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Supplements for Athletes Draw Alert From F.D.A.

By NATASHA SINGER and [MICHAEL S. SCHMIDT](#)

Federal regulators warned consumers on Tuesday not to use body-building products that are sold as nutritional supplements but may contain [steroids](#) or steroidlike substances, citing reports of acute liver injury and [kidney failure](#).

The [Food and Drug Administration](#) said it issued [the warning](#) because of increased reports of medical problems in men who had used such products.

But except for naming eight specific supplements sold by a single company, the Food and Drug Administration did not provide much clear guidance to consumers on what other products to avoid. The F.D.A. acknowledged that it did not know how many products its warning affects.

Generally, the F.D.A. said, buyers should beware of body-building products that claim to enhance or diminish the effects of hormones like [testosterone](#), [estrogen](#) or progesterin. In particular, the agency said consumers should not buy products labeled with code words like "anabolic" and "tren," or phrases like "blocks estrogen," and "minimizes gyno." The references to estrogen and "gyno" are meant to indicate the products do not have a feminizing effect on the body, like [swelling](#) breasts or shrinking testicles, which can be unwanted side effects of steroid use in men.

The F.D.A. cited eight popular products from American Cellular Labs, including Mass Xtreme and Tren Xtreme, that the agency found to contain hidden and potentially hazardous steroids. The agency sent a [letter](#) on Monday warning the company to make the products comply with federal regulations. Last week, federal agents in San Francisco [executed search warrants](#) for the company and for a San Francisco outlet of Max Muscle, a chain of sports [nutrition](#) stores, some of which sold the products cited by the F.D.A.

"We think that there may be a number of firms that are marketing similar products, if not products that are exactly the same," Michael Levy, director of the Division of New Drugs and Labeling at the agency's Center for Drug Evaluation and Research, said in a conference call with reporters on Tuesday. The agency, he said, is considering taking action against those firms as well.

The warning is part of a larger investigation into body-building products that contain hidden steroids, according to court documents in the American Cellular Labs case. A spokesman for Joseph P. Russoniello, the United States attorney for the Northern District of California, said he could not comment on open investigations.

But Travis Tygart, the chief of the [United States Anti-Doping Agency](#), which oversees the drug

testing of Olympic athletes, estimated that there could be 50 or more other brands on the market that contain the same steroids as those in the American Cellular products. The F.D.A. warning follows the agency's crackdown on more than 70 brands of weight-loss supplements that the [agency found](#) to illegally contain hidden and potentially dangerous active pharmaceutical ingredients.

But the federal regulations governing [dietary supplements](#) are inadequate to protect consumer health, [according to some experts](#) who have studied the safety of such products.

Unlike drug makers, which must demonstrate that a drug is safe and effective before the agency approves it for sale to the public, dietary supplements are a largely self-regulating industry. Manufacturers of such products are themselves responsible for the safety and effectiveness and marketing claims of their products, and for voluntarily recalling them if problems arise. The F.D.A. has authority to act only after it has received reports of serious health problems associated with products already on sale and it is able to prove a serious health hazard. If a company refuses to voluntarily recall problem products, the agency can then file an injunction and seize the products.

Such a reactive strategy puts consumers at risk, critics said.

"I applaud what the F.D.A. is doing, but the law handcuffs their hands behind their backs when they are dealing with the tsunami of products that get on the shelves," said Mr. Tygart, the antidoping official. "This shows a glaring light on the ineffective regulatory scheme that allows these products to get to the market."

He added: "The reality is that these products are still out, and consumers who don't hear or read about the warning will continue to use them because it's so hard to recall them."

Over the last two years, the F.D.A. has received 15 reports of serious health problems — including stroke, liver problems and pulmonary embolism — associated with body-building products from various makers, the agency said. One of the five reports connected to American Cellular products concerned a 38-year-old man who had severe liver and kidney problems that needed to be treated with [dialysis](#) after he used the company's products, according to warrants issued in the case.

Steroids are organic compounds, like hormones or [cholesterol](#), that naturally occur in the body. Some compounds called anabolic androgenic steroids, which affect both the metabolism and the endocrine system, are approved as drugs to treat medical problems like testosterone deficiencies.

But the F.D.A.'s action pertains to unapproved forms of synthetic steroids — popularly known as designer steroids because they are intended to evade detection by sports authorities who test athletes for performance-enhancing drugs.

Under the law, dietary supplements are defined as products that contain natural foodstuffs like minerals or herbs and do not claim to prevent, mitigate or cure specific illnesses. But it is illegal for dietary supplements to contain ingredients like synthetic steroids, said Mr. Levy of the F.D.A.

The F.D.A. considers body-building products that contain synthetic steroids — like modified forms of testosterone or progestin — to be illegal, unapproved drugs that may put consumers at

risk because they have not been evaluated for safety or efficacy, he said.

The overwhelming majority of dietary supplements are made by reputable manufacturers that ensure the products are safe, said Andrew Shao, the vice president for science and regulation at the Council for Responsible Nutrition, an industry trade group representing manufacturers and distributors.

Americans spent nearly \$24 billion on dietary supplements in 2007, according to Nutrition Business Journal, a market research firm.

Of that total, Mr. Shao estimated that tablets or capsules that claim to build muscles or enhance athletic performance represented perhaps \$2.8 billion in sales. He advised consumers not to buy body-building products with hyped-up claims.

But a law firm that represents sports nutrition companies said the F.D.A.'s action left consumers and manufacturers in the dark as to what specific products the agency considered to be problematic. Moreover, the agency seems to be taking action against some steroid ingredients that the [Drug Enforcement Administration](#), which has jurisdiction over controlled substances, has not yet declared to be illegal unless prescribed by a physician, said Michael J. DiMaggio, a lawyer in Mineola, N.Y.

“The F.D.A. kind of kicked the door in and said ‘we believe they are illegal now,’” Mr. DiMaggio said. “This is going to come as a shock to many companies and big distributors.”

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