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Justice Department and Federal Partners Announce Enforcement Actions of Dietary Supplement Cases

Criminal Charges Brought against Bestselling Supplement Manufacturer

As part of a nationwide sweep, the Department of Justice and its federal partners have pursued civil and criminal cases against more than 100 makers and marketers of dietary supplements. The actions discussed today resulted from a year-long effort, beginning in November 2014, to focus enforcement resources in an area of the dietary supplement market that is causing increasing concern among health officials nationwide. In each case, the department or one of its federal partners allege the sale of supplements that contain ingredients other than those listed on the product label or the sale of products that make health or disease treatment claims that are unsupported by adequate scientific evidence.

Among the cases announced today is a criminal case charging USPlabs LLC and several of its corporate officers. USPlabs was known for its widely popular workout and weight loss supplements, which it sold under names such as Jack3d and OxyElite Pro.

The sweep includes federal court cases in 18 states and was announced today by Principal Deputy Assistant Attorney General Benjamin C. Mizer, head of the Justice Department's Civil Division; Deputy Commissioner for Global Regulatory Operations and Policy Howard Sklamberg J.D. of the Food and Drug Administration (FDA); Acting Deputy Director J. Reilly Dolan of the Federal Trade Commission (FTC)'s Bureau of Consumer Protection; Acting Deputy Chief Inspector Gary Barksdale of the U.S. Postal Inspection Service (USPIS); and Chief Richard Weber of the Internal Revenue Service's (IRS) Criminal Investigation (CI) Division. The Department of Defense (DoD) and the U.S. Anti-Doping Agency (USADA) are also participating in the sweep to unveil new tools to increase awareness of the risks unlawful dietary supplements pose to consumers and, in particular, to assist service members targeted by illegitimate athletic performance supplements.

"The Justice Department and its federal partners have joined forces to bringing to justice companies and individuals who profit from products that threaten consumer health," said Principal Deputy Assistant Attorney General Mizer. "The USPlabs case and others brought as part of this sweep illustrate alarming practices the department found—practices that must be brought to the public's attention so consumers know the serious health risks of untested products."

During the period of the sweep, 117 individuals and entities were pursued through criminal and civil enforcement actions. Of these, 89 were the subject of cases filed since November 2014.

Criminal Matters

An 11-count indictment was unsealed earlier today against USPlabs LLC, a Dallas firm, which formerly manufactured highly popular workout and weight loss supplements. The indictment charges USPlabs, S.K.

Laboratories Inc., based in Anaheim, California, and their operators with a variety of charges related to the sale of those products. Jacobo Geissler, 39, of University Park, Texas, the CEO of USPlabs; Jonathan Doyle, 37, of Dallas, the president of USPlabs; Matthew Hebert, 37, of Dallas, responsible for product packaging design at USPlabs; Kenneth Miles, 69, of Panama City, Florida, the quality assurance executive in charge of compliance at USPlabs; S.K. Laboratories Inc.; Sitesh Patel, 32, of Irvine, California, the vice president of S.K. Laboratories; and Cyril Willson, 34, of Gretna, Nebraska, a consultant to USPlabs, are charged with various counts associated with the unlawful sale of dietary supplements. Additionally, USPlabs, Geissler, Doyle and Hebert are charged with obstruction of an FDA proceeding and conspiracy to commit money laundering.

Four of the defendants were arrested earlier today and the other two will self-surrender. Along with the arrests, FDA and IRS-CI special agents seized assets in dozens of investment accounts, real estate in Texas and a number of luxury and sports cars.

The indictment alleges that USPlabs engaged in a conspiracy to import ingredients from China using false certificates of analysis and false labeling and then lied about the source and nature of those ingredients after it put them in its products. According to the indictment, USPlabs told some of its retailers and wholesalers that it used natural plant extracts in products called Jack3d and OxyElite Pro, when in fact it was using a synthetic stimulant manufactured in a Chinese chemical factory.

The indictment also alleges that the defendants sold some of their products without determining whether they would be safe to use. In fact, as the indictment notes, the defendants knew of studies that linked the products to liver toxicity.

The indictment also alleges that in October 2013, USPlabs and its principals told the FDA that it would stop distribution of OxyElite Pro after the product had been implicated in an outbreak of liver injuries. The indictment alleges that, despite this promise, USPlabs engaged in a surreptitious, all-hands-on-deck effort to sell as much OxyElite Pro as it could as quickly as possible. It was sold at dietary supplement stores across the nation.

“This joint agency effort is a testament to our commitment to protecting consumers from potentially unsafe dietary supplements and products falsely marketed as dietary supplements,” said Deputy Commissioner Sklamberg. “The criminal charges against USPlabs should serve as notice to industry that if products are a threat to public health, the FDA will exercise its full authority under the law to bring justice.”

Today’s criminal charges are among 14 criminal cases prosecuted by the Civil Division’s Consumer Protection Branch and U.S. Attorney’s Offices across the country from November 2014 to November 2015. See this [chart](#). Of the 14 criminal cases prosecuted during this timeframe, 11 cases against 29 individuals and entities have been filed since November 2014.

The charges and allegations in the indictments are merely accusations, and the defendants are presumed innocent unless and until proven guilty.

Civil Cases

The Department of Justice also filed in the past week five civil cases seeking injunctive relief against a number of businesses and individuals that allegedly sold supplements as disease cures or that were otherwise in violation of the law. These matters, investigated by USPIIS and the FDA, include the following:

- *United States v. Clifford Woods LLC, doing business as Vibrant Life, and Clifford Woods*. A [complaint](#), filed in the U.S. District Court for the Central District of California, alleges that the defendants unlawfully sold Taheebo Life Tea, Life Glow Plus, Germanium and Organic Sulfur (identified as methyl

sulfonyl methane) as treatments for various diseases including Alzheimer’s disease and cancer. The complaint alleges that the defendants’ conduct defrauded consumers through the sale of unapproved new and misbranded drugs.

- *United States v. James R. Hill, doing business as Viruxo*. A complaint, filed in the U.S. District Court for the Middle District of Florida, alleges that the defendants unlawfully sold a dietary supplement called Viruxo as a treatment for herpes. The complaint alleges that the defendants’ conduct defrauded consumers through the sale of unapproved new and misbranded drugs.
- *United States v. Lehan Enterprises, Inc., doing business as Optimum Health, and Lesa Sverid*. A complaint, filed in the U.S. District Court for the District of Massachusetts, alleges that the defendants unlawfully sold products called DMSO Cream, DMSO Cream with Aloe and DMSO Roll On as treatments for conditions and diseases including arthritis and cancer. The complaint alleges that defendants sold unapproved new and misbranded drugs.
- *United States v. Bethel Nutritional Consulting, Felix Ramirez, and Kariny Ramirez*. A complaint, filed in U.S. District Court for the District of New Jersey, alleges that the defendants distribute dietary supplements in a manner that does not conform to current good manufacturing practice for dietary supplements and that they are making claims about the uses for many of the products that render them unapproved and misbranded drugs. Furthermore, FDA testing has revealed that some of defendants’ products contain active pharmaceutical ingredients that are not listed on the products’ labels, including one ingredient that was withdrawn from the market in 2010 because of safety concerns. The defendants in this matter have agreed to be bound by a consent decree of permanent injunction banning them from selling dietary supplements until they come into compliance with the law.
- *United States v. VivaCeuticals, Inc., doing business as Regenecca Worldwide, and Matthew Nicosia*. A complaint filed in U.S. District Court for the Central District of California alleges that dietary supplements sold by the defendants are adulterated because they are not manufactured in accordance with the FDA’s current good manufacturing practice regulations. One of the dietary supplements, a product called RegeneSlim Appetite Control (RegeneSlim), contains the ingredient 1, 3 dimethylamylamine (DMAA), an unsafe food additive under the federal Food, Drug and Cosmetic Act, but does not declare DMAA as an ingredient. In addition, the defendants market RegeneSlim to be used as a disease cure.

“Postal Inspectors have a long history of effectively enforcing the mail fraud statute to halt snake oil salesmen and medical quacks from using the mails to purvey their wares upon unsuspecting citizens,” said Acting Deputy Chief Postal Inspector Barksdale. “We look at these latest misrepresentations and frauds as ‘old wine in a new bottle.’ Working with our law enforcement and regulatory partners, we hope to protect American consumers by keeping these scams ‘bottled up.’”

Civil actions brought by the FTC as part of the sweep to combat unsubstantiated supplement claims include the following:

- *Sunrise Nutraceuticals, LLC*. According to the FTC’s complaint, Sunrise, based in Boca Raton, Florida, deceptively claims that its dietary supplement Elimidrol, a “proprietary blend” of herbs and other compounds, alleviates opiate withdrawal symptoms and increases a user’s likelihood of overcoming opiate addiction. The FTC’s complaint alleges, however, that Sunrise’s ads for Elimidrol are deceptive because they are false or unsubstantiated.
- *Health Nutrition Products*. The FTC’s complaint charged Crystal Ewing, five other individuals and five companies with making false and misleading health and efficacy claims in direct mail ads and on a website owned by Ewing. In ads for W8-B-Gone, CITRI-SLIM 4 and Quick & Easy diet pills, the defendants featured bogus weight-loss experts. Citing fake scientific studies, the defendants also

deceptively claimed to have clinical proof that consumers would experience a “RAPID FAT meltdown diet program” that lets them shed five pounds in four days with one pill, or up to 20 pounds in 16 days with four pills. The proposed court orders announced today will settle the FTC’s charges against three defendants involved in the scheme. The order against repeat offender Ewing and her company Classic Productions LLC requires them to admit liability in the case, bans them from selling weight-loss programs, products and services, and imposes a non-suspended judgment of \$2.7 million.

- ***NPB Advertising, Inc.*** According to the FTC’s complaint filed in the U.S. District Court for the Middle District of Florida’s Tampa Division, Florida-based NPB and others capitalized on the green coffee bean diet fad by using false weight-loss claims and fake news websites to market a dietary supplement called Pure Green Coffee. The proposed court order announced today settles the FTC’s charges, bars the defendants from the deceptive acts and practices described in the complaint and imposes a \$30 million judgment that will be suspended upon the sale of certain assets, payment of \$160,800, and the collection and turnover of an additional \$155,760 that was lent to a third party.

“People looking for a dietary supplement to improve their health have to wade through a swamp of misleading ads,” said Director Jessica Rich of the FTC’s Bureau of Consumer Protection. “Be skeptical of ads for supplements that claim to cure diseases, reverse the signs of aging or cause weight loss without diet or exercise.”

Today’s cases are among 25 civil actions pursued by the Civil Division’s Consumer Protection Branch, U.S. Attorney’s Offices and the FTC from November 2014 to November 2015. Of the 25 actions, 22 civil cases against 60 individuals and entities have been filed since November 2014. To date, courts have entered judicial orders in 11 cases, requiring dietary supplement makers to change their business practices to ensure that they are selling their products in compliance with the law.

Educational materials

As part of today’s sweep, the Uniformed Services University of the Health Sciences’ Consortium for Health and Military Performance partnered, through its Human Performance Resource Center (HPRC), with the USADA to develop educational resources for service members to protect them from risky dietary supplements. Through this partnership, the organizations will jointly launch an online interactive educational module called “Get the Scoop on Supplements: Realize, Recognize, and Reduce Your Risk.” Also launching today are two mobile applications: the HPRC’s Operation Supplement Safety (OPSS) High-Risk Supplement List mobile application for Service members and USADA’s Supplement 411 mobile application for athletes (both accessible via the Google Play and Apple App stores and available to the general public).

These educational products will augment the important information available on USADA’s [Supplement411.org](http://www.supplement411.org) website and the [OPSS website](http://www.opss.org), including the OPSS High-Risk Supplement List which was launched in February 2015. To access more information available to service members, consult the OPSS website and a recently released video at <http://hprc-online.org/blog/decoding-the-dietary-supplement-industry>. To access the educational resources USADA provides for athletes and general consumers to help realize, recognize and reduce the risks associated with using supplement products visit USADA’s website <http://www.supplement411.org>.

“Ensuring readiness of the force is one of the Department of Defense’s top goals,” said Deputy Assistant Secretary of Defense for Health Affairs Dr. Dave Smith of DoD’s Military Health System. “Unsafe dietary supplements are a threat to readiness in DoD.”

“A combined effort like this is vitally important to protecting the health and safety of athletes at every level,” said USADA CEO Travis T. Tygart. “We work to educate athletes on the risks associated with choosing to use supplements, and we will continue to support further action at a national level to prevent dangerous

substances and products from being allowed in the marketplace where they can easily be attained by unsuspecting athletes and other consumers.”

To promote today’s joint sweep, the FTC created an [infographic](#) to help consumers understand the range of dietary supplement products and claims, the potential risks of taking supplements and questions to ask a health professional before taking any supplements. The FTC also published blogs for [consumers](#) and [businesses](#), and has articles and videos with more information at ftc.gov/dietary-supplements.

The FDA continues to warn consumers about the risks associated with some over-the-counter products, falsely marketed as dietary supplements, which contain hidden active ingredients that could be harmful. In the last year, the agency has [warned of more than 100 products](#) found to contain hidden active ingredients. These products are most frequently marketed for [sexual enhancement](#), [weight loss](#) and [body building](#).

Within the last year, the FDA also sent warning letters to manufacturers selling dietary supplements that contain [BMPEA](#) and [DMBA](#), two ingredients that do not meet the statutory definition of a dietary ingredient as well as to several companies selling [pure powdered caffeine](#) products that the agency determined to be dangerous and present a significant or unreasonable risk of illness or injury to consumers.

Attachment(s):

[Download Bethel Nutritional complaint](#)
[Download optimum complaint - filed](#)
[Download vibrant life complaint - filed](#)
[Download Viruxo filed complaint](#)
[Download Vivaceuticals Inc Complaint](#)
[Download Supplement Sweep Chart to release 2015-11-12 updated](#)
[Download USP Labs indictment_with redactions](#)

[final](#)

Topic(s):

Consumer Protection

Component(s):

[Civil Division](#)

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