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December 17, 2001

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

Re: Docket No. 01N-0459

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 October 25, 2001 Notice "Agency Information Collection Activities; Proposed Collection; Comment Request; Food Labeling; Notification Procedures for Statements on Dietary Supplements."

NNFA is a trade association representing the interests of more than 1,000 manufacturers, suppliers and distributors and 3,000 retailers of natural foods, dietary supplements and other natural products throughout the United States. The Association 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 on the market are safe.

NNFA believes that FDA must continue collecting information about structure/function claims under 21 U.S.C. §403(r)(6).[1] In fact, the statute, 21 U.S.C. §403(r)(6), mandates that notifications be submitted. Any change would need to be achieved by a statutory modification.

In any case, the section is not burdensome, and involves nothing more than sharing marketing information that a company necessarily already has on file.

[1] 21 U.S.C. §403(r)(6) requires companies to notify the agency that they are marketing a dietary supplement product that bears a structure/function claim 30 days after the first marketing of the product. Information required includes: (1) the name and address of the manufacturer, packer, or distributor of the dietary supplement; (2) the text of the structure/function statement; (3) the name of the dietary ingredient; (4) the name of the dietary supplement; and (5) a signature of a responsible party.

Keeping the notification requirement is also consistent with the aims of the Hatch-Harkin Amendment included in the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act for 2002 (H.R. 2230), which was passed into law on November 28, 2001. The Amendment, supported by NNFA and approved by unanimous consent, provides $1 million in new funding for the FDA to hire investigators and additional staff to pursue companies that mislabel their products in violation of DSHEA. By introducing the amendment, Senators Hatch and Harkin aimed to ensure that labeling provisions included in DSHEA are being actively enforced. Continuing to require notifications under 21 U.S.C. §403(r)(6) would seem to be an integral part of this enforcement activity.

21 U.S.C. §403(r)(6) is an important part of FDA's monitoring of the dietary supplement industry under DSHEA. The submission of notifications under this section gives the agency a database of dietary supplement products. This information makes it possible for FDA to begin to respond efficiently in the event of any safety issues that emerge, and it keeps the agency apprised of trends in how products are being marketed. Moreover, the information gives the agency a clear monitoring role and helps silence critics who claim that there is no federal oversight of dietary supplement claims.

For these reasons, NNFA respectfully urges FDA to continue collecting notifications of structure/function claims under 21 U.S.C. §403(r)(6).

NNFA appreciates the opportunity to file these comments.

Respectfully submitted,

NATIONAL NUTRITIONAL FOODS ASSOCIATION
Mark Stowe, President
David Seckman, Executive Director

SIDLEY AUSTIN BROWN & WOOD
General Counsel

By Diane C. McEnroe
Diane C. McEnroe

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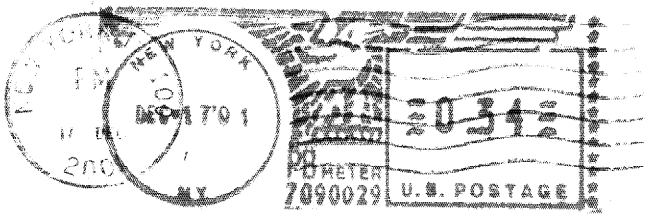


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