

FDA Drug Topics: Fraudulent Drugs: You're Taking What?

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“Scientific literacy is an intellectual vaccine against the claims of charlatans who would exploit ignorance.” – Neil Degrasse Tyson



Learning Objectives

Recognize various categories of commonly used, unapproved drugs sold directly to patients.

Identify and anticipate scenarios where a patient may resort to risky products.

Discuss where patients may encounter fraudulent unapproved products.

Locate where to find helpful resources related to fraud on www.fda.gov.

What is Drug Fraud?

- Fraud drugs are drugs that are marketed with unproven, false, or misleading claims about the products' ability to diagnose, mitigate, treat, or prevent diseases or conditions, or to affect the structure or function of the body.
- FDA has both civil and criminal authority over companies and individuals that market drug products.
- Selling fraudulent drugs is a violation of federal law. These drugs are typically considered “unapproved new drugs” and “misbranded drugs” under the U.S. Food, Drug, and Cosmetic Act.
- FDA frequently works with the U.S. Federal Trade Commission (FTC) on nonprescription drug advertising, and Customs and Border Patrol (CBP) on imported drugs.



The Marketplace – What We’re Up Against

- As of May 2024, there were 142,091 drugs listed and over 10,000 firms registered in FDA’s electronic Drug Registration and Listing System (eDRLS). Fraud drugs are generally not registered and listed with FDA, but they can be.
- A drug can be masquerading as a dietary supplement, cosmetic, device, tobacco product, food, bath salt, aromatherapy, potpourri, liquor, research chemical, and the list goes on.
- Products can be distributed in so many different contexts:

Major drug chains

Social Media

Online marketplaces

International grocery stores

Health food stores

Healthcare practitioner offices

Dark Web

Smoke shops

Convenient stores

Flea markets

Individual online stores

Multi-level marketing companies

Online pharmacies

Farmer’s markets

TV informercials

Door to door

Mail order

Animal feed stores

Political campaigns

Beauty shops

Salons

Online Marketplaces

- Online marketplaces are e-commerce websites that sell primarily products listed by third parties. Some of these e-commerce websites also sell their own brand products.
- Popular examples: Amazon, Walmart, eBay, and Etsy
- FDA has issued warning letters to some marketplaces for failing to adequately police unapproved new drugs.
- Where did the drug come from? Where was it stored? Can anyone sell anything? Who is overseeing it?
- Beware of counterfeits and look-alikes!





How Does FDA Prioritize Action?

Types of Harm

Direct Harm → use of a fraudulent product results in injuries or adverse reactions.

Indirect Harm → product itself does not cause harm but its use may keep someone away from proven, sometimes essential, medical treatment.

Can FDA Stop All Fraud?

- NO – not even close. We need your help spreading information.
- While FDA remains vigilant against health fraud, many fraudulent products escape regulatory scrutiny, maintaining their hold in the marketplace.
- How do we attempt to rein in fraud products?
 - Outreach - Press releases and fda.gov
 - Inspections
 - Warning letters
 - Recalls - but no mandatory recall authority
- If companies do not voluntarily comply, FDA refers cases to DOJ.
 - Seizures
 - Injunctions
 - Criminal prosecution

1. Quick Cures

Scenario

Patient learns about a concerning disease diagnosis.

Patient Response

Patient may immediately go online to find treatments. Some may sound quick, painless, and safe. There is great temptation to jump at anything that appears to offer a chance for a quick cure without the potential side effects of approved treatments.



1. Quick Cures

Cancer Cures

- Can come in many forms: capsules, powders, creams, injectables, teas, and oils
- Watch out for:
 - Skin cancer removal creams, often called black salves or drawing salves
 - Laetrile/Amygdalin (apricot pits)
- Claims such as:
 - Treats all forms of cancer
 - Shrinks malignant tumors
 - More effective than chemotherapy
 - Attacks cancer cells, leaving healthy cells intact



1. Quick Cures

Black Salves – Skin Cancer

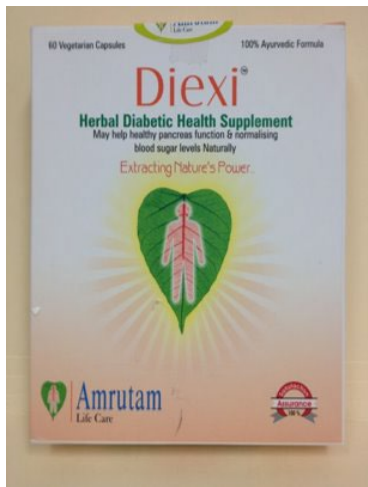


- Corrosive salves or creams claiming to treat or cure cancer, boils, moles and skin tags.
- Applied to superficial tumors to burn them away or “draw out” the cancer.
- Ingredients can be dangerous at high levels: sanguinaria canadensis, bloodroot, zinc chloride
- Destroys the skin and can result in permanent disfigurement, tissue necrosis, and infection.
- Using salve products such as black salve for serious conditions like skin cancer can result in delayed cancer diagnosis and cancer progression.

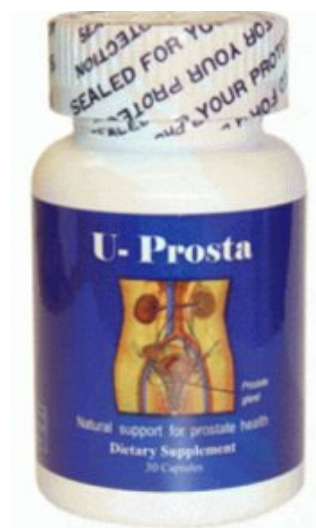
1. Quick Cures



Pro ArthMax
 Diclofenac
 Ibuprofen
 Naproxen
 Indomethacin
 Chlorzoxazone
 Nefopam



Diexi
 Metformin



U-Prosta
 Terazosin

**NONE OF THESE ACTIVE INGREDIENTS WERE
 DECLARED ON THE LABEL!**

2. COVID-19

Scenario:

Patient presents with the symptoms of a frightening new contagious disease and is looking for ways to treat it OR wants to know how to prevent it.

Patient Response:

Patients are tempted to buy or use questionable products promoted through social media that claim to help diagnose, treat, cure and even prevent coronavirus disease.



2. COVID-19

COVID-19 fraud: During the COVID-19 pandemic, thousands of products were illegally marketed to treat, mitigate, prevent, or cure COVID-19.



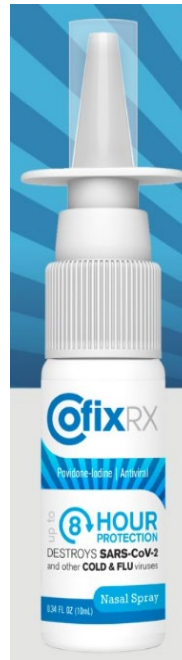
Miracle Mineral Solution

- Usually sold as two solutions to mix. Creates a dangerous bleach which has caused serious and life-threatening side effects.
- Promoted as a remedy for treating COVID-19, as well as autism, cancer, HIV/AIDS, and hepatitis.
- Some directions claim that vomiting and diarrhea are common and that such reactions are evidence that the product is working.

2. COVID-19

Nasal and throat sprays: Products with unproven claims to provide a protective barrier to airborne viruses.

- Popular during the COVID-19 pandemic and marketed to high-risk individuals to use and be safe in crowded spaces.
- “Antiviral nasal spray that offers up to 8 hours of protection from many cold and flu viruses.”
- “Destroys SARS CoV-2 and other cold & flu viruses in 15 seconds.”



2. COVID-19

Homeopathic drugs: Homeopathic drugs have not met FDA's requirements for safety and effectiveness. FDA is not aware of any proven benefits of these products.

- Often marketed as natural, safe and effective alternatives. Can contain a wide range of substances, including ingredients derived from plants, healthy or diseased animal or human sources, minerals, and chemicals.
- While generally highly diluted, some of these products have been found to contain measurable amounts of active ingredients and therefore could cause harm.
- COVID pandemic – Vaccine alternatives and Oleander 4X



3. Tempting Topicals

Scenario: Patient is complaining of an ongoing skin issue. Examples include moles, molluscum, skin tags, seborrheic keratoses, herpes sores, and genital warts.

Patient Response: Patient may first check the online marketplaces for products that have good reviews with the mistaken belief that topicals can't really harm you. Patient may even try to avoid doctor visits for these types of issues.



3. Tempting Topicals

- Currently, there are no legally marketed OTC drugs for treating moles, seborrheic keratoses, skin tags, molluscum, genital herpes or genital warts.
- Products can come in ointments, gels, sticks, and liquids and may contain high concentrations of various acidic ingredients including salicylic acid, trichloroacetic acid (TCA), lactic acid and others which could lead to permanent scarring.
- Beware of DIY skin peels!!



3. Tempting Topicals



Skin Whitening

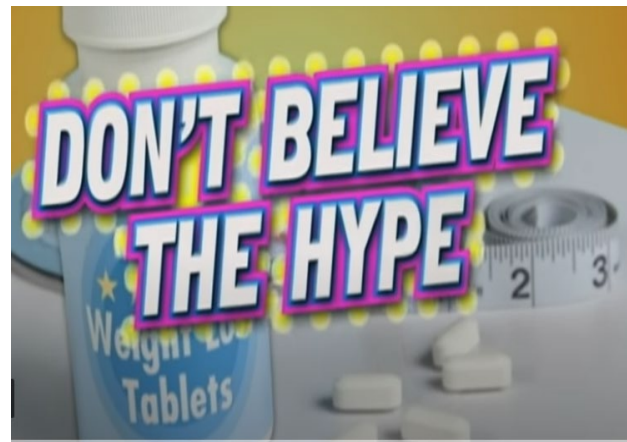
- There are no legal OTC products for skin lightening, including those containing hydroquinone.
- Some skin lightening products contain mercury and can cause serious injury.
- Most are topical, but some are intended for injection.
- Companies may describe skin lightening products as skin bleaching, fading, evening, brightening, or whitening products.
- These products are often sold in shops catering to Hispanic/Latino, Asian, African, or Middle Eastern communities.

4. Lifestyle Drugs



Scenario: Patient may not want to discuss certain issues – sexual enhancement, weight loss, muscle building – with a healthcare practitioner.

Patient Response: Search for products marketed as “natural” dietary supplements that promise fast results.



4. Lifestyle Drugs

FDA has discovered over 1000 products with undeclared active pharmaceutical ingredients. Over 50 different APIs identified.

Falsely marketed as all natural “dietary supplements” intended for sexual enhancement, weight loss, or muscle building.

APIs commonly found include sildenafil, tadalafil, sibutramine, and anabolic steroids.

Generally found online, beauty shops, and convenient stores (near the register).



4. Lifestyle Drugs

FDA NEWS RELEASE

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

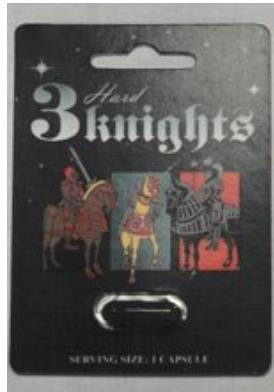


All 26 of the products the FDA purchased on Amazon and 20 of 25 products, or 80 percent, purchased on eBay contained undeclared active pharmaceutical ingredients.



4. Lifestyle Drugs

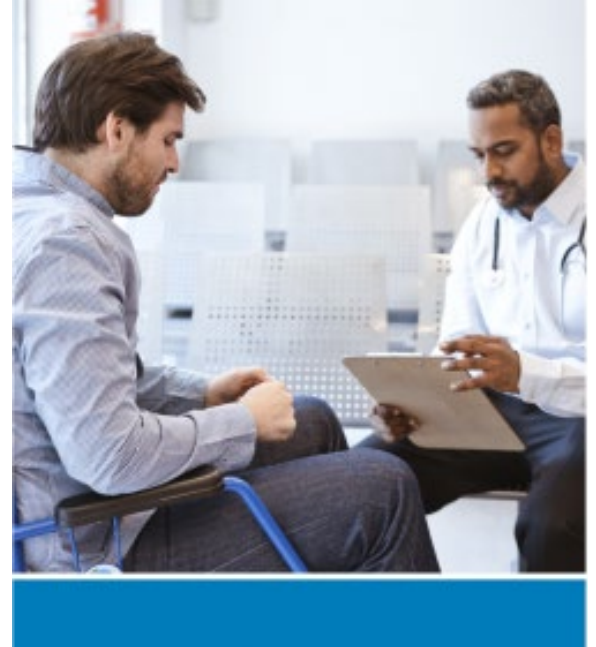
Undeclared API in Sexual Enhancement



5. Recreational Drugs

Scenario: Recreational drugs can be used by anyone, knowingly or unknowingly. More commonly used by younger people.

Patient Response: If it's sold openly in a store, it is probably low risk. It wouldn't be allowed otherwise.



5. Recreational Drugs

Tianeptine

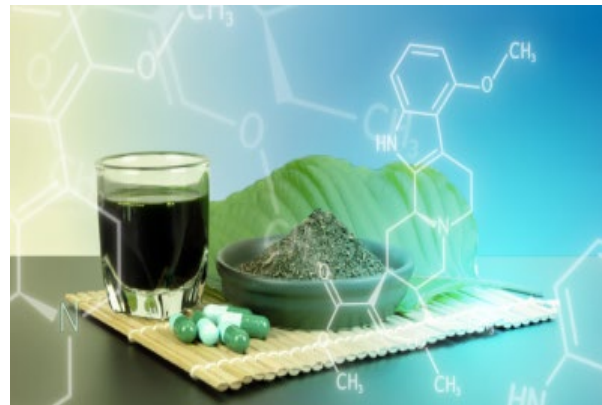
- A potentially dangerous substance that is not FDA-approved for any medical use but is illegally sold with claims to improve brain function and treat anxiety, depression, pain, opioid use disorder and other conditions.
- Commonly referred to as “gas station heroin”
- FDA has received severe adverse event reports after use of Neptune’s Fix products, including seizures and loss of consciousness leading to hospitalization.
- Commonly found online and at gas stations, vape or smoke shops.



5. Recreational Drugs

Kratom

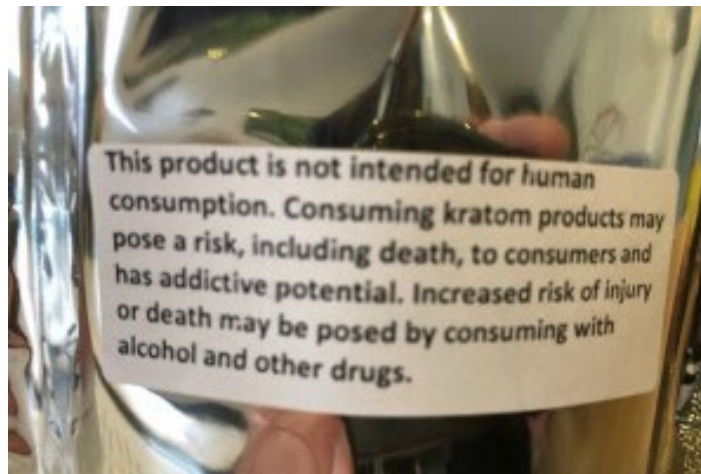
- A tropical tree (*Mitragyna speciosa*) native to Southeast Asia.
- Not legally marketed as a drug or dietary supplement. It is currently not a controlled substance.
- Kratom is often used to self-treat conditions such as pain, coughing, diarrhea, anxiety and depression, opioid use disorder, and opioid withdrawal.
- FDA has warned consumers not to use kratom because of the risk of serious adverse events, including liver toxicity, seizures, and substance use disorder (SUD). In rare cases, deaths have been associated with kratom use, as confirmed by a medical examiner or toxicology reports. However, in these cases, kratom was usually used in combination with other drugs, and the contribution of kratom in the deaths is unclear.



5. Recreational Drugs

Research Chemicals

- “Not for human use”
- “Research purposes only”
- “Lab testing only”



Product Usage: This **PRODUCT IS INTENDED AS A RESEARCH CHEMICAL ONLY**. This designation allows the use of research chemicals strictly for in vitro testing and laboratory experimentation only. All product information available on this website is for educational purposes only. Bodily introduction of any kind into humans or animals is strictly forbidden by law. This product should only be handled by licensed, qualified professionals. This product is not a drug, food, or cosmetic and may not be misbranded, misused or mislabeled as a drug, food or cosmetic.

Misleading Labeling

- “Listed with FDA”
- “FDA registered”
- “FDA approved”
- “Made in an FDA-registered facility”
- “Complies with FDA Current Good Manufacturing Practices” – FDA does not provide any certification of CGMP compliance
- “FDA approved ingredient” – FDA does not approve ingredients
- Use of the FDA logo

Fact: An NDC number does not equal legal marketing



Reporting Problems to FDA

fda.gov/safety

Reporting Unlawful Sales of Medical Products on the Internet



Report a website that you think is illegally selling human drugs, animal drugs, medical devices, biological products, foods, dietary supplements or cosmetics.

Report Unlawful Sales

En Español

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

- If your report involves a life-threatening or otherwise serious reaction, please fill out [FDA's MedWatch reporting form](#). (Also contact your health professional for medical advice.)

Although FDA cannot respond to every e-mail individually, the agency will evaluate every complaint received and take suitable action.

MedWatch Online Voluntary Reporting Form



Welcome

If this is a medical emergency, please call 911.
If you have a mental health crisis, please call 988.

Health professionals, consumers and patients can voluntarily report observed or suspected adverse events for human medical products to FDA. Voluntary reporting can help FDA identify unknown risk for approved medical products. Reporting can be done through our online reporting portal or by downloading, completing and then submitting FDA Form 3500 (Health Professional) or 3500B (Consumer/Patient) to MedWatch. The FDA Safety Information and Adverse Event Reporting Program.

While not mandatory, FDA encourages reporters to provide their contact information in case FDA needs to gather more information. Note that reporters can request, within the report, FDA not release their contact information to the manufacturer.

Begin Online Report



Health Professional
(FDA Form 3500)



Consumer/Patient
(FDA Form 3500B)

Click aquí para instrucciones generales En español

En español para el consumidor / paciente (formulario 3500B de la FDA)



Continue an incomplete report

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Health Fraud Information



Health Fraud Scams

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Subscribe to receive FDA health fraud alerts

Health fraud scams refer to products that claim to prevent, treat, or cure diseases or other health conditions, but are not proven safe and effective for those uses. Health fraud scams waste money and can lead to delays in getting proper diagnosis and treatment. They can also cause serious or even fatal injuries.

fda.gov/healthfraud

Subscribe to receive FDA health fraud alerts



Health Fraud Information



Health Fraud Product Database

fda.gov/healthfraud

Search Database

(Table results update automatically as you type)

Search:

Export Excel

Show entries

Date	Product ¹	Firm	Firm Address	Source/URL(s)	Subject	Action	Program Area(s)	Additional Outcome
04/17/2024	Ossos-Sans	n/a	n/a	https://alnaturaleshop.com	Undeclared diclofenac and methocarbamol	Public Notification	Drugs	
04/05/2024	Eva Nutrition Mexican Tejocote root	Global Mix, Inc.	New York	etsy.com; amazon.com; eva-nutrition.com; tejocotemexican.com; niwali.com; scienceofalpha.com	Contains undeclared yellow oleander	Recall	Foods	
04/05/2024	Science of Alpha Mexican Tejocote root	Global Mix, Inc.	New York	etsy.com; amazon.com; eva-nutrition.com; tejocotemexican.com; niwali.com; scienceofalpha.com	Contains undeclared yellow oleander	Recall	Foods	

Health Fraud Information


fda.gov/consumers



Consumer Updates

Science-based health and safety information you can trust.

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 Email

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Health Fraud Information

fda.gov/besaferx



BeSafeRx: Your Source for Online Pharmacy Information

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References

[Medication Health Fraud](#)

[Health Fraud Scams](#)

[Health Fraud Scams are Everywhere](#)

[6 Tip-offs to Rip-offs: Don't Fall for Health Fraud Scams](#)

[Warning Letters - Health Fraud](#)

[Health Fraud Product Database](#)



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