Industry News

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—Michael Taylor, FDA, on USPlabs recall

USPlabs Recalls OxyElite Pro Supplements Amid Links to Liver Illness

Dallas, TX-based USPlabs LLC has recalled certain OxyElite Pro dietary supplement products that the company markets after receiving a letter from FDA stating that the products have been linked to liver illnesses and that there is a reasonable probability that the products are adulterated.

The letter also notified USPlabs that if the company did not initiate a voluntary recall, FDA could by law order the company to immediately stop distributing the products and immediately notify other parties to stop distributing the supplements. The action marks the second time the FDA has exercised its recall authority under the FDA Food Safety Modernization Act (FSMA) by sending such a letter.

"We took this step to ensure that adulterated and harmful products do not reach the American public," said Deputy Commissioner for Foods and Veterinary Medicine Michael Taylor. "We will continue to work with our state, industry and regulatory partners to prevent such products from reaching the public."

By letter dated Nov. 6, the FDA notified USPlabs about findings indicating a link between the use of several OxyElite Pro products and a number of liver illnesses reported in Hawaii. The FDA also noted that cases of liver damage after use of these OxyElite Pro products had been found in a number of other states. In a review of 46 medical records submitted to the FDA by the Hawaii Department of Health, the records indicated that 27 patients, or 58%, had taken a dietary supplement labeled as OxyElite Pro prior to becoming ill. Seventeen of the 27 patients (or 63%) reported that OxyElite Pro was the only dietary supplement they were taking. At least one death has occurred among these patients, and others required liver transplant.

In a warning letter issued to USPlabs LLC on Oct. 11, 2013, the FDA informed the company that OxyElite Pro and another dietary supplement called VERSA-1 were deemed to be adulterated. The products contained aegeline, a new dietary ingredient (i.e., an ingredient not marketed in the U.S. before Oct. 15, 1994) that lacks

Global Sales of Non-GMO Food and Beverages to Reach $800 Billion by 2017

Non-GMO products will account for about 15% of total global food and beverage sales.

Non-GMO labeling will become more available as certified testing operations join the verification market.

Global sales of non-GMO food and beverages are projected to rise to $800 billion by 2017 at a compound annual growth rate (CAGR) of 15%, and will account for about 15% of total global food and beverage sales at that point, according to Packaged Facts' recently released report, "Non-GMO Foods: Global Market Perspective." Global sales of non-GMO products reached $400 billion in 2012, accounting for 8% of the overall global food and beverage sales of $5 trillion.

Excluding the U.S. and Canada, Packaged Facts identified 10 countries that represent as much as two-thirds of the new global non-GMO product introductions from 2009-2013. Russia is the leader with 15% share, followed by the U.K. with a share of 10%. From a comprehensive global perspective, the U.S. share is roughly 40%. Aside from the U.S. and Canada, Europe represents seven in 10 global non-GMO food and beverage rollouts between 2009 and 2013. Europe is followed at a considerable distance by Asia and Oceania.

Packaged Facts projected that non-GMO sales will increase in all regions of the globe, as will the practice of labeling foods and beverages with non-GMO verified or certified labels. Prompting increases will be the inevitable expansion of GMO crops into territories where they had previously been banned or limited. Concerned shoppers will want GMO and non-GMO labeling to help them distinguish between the two types of products. The BRIC nations—Brazil, Russia, India and China—will be fertile territory for non-GMO sales as their emerging middle classes look for healthier eating options, according to David Sprinkle, research director for Packaged Facts.

As other nations seek to clarify the labeling of their products, both GMO and non-GMO, Packaged Facts projected the portion of the global non-GMO market represented by sales in the U.S. will decline through 2017. In addition, non-GMO labeling will become more available as certified testing operations, like NSF International, join Cert ID in the non-GMO verification market to take advantage of a growing demand from marketers.

a history of use or other evidence of safety. The letter stated that failure to immediately cease distribution of all dietary supplements containing aegeline may result in enforcement action.

U.S. Marshals Seize Adulterated Supplements Worth More Than $2 Million

At the request of FDA, U.S. Marshals seized dietary supplements manufactured and held by Hi-Tech Pharmaceuticals, Inc., located in Norcross, GA, after agency investigators found the products contained 1, 3-Dimethylamylamine HCl (DMAA) or its chemical equivalent in early November. The retail value of the seized products is more than $2 million.

A complaint filed in the U.S. District Court for the Northern District of Georgia alleged that the products were adulterated according to the Federal Food, Drug, and Cosmetic Act because they contain DMAA, an unapproved food additive that is deemed unsafe under the law.

DMAA can elevate blood pressure and could lead to cardiovascular problems, including heart attack, shortness of breath and tightening of the chest. Given the known biological activity of DMAA, the ingredient may be particularly dangerous when used with caffeine. The FDA has warned consumers about the health risks of DMAA on its website.

On Nov. 12, U.S. Marshals seized more than 1,500 cases of finished goods and more than 1,200 pounds of in-process/raw material goods from the Hi-Tech Pharmaceuticals, Inc. facility.

"This company has a responsibility to ensure its products are safe for distribution and human consumption," said Melinda Plaisier, the FDA's associate commissioner for regulatory affairs. "We have taken action to protect consumers and demon-

Trade Groups Defend Supplement Use Following Multivitamin Review

Meta-analysis concludes more research needed on use of vitamin/mineral supplements for CVD and cancer prevention.

A systematic review of published studies found insufficient evidence that vitamin and mineral supplements are effective for preventing cardiovascular disease (CVD), cancer or mortality from those diseases in healthy adults, according to an article published in *Annals of Internal Medicine*.

More than 150 million Americans use dietary supplements on a daily basis.

Two studies included in the review found lower overall cancer incidence in men who took a multivitamin for more than 10 years. Those same studies showed no cancer protection benefit for women. Researchers cautioned that more research is needed before it can be determined whether or not multivitamin supplementation is beneficial.

The evidence review was conducted by researchers for the U.S. Preventive Services Task Force (USPSTF) to update its previous recommendation. In 2003, the USPSTF found insufficient evidence to recommend for or against the use of vitamins A, C and E, multivitamins with folic acid or antioxidant combinations for the prevention of CVD or cancer. At the time, the USPSTF recommended against beta-carotene supplements alone or in combination with other supplements because they had no benefit and actually harmed patients at risk for lung cancer. The current research review reconfirmed the beta-carotene findings and also found good evidence that vitamin E does not protect against cancer or cardiovascular disease.

In response to the review, industry trade associations offered their analysis.

"Cancer is a complex disease, and the fact that there is even some, albeit limited, evidence that a simple multivitamin could prevent cancer demonstrates promise and should give consumers added incentive to keep taking their multivitamins," said Duffy MacKay, ND, vice president, scientific and regulatory affairs, Council for Responsible Nutrition (CRN), Washington, D.C. "We believe the paucity of clinical trial evidence should not be misinterpreted as a lack of benefit for the multivitamin. We know for sure that multivitamins can fill nutrient gaps, and as so many people are not even reaching the recommended dietary allowances for many nutrients, that's reason enough to add an affordable and convenient multivitamin to their diets.

"Further, given the encouraging results from the Physicians' Health Study (PHS) II (Gaziano et al, 2012)—the study referenced in this report as demonstrating benefit for multivitamins and cancer risk in men—academics and government, as well as our own industry, should continue to support and fund research to clarify this relationship and to determine additional benefits for vitamins and other dietary supplements.

Cara Welch, PhD, senior vice president of scientific and regulatory affairs, noted the scope of this recent research has its limitations. "The meta-analysis focused on studies that researched generally healthy people, avoiding any instances for targeted use of nutrients. Additionally, the researchers only concentrated on studies with vitamins and mineral supplements as the primary source of prevention. Multivitamin supplements should not be expected, without the combination of a healthy lifestyle, to prevent chronic disease. The results of this review should not lead to widespread concern among consumers who take vitamin and mineral supplements."

John Shaw, executive director, NPA, added, "Dietary supplements are used by more than 150 million Americans on a daily basis. Research has shown that when taken in combination with other healthy lifestyle practices, such as consuming a wholesome diet and exercising regularly, people can benefit from dietary supplements. Consumers should be comfortable following a variety of healthy habits, which includes supplementation. As always, NPA encourages consumers to speak with their healthcare professionals regarding their dietary supplement regimen."