



American Academy of Family Physicians

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April 4, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Dietary Supplements Containing Ephredra [Docket No. 95N-0304]

The American Academy of Family Physicians would like to commend the Commissioner of the Food and Drug Administration (FDA) for reopening the comment period regarding the health risks associated with dietary supplements containing ephedra alkaloids.

The American Academy of Family Physicians (AAFP) supports the American Medical Association (AMA) in urging that the Food and Drug Administration (FDA) initiate proceedings to remove dietary supplements containing ephedra alkaloids from the United States market.

Dietary supplements are classified as foods under the Dietary Supplement Health and Education Act of 1994 (DSHEA). In order to remove a product from the market, the FDA must demonstrate that a dietary supplement presents an "unreasonable risk of illness or injury" to American consumers under conditions of use recommended or suggested in labeling. While it is difficult to prove cause and effect relationships based upon voluntary reports of adverse events, the safety record and the lack of a clear risk/benefit ratio for ephedra alkaloids suggests a continuing risk to the health of the American public.

Since ephedra alkaloids are currently classified as food supplements, rather than drugs, they are available to all persons without a prescription or medical examination. Although the public should be assured of a higher margin of safety for such products, reports of adverse events associated with the use of ephedra-containing products currently strongly suggest that the risks of use outweigh any potential benefits.

After ephedra alkaloid containing products have been removed from the market, they should be reclassified by the FDA as a drug with appropriate testing and regulation.

Thank you for the opportunity to provide these comments.

Sincerely,

Warren A. Jones, M.D., FAAFP
Board Chair

cc: Martin C. Mahoney, M.D., Ph.D., FAAFP, Chair, Commission on Clinical Policies and Research
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