



Council for Responsible Nutrition

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Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**RE: Docket No. 98N-0359
Program Priorities for CFSAN, FY 2003**

The Council for Responsible Nutrition (CRN) is pleased to submit these comments on the FY 2003 priorities in the dietary supplement arena for the Center for Food Safety and Applied Nutrition (CFSAN). CRN has a vital interest in the actions and priorities of the Food and Drug Administration (FDA) that concern dietary supplements.

CRN represents leading companies in the dietary supplement industry, including bulk ingredient suppliers as well as finished product manufacturers. CRN members market their products through various channels including the mass market, the natural food trade, direct sales, and mail order. Members include manufacturers of national brands of dietary supplements as well as several large manufacturers of the store brands available in most supermarkets, drug stores, health food stores, and super stores.

The Big Three

CRN and its member companies believe FDA should put a high priority on the following “**Big Three**” activities for FY 2003:

1. **GMPs:** Publish proposed GMPs for dietary supplements, solicit comments from industry in writing and through stakeholder meetings, and move expeditiously to finalize GMPs, taking into account the input received. CRN and its members are committed to launching a major education campaign following publication of the proposed rule, in order to ensure that industry members are fully informed of the provisions and are provided with every opportunity for meaningful analysis and comment.
2. **Safety Enforcement:** Strengthen FDA oversight and enforcement relating to the safety of dietary supplements. This should include taking

action against ingredients that are not grandfathered and are not the subject of 75-day notifications. As part of this activity, it would also be desirable for the agency to develop guidance regarding the information to be included in the 75-day notifications. An integral aspect of FDA's safety oversight is the management of the Adverse Event Reporting System. This system needs substantial improvement, including expediting the investigation of adverse events and making redacted AERs promptly available to manufacturers, so they are promptly alerted to potential issues requiring investigation or action.

3. **Enforcement With Respect to Claims:** Strengthen FDA oversight and enforcement against inappropriate claims for dietary supplements. This should include following up on courtesy letters relating to drug claims being made under the guise of structure/function statements. Consistent follow-through on courtesy letters and warning letters is essential to provide a level playing field for responsible companies.

Meaningful action in these three areas will result in implementing the key provisions of DSHEA and will protect responsible manufacturers as well as American consumers against those who would abuse the provisions of the law and the regulations. The lack of adequate enforcement has, we believe, contributed to the pervasive but false perception purveyed by the media that dietary supplements are "unregulated."

Need for an Office of Dietary Supplements within CFSAN

CRN is cognizant of the fact that dietary supplements are only one of many priority areas for which CFSAN has responsibility. Even given the broad scope of competing activities, however, it is important that consumers be protected by appropriate regulatory attention to dietary supplement issues, in order to ensure that products are safe, made to high quality standards, and properly labeled. Thus, it is appropriate that dietary supplements should have a high priority within CFSAN.

Indeed, CRN would suggest that there is a need for increased regulatory visibility for the dietary supplement category. We believe this might best be accomplished by creating a special office of dietary supplements within CFSAN, with the sole assignment of overseeing the appropriate regulation of this product category.

CRN is prepared to support this proposal conceptually among legislators (although no legislation is needed to make it happen) and to work with FDA to make a special office of dietary supplements a reality, with appropriate staffing and funding to permit solid policy development, regulatory oversight, and enforcement of DSHEA.

Importance of a Dietary Supplement Advisory Committee

CRN is convinced that FDA would benefit from expert advice and counsel on policy and implementation issues relating to dietary supplements, and we have consistently supported the formation of a Dietary Supplement Advisory Committee comparable to the

existing Food Advisory Committee for this purpose. We are encouraged by FDA's decision to establish an expanded Food Advisory Committee with a subcommittee on dietary supplements, and we look forward to working with FDA and the committee in every way possible. However, we urge that the agency not lose sight of the goal of eventually establishing a separate Dietary Supplement Advisory Committee, with a full complement of advisors with expertise in dietary supplement safety, benefits, manufacturing, marketing, and research.

Ephedra-Containing Dietary Supplements

CRN urges CFSAN to put a high priority on resolving the regulatory issues surrounding ephedra in the most expeditious and appropriate manner possible in FY 2003, based in part on the evaluation being supported by the Office of Dietary Supplements. There is general industry support for a comprehensive and nationally uniform warning label, for example. Manufacturers are now using an extensive voluntary warning developed by industry groups and incorporating the features FDA proposed in 1997, but specific requirements exist in some states and these provisions vary from one state to another. A uniform federal policy would ensure that consumers nationwide are provided with the same meaningful information regarding cautions and contraindications. Such action was requested in an industry petition filed with FDA in October 2000 and was also referenced earlier this year in comments submitted by industry groups on a petition filed by Public Citizen.

Other "A List" Priorities for Dietary Supplements

CRN believes the following item that appeared on the "B list" for FY 2002 should be elevated to the "A List" for 2003:

- Train field staff and State officials on regulatory provisions and safety issues relating to dietary supplements.

In addition, CRN believes the following items mentioned in FDA's 10-year plan deserve elevation to "A List" status in FY 2003:

- Identify criteria for substantiation of structure/function statements and identify conditions under which substantiation information must be shared with FDA. CRN has recently initiated an effort to draft substantiation requirements, based on numerous models including the FTC guidance on dietary supplement advertising, the report of the Commission on Dietary Supplement Labels, and WHO publications relating to the substantiation of claims for alternative medicines.
- Build meaningful working relationships with organizations such as CRN that express a sincere interest in cooperative efforts, and create an ombudsman within CFSAN to facilitate interactions with the dietary supplement industry.

Finally, there are at least three other general priorities for CFSAN that have particular significance for all foods, including the dietary supplements category, and we believe it would be appropriate to enumerate these as “A List” activities for dietary supplements:

- Continue direct involvement in international activities affecting dietary supplements, including Codex Alimentarius and the Trans-Atlantic Business Dialogue, and serve a leadership role in supporting international policies consistent with the provisions of DSHEA.
- Continue to maintain and improve policies and actions that will protect the United States from BSE and apply those policies consistently for the dietary supplement category as well as for other FDA-regulated industries.
- Pursue full implementation of the requirements of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, with respect to dietary supplements as well as other FDA-regulated products, within the timeframes specified by Congress.

Commitment to full implementation of DSHEA

CRN is convinced that achievement of the above activities would effectively represent full implementation of DSHEA, with the understanding that review and enforcement activities will be ongoing, for dietary supplements as for any other product category. FDA’s 10-year plan for dietary supplements includes numerous other activities that fall in the category of institution-building and exposition of the philosophical concepts underlying the entire scope of food/drug inter-relations set forth in the Food, Drug and Cosmetic Act. We believe these activities are not correctly considered as components of the implementation of DSHEA, but instead represent FDA structural and management initiatives that transcend DSHEA. CRN encourages the agency to modify the 10-year plan to identify those activities directly related to the implementation of DSHEA (as opposed to general institution-building), and target those activities for completion by the end of FY 2004.

CRN urges FDA to commit to the activities highlighted above, with the full support and cooperation of industry. CRN believes this is feasible, and we are anxious to work with the agency to make full implementation of DSHEA a reality.

Sincerely,



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VP, Scientific and Regulatory Affairs