Drug or Dietary Supplement?  
When to Say “No” to Dietary Supplement Merchants

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MAC is an organization comprised of members from Banks, Acquirers, ISOs, Card Associations, Law Enforcement and others involved in risk management and compliance of the electronic payment processing industry. The purpose of MAC is to educate members in the electronic payment industries regarding the compliance with electronic payments regulations along with the detection, prevention and prosecution of those involved in electronic payment fraud. In the context of fulfilling MAC’s ongoing educational obligations to its members, this webinar is being presented by the MAC Education Committee in support of the MAC mission regarding the exchange of information and continuous education of its’ members.
A Quick Introduction

Merchant Monitoring

We work in over a dozen languages.

We collect extensive data about rogue drug and supplement websites, networks and merchants…

LegitScript maintains the world’s largest list of online healthcare merchants, such as Internet pharmacies, supplement and other drug merchants organized by legitimacy and country.

Wide Coverage

LegitScript works with numerous companies and government entities on a global basis.

Healthcare Crime Analysis

…resulting in in-depth analyses.

LegitScript is endorsed by the National Association of Boards of Pharmacy and has formal or informal relationships with multiple regulatory agencies (including the FDA) from around the world.

Trusted by Regulators
Types of Products We Monitor

- Pharmaceuticals
- Dietary Supplements
- Bodybuilding Supplements
- Psychoactive ("Legal") Highs
- Cosmetics/Topical/Injectables
“Dietary supplement” is the term used by regulatory authorities in the US. “Food supplement” is the term used by EU regulators. Common industry term is “nutraceutical.”

Product (taken by mouth) intended to supplement the diet. Ingredients may include vitamins, minerals, herbs or other botanicals, amino acids.

Found in many forms: tablets, capsules, softgels, gelcaps, liquids, or powders.

In most countries, dietary supplements are regulated as food, not drugs (so different, and far less stringent, rules apply).
If a dietary supplement contains ingredients that are not permitted “dietary ingredients,” then the FDA considers it a “new drug” – and drugs have to be approved. So the dietary supplement becomes an “unapproved drug.”*

If a dietary supplement claims to diagnose, cure, prevent, mitigate, or treat a disease, the FDA considers it a drug (as do other countries’ medicines agencies). So again, the dietary supplement becomes an unapproved drug.**

Stay away from dietary supplement merchants that break the rules!

* See, e.g., http://www.fda.gov/Safety/Recalls/ucm390693.htm. This is true in other countries, but they use different terms, e.g., “unlicensed medicines.”
** See, e.g., http://www.mhra.gov.uk/home/groups/is-pol/documents/websiteresources/con2023338.pdf
Increasing Scrutiny from Regulators...

FDA NEWS RELEASE
For Immediate Release: Dec. 23, 2013
Media Inquiries: Tara Goodin, 240-402-3157, tara.goodin@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

FDA warns consumers not to use muscle growth product

Product marketed as a dietary supplement contains potentially harmful synthetic steroids

The U.S. Food and Drug Administration is advising consumers to immediately stop using a product called Mass Destruction, marketed as a dietary supplement for muscle growth. The product is labeled to contain at least one synthetic anabolic steroid and has been linked to at least one reported serious illness.

The FDA was alerted by the North Carolina Department of Health and Human Services of a serious injury associated with use of Mass Destruction. The report described a previously healthy 28-year-old male with liver failure requiring transplant after several weeks of product use. Liver injury is generally known to be a possible outcome of using products that contain anabolic steroids and steroid-like substances. The product’s ingredients are undergoing further analysis by the FDA.

Mass Destruction is manufactured by Blunt Force Nutrition in Sirm, N.C. and sold in retail stores, fitness gyms, and on the Internet. An investigation is underway to identify the product’s manufacturer. Consumers who suspect they are experiencing problems associated with Mass Destruction or other body building products should consult a health care professional, especially if they have experienced unexplained fatigue, abdominal or back pain, discolored urine, or any other unexplained changes in their health.

“Products marketed as supplements that contain anabolic steroids pose a real danger to consumers,” said Howard Shelton, director of the Office of Compliance in the FDA’s Center for Drug Evaluation and Research. “The FDA is committed to ensuring that products marketed as dietary supplements and vitamins do not pose harm to consumers.”

View a larger version of this image on FDA.gov
Maker pulls OxyElite Pro products linked to liver ills

Alison Young, USA TODAY  6:49 p.m. EST November 13, 2013

The Food and Drug Administration announced Sunday that USPlabs is recalling certain OxyElite Pro sports supplement products that have been linked to an outbreak of liver illnesses, including one death.

The action follows a letter the FDA sent Wednesday notifying the Dallas-based dietary supplement maker that if it did not recall the supplements voluntarily, the agency would order the company to stop distribution of the products immediately and notify other distributors and retailers to stop selling them.

“We took this step to ensure that adulterated and harmful products do not reach the American public,” FDA Deputy Commissioner Michael Taylor said.

Private Sparling had recently graduated from basic training and was in excellent physical condition. Before the exercise, he had taken the recommended dose of a workout supplement called Jack3d, bought at a GNC store on the base, according to legal filings.

Here's the bad news: A dietary supplement named OxyElite Pro is still apparently making people sick, more than a year after the Hawaii Department of Health was alerted to seven cases of acute hepatitis and liver failure among its users. As of last February, the Centers for Disease Control and Prevention had linked 47 hospitalizations, three liver transplants and one death to the diet product.
Teenage rugby star killed by online diet pills

Police are investigating how a promising young rugby star got hold of the "fat burning" pills that killed him.

Chris Mapletoft was a student at the prestigious Hampton School in west London and a star player for Hampton's 1st XV rugby team. Photo: National

By Hayley Dixon
5:06PM BST 15 Sep 2013

Chris Mapletoft, 18, an A-Level student at one of Britain's top independent schools, is believed to be the youngest victim of the toxic chemical which is widely sold online as a quick-fix diet aid. His is the 16th death linked to the drug in Britain in the past decade.

Although 2,4-dinitrophenol, a "poison" used in pesticides commonly known as DNP, is banned for human consumption, it is widely available over the internet.

Father dies after taking male enhancement pill, family sues

By: 1511.com staff
POSTED: 2010 AM, Dec 30, 2013

KANSAS CITY - Last September, the family of David McFhew claims he bought a male sexual stimulant that ultimately led to his death.

He purchased the product at Erotic City in Kansas City. A day after he took the product, McFhew suffered such low blood pressure that he lost consciousness and went into cardiac arrest. He didn't survive.

The mother of his two children, Trisha Hale, is now suing the parent company of Erotic City, Enlightened Retailing Inc, as well as manufacturers Novacare and Impulsar.

The suit claims the label of the product, Stiff Nights, didn't show that it contained "a controlled ingredient, Sildenafil citrate and/or
How Big is the Problem?

• Over 55,000 dietary supplements are sold in the US alone, mostly unregulated.*

• Global dietary supplement industry: approx. $85 billion/year**

• According to the Journal of the American Medical Association, out of more than two dozen supplements that were recalled because they were tainted with anabolic steroids or prescription drugs, two-thirds were back on the market a year later, with the same illegal ingredients.***

• Dietary supplements account for nearly 20 percent of drug-related liver injuries that turn up in hospitals.****

• LegitScript’s database includes over 20,000 problematic products. We have classified over 19,000 dietary supplement websites (many of which sell problematic products).

Dietary supplements that have been tainted with active pharmaceutical ingredients (i.e., drugs).

Dietary supplements that are inherently dangerous, even if used as directed.

- Dietary supplements that contain ingredients that may be permissible in one country, but are prescription-only in other jurisdictions.

- Dietary supplements whose name is confusingly similar to a prescription drug.

- “Botanicals” that are really psychoactive highs.
Tainted Supplements: How to Find Them

- Heightened levels of scrutiny for certain categories of supplements: sexual enhancement, bodybuilding, and weight loss


- Search engines: Search product name plus “recall” or “tainted”

- legitscript.com
Certain products have been deemed dangerous by government regulatory bodies, even if used as directed. Some examples:

- DNP (no legitimate dietary use)
- Germanium*
- Vitamin B17 (also known as laetrile, amygdalin, or “bitter apricot” capsules or kernels)**

* [http://www.accessdata.fda.gov/cms_ia/importalert_139.html](http://www.accessdata.fda.gov/cms_ia/importalert_139.html)
Prescription-only Ingredients

- There are a number of ingredients that are permissible dietary supplement ingredients in the United States, but are prescription-only drug ingredients in other countries.
  
  Merchants who sell supplements to other jurisdictions must comply with those countries’ laws.
  
  Examples: yohimbe, yohimbine, ginkgo biloba, DHEA, serrapeptase, epimedium, vinpocetine.
Some dietary supplements have names and described effects that are confusingly similar to prescription drugs, implying the same safety and efficacy as the prescription drug.

Example: Phentemine 375 (confusingly similar to phentermine, a controlled substance in many countries).
Yes. Bodybuilding supplements are just a sub-category of dietary supplements. But a few things to look out for:

These products may be tainted with anabolic steroids or “synthetic designer steroids.”

Unlike other types of dietary supplements, many bodybuilding supplements don’t hide their problematic ingredients (they can be found right on the label).

DMAA: Until recently, DMAA was a common bodybuilding ingredient. Banned in many jurisdictions (because of risk of heart attacks, seizures, death).

New problematic ingredients being added on a yearly basis. When ephedrine was banned, manufacturers replaced it with DMAA, which was then declared illegal. Manufacturers replaced DMAA with aegeline, which was then linked to liver failure and recalled. Currently, regulators are investigating AMP-Citrate (but no conclusion yet).
Kratom (controlled in a number of EU Member States; subject of an import alert in the US).

Salvia divinorum (placed under regulatory controls in a number of countries, including Australia, Italy, Japan, Spain, Sweden; in the US, it is included in the DEA’s “Drugs of Concern”)

CBD (Schedule II controlled substance in Canada; legal grey area in the US)
Dietary supplement merchants that make problematic claims about their products, in violation of US’ (and most other countries’) laws.

Dietary supplement merchants that have been the recipient of FDA “warning letters” (sometimes other government regulatory agencies send out something similar, but it is rare).
Dietary supplements cannot be marketed for the cure, mitigation, treatment, or prevention of diseases. This is a global rule.

Dietary supplements cannot claim to affect the structure or function of the body, without adequate substantiation.

These claims can be found anywhere – packaging, advertisement, testimonials, ingredients, “doctor recommendations,” etc.
BioAnue Alzheimer's Mender Naturally Reverses Alzheimer's Disease

Alzheimer's disease affects about 10% of the population at age 65 and affects an astonishing 50% by age 80. This article explores the use Alzheimer's Mender to effectively remove oxidative stress from the brain, repair the neurological-network, encourage the production of brain cells, and help rebuild the hippocampus.
FDA sends warning letters to manufacturers or distributors of dietary supplements that are marketing their products with problematic claims.

Link to FDA warning letters: http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/

Vitamins Direct (USA), Inc. 10/17/14

We reviewed your website at www.vitaminsdirectonline.us in July 2014 and determined that you take orders there for the products Pulsate Plus, Lipid Results, OC-Max, Cardio Results Omega III, Flexezy FLX, Flexezy-GC, Honey Bee Propolis and Glyco Results which the website promotes for conditions that cause the products to be drugs under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)]. The therapeutic claims on your website establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act.
Dietary supplement merchants are not all created equal.

If a merchant sells a “Red Flag” product, that merchant is acting unlawfully (the merchant should remove all “Red Flag” products, or if the website is primarily selling “Red Flag” products, steer clear!)

If a merchant claims that its products diagnose, mitigate, treat, cure, or prevent diseases: that merchant is acting unlawfully (but can be given a chance to clean up the marketing!).
Questions?
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MAC Mission Statement

Strengthen the payment ecosystem through ongoing education, communication and cooperation among acquirers, card brands and enforcement agencies.

**Who we serve:**
- Acquiring Bank
- Acquiring Savings & Loan
- Acquiring Credit Union
- Gateway Provider
- Internet Service Provider
- ISO/MSP
- Merchant Acquirer
- Processor
- Risk Management Professional

Your membership in MAC is an investment that should not be overlooked.

**If you are not a member of MAC... JOIN TODAY!**

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