Health and Human Services warns against use of Androstenedione

In a press release statement, Tommy G. Thompson secretary of the Health and Human Services (HHS) announced that the agency is beginning a crackdown on companies that manufacture, market and distribute products containing androstenedione. Because androstenedione acts like a steroid once it is metabolized by the body it can, therefore, pose similar kinds of health risks as steroids. The HHS warned that products containing androstenedione are generally advertised as dietary supplements that enhance athletic performance based on their claimed anabolic and androgenic properties to stimulate muscle growth and increase production of testosterone.

The HHS' Food and Drug Administration (FDA) sent warning letters to 23 companies asking them to cease 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. Secretary Thompson also encouraged Congress to pass legislation in the House that would classify androstenedione-containing products as a controlled substance. Such legislation would enable the US Drug Enforcement Agency (DEA) to regulate these types of products as anabolic steroids under the Controlled Substances Act.

"While andro products may seem to have short-term benefits, the science shows that these same properties create real and significant health risks," said FDA Commissioner Mark B. McClelan, Ph.D., M.D., in a press-release statement. Androstenedione is produced naturally in humans during the production of testosterone and estrogen. It is considered an anabolic steroid precursor because it can be converted in the body to testosterone. 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 these products in men include testicular atrophy, 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 may also develop gynecological problems, and women who use these products may also be at increased risk for breast cancer and endometrial cancer. Children who use these products are at risk of early onset of puberty and of premature cessation of bone growth.

Approximately 1 out of 40 high-school seniors and 1 out of 50 high-school sophomores reported that they had used androstenedione in the past year, according to HHS' 2002 Monitoring the Future survey (conducted by HHS' National Institute on Drug Abuse), which tracks drug use among students.

The HHS actions represent the most recent steps in a broader effort to ensure that dietary supplements are safe for the consumers who use them. If androstenedione is a dietary ingredient, FDA believes that it is also a new dietary ingredient for which a premarket safety notification is required. Because no such notification has been submitted by any manufacturer or distributor who has received a warning letter, these products are adulterated and their marketing is prohibited under the Federal Food, Drug, and Cosmetic Act.

For more information, visit: http://www.cfsan.fda.gov/~dms/androlist.html.

NCAM NEWS AND EVENTS

NCAM News and Events A telephone educational workshop will be held on June 22, 2004 from 1:30-2:30 PM Eastern Time. The workshop, which is entitled, "An Overview of Complementary and Alternative Medicine and Cancer," will be hosted by speaker Stephen E. Strauss, M.D., Director of the National Center for Complementary and Alternative Medicine (NCCAM).

The telephone workshop is designed for people with cancer and their family and friends, and is a collaboration between NCCAM, Cancer Care, Inc., and the American Society for Clinical Oncology. Participants will listen by telephone, and both registration and the telephone call are free.

To register, go to www.cancercare.org or call 1-800-813-4673. The workshop will also be archived at www.cancercare.org. On June 4, 2004, at the time of press, the meeting of the National Advisory Council for Complementary and Alternative Medicine was held. For more information on this quarterly event, please visit: nccam.nih.gov/about/advisory/naccam.

New Survey Released

The results of the 2002 National Health Interview Survey (NHIS), which was developed by NCCAM and the Centers for Disease Control and Prevention's (CDC's) National Center for Health Statistics (NCHS), were recently released.

The survey, which was administered to more than 31,000 representative US adults, included questions on 27 types of CAM therapies commonly used in the United States. These included 30 types of provider-based therapies, such as acupuncture and chiropractic, and 17 other therapies that do not require a provider, such as natural products (herbs or botanical products), special diets, and megavitamin therapy.