FDA News Release

Federal judge approves consent decree with California dietary supplement distributor, Regeneca Worldwide

Company sold products containing DMAA

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Release

A California dietary supplement distributor has been ordered by a federal court to stop selling its products, which were found to contain unsafe ingredients including 1, 3-dimethylamylamine (DMAA).

U.S. District Judge Josephine L. Staton for the Central District of California entered a consent decree of permanent injunction yesterday between the United States and VivaCeuticals Inc., doing business as Regeneca Worldwide, and its owner, Matthew A. Nicosia, a distributor of dietary supplements. The complaint, filed by the U.S. Department of Justice on behalf of the U.S. Food and Drug Administration, sought a permanent injunction against Regeneca Worldwide for unlawfully distributing unapproved new drugs, and adulterated and misbranded dietary supplements.

DMAA is an amphetamine derivative that has been widely used in sports supplements sold in the United States. DMAA is often touted as a “natural” stimulant, with many claimed functional uses including as a body-building aid, an athletic performance enhancer, and a weight-loss aid. Although DMAA at one time was approved as a drug for nasal decongestion, no medical use of DMAA is recognized today.

DMAA narrows blood vessels and arteries, which can elevate blood pressure, and may lead to cardiovascular problems such as shortness of breath, arrhythmias, tightening in the chest, and heart attack, as well as seizures and other neurological and psychological conditions.

“Consumers have a right to expect safe dietary supplements,” said Melinda Plaisier, the FDA’s associate commissioner for regulatory affairs. “When a company continues to defraud and deceive consumers, risking public health, we will take action to protect the American public.”

In August 2012, the FDA sent Regeneca a warning letter for marketing a dietary supplement containing DMAA. Despite assurances that Regeneca was correcting violations noted in the

warning letter, Regeneca continued to distribute a dietary supplement that was found to contain DMAA.

The consent decree prohibits Regeneca from marketing unapproved new drugs, and adulterated and misbranded dietary supplements. Before Regeneca can resume operations, the company must, among other things, hire good manufacturing practice and labeling experts, implement procedures to comply with good manufacturing practice and labeling requirements and receive written permission from the FDA to resume operations. In addition, the decree requires Regeneca to destroy all remaining products.

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.

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