National Nutritional Foods Association

April 3, 2003

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

Re: Docket No. 95N-0305: Dietary Supplements Containing Ephedrine Alkaloids; Reopening of Comment Period; 68 Fed. Reg. 10417 (March 5, 2003)

To Whom It May Concern:

The National Nutritional Foods Association ("NNFA") is submitting these comments to the Food and Drug Administration ("FDA") in response to the March 5, 2003 Reopening of Comment Period for "Dietary Supplements Containing Ephedrine Alkaloids" published at 68 Fed. Reg. 10417.

NNFA is a trade association representing the interests of more than 3,000 retailers and 1,000 manufacturers, suppliers and distributors of natural foods, dietary supplements and other natural products throughout the United States. NNFA has consistently supported FDA's ability and efforts to enforce the Dietary Supplement Health and Education Act of 1994 ("DSHEA") and to ensure that dietary supplements continue to be safe.

NNFA appreciates the opportunity to comment on the questions raised by FDA in its "Reopening of Comment Period" on ephedrine alkaloids. NNFA would like to take this opportunity to respond to the two issues FDA is considering, namely:

1. A new mandatory warning statement and additional labeling information for packages containing ephedrine alkaloids (68 Fed. Reg. 10419); and

2. What additional legislative authorities, if any, are necessary or appropriate to enable FDA to address products presenting a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling (68 Fed. Reg. 10419).

I. Proposed Warning Statement and Additional Label Information

NNFA does not object to the warning statement proposed in the Federal Register notice. NNFA has long taken the position that ephedrine alkaloids are appropriate for use as dietary ingredients when the dietary supplements are responsibly manufactured, labeled and used

95N-0304 C 3874

3931 MacArthur Blvd., Suite 101 • Newport Beach, CA 92660 • (949) 622-6272 • Fax (949) 622-6266 • www.nnfa.org

and has for years recommended a strong label warning. FDA's proposed warning does not raise concerns to NNFA members.

II. FDA Has Ample Authority Under DSHEA to Address Safety Issues; No Additional Legislative Authority Is Necessary

NNFA believes that FDA already has ample authority under DSHEA to address safety issues posed by dietary supplements. DSHEA states that a dietary supplement will be considered adulterated and subject to enforcement action where there is a "significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling, or under ordinary conditions of use." 21 U.S.C. §342(f)(1)(A). Further, in particularly compelling cases, DSHEA allows the Secretary of the Department of Health and Human Services to ban a dietary supplement if it is found to be an "imminent hazard." 21 U.S.C. §342(f)(1)(C).

Finally, FDA also has at its disposal the general food safety standard which allows the agency to take enforcement action against a dietary supplement if "it bears or contains any poison or deleterious substance which may render it injurious to health." 21 U.S.C. §342(a)(1). For dietary supplements, this determination is based on the recommended dosage

In the past, FDA has taken the position that these statutory powers are sufficient to ensure the safety of dietary supplement products.[1] FDA has appropriately used those powers since the passage of DSHEA in a number of incidents.

---

[1] On March 25, 1999, for example, then-FDA Commissioner Jane E. Henney, M.D testified before the U S. House of Representatives Committee on Government Reform that.

> FDA also is committed to quickly removing unsafe products from the market or taking other timely actions to protect consumers. FDA has tools at its disposal to take enforcement actions against dietary supplements found to have safety, labeling, or other violations of the FD&C Act, as amended by DSHEA. The Agency has used a variety of regulatory tools from enforcement actions to rulemaking, when it has found dietary supplements that cause safety concerns. *Statement on FDA Regulations on Dietary Supplements Before the House Committee on Government Reform*, 106th Cong. (1999) (Statement by Jane E. Henney, M.D., Commissioner, Food and Drug Administration, U.S. Department of Health and Human Services)

Dr. Henney concluded with the comment, "I . . . believe DSHEA provides FDA with the necessary legal authority to protect the public health." Id.

- In 1997, FDA issued a consumer warning and asked manufacturers and retailers to recall digitalis-contaminated plantain from the market after being notified about the case of a young woman who developed life-threatening abnormal heart function after consuming the product. The agency traced the contaminated products and was able to quickly and effectively remove them from the market.

- In 1997, FDA warned against consumer use of the "Chomper" product based on one case where the consumption of the product resulted in an abnormal heart rate with heartblock, a potentially life-threatening condition. Based on this information, the agency found that the product posed a potentially significant and unreasonable risk to public health.

- In 1999, the agency issued a consumer warning and asked manufacturers to voluntarily recall products, some of which were inappropriately labeled as dietary supplements, containing gamma butyrolactone ("GBL") from the market. FDA's statement on the issue indicated that GBL related products had been implicated in 55 adverse health effects, including one death. For the agency, that information was sufficient to move quickly to remove the product.

Despite these past successes in taking action against dietary supplements deemed to pose an "unreasonable risk," FDA has presented a novel approach to dietary supplement safety in the agency's White Paper on Ephedra, ("Evidence on the Safety and Effectiveness of Ephedra: Implications for Regulation," February 28, 2003). There, FDA states that any agency determination that a product presents "unreasonable risk" under 21 U.S.C. §342(f)(1)(A) requires a "risk-benefit calculus," which would take into account the available scientific evidence and assess it against product benefits.

FDA may not proceed with such an approach absent extensive review by, and input from, the regulated food and dietary supplement industries. For that reason, NNFA will be submitting a White Paper further detailing this issue, and addressing the question of whether the Chevron, U.S.A. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984) deference doctrine survives in this context.

In brief, NNFA takes the position that no such calculus is appropriate and that the Chevron doctrine continues to apply. FDA has never adopted a risk/benefit analysis in assessing the safety of foods, even though the relevant food standards contain qualitative language analogous to 21 U.S.C. §342(f)(1)(A). Moreover, DSHEA did not add a risk/benefit analysis. There is nothing in DSHEA's legislative history that indicates that Congress had any intent to establish a risk/benefit analysis for dietary supplements.

The sole purpose of the DSHEA safety provisions was to establish *easier* standards for FDA to meet in finding a dietary supplement product unsafe. Section 342(f)(1)(A) of the United States Code provides FDA with a lighter burden, not a more difficult one, than 21 U.S.C. §342(a), which was previously used and subject to varying interpretations. The only reason FDA had to resort to the food additive argument in years past was to get around these varying interpretations.

NNFA believes that the agency can exert its authority over dietary supplements in the same manner as food – as it has in the past – by determining that the risks posed are "unreasonable," without resorting to an assessment of the benefits of the products. NNFA urges FDA to continue to apply its statutory authority under 21 U.S.C. §342(f)(1)(A) when necessary to remove products that pose "unreasonable risks" from the market.

Sincerely,

David Seckman
CEO/Executive Director