



August 15, 2002

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

Re: Program Priorities in the Center for Food Safety and Applied Nutrition;
Request for Comments [Docket No. 98N-0359], 67 FR 42272-01, June 21, 2002

Dear Sir/Madam:

NNFA is the oldest and largest, non-profit trade association dedicated to protecting and advancing the natural products industry. Our members include retailers, manufacturers and distributors of health food products, dietary supplements, and natural cosmetics. We submit the following recommendations regarding the establishment of FY 2003 program priorities in the Center for Food Safety and Applied Nutrition.

- I. *Publish the proposed rule on Good Manufacturing Practices for dietary supplements and make finalization of such rule a top priority.*

Since FY2000, FDA has placed the publication of a proposed rule on dietary supplement GMPs on its "A" list and for the past three years our principal comment has been to move this issue forward. This year is no different: publication of a proposed rule on GMPs for the dietary supplement industry and the quick review of comments regarding the proposal should be an absolute priority in FY2003.

GMPs should be at the center of a joint effort by Congress, industry and FDA to ensure that only safe, quality dietary supplements are sold to consumers. Unfortunately, consumers are still waiting.

In July, Sen. Richard Durbin (D-Ill.), chair of the Senate oversight subcommittee on governmental affairs, demanded the immediate release of FDA GMPs for dietary supplements. He joins Senators Orrin Hatch, Tom Harkin and Representative Dan Burton who have asked for this rule to be proposed in separate letters to HHS Secretary Tommy Thompson (July 17, 2001) and acting FDA Commissioner Bernard Schwetz, DVM (January 22, 2002).

In 1999, NNFA established a process oriented GMP Third party certification program and last year we aligned with NSF International to make certified finished product testing

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and label review available. Some of the largest and best-known dietary supplement companies in the U.S. are NNFA GMP certified and adhering to these quality standards.

As good as this alliance is, however, FDA still needs to move quickly and give supplement GMPs the force of law so that every company that manufactures a dietary supplement must adhere to the quality procedures called for by DSHEA. Consumers deserve no less.

II. Continue enforcement against unsafe products

NNFA is committed to supporting the development, marketing and use of only safe natural products. We strongly urge the Center to identify priority safety issues and initiate rigorous yet positive enforcement action. In so doing, publicize the procedures utilized to take such action and illustrate for the public and press the ability of FDA to regulate the industry under the Dietary Supplement Health and Education Act of 1994 (DSHEA).

Full enforcement of the powers given to the Agency through DSHEA is critical to conducting a fair and effective public debate on dietary supplement safety and regulation. This is especially so in light of the Agency's interest and involvement in several areas: consolidating and updating various adverse events reporting systems within CFSAN and the Institute of Medicine's proposed framework for categorizing and prioritizing dietary supplement ingredients based on safety.

III. Continue enforcement against products that make outrageous structure/function claims.

NNFA is supportive of the FDA's plans to intensify enforcement against inappropriate structure/functions claims and note that the Agency was provided with additional funds to carry this out in FY2002. Unfortunately, there are numerous products making "outrageous" claims in the marketplace, and they are especially evident on the Internet, and we urge the Agency to focus on those claims.

NNFA looks forward to a thoughtful discussion on claims that border the distinction between a supplement and drug claim, the use of disclaimers, and the ability to discuss the science behind an ingredient, in light of the Agency's request for comments on First Amendment issues. Again, a fair and effective public debate on dietary supplement claims can only be conducted when FDA is exercising its full statutory authority to regulate under DSHEA.

IV. Be forward thinking on nutrition labeling and claims issues.

We believe that FDA has an obligation to be forward thinking in terms of nutrition labeling and claims issues. In the past, FDA has surveyed consumer knowledge, perceptions, attitudes and practices related to foods and sought to determine just how consumers interpret label claims. 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 and to act on that information.

NNFA strongly supported your proposal that trans fatty acids, when present in a packaged food or dietary supplement, be required to be separately declared in grams per serving in the Nutrition Facts or Supplement Facts box on the label. We encourage you to make this information meaningful to consumers by allowing a Daily Value to be listed. This could be done by using the existing Daily Value for saturated fat or permitting the use of an asterisk leading consumers to additional label information about trans fatty acids. A nutrient content claim specific to trans fatty acids, or other supplemental label information, could also be allowed by the Agency.

You may recall that NNFA also met with the FDA in 2001 to inquire about ways to make carbohydrate labeling more meaningful to consumers. This meeting, and our comments on trans fatty acids, were done at the urging of our members in response to consumers demanding more specific information about the content of the foods they were purchasing.

V. Seek GRAS submissions on supplement ingredients being used in conventional foods.

NNFA continues to recommend that FDA move forward in the “functional food” arena by seeking GRAS submissions on certain ingredients understood to be acceptable in dietary supplements and which are currently being incorporated into conventional foods.

VI. Continue to work with industry groups to implement the voluntary Food Allergen Labeling Guidelines developed by the Food Allergy Issues Alliance

American consumers with allergies deserve to have confidence in the safety and labeling of their foods, including dietary supplements. We believe that, in conjunction with the regulatory authority FDA already has, this can be achieved through the Food Allergen Labeling Guidelines developed by the Food Allergy Issues Alliance and have asked our members to implement them. We appreciate FDA’s accomplishments in this area and urge that the Agency continue with consumer and industry outreach and awareness.

NNFA is also supportive of your efforts to determine whether biotech foods pose an allergenic risk and encourage you to continue work in this area. So that consumers can be correctly informed if a product poses an allergenic risk, NNFA again asks that FDA require that all raw materials and ingredients/foods containing or produced by genetically modified organisms (GMO) be identified throughout the chain of commerce, from seed to finished product, as containing or produced by GMOs. It is only in this manner that traceability and accurate labeling can be ensured.

VII. Develop “small business” guidance to dietary supplement manufacturers in several areas.

It is likely that the majority of firms in the dietary supplement industry are considered small according to the Economic Characterization of the Dietary Supplement Industry, a report prepared for CFSAN by the Research Triangle Institute (RTI Project Number 6673-03), in March 1999. In fact, in 2002, NNFA's membership is still largely comprised of small businesses. Small business compliance guides could be used by the Agency to facilitate compliance with DSHEA by these companies. NNFA would certainly be willing to assist the Center in this effort.

For example, FDA should develop guidance on the appropriate information to include under the premarket notification requirement for a New Dietary Ingredient (NDI) under section 413 of the Federal Food Drug and Cosmetic Act. Under DSHEA, the NDI notification process offers FDA the best opportunity to screen new ingredients and review safety data before a product is marketed. NNFA appreciates that FDA has been vigilant about requiring NDI notifications, and believe that this additional guidance would complement your efforts.

A small business guidance could also be used to clarify the boundary between conventional foods and other product categories and enumerate the safety standards and labeling regulations that apply to each. It is clear that as foods with a range of added dietary ingredients come to market, the line separating them from dietary supplements is beginning to blur. A guidance document would be useful in working with our smaller members to encourage compliance with the proper set of requirements.

Finally, many NNFA members find the procedure for obtaining an export certificate difficult to understand. As you know, these certificates are often requested by foreign businesses who want to purchase products from U.S. dietary supplement companies. Guidance to small U.S. business could be offered in this area as part of your overall objective (3.3.4 in last year's program plan) to assure consistency of international guidance and U.S. practices.

NNFA appreciates the opportunity to provide these recommendations regarding FDA's 2002 Plan and we appreciate that FDA's focus for 2003 will emphasize the security of the Nation's food supply. We stand ready to assist in this area.

Respectfully submitted,



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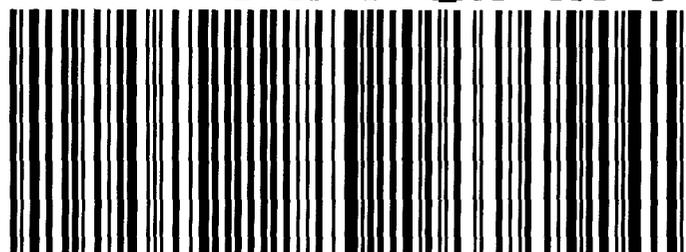
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