

## Ephedra

The U.S. Food and Drug Administration (FDA) advises consumers to stop using dietary supplements containing ephedra. In order to protect consumers, the FDA published a final rule on April 12, 2004, that bans the sale of dietary supplements containing ephedrine alkaloids.

After a careful review of the available evidence about the risks and benefits of ephedra in supplements, the FDA found that these supplements present an unreasonable risk of illness or injury to consumers. The data showed little evidence of ephedra's effectiveness, except for short-term weight loss, while confirming that the substance raises blood pressure and stresses the heart. The increased risk of heart problems and strokes negates any benefits of weight loss.

### What is ephedra?

Ephedra is a naturally occurring substance that comes from botanicals. The principal active ingredient ephedrine is an amphetamine-like compound that can powerfully stimulate the nervous system and heart. Ephedrine alkaloids are found naturally in a number of plants, including the ephedra species (also known by the traditional Chinese medicine name—ma huang or Chinese ephedra, or ephedron). In recent years, ephedra products have been marketed as dietary supplements to promote weight loss, increase energy, and enhance athletic performance.

### What evidence was collected to determine the safety and effectiveness of ephedra products?

The FDA reviewed information about ephedra's pharmacology, studies of its safety and effectiveness, newly available adverse event reports, and the RAND Corporation report—a review of the published scientific literature on ephedra efficacy and safety, sponsored by NCCAM and the National Institutes of Health's Office of Dietary Supplements. In addition, the FDA considered additional recent studies confirming that ephedra use raises blood pressure and otherwise stresses the circulatory system. In February 2003, the agency solicited public comments regarding ephedra's side effects and whether ephedra-containing dietary supplements pose a "significant or unreasonable risk of illness or injury."

### NCCAM Ephedra Research



In addition to supporting the RAND study, NCCAM supported a study of calls to poison control centers that revealed a disproportionate rate of reactions to ephedra

relative to other herbal products. NCCAM will support to their completion two ongoing laboratory studies to better understand the mechanism of action and chemical properties of ephedra:

- Pharmacology of Combined Ephedrine/Caffeine Supplements (University of California, San Francisco)
- Effects of Ephedra on Human Adrenoceptor Subtypes (University of Mississippi)

NCCAM will not fund any new studies of existing ephedra-containing products.

### **What is covered by these actions?**

Essentially all currently marketed dietary supplements that contain a source of ephedrine alkaloids, such as ephedra, ma huang, *Sida cordifolia*, and pinellia, are affected by this rule. The rule does not pertain to traditional Chinese herbal remedies. It generally doesn't apply to products like herbal teas that are regulated as conventional foods. In addition, products regulated as drugs that contain chemically synthesized ephedrine are not dietary supplements and not covered by this rule. These include drugs used for the short-term treatment of asthma, bronchitis, and allergic reactions.

### **Summary**

There is strong evidence that ephedra is associated with an increased risk of side effects, possibly even fatal ones. There is no evidence that ephedra products enhance athletic performance. There is little evidence of any benefit except for short-term weight loss. Taken together, the FDA recommends that consumers immediately stop using dietary supplements containing ephedra or ephedrine alkaloids.

While respecting the traditional uses of herbal medicines, their long history of use, and their potential health benefits, NCCAM believes that ephedra poses unique public health risks that warrant the FDA's actions to prohibit the sale of ephedra-containing dietary supplements.

Consumers need to be informed of the potential risks and benefits of herbal products. It is best to discuss use of herbal products with one's health care provider.

### **More Information**

- FDA Statement (4/12/2004) [www.fda.gov/bbs/topics/news/2004/new01050.html](http://www.fda.gov/bbs/topics/news/2004/new01050.html)
- FDA Consumer Alert (12/30/2003) [www.fda.gov/oc/initiatives/ephedra/december2003/advisory.html](http://www.fda.gov/oc/initiatives/ephedra/december2003/advisory.html)
- NCCAM Update on Government Actions to Reduce Risks of Ephedra (Updated 12/30/2003) [nccam.nih.gov/health/alerts/ephedra/consumeradvisory](http://nccam.nih.gov/health/alerts/ephedra/consumeradvisory)

National Institutes of Health



U.S. Department of Health and Human Services