FDA: Tainted products marketed as dietary supplements potentially dangerous
Agency working with trade associations to increase company vigilance and protect public

In a letter sent today to dietary supplement manufacturers, the U.S. Food and Drug Administration expressed concern about undeclared or deceptively labeled ingredients in products marketed as dietary supplements. These substances include the active ingredients in FDA-approved drugs or their analogs (closely-related drugs), or other compounds, such as novel synthetic steroids, that do not qualify as dietary ingredients.

In recent years, FDA has alerted consumers to nearly 300 tainted products marketed as dietary supplements and received numerous complaints of injury associated with these products.

The FDA's letter emphasizes that manufacturers and distributors are responsible for ensuring that their products comply with the law. Five major trade associations – Council for Responsible Nutrition, Natural Products Association, United Natural Products Alliance, Consumer Healthcare Products Association and American Herbal Products Association– are joining FDA on a call for media and have agreed to share the letter widely within the industry.

"These tainted products can cause serious adverse effects, including strokes, organ failure, and death," said FDA Commissioner Margaret A. Hamburg, M.D. "The manufacturers selling these tainted products are operating outside the law."

The FDA is seeking input and collaboration from dietary supplement trade associations to educate the industry about this problem and to help develop new strategies to combat it, according to Hamburg.

The agency also announced a new RSS feed to warn consumers more quickly about tainted products marketed as dietary supplements.

The FDA has noted the three most common categories of these illegal products:

1, Weight loss products containing active ingredients such as sibutramine: Sibutramine is the active ingredient in the drug Merida, which was recently withdrawn from the market due to increased risk of heart attack and stroke. The FDA has discovered dozens of products, such as Slimming Beauty, Solo Slim, Slim-30, and others, which contain sibutramine or closely related drugs (analogs).

2, Body-building products containing anabolic steroids or steroid analogs: These products can cause acute liver injury and increase the risk for heart attack, stroke and death. Products like Tren Xtreme, ArimaDex, and Clomed have been labeled to contain either anabolic steroids or aromatase inhibitors, which prevent anabolic steroids from being converted to estrogen.

3, Sexual enhancement products that contain the same active ingredient or an analog of the active ingredient in the approved drugs Viagra, Cialis, and Levitra. The approved products are available only by prescription, and they should not be used by people who have certain medical conditions, such as cardiovascular disease. Products determined to be in violation of federal law by the FDA include Vigor-25, Duro Extend Capsules for Men, Magic Power Coffee, and others.

“The labeling of these tainted products may claim that they are ‘alternatives’ to FDA-approved drugs, or ‘legal’ alternatives to anabolic steroids,” said Michael Levy, director of the Division of New Drugs and Labeling Compliance at the FDA’s Center for Drug Evaluation and Research. “Consumers should avoid products marketed as supplements that claim to have effects similar to prescription drugs. Consumers should also be wary of products with labeling only in a foreign language or that are marketed through mass e-mails.”

Companies that make or distribute tainted products may receive warning letters and/or face enforcement actions such as product seizures, injunctions, and criminal prosecution. Responsible individuals may also face criminal prosecution.

Lawful dietary supplements contain minerals, vitamins or other dietary ingredients and are intended to be an addition to a standard diet. The FDA regulates these products under the Dietary Supplement Health and Education Act, passed by Congress in 1994. Unlike drugs, dietary supplements do not have to be approved by the FDA prior to marketing. Dietary supplement manufacturers and distributors are responsible for selling a safe product. FDA’s Current Good Manufacturing Practices require dietary supplement manufacturers to have proper manufacturing and quality assurance controls in place to ensure the quality of their products, including controls to prevent the inclusion of contaminants that could adulterate their products.

Detail of Media Release from *FDA website*