

FDA cracks down on illegal supplements

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(AP) -- The Food and Drug Administration is cracking down on manufacturers of certain weight loss, body building and sexual enhancement supplements that contain potentially dangerous ingredients.

The FDA said Wednesday that some manufacturers are deceptively labeling products to hide that they contain ingredients known to cause <u>adverse health effects</u>. Other supplements contain ingredients that should only be available by prescription.

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

<u>Dietary supplements</u> can slip through the regulatory cracks because, unlike drugs, they do not have to be approved by the FDA before they are marketed. Manufacturers are responsible for making sure their products are safe.

The FDA has pressured companies to recall nearly 200 inappropriately-formulated products since 2007, including 80 that were marketed as body building supplements, according to the agency. The recalled products were linked to reports of stroke, kidney failure, liver injury and death.

Government regulators do not have the power to force companies to recall products, and instead the FDA usually issues warning letters to draw attention to illegal products.

In a letter to the supplement industry, the agency said manufacturers who distribute tainted products could face criminal prosecution.

Executives from the supplement industry said they support the FDA crackdown and would share the letter with companies.

"The spiking of supplements with drugs is a crime,

it endangers the public and undermines our members and other legitimate manufacturers and retailers of supplements," said John Gay, executive director of the Natural Products Association, on a media call with FDA leadership.

The FDA said the agency is targeting weight loss products containing sibutramine, which has been withdrawn from the market for causing increased risk of heart attack and stroke. The agency said it has discovered "dozens of products" that contain the ingredient, including those marketed under the brand names Slimming Beauty, Solo Slim and Slim-30.

Body building products under scrutiny include those containing anabolic steroids or steroid analogs. The agency cited Tren Xtreme, ArimaDex, and Clomed as supplements that have been labeled to contain those products.

The agency also warned consumers to be wary of sexual enhancement products that include similar ingredients to the approved drugs Viagra, Cialis, and Levitra. Those ingredients should only be available by prescription. The FDA said products marketed under the names Vigor-25, Duro Extend Capsules for Men, and Magic Power Coffee have been determined to be in violation of federal law.

"Consumers should avoid products marketed as supplements that claim to have effects similar to prescription drugs," said Michael Levy, director of labeling compliance for the agency. "Consumers should also be wary of products with labeling only in a foreign language or that are marketed through mass e-mails."

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