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BY FEDERAL EXPRESS

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

Re: Program Priorities in the Center for Food Safety and Applied Nutrition; Request for Comments, [Docket No. 98N-0359], 66 Fed. Reg. 37480, July 18, 2001

Dear Sir/Madam:

On behalf of the National Nutritional Foods Association ("NNFA"), we submit the following comments regarding the Program Priorities in the Center for Foods Safety and Applied Nutrition; Request for Comments, published on July 18, 2001, at 66 Fed. Reg. 37480. NNFA is the oldest and largest, non-profit trade organization dedicated to protecting and advancing the natural products industry. Its members include retailers, manufacturers and distributors of health food products, dietary supplements, and natural cosmetics.

I. *Publish the Proposed Rule on Good Manufacturing Practices for Dietary Supplements, and Make the Finalization of such Rule Top Priority*

NNFA continues to be committed to supporting the development, marketing and use of safe health food products. That is in large part why NNFA established its GMP 3rd Party Certification Program. The program was created in an effort to help ensure the integrity and quality of products manufactured at certified facilities. NNFA was happy to see that FDA placed the publication of a proposed rule on dietary supplement GMPs on the "A" list last year, but is extremely unhappy that it continues to be there this year. It must be moved forward.

While NNFA recognizes that the Center has a full plate in terms of programs and priorities, this issue is at the core of ensuring the continued distribution of safe, quality dietary supplements. The supplement industry continues to be challenged as "unregulated" by the press, which uses the lack of GMPs as its cornerstone for such argument. NNFA requests that the

98N-0359

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Center make the publication of a proposed rule and the quick review of comments regarding the proposal its absolute priority in the year 2002.

In addition, FDA indicated at an industry meeting this year that it would begin to enforce against unsafe products. To date, the industry has seen very little activity, but would support an effort by FDA to initiate appropriate enforcement action against unsafe products. In so doing, the Agency should publicize the procedures utilized to take such action and illustrate for the public and press the ability of FDA to act and enforce. NNFA does not condone the marketing of unsafe products.

II. *Move Forward with Meaningful Guidance on Product Categories and Labeling Concerns*

NNFA would also like to see FDA move forward in the "functional food" arena. FDA needs to establish a clear delineation between conventional foods and dietary supplements. In connection with this effort, FDA should seek GRAS submissions on certain ingredients understood to be acceptable in dietary supplements, which are presently being incorporated into conventional foods. Warning letters are not enough; FDA should provide clear guidance on these overlapping issues.

This Center must also work with those at the Agency discussing a policy on combination dietary supplements and over-the-counter drug products. FDA should recognize that such products have merit, and that they can be safely formulated and distributed, provided they meet certain requirements set by FDA. NNFA believes that the overlap between these two categories is already present in terms of label claims, and that the only remaining issues are clarity and consistency on label copy, and safety.

Finally, NNFA believes that FDA has an obligation to be forward thinking in terms of nutrition labeling and claims issues. NNFA believes that it is time for FDA to develop a survey to assess what consumers want to know about the content of the food products they purchase. FDA seems to be willing to issue Warning Letters regarding every technical violation of NLEA, without considering that the time may be right for a re-analysis of the NLEA label content. NNFA would be very willing to assist in this endeavor, in an effort to help FDA provide meaningful, currently relevant, information to consumers. The trans-fat labeling effort is one aspect of this; but, in connection with this effort, it is also appropriate to determine if the definitions of other nutrients may also be more refined. One example is carbohydrate labeling.

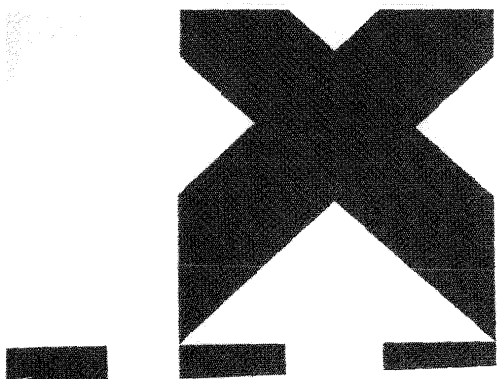
NNFA appreciates the opportunity to provide these recommendations regarding FDA's 2002 Plan, and urges the Agency to continue to work with industry in terms of ensuring the continued marketing of safe and effective natural products, including dietary supplements.

Respectfully submitted,

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

SIDLEY & AUSTIN
General Counsel

By Diane C. McEnroe
Diane C. McEnroe



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