



FDA NEWS RELEASE

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FDA takes enforcement action against Pennsylvania dietary supplement maker

First permanent injunction of its kind; more than 400 products affected

The FDA today took legal action against a dietary supplement maker and owner for substituting ingredients and products without noting the changes on the final product labels. The permanent injunction, filed on behalf of the FDA by the U.S. Department of Justice, would stop the defendants from making and distributing more than 400 products for being in violation of the Federal Food, Drug, and Cosmetic Act.

This is the first time FDA has taken legal action against a dietary supplement manufacturer of this size for failure to comply with the dietary supplement current Good Manufacturing Practice (cGMP) regulations. The cGMPs for dietary supplements went into effect in 2007, in a stepped process based on company size. This company's compliance date came into effect in 2010, and they did not meet the relevant cGMP requirements after that date.

The FDA requested the permanent injunction against ATF Fitness Products Inc. (ATF), Manufacturing ATF Dedicated Excellence, Inc. (MADE), and James G. Vercellotti of Oakmont, Pa., owner and operator of both companies. The cGMP regulations require manufacturers to ensure quality in their dietary supplements by controlling all aspects of their processes and procedures. MADE makes more than 400 dietary supplements, including vitamins and minerals, under the brands “Sci-Fit,” “Nature’s Science” and “For Store Only.” ATF purchases dietary supplements exclusively from MADE and distributes them throughout the United States.

“Dietary supplements have a significant role in the public’s health,” said Dara Corrigan, associate commissioner for regulatory affairs. “Today’s injunction reinforces our commitment to ensuring that these supplements meet the cGMP requirements the law establishes.”

The government's complaint, filed Nov. 23, 2011, in the U.S. District Court for the Western District of Pennsylvania, alleges that in addition to “adulterating” and “misbranding” their final products, the manufacturer and its owner failed to report serious adverse events associated with their products. In one case an individual who consumed one of the products reported experiencing a spike in blood pressure, hospitalization and a subsequent mild heart attack.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.