Crackdown on ‘Andro’ Products

Federal health officials say a crackdown on companies that manufacture, market, or distribute products containing androstenedione, or “andro,” is necessary due to concerns about the safety of the substance. Widely marketed to athletes and bodybuilders, androstenedione has been advertised to promote muscle growth, improve muscular strength, reduce fat, and slow aging. But androstenedione acts like a steroid once it is metabolized by the body, and can pose similar kinds of health risks as steroids.

“Young people, athletes and other consumers should steer clear of andro because there are serious, substantial concerns about its safety,” Health and Human Services Secretary Tommy G. Thompson said in announcing the crackdown. “Young people should understand that there are no shortcuts to a stronger body and that the best way to get faster and stronger is through good diet, nutrition, and exercise.”

“Athletics benefit young people’s health and give them a lesson in the value of hard work,” added John P. Walters, director of the White House Office of National Drug Control Policy. “Androstenedione and other performance-enhancing drugs undercut these benefits by endangering our children’s healthy development and teaching them that cheating is an acceptable component of pursuing excellence.”

As part of the crackdown, the Food and Drug Administration sent letters in March 2004 to 23 companies, asking them to stop distributing products sold as dietary supplements that contain androstenedione and warning them that they could face enforcement actions if they do not take appropriate actions.

About 1 out of 40 high school seniors reported that they had used andro in the past year, according to the HHS 2002 Monitoring the Future survey, which tracks drug use among students. The survey, conducted by the National Institute on Drug Abuse, also found that about 1 out of 50 10th-graders had taken andro during the previous year.

People produce androstenedione naturally during the making of testosterone and estrogen. When people consume androstenedione, it is converted to testosterone and estrogen. Scientific evidence shows that when androstenedione is taken over time and in sufficient quantities, it may increase the risk of serious and life-threatening diseases.

Potential long-term consequences of the use of androstenedione products in men include decreased testicle size, impotence, and the development of female characteristics such as breast enlargement. Women who use these products may develop male characteristics such as male pattern baldness, deepening of the voice, and increased facial hair. In addition, women also may develop abnormal menstrual cycles, abnormal menstrual bleeding, and blood clots. Androstenedione use also increases the risks for breast cancer and endometrial cancer in women. Children who use these products are at risk for puberty beginning earlier and bone growth stopping prematurely.

The FDA considers dietary supplements that contain androstenedione to be adulterated under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Supplements containing new dietary ingredients have to meet certain requirements, and because these requirements have not been met for androstenedione, supplements containing the ingredient cannot be marketed legally.

Under the FD&C Act, the FDA is also responsible for taking action against any unsafe dietary supplement product after it reaches the market. The FDA also informed firms that it is aware of no history of use or other information establishing that a dietary supplement containing androstenedione is safe.

The National Collegiate Athletic Association, the National Football League, and the International Olympic Committee have all banned the use of androstenedione. The American Academy of Pediatrics, the Endocrine Society, the American Medical Association, and other health professional groups have cautioned against the use of certain steroids and their precursors, like androstenedione, because of their potential long-term adverse health consequences.

The FDA will determine whether further actions are necessary if firms refuse to stop distribution of androstenedione products. Such actions could include seizing illegal products as well as pursuing injunctions or seeking criminal sanctions against people who violate the law.

For More Information
www.cfsan.fda.gov/~dms/dsandro.html