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Dietary Supplements - Global Safety Signals

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The objective of this paper is to increase awareness of safety issues related to the use of dietary supplements and herbal products and to describe the role of healthcare providers in that regard and shedding light on issues of concern to healthcare providers and consumers.

Two major classes of natural products for medicinal purposes are generally available: drugs of herbal origin and dietary supplements. Consumer consumption of Dietary Supplements is growing day by day. The US Food and Drug Administration (FDA) plays an essential role in ensuring the safety of vitamins, minerals, botanicals, probiotics, amino acids, and extracts sold as dietary supplements in the United States. While the FDA does not assess the safety of supplements prior to market, the agency is tasked with identifying and removing adulterated and hazardous supplements from the marketplace.

Dietary supplements come in many forms, including tablets, capsules, powders, energy bars, and liquids. These products are available in stores throughout and through, as well as on the Internet. They are labeled as dietary supplements and include among others:

- Vitamin and mineral products;
- "Botanical" or herbal products-These come in many forms and may include plant materials, algae, macroscopic fungi, or a combination of these materials.
- Amino acid products-Amino acids are known as the building blocks of proteins and play a role in metabolism.
- Enzyme supplements-Enzymes are complex proteins that speed up biochemical reactions.

Dietary Supplement Health & Education Act (DSHEA)

DSHEA, which became law in 1994, is a dietary supplement - a product (other than tobacco) that :

- Is intended to supplement the diet;
- Contains one or more dietary ingredients (including vitamins; minerals; herbs or other botanicals; amino acids; and other substances) or their constituents;
- Is intended to be taken by mouth as a pill, capsule, tablet, or liquid; and
- Is labeled on the front panel as being a dietary supplement.

The 1994 Dietary Supplement Health and Education Act (DSHEA) made dietary supplements a separate category of foods and established separate regulations for them. The Act determined that the responsibility for the safety and efficacy of products and the accuracy of health claims on labels rested solely on firms, not the FDA

Dietary Supplements and FDA

Dietary supplements, in general, are not FDA-approved. Under the law (Dietary Supplement Health and Education Act of 1994), dietary supplement firms do not need FDA approval prior to marketing their products. It is the company's responsibility to make sure its products are safe and that any claims are true.

Just because you see a supplement product on a store shelf does NOT mean it is safe or effective. When safety issues are suspected, the FDA must investigate and, when warranted, take steps to have the product removed from the market. However, it is much easier for a firm to get a product on the market than it is for FDA to take a product off the market.

In August 2009, the U.S. Food and Drug Administration (FDA) discovered more products, most of them labeled as dietary supplements, that contain a wide variety of undeclared active pharmaceutical ingredients. Now, more than 140 contaminated products have been identified, but these represent only a fraction of the contaminated supplements on the market. Unfortunately, lenient regulatory oversight of dietary supplements, combined with the FDA's lack of resources, has created a marketplace in which manufacturers can introduce hazardous new products with virtual impunity. Although manufacturers have since 2007 been required to report serious supplement-related adverse events to the FDA, the great majority of the estimated 50,000 adverse events that occur annually remain unreported.

Adulteration of dietary supplements typically involves 1 of 2 patterns: economic adulteration, in which a less expensive ingredient is used in place of a more expensive ingredient listed on the label, or pharmaceutical adulteration, in which an active drug is included in a purportedly botanical supplement, for example, sildenafil in a "natural" sexual enhancement supplement. The FDA maintains a public database listing the brands of supplements it has identified as adulterated with drugs and the actions, if any, it has taken to remove the product from commerce Cohen Herbal drugs are used as first-line drug therapy in many instances. Unfortunately, undeclared active pharmaceutical ingredients have been detected in these supplements.

The dietary supplement industry has been criticized for problems related to poor quality control, safety, misbranding, and adulteration. Let us see how the US Food and Drug Administration (FDA) regulates dietary supplements within the framework of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The Dietary Supplement Health and Education Act of 1994 (DSHEA), which amended the FD&C Act, gave the FDA the authority to promulgate Good Manufacturing Practices for dietary supplements and required that manufacturers provide the FDA information supporting a conclusion that the ingredients are reasonably expected to be safe if the dietary ingredients were not marketed in the USA before 15 October 1994. Recent amendments to the FD&C Act require that serious dietary supplement-related adverse events be reported to the FDA and provide the agency with mandatory recall authority.

In one of the most dangerous cities in the United States, one portly police sergeant has more to worry about than crime. His doctor had been encouraging him for years to lose weight, and like millions of other Americans, he decided to try a weight-loss supplement to help him shed his extra pounds. But instead of losing weight, he lost his job. According to the label, his diet pills, which were imported from Brazil and sold in the United States, contain vitamin E, Centella, senna, and cascara, among other "natural" ingredients. Not included on the label was the amphetamine detected in his urine drug screen. The now- unemployed sergeant is not alone. Such contaminated supplements represent an emerging risk to public health. The presence of naturally occurring (e.g. Ephedra, Citrus aurantium, Acacia) and synthetic (e.g. β-methylphenethylamines, methylsynephrine, α-ethyl-phenethylamine) biologically active phenethylamines (PEAs) in dietary supplements and of PEA drugs (e.g. clenbuterol, fenfluramine, sibutramine, lorcaserin) in weight-loss products. Regulatory actions against manufacturers of products labeled as dietary supplements that contain the aliphatic amines 1,3-dimethylamine and 1,3-dimethyl butylamine, and PEAs such as β-methylphenethylamine, Angeline, and Dendrobium illustrate the FDA's use of its authority under the FD&C Act to promote dietary supplement safety [1].

For Immediate Release: (May 11, 2009, Media Inquiries)
Dietary Supplements Worth $1.3 Million Condemned and Forfeited to the United States Under Consent Decree.

FDA alleged 'Body-building' products contained unapproved food additives and new dietary ingredients and these products will now be destroyed.

The U.S. District Court for the Eastern District of Michigan, Southern Division, today entered a consent decree that condemns and forfeits to the United States for the destruction of about $1.3 million worth of dietary supplements.

"The court order is the result of efforts by the federal government to protect consumers from products for which there is inadequate information to assure that they do not present a significant or unreasonable risk of illness or injury," said Michael Chappell, FDA's acting associate commissioner for regulatory affairs. "It shows that the agency is prepared to use the necessary legal means to keep such products out of the marketplace."

At the request of the FDA, U.S. Marshals seized more than 23,300 bottles of three dietary supplement products distributed by LG Sciences LLC, of Brighton, Mich. The seized products were marketed for use by bodybuilders and distributed on the Internet and in retail stores under the names "Methyl 1-D," "Methyl 1-D XL," and "Formadrol Extreme XL."

Based on laboratory tests, the FDA determined that the products contain one or more unapproved food additives and/or new dietary ingredients for which there is inadequate information to assure that the ingredients do not present a significant or unreasonable risk of illness or injury. Specifically, the condemned Methyl 1-D and Methyl 1-D XL contained 1,4,6-androstatriene-3,17-dione, also known as "ATD" or 1,4,6-etioallocholan-dione. The condemned Formadrol Extreme XL contained ATD and 3,6,17-androstenetrione (also known as "6-OXO"). Both of these substances are steroids that inhibit the activity of the enzyme aromatase and may be found in dietary supplements promoted to boost testosterone levels.

Federal regulators continue to warn consumers about tainted, dangerous products that are marketed as dietary supplements. These fraudulent products can cause serious injury or even death. The Food and Drug Administration (FDA) has found nearly 300 fraudulent products-promoted mainly for weight loss, sexual enhancement, and bodybuilding-that contain hidden or deceptively labeled ingredients, such as:

- The active ingredients in FDA-approved drugs or their analogs (closely related drugs)
- Other compounds, such as novel synthetic steroids, that do not qualify as dietary ingredients

"These products are masquerading as dietary supplements-they may look like dietary supplements but they are not legal dietary supplements," says Michael Levy, director of FDA's Division of New Drugs and Labeling Compliance. "Some of these products contain hidden prescription ingredients at levels much higher than those found in an approved drug product and are dangerous."

FDA has received numerous reports of harm associated with the use of these products, including stroke, liver injury, kidney failure, heart palpitations, and death.

'All Natural' Alternatives for Erectile Dysfunction: A Risky Proposition
Thus far, FDA lab tests have found that nearly 300 of these products contain undisclosed drug ingredients. These can include the same active ingredients found in prescription drugs that are FDA-approved for the treatment of erectile dysfunction (ED), such as Viagra, Cialis and Levitra. Not only do these products contain undisclosed drug ingredients, but they also sometimes may include combinations of undisclosed ingredients or excessively high doses, both potentially dangerous situations.

Even a cautious consumer can't tell that these products are, in fact, tainted with undisclosed drug ingredients, because their labels do not list the potentially hazardous ingredients, says M. Daniel Dos Santos, Pharm.D., Ph.D., of FDA's Division of Dietary Supplement Programs. Consumers may be misled to believe these products are safe because their labeling often suggests they are "all-natural" or "herbal" alternatives to FDA-approved prescription drugs for the treatment of ED.

Unknown Contaminants

Erectile dysfunction is a medical condition. Because dietary supplements can't legally claim to prevent, diagnose, or treat a medical condition or a disease, the "alternative" ED products are often advertised for "sexual enhancement." Their availability in the market doesn't make them safe.

"These products are not harmless or recreational," Dos Santos warns. "They often claim to have the same effects as drugs that are FDA-approved for the treatment of ED, such as Cialis and Viagra, promising to work quickly -within 30 to 40 minutes. That's a red flag."

In many cases, we don't know where or how these products are manufactured, says Brad Pace, regulatory counsel at FDA's Health Fraud Branch. Many of these products are produced overseas in facilities that have not yet been inspected by FDA.

"Some of the ingredients in these products have chemicals that have never undergone any type of safety analysis in the United States. You just don't know what you're getting," Pace says.

FDA issues numerous alerts warning consumers and health care professionals about potentially dangerous products. It also works to stop the sale of illegal products and have them voluntarily recalled or destroyed. As part of this mandate, FDA sends advisory letters to companies warning that they are breaking the law and must stop. Failure to cease illegal behavior could lead to seizures, import alerts, injunctions, recalls and criminal prosecutions. An import alert allows FDA to detain, without physically examining, products that appear to violate certain parts of the Food, Drug, and Cosmetic Act.(FDA, October 1, 2015).

5K Contains Hidden Drug Ingredient

[8-13-2018] The Food and Drug Administration is advising consumers not to purchase or use 5K, a product promoted and sold for sexual enhancement. This product was identified during an examination of international mail shipments.5K

FDA laboratory analysis confirmed that 5K contains sildenafil, the active ingredient in the FDA-approved prescription drug Viagra, used to treat erectile dysfunction. 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.

America Treasure Contains Hidden Drug Ingredients

FDA laboratory analysis confirmed that America Treasure contains sildenafil, the active ingredient in the FDA-approved prescription drug Viagra, used to treat erectile dysfunction. 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.

Best Leopard Miracle of Honey Contains Hidden Drug Ingredients

FDA laboratory analysis confirmed that Best Leopard Miracle of Honey contains sildenafil and tadalafil, the active ingredients in the FDA-approved prescription drugs Viagra and Cialis, respectively, used to treat erectile dysfunction. These undeclared ingredients 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.

Boss Rhino 15000 Contains Hidden Drug Ingredients

FDA laboratory analysis confirmed that Boss Rhino 15000 contains sildenafil, the active ingredient in the FDA-approved prescription drug Viagra, used to treat erectile dysfunction. 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.

DMAA in Dietary Supplements

Also known as methylhexanamine or geranium extract, DMAA is often touted as a "natural" stimulant; however, the FDA is not aware of any reliable science indicating that DMAA exists naturally in plants. Although DMAA at one time was approved as a drug for nasal decongestion, it is no longer approved for this use and no medical use of DMAA is recognized today. DMAA, especially in combination with other stimulant ingredients such as caffeine, can be a health risk to consumers. Taking DMAA can raise blood pressure and lead to cardiovascular problems ranging from shortness of breath and tightening in the chest to heart attack.

The FDA continues to advise consumers not to buy or use products marketed as dietary supplements that contain DMAA due to the health risks they present.

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At the request of the FDA, U.S. Marshals seized more than 23,300 bottles of three dietary supplement products distributed by LG Sciences LLC, of Brighton, Mich. The seized products were marketed for use by bodybuilders and distributed on the Internet and in retail stores under the names "Methyl 1-D," "Methyl 1-D XL," and "Formadrol Extreme XL."

Based on laboratory tests, the FDA determined that the products contain one or more unapproved food additives and/or new dietary ingredients for which there is inadequate information to assure that the ingredients do not present a significant or unreasonable risk of illness or injury. Specifically, the condemned Methyl 1-D and Methyl 1-D XL contained 1,4,6-androstatriene-3,17-dione, also known as "ATD" or 1,4,6-etioallocholan-dione. The condemned Formadrol Extreme XL contained ATD and 3,6,17-androstenedione (also known as "6-OXO"). Both of these substances are steroids that inhibit the activity of the enzyme aromatase and may be found in dietary supplements promoted to boost testosterone levels.

The FDA has no scientific information concerning the safety of the condemned products or their ingredients and, thus, cannot determine whether they represent a hazard to consumers. Under the circumstances, consumers who use or have used the products should discuss their use with their health care professionals.

Amphetamine-like Stimulant Remains in Dietary Supplements 2 Years after FDA Discovery
Last Updated: Wednesday 8 April 2015 at 8 am PST

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In January 2014, the US Food and Drug Administration published a study in which they identified an amphetamine-like stimulant in a number of commonly used dietary supplements. More than 2 years later, a new study led by a researcher from Harvard Medical School in Cambridge, MA, finds that not only are products containing the supplement still on the market, but their abundance has increased.

Dietary supplements
"Since the FDA discovered BMPEA in supplements, the percentage of brands of Acacia rigidula supplements that contain BMPEA has appeared to increase, from 42.9% in 2012 to 52.4% in 2014," note the researchers.

The 2014 study from the Food and Drug Administration (FDA), published in the Journal of Pharmaceutical and Biomedical Analysis, revealed that nine of the tested 21 dietary supplements marketed for weight loss, improved cognitive function or enhanced athletic performance containing a plant extract called Acacia rigidula also contained beta-methyl phenylethylamine (BMPEA).

BMPEA is a synthetic compound closely related to amphetamine. Though the safety of the substance has not been tested in humans, studies in cats and dogs have shown it to increase blood pressure and heart rate - conditions known to raise the risk of heart attack and stroke in humans.

But despite the FDA's findings, it seems the organization has taken no action to enforce the removal of BMPEA from dietary supplements or warn consumers about the potential risks.

Findings Represent a 'Profound Leadership Failure at the FDA'
On Tuesday, Dr. Pieter A. Cohen, of the Cambridge Health Alliance at Harvard, and colleagues published a study in the journal Drug Testing and Analysis, revealing that BMPEA was identified in 11 of the 21 Acacia rigidula dietary supplements they purchased 1 year after the FDA's findings.

"Since the FDA discovered BMPEA in supplements, the percentage of brands of Acacia rigidula supplements that contain BMPEA has appeared to increase, from 42.9% in 2012 to 52.4% in 2014," note the researchers.

"Whether this represents a true increase in the prevalence of BMPEA or is due to differences in sampling methods or other factors is not known," they add. "Regardless, the continued presence of BMPEA in mainstream supplements continues to expose consumers to potential risks."

Dr. Cohen told Medical News Today that he was "shocked" by their findings. "I had assumed that the FDA's original research would have led manufacturers to quietly withdraw this stimulant since the FDA had discovered it," he said.

He told us that the results represent a "profound leadership failure" at the FDA. "The problem starts with the commissioner ignoring supplements and continues all the way down to the supplement division, which is intertwined with the supplement industry," he added.

The team says immediate action needs to be taken to remove BMPEA from all supplements and ensure consumers avoid such products.

FDA warns of prescription drugs in weight loss supplements: Tainted dietary supplements
The Food and Drug Administration (FDA) is warning consumers **not to use six different weight loss supplements** because they contain a dangerous drug that was pulled from the market in 2010 because of the risk of heart attack and stroke. The supplement contains sibutramine, marketed under the brand name Meridia as a weight loss drug before its withdrawal.

The Tainted Supplements are:
Mix Fruit Slimming, capsules sold on Amazon and other online retailers that are advertised as a "100% natural herbal new slimming pill without any side effects." The pills also contain phenolphthalein, a laxative ingredient the FDA banned in the 1990's because it is potentially carcinogenic.

Lingzhi Cleansed Slim Tea, also sold on Amazon and other online retailers, is advertised to "help to improve the function of intestines and stomach and speed up metabolism."

Trim Fast, available online and possibly in some retail stores, advertised to "suppress appetite, increase your metabolism by up to 18 times, and significantly increase energy."

24 ince, a slimming drink**,** is advertised online as "useful for health management such as weight control, reduces glucose level in our blood, reduce fat and cholesterol level."

Sliming (sic) Diet by Pretty White, sold on eBay and other online retailers in packages with ten capsules, is marketed as "harmless because it is natural."

Lipo 8 is also sold online and in some retail stores as a weight loss pill made from white kidney bean extract to "help eliminate fat before it gets absorbed into the body."

FDA analysis confirmed the presence of the drugs in each supplement. The agency has discovered sibutramine in more than 50 weight loss supplements since January of 2013, including capsules, powders, and slimming coffee or tea drinks.

Sibutramine, marketed as Meridia in the U.S. until it was removed from the market in 2010, has the potential to interact with other prescription medications and poses a particular risk for people with heart conditions. In a clinical trial called SCOUT, the drug increased the risk of major adverse cardiovascular events (composite of non-fatal heart attack, non-fatal stroke, resuscitation after cardiac arrest, and cardiovascular death) by 16 percent in patients treated with Meridia compared to patients taking a placebo.

Weight Loss Supplement Found to Contain DMAA Recalled
(Date Posted: 8/8/2015)
On August 6, 2014, Regeneca Worldwide issued a recall of two lots of appetite control supplements RegenESlim because FDA tests found them to contain DMAA (1,3-dimethylamylamine).

Dietary supplements containing DMAA (also known as 1,3-dimethylamylamine, methylhexanamine or geranium extract) are illegal. The chemical has been linked to a number of serious adverse effects, including narrowing of blood vessels and arteries, and increased risk of elevated blood pressure, shortness of breath, and heart attack.

The Department of Defense (DoD) does not maintain a list of dietary supplements or supplement ingredients that are either "allowed" or "banned." If the Food and Drug Administration (FDA) or the Drug Enforcement Administration (DEA) has not banned or declared an ingredient or dietary supplement product illegal, then DoD does not consider it banned or illegal. Substances "banned" for use by U.S. military service members include:

- Anything on DEA's controlled substance list (spice, marijuana, synthetic cannabinoids, amphetamines, mood-altering substances, anabolic steroids);
- Any substance FDA has declared "illegal" or "not allowed" for use in dietary supplements (such as "ephedra"/ephedrine alkaloids, DMAA, DMBA, BMPEA);
- Salvia divinorum (diviner's sage; see the OPSS FAQ about Salvia for service-specific policies); and
- Any prescription drug without a current prescription written specifically for you.

However, the FDA has found that many dietary supplements—especially weight-loss, bodybuilding, and sexual enhancement products—contain undeclared drug ingredients that could be potentially harmful and/or produce unwanted urinalysis test results. (Updated 18 August 2015).

FDA Warns Seller of Tainted Enhancement Supplements
(Date Posted: 8/15/2015)
On July 31, 2015, the FDA issued a warning letter to R Thomas Marketing following a review of the company's website, which found it sold the male enhancement supplements **Black Ant, Herb Viagra, Real Skill, and Stree Overlord**. These supplements contain undeclared sildenafil.

Sildenafil, the active ingredient in the prescription drug Viagra is prescribed for erectile dysfunction. This drug can cause symptoms like headache and flushing and can interact with medications containing nitrates such as nitroglycerine, resulting in dangerously low blood pressure.

Talk with a Health Care Professional
The Food and Drug Administration (FDA) suggests that you consult with a healthcare professional before using any dietary supplement. Many supplements contain ingredients that have strong biological effects, and such products may not be safe for all people.

If you have certain health conditions and take these products, you may be putting yourself at risk. Your healthcare professional can discuss with you whether it is safe for you to take a particular product and whether the product is appropriate for your needs. Here is some general advice:

- Dietary supplements are not intended to treat, diagnose, cure, or alleviate the effects of diseases. They cannot completely prevent diseases, as some vaccines can. However, some supplements are useful in reducing the risk of certain diseases and are authorized to make label claims about these uses. For example, folic acid supplements may make a claim about reducing the risk of birth defects of the brain and spinal cord.
- Using supplements improperly can be harmful. Taking a combination of supplements, using these products together with medicine, or substituting them in place of prescribed

medicines could lead to harmful, even life-threatening, results.
- Some supplements can have unwanted effects before, during, or after surgery. For example, bleeding is a potential side effect risk of garlic, ginkgo biloba, ginseng, and Vitamin E. In addition, kava and valerian act as sedatives and can increase the effects of anesthetics and other medications used during surgery. Before surgery, you should inform your healthcare professional about all the supplements you use.

How Are Supplements Regulated?

You should know the following if you are considering using a dietary supplement.
- Federal law requires that every dietary supplement be labeled as such, either with the term "dietary supplement" or with a term that substitutes a description of the product's dietary ingredient(s) for the word "dietary" (e.g., "herbal supplement" or "calcium supplement").
- Federal law does not require dietary supplements to be proven safe to FDA's satisfaction before they are marketed.
- For most claims made in the labeling of dietary supplements, the law does not require the manufacturer or seller to prove to FDA's satisfaction that the claim is accurate or truthful before it appears on the product.
- In general, FDA's role with a dietary supplement product begins after the product enters the marketplace. That is usually the agency's first opportunity to take action against a product that presents a significant or unreasonable risk of illness or injury, or that is otherwise adulterated or misbranded.
- Dietary supplement advertising, including ads broadcast on radio and television, falls under the jurisdiction of the Federal Trade Commission.
- Once a dietary supplement is on the market, the FDA has certain safety monitoring responsibilities.

These include monitoring mandatory reporting of serious adverse events by dietary supplement firms and voluntary adverse event reporting by consumers and health care professionals. As its resources permit, the FDA also reviews product labels and other product information, such as package inserts, accompanying literature, and Internet promotion.
- Dietary supplement firms must report to the FDA any serious adverse events that are reported to them by consumers or health care professionals.
- Dietary supplement manufacturers do not have to get the agency's approval before producing or selling these products.
- It is not legal to market a dietary supplement product as a treatment or cure for a specific disease or to alleviate the symptoms of a disease.
- There are limitations to FDA oversight of claims in dietary supplement labeling. For example, FDA reviews substantiation for claims as resources permit.

Are Supplements Safe?

Many dietary supplements have clean safety histories. For example, millions of Americans responsibly consume multivitamins and experience no ill effects.

Some dietary supplements have been shown to be beneficial for certain health conditions. For example, the use of folic acid supplements by women of childbearing age who may become pregnant reduces the risk of some birth defects.

Another example is the crystalline form of vitamin B12, which is beneficial in people over age 50 who often have a reduced ability to absorb naturally occurring vitamin B12. However further study is needed for some other dietary supplements.

Some supplements have had to be recalled because of proven or potential harmful effects. Reasons for these recalls include:
- Microbiological, pesticide, and heavy metal contamination
- Absence of a dietary ingredient claimed to be in the product
- The presence of more or less than the amount of the dietary ingredient claimed on the label
- In addition, unscrupulous manufacturers have tried to sell bogus products that should not be on the market at all.
- Before taking a dietary supplement, make sure that the supplement is safe for you and appropriate for the intended purpose.
- Be a Safe and Informed Consumer
- Let your healthcare professional advise you on sorting reliable information from questionable information.
- Contact the manufacturer for information about the product you intend to use.
- Be aware that some supplement ingredients, including nutrients and plant components, can be toxic. Also, some ingredients and products can be harmful when consumed in high amounts, when taken for a long time, or when used in combination with certain other drugs, substances, or foods.
- Do not self-diagnose any health condition. Work with healthcare professionals to determine how best to achieve optimal health.
- Do not substitute a dietary supplement for a prescription medicine or therapy, or for the variety of foods important to a healthful diet.
- Do not assume that the term "natural" in relation to a product ensures that the product is wholesome or safe.
- Be wary of hype and headlines. Sound health advice is generally based upon research over time, not a single study.
- Learn to spot false claims. If something sounds too good to be true, it probably is.

Report Problems

Adverse effects of dietary supplements should be reported to the FDA as soon as possible. If you experience such an adverse effect, contact or see your healthcare professional immediately. Both of you are then encouraged to report this problem to FDA. For information on how to do this, go to www.fda.gov/FDAgov/Food/DietarySupplements/Alerts/ucm111110.htm.

Adverse effects can also be reported to the product's manufacturer or distributor through the address or phone number listed on the product's label. Dietary supplement firms are required to forward reports they receive about serious adverse effects to the FDA within 15 days.

For a general, nonserious complaint or concern about dietary supplements, contact your local FDA Consumer Complaint Coordinator.(Updated: July 15, 2015).

Advice for Consumers

"We need consumers to be aware of these dangerous products and to learn how to identify and avoid them," says Levy. Consumers should look for potential warning signs of tainted products marketed as dietary supplements, such as:
- Products claiming to be alternatives to FDA-approved drugs or to have effects similar to prescription drugs
- Products claiming to be a legal alternative to anabolic steroids
- Products that are marketed primarily in a foreign language or those that are marketed through mass e-mails
- Sexual enhancement products promising rapid effects, such as working in minutes to hours, or long-lasting effects, such as working for 24 to 72 hours

- Product labels warning that you may test positive in performance enhancement drug tests
- Generally, if you are using or considering using any product marketed as a dietary supplement, the FDA suggests that you
- Check with your health care professional or a registered dietician about any nutrients you may need in addition to your regular diet
- Ask your healthcare professional for help distinguishing between reliable and questionable information
- Ask yourself if it sounds too good to be true
- Be cautious if the claims for the product seem exaggerated or unrealistic.
- Watch out for extreme claims—for example, "quick and effective," "cure-all," "can treat or cure diseases," or "totally safe."
- Be skeptical about anecdotal information from personal "testimonials" about incredible benefits or results obtained from using a product [2-5].

References

1. Rahul S Pawar (2016) Overview of the regulation of dietary supplements in the USA and issues of adulteration with phenethylamines (PEAs). Analytical Science Journals https://analyticalsciencejournals.onlinelibrary.wiley.com/doi/epdf/10.1002/dta.1980.
2. (2011) Beware of Fraudulent Dietary Supplements, FDA march 2011 and updated versions Consumer Inquiries 888-INFO-FDA. https://d3n8a8pro7vhmx.cloudfront.net/liverinfosource/pages/46/attachments/original/1489598852/FDA-dietary-fraud.pdf?1489598852.
3. Stephanie Kwisnek (2009) Overview of regulation of dietary supplements in the USA and issues of adulteration with phenethylamines (PEAs). Analytical Science https://analyticalsciencejournals.onlinelibrary.wiley.com/doi/10.1002/dta.1980.
4. Pieter A Cohe MD (2009) American Roulette-Contaminated Dietary Supplements. N Engl J Med 361: 1523-1525.
5. Pieter A Cohen (2018) The FDA and Adulterated Supplements - Dereliction of Duty. JAMA Netw Open 1: e183329.