



American Society of
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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: Docket No. 95N-0304 Dietary Supplements Containing Ephedrine Alkaloids

TO WHOM IT MAY CONCERN:

The American Society of Health-System Pharmacists (ASHP) is pleased to provide comments on the Food and Drug Administration's (FDA's) March 5, 2003, *Federal Register* notice requesting comments on the agency's proposed rule entitled "Dietary Supplements Containing Ephedrine Alkaloids." ASHP is the 30,000-member national professional and scientific association that represents pharmacists who practice in hospitals (including outpatient services), health maintenance organizations, long-term care facilities, home care agencies, and other components of health care systems.

Among the issues that ASHP and its members have become concerned about is the widespread use of dietary supplements. This use presents substantial risks to the public health, and we recognize that pharmacists have an opportunity – as well as a professional responsibility – to help reduce those risks.

Specifically in regard to dietary supplements containing ephedrine alkaloids, we contacted the 10 members of ASHP's Commission on Therapeutics (COT) for their assistance and guidance. The COT is ASHP's expert therapeutic advisory body. We asked the COT whether the agency's proposed warning statement intended to appear on the principal display panel of dietary supplements containing ephedrine alkaloids would result in a reduction in the risks associated with use of these products, and whether such products present such "a significant or unreasonable risk of illness or injury" that they should be banned from the market.

Based on the COT's unanimous recommendation, ASHP has developed a formal policy stating that dietary supplements containing ephedrine alkaloids pose a significant and unreasonable risk of illness and injury and, therefore, should be banned. The following policy recommendation was approved by ASHP's Board of Directors:

Sale and Manufacture of Dietary Supplements Containing Ephedrine Alkaloids

To support a ban on the manufacture and sale of dietary supplements containing ephedrine alkaloids because: 1) ephedrine alkaloids pose a significant risk of illness and injury, 2) changes in product labeling are not adequate to protect the public from these

95N-0304

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dangers, 3) the use of these products represents significant expenditures for a health-related remedy of unsubstantiated value, and 4) other safe and effective interventions are available for all common uses of these products.

Although labeling changes such as those proposed in the March 5 *Federal Register* notice may reduce somewhat the risks posed by ephedra, this reduction in risk is not adequate to protect the public from the dangers inherent in using these products. ASHP further believes that the use of ephedra represents a significant health-related expenditure for remedies of unsubstantiated value. These resources would be better directed toward interventions that are known to be safe and effective such as proven medical therapies and lifestyle changes.

The March 5 *Federal Register* notice solicits comments “on what additional legislative authorities, if any, would be necessary or appropriate” to ensure that the FDA can address the issue of health risks associated with the use of dietary supplements containing ephedrine alkaloids. ASHP believes that the FDA has sufficient current authority under the Food, Drug, and Cosmetic Act as amended by the Dietary Supplement Health and Education Act (21 USC 342(f)(1)(A)) to ban dietary supplements from the market when specific products present a “significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use.” ASHP’s new policy supports the FDA taking such action.

While ASHP supports a ban on dietary supplements containing ephedrine alkaloids, which can be accomplished under current FDA authority, ASHP’s Board of Directors has approved the following interim policy on dietary supplements that we expect will be ratified by our House of Delegates when it meets in June:

Regulation of Dietary Supplements

To advocate a change in the Dietary Supplement Health Education Act such that dietary supplements shall at a minimum meet the same legal requirements as nonprescription drugs; further,

To support the routine reporting and monitoring of product defects and adverse effects associated with dietary supplements through the FDA MedWatch and United States Pharmacopeia reporting programs.

ASHP developed this policy because we strongly believe that the FDA should have strengthened authority over dietary supplements. The current regulatory framework governing dietary supplements provides neither consumers nor health care providers with sufficient information on the products’ safety and efficacy they need to help consumers make informed decisions. In addition, standards for product quality are currently inadequate. The widespread use of dietary supplements, combined with the absence of appropriate regulation of these products, presents the following dangers to the public health which are of deep concern to ASHP’s members:

- Some dietary supplements are inherently unsafe (e.g., products containing ephedrine alkaloids).

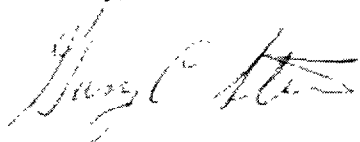
- Lax regulation of dietary supplement manufacturing presents the risk of contamination or adulteration with harmful substances and of dangerous variability in active ingredient content between products.
- The use of dietary supplements may compromise, delay, or supplant treatment with therapies of proven efficacy.
- Dietary supplements may present specific, uncharacterized dangers to special populations (e.g., children, the elderly, pregnant women, patients undergoing surgery, or those with impaired organ or immunologic function).

Because the public's use and perception of dietary supplements is similar to that for non-prescription drugs, ASHP believes that Congress should amend the Dietary Supplement Health and Education Act to require that these products receive FDA approval for evidence of safety and efficacy; meet manufacturing standards for identity, strength, quality, purity, packaging, and labeling; and undergo post-marketing reporting of adverse events.

Only recently has the FDA, with its publication of a proposed rule on March 13, 2003, requiring dietary supplements to meet Current Good Manufacturing Practice (CGMP) standards, begun to unambiguously address the general problem of assuring the safety and efficacy of dietary supplements. The FDA has taken almost a decade to issue its first proposed rule on CGMPs for these products. While we commend the agency for at last taking this logical first step, if past experience is a guide, without explicit statutory authority to regulate dietary supplements as nonprescription drugs, the proposed rule is more likely to spawn another decade of legal wrangling than it is to lead to the manufacture of safe and effective dietary supplements. This is the primary reason we encourage the FDA, consistent with its public health mission, to work with Congress in developing legislation to amend the Dietary Supplement Health and Education Act to provide the agency with the authority necessary to fully address the issue of health risks associated with the use of dietary supplements.

ASHP appreciates this opportunity present its comments on ephedrine alkaloids to the FDA. Feel free to contact me if you have any questions regarding our comments.

Sincerely,



Gary C. Stein, Ph.D.
Director, Federal Regulatory Affairs

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