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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 2002

The Council for Responsible Nutrition (CRN) is pleased to submit these comments on the FY 2002 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 more than 100 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.

Need to Correct False Perceptions

There is a pervasive but false perception purveyed by the media that dietary supplements are "unregulated." CRN representatives have met repeatedly with reporters and editorial boards, and we are convinced that the media is laboring under a false sense of self-righteousness that seems to justify falsehoods in the name of furthering the goal of getting dietary supplements classified as and regulated as drugs. CRN and its members appreciate the efforts of some FDA officials to help correct the false impression that our products are unregulated, but more is needed. We are anxious to cooperate in any way possible in joint efforts to educate the media and the public about the actual federal and state regulatory system applicable to dietary supplements. As discussed below, a key feature of that program needs to be the incorporation of meaningful and appropriate enforcement of the regulatory provisions at all levels.

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Priority of Dietary Supplements for CFSAN:
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. To put dietary supplement issues in the total context of CFSAN overall activities, Appendix A provides a list of the many critical topic areas included among CFSAN program priorities.

Even given the broad scope of CFSAN activities, it is important that consumers be ensured of 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 this product category.

CRN is prepared to support this proposal in the legislative arena 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.

Good Manufacturing Practice Regulations

Industry, consumer groups, and health professionals all agree that the promulgation of Good Manufacturing Practice regulation for dietary supplements, as specifically authorized by DSHEA, is critical to ensuring product quality and providing FDA with an appropriate framework for inspections and appropriate enforcement. In the calendar year 2000, FDA pursued the completion of a proposed rule and submitted the proposal to OMB. That proposal is still sitting at OMB, six years after CRN led a number of industry groups in providing FDA with draft GMPs and more than four years after FDA published

an ANPR based on the industry draft. Even when the proposed rule is published, it will be necessary for FDA to receive and evaluate comments and then move to a final rule -- a process that typically requires at least a year and has been known to require several years.

In the meanwhile, all the major trade associations, including CRN, have adopted the GMPs set forth in the ANPR as the basis for their members' current manufacturing practices, and several certification programs have been developed to provide assurance that the GMPs are being followed. CRN continues to urge progress toward providing such assurance, both through voluntary industry programs, third party certification, and ultimately a final mandatory regulation. CRN and its members are committed to launch 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.

CRN recognizes that the proposed GMP rule is likely to differ significantly from the ANPR, but we are hopeful that the industry and FDA can work together to agree ultimately on provisions that can be supported by all parties and that will provide consumers with the intended assurance that manufacturers are following recognized principles designed to ensure product safety and quality, proper labeling, and compliance with all applicable regulations.

Ephedra-Containing Dietary Supplements

The ephedra issue has been a matter of continuing concern and public debate since 1993, when CRN, other industry groups, and FDA first began regular meetings to consider the implications of adverse event reports that initially came out of Texas and at first appeared to be associated with a single company's product. In its final report published in 1997, the Commission on Dietary Supplement Labels urged FDA to bring this issue to a satisfactory conclusion, emphasizing that the ongoing lack of resolution undermined confidence in the regulatory system as well as the product category.

Developing a strategy for the regulation of ephedra-containing dietary supplements was initially targeted for the "A" list in FY 2001 by CFSAN, but was dropped to the "B" list due to other urgent activities, including those relating to BSE/TSE, food allergens, and biotechnology. The implication was that the ephedra strategy would return to the "A" list for 2002.

CRN urges CFSAN to put a high priority on resolving the regulatory issues surrounding ephedra in the most expeditous and appropriate manner possible in FY 2002. We believe there is general industry and consumer support for some aspects of this policy, especially the need for a comprehensive and nationally uniform warning label.

In the calendar year 2000, CRN contracted with Cantox Health Sciences International, a consulting firm with recognized scientific expertise in quantitative risk assessment, to prepare a report on ephedra-containing products and to identify a safe upper level of intake. CRN continues to believe the Cantox report provides FDA and the industry with

the best and most scientifically sound basis for identifying an appropriate upper limit for ephedrine alkaloids in these products, as well as appropriate provisions relating to warning statements, duration of use, and the need for postmarket surveillance. We again urge FDA to use the Cantox report as the basis for a final regulation for ephedra-containing products. The industry associations have already adopted voluntary upper limits and extensive warning labels consistent with the Cantox report and with state laws affecting ephedra-containing products.

Appropriate Enforcement

The purpose of DSHEA was to ensure continued consumer access to a broad variety of safe dietary supplements and to provide consumers with more information about those products. But these guarantees were accompanied by provisions intended also to ensure that products were manufactured in accordance with GMPs, that products were safe, and that manufacturers had substantiation for label claims.

While the industry is largely composed of responsible firms committed to providing consumers with safe products and sound information, no industry or society is free of elements that require control. Appropriate enforcement by federal and state authorities is critical to maintaining the necessary level of control within the industry. Lack of enforcement leads to the false perception that the agencies are lacking in authority. It must also be recognized that, even if lack of enforcement is due to inadequate resources, the end result is the same as if there were a lack of authority -- those who choose to push the envelope will get away with it, and next time they will push harder. Ultimately, this situation leads to an expanding lack of respect for the regulations and the law, and to a marketplace spinning out of control. Such a situation is damaging to the regulatory agencies, consumers, and the responsible industry.

As we have in the past, CRN calls on FDA and other federal and state officials to undertake appropriate enforcement activities, in order to increase respect for these requirements and in order to provide adequate consumer protection. These enforcement activities need to address the illegal marketing of new ingredients without submission of safety information, the marketing of products that do not contain the levels of substances claimed on the label, and the making of unsubstantiated claims. In addition, FDA and the industry need to find a way to cooperate in stopping the marketing of "designer drugs" and "street drugs" illegally under the guise of dietary supplements. CRN stands ready to support appropriate enforcement efforts toward these ends.

Other "A List" Priorities for Dietary Supplements

In addition to the key priorities specifically mentioned above, CRN wishes to support a continued "A List" priority for the following efforts that were included in the FY 2001 "A List":

- Ongoing review of 75-day notifications for new dietary ingredients.

- Improve AER system, expedite adverse event investigations, and make redacted AERs promptly available to manufacturers.

CRN believes the following items that appeared on the "B list" for FY 2001 should be elevated to the "A List" for 2002:

- Provide guidance regarding the information to be included in the 75-day notifications for new dietary ingredients.

- Provide guidance or a proposed regulation on pregnancy labeling.

- Ongoing review of 30-day notifications for structure/function statements and appropriate enforcement against unsubstantiated or nonpermissible statements.

In addition, CRN believes the following items mentioned in FDA's 10-year plan deserve elevation to "A List" status in FY 2002:

- Identify criteria for substantiation of structure/function statements and identify conditions under which substantiation information must be shared with FDA.

- Build meaningful working relationships with organizations such as CRN that express a sincere interest in cooperative efforts.

Finally, there are at least two other general priorities for CFSAN that have particular significance for the dietary supplements category, and we believe it would be appropriate to recognize 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.

Commitment to full implementation of DSHEA

CRN is convinced that achievement of the above activities would 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 structural and management initiatives that transcend DSHEA.

CRN urges FDA to commit to the activities highlighted above, with the full support and cooperation of industry, and move toward a target of completing the framework for implementation of DSHEA by the end of FY 2003. CRN believes this is feasible, and we are anxious to work with the agency to make full implementation of DSHEA a reality.

Sincerely,

A Dickinson

Annette Dickinson, Ph.D.
VP, Scientific and Regulatory Affairs

APPENDIX A: Overall CFSAN Program Priorities, Within Which An Appropriate Priority Must be Assigned to the Dietary Supplement Program Area

Food Safety Initiative

- Domestic inspections
- Imports and foreign inspections
- Seafood safety
- Fruits and vegetables
- Egg safety action plan
- Listeria action plan
- Education
- Food safety research
- Food code
- Dairy safety
- Surveillance
- Outbreak response

Major Program Areas

- Premarket review of food and color additives and other food ingredients
- Nutrition, health claims, and labeling
- **Dietary supplements**
- Chemical contaminants, pesticides and other hazards
- Cosmetics

Cross-Cutting Areas

- CFSAN relocation
- Science base
- International activities
- Emerging areas
  - Biotechnology
  - Food allergens
  - BSE/TSE issues
  - Adverse event reporting
- Regulatory processes
- Economic-based regulations
- Management inititiatives