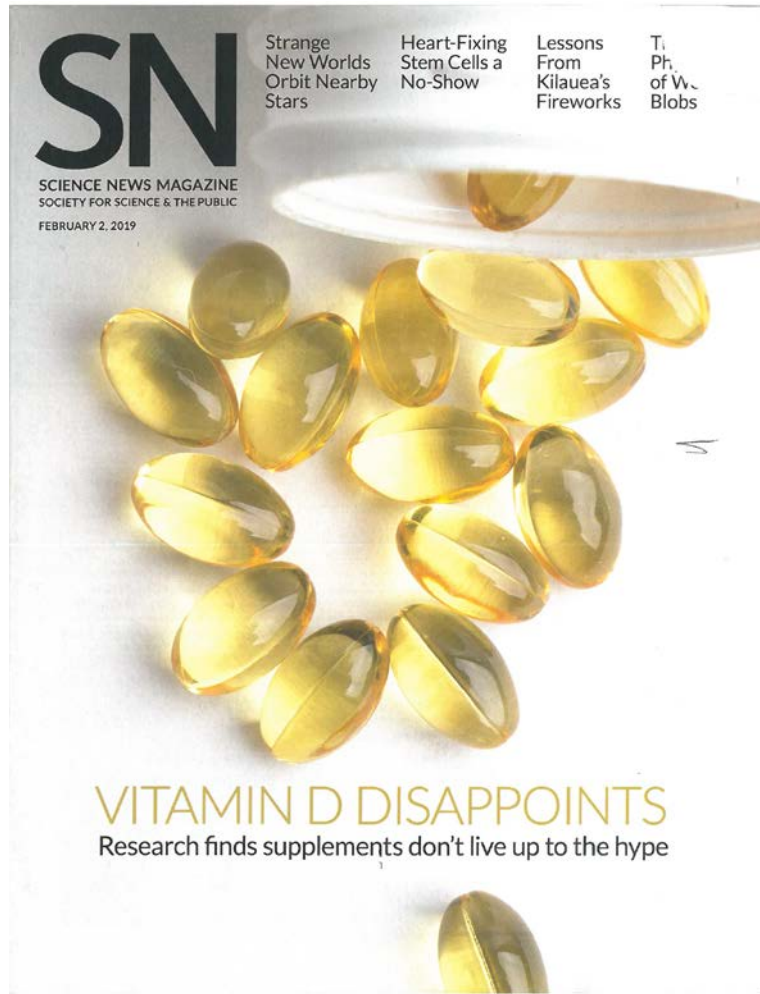
Former Naturopath Charged Criminally for Trafficking in Misbranded Drugs Claiming They Could Prevent COVID-19



THE UNITED STATES
DEPARTMENT of JUSTICE

Owner of Pennsylvania Diet Supplement Business Sentenced to 30 Months Imprisonment for Selling Misbranded Drugs as Weight Loss Products over the Internet

Science v the Internet



Health Benefits of Vitamin D



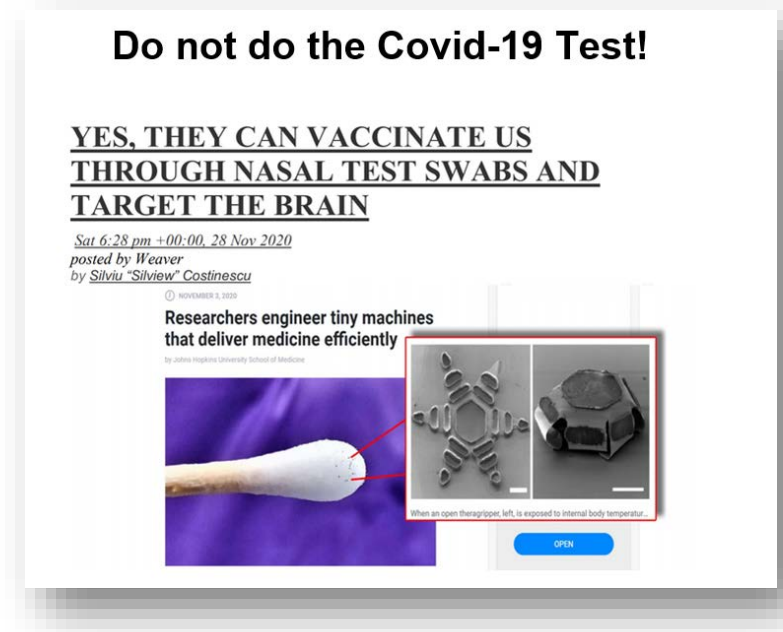
Why is vitamin D so important?

One reason is that it helps maintain normal blood levels of calcium and phosphorus – and that's good for our bones! Therefore, it decreases our chances of fractures, and developing osteoporosis. Studies have even shown that maintaining optimal levels of **vitamin D can reduce the risk of 16 different types of cancer!** How? By slowing down the production of cancer cells and preventing the formation of new ones.

Vitamin D can help reduce the risk of diabetes, decrease chronic inflammation, lower high blood pressure and lower your risk for Alzheimer's disease.

“Infodemic of Disinformation”

- WHO, professional organizations, academic researchers: Beware of the impact of **disinformation**
 - “Digital Superspreaders”
 - Most common on social media including new platforms, podcasts, streaming events, microblogs, emailed newsletters
 - Misinformation often accompanied with sales for unapproved products





Consumer Outreach

Consumer Outreach

- “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



Consumer Outreach

- [Health Fraud Product Database](#)
- Drug Alerts
- Import Alerts
- Press Announcements
- Consumer Updates
- Social Media
- www.fda.gov/healthfraud



FDA_ORA @FDA_ORA · Jan 31

#FDAORA issues advisory letter to Gallbladder Attack for using website to market unapproved drugs making false claims to treat or prevent many diseases, including dementia, cancer, Alzheimer's: go.usa.gov/xnpzY #healthfraud



FDA_ORA @FDA_ORA · Jan 25

Trying to lose weight this New Year? Some bee pollen products marketed as #dietarysupplements for #weightloss can be tainted w/drugs. #FDAORA has received 50+ adverse event reports associated w/the use of these products. LEARN MORE: go.usa.gov/xnNcs #healthfraud



Online Reporting System

Reporting Unlawful Sales of Medical Products on the Internet

SHARE | TWEET | LINKEDIN | PRINT | EMAIL | PRINT

[What should I report on this form?](#)

Did you experience a serious reaction or problem with the use of a product?

- Yes. Please fill out [FDA's MedWatch reporting form](#). (Also contact your health professional for medical advice.)
- No. Continue with this form. ([En Español](#))

* Indicates Required information

***About the Product/Problem**

*** Name of Product**

*** Tell us what happened (include as many details as possible)**

Total of 4000 characters allowed. You have 4000 left.

*** Where did you find this product? (Select ALL that apply)**

*** Date found?**

<input type="checkbox"/> Website Website details	<input type="checkbox"/> Phone Call Phone Call details
<input type="checkbox"/> Social Media Social Media details	<input type="checkbox"/> TV/Infomercial TV/Infomercial details
<input type="checkbox"/> Email Email details	<input type="checkbox"/> Other Other details
<input type="checkbox"/> Retail Store Retail Store details	<input type="checkbox"/> Product from outside the USA Country



Resources and References

Resources

- Health Fraud Scams : www.fda.gov/healthfraud
- Health Fraud Product Database:
<https://www.fda.gov/consumers/health-fraud-scams/health-fraud-product-database>
- Fraudulent Coronavirus (COVID-19) Products:
<https://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products>
- Medication Health Fraud:
<https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/default.htm>
- Multilingual Health Fraud Protection Initiative:
www.FDA.gov/SupplementSafety

Resources

- Reporting a Tainted Product: TaintedProducts@fda.hhs.gov
- Reporting Unlawful Sales of Medical Products on the Internet: <https://www.fda.gov/safety/report-problem/reporting-unlawful-sales-medical-products-internet>
- Report Suspected Criminal Activity: www.fda.gov/oci
 - <https://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm>
- MedWatch: www.fda.gov/MedWatch/report.htm
- Consumer Complaint Coordinators: <https://www.fda.gov/Safety/ReportaProblem/default.htm>

References

1. FDA, FTC warn companies for selling illegal, unapproved opioid cessation products using deceptive claims <https://www.fda.gov/news-events/press-announcements/fda-ftc-warn-companies-selling-illegal-unapproved-opioid-cessation-products-using-deceptive-claims>
2. FDA, FTC Warn 10 Companies Illegally Selling Dietary Supplements Claiming to Treat Diabetes: <https://www.fda.gov/news-events/press-announcements/fda-ftc-warn-10-companies-illegally-selling-dietary-supplements-claiming-treat-diabetes>
3. FDA Warns Consumers to Avoid Certain Male Enhancement and Weight Loss Products Sold Through Amazon, eBay and Other Retailers Due to Hidden, Potentially Dangerous Drug Ingredients: <https://www.fda.gov/news-events/press-announcements/fda-warns-consumers-avoid-certain-male-enhancement-and-weight-loss-products-sold-through-amazon-ebay>
4. FDA warns consumers to avoid Rhino male enhancement products found at retailers because of undeclared and potentially dangerous drug ingredients: <https://www.fda.gov/news-events/press-announcements/fda-warns-consumers-avoid-rhino-male-enhancement-products-found-retailers-because-undeclared-and>
5. FDA Warns Companies Illegally Selling Hangover Remedies: <https://www.fda.gov/news-events/press-announcements/fda-warns-companies-illegally-selling-hangover-remedies>
6. Label Claims for Conventional Foods and Dietary Supplements: <https://www.fda.gov/food/food-labeling-nutrition/label-claims-conventional-foods-and-dietary-supplements>

References

7. Operation Quack Hack: <https://www.fda.gov/news-events/fda-voices/fda-protects-patients-and-consumers-fraud-during-covid-19>
8. Unproven Infertility Supplements: <https://www.fda.gov/consumers/health-fraud-scams/unproven-infertility-supplements>
9. Unproven Alzheimer's Disease Products: <https://www.fda.gov/consumers/health-fraud-scams/unproven-alzheimers-disease-products>
10. Some Imported Dietary Supplements and Nonprescription Drug Products May Harm You: <https://www.fda.gov/consumers/consumer-updates/some-imported-dietary-supplements-and-nonprescription-drug-products-may-harm-you>
11. Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency's new efforts to strengthen regulation of dietary supplements by modernizing and reforming FDA's oversight: <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-agencys-new-efforts-strengthen-regulation-dietary>
12. Watch Out for False Promises on Some Dietary Supplements:
13. <https://www.fda.gov/consumers/consumer-updates/watch-out-false-promises-some-dietary-supplements>

