

A Weekly FAX from the Center for Substance Abuse Research

University of Maryland, College Park

FDA to Ban the Sale of Ephedra-Containing Supplements in Early 2004

On December 30, 2003, the federal Food and Drug Administration (FDA) announced that a ban on the sale of dietary supplements containing ephedra will be issued in early 2004, based on the agency's conclusion that these supplements present an unreasonable health risk. This represents the first time that the FDA will impose major restrictions on the sale of a dietary supplement.

What is ephedra? Ephedra is a naturally occurring substance extracted from the ephedra plant, with varieties growing in parts of Asia, Australia, Europe, and North America. The principal active ingredient in ephedra is ephedrine, which is regulated as a drug when chemically synthesized. Ephedra is an ingredient in nearly 200 dietary supplements sold over-the-counter in the U.S., including Stacker 2®, Stacker 3®, Ripped Fuel®, Xenadrine®, Metabolife 356®, Yellow Jackets, and Yellow Swarm.

What are other names for ephedra? Ephedra is sometimes listed on dietary supplements under other names such as ma huang, epitonin, sida cordifolia, and sinica. It has also been called squaw tea, desert tea, desert herb, and Mormon tea.

How is ephedra used? Ephedra is most commonly taken orally as part of the supplement in which it is contained. The herb can also be brewed as a tea.

Why is ephedra used? This herb has a long history of medicinal uses in both China and India, predominantly to treat respiratory infections. Ephedra is often used in the U.S. to aid in weight loss and to enhance athletic performance. However, a recent review of ephedra research concluded that ephedra promotes only modest short-term weight loss and that evidence to support the use of ephedra for athletic performance is insufficient (Shekelle et al. 2003).

How does ephedra affect the body? Ephedra is a stimulant with effects similar to amphetamines, including increased blood pressure, cardiac arrhythmia, heart attacks, strokes, seizures and sudden death. A 2003 study reported that ephedra sales make up 4% of all dietary supplement sales, yet account for 64% of all adverse events associated with dietary supplements reported to poison control centers in the U.S. (Annals of Internal Medicine, 2003).

Why wasn't ephedra banned earlier? Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), manufacturers are not required to prove the safety or effectiveness of dietary supplements before marketing them. Once a supplement is on the market, the FDA can regulate its sale only if the agency can prove that the product presents "an unreasonable risk of illness or injury." The FDA first proposed regulating ephedra in 1997, but there was insufficient scientific evidence to justify a ban until recently. Ephedra has already been banned by several athletic agencies, retail establishments, and three states (Illinois, New York, and California).

SOURCES: A complete list of sources is available at www.cesar.umd.edu. For more information on the FDA ephedra ban, go to <http://www.fda.gov/oc/initiatives/ephedra/december2003/>.

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