99N-1174

Council for Responsible Nutrition
1875 Eye Street, N.W., Suite 400
Washington, D.C. 20006-5409
(202) 872-1488 • Fax (202) 872-9594
www.crnusa.org

FDA'S OVERALL STRATEGY FOR DIETARY SUPPLEMENTS

Presentation at an FDA public meeting,
June 8, Washington, D.C.

Annette Dickinson, Ph.D.
Vice President, Scientific and Regulatory Affairs
Council for Responsible Nutrition

These comments are submitted by the Council for Responsible Nutrition (CRN) for purposes of the public presentations at the June 8 meeting called by FDA on the subject of an overall strategy for dietary supplement regulation under DSHEA. Our full written comments will be submitted at a later date.

CRN represents approximately 100 companies in the dietary supplement industry, including bulk ingredient suppliers as well as finished product manufacturers. Our members market their products through various channels including the mass market, the natural food trade, direct sales, and mail order. We represent 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.

While we are encouraged by the stated FDA/CFSAN commitment to an open and participatory planning process, we hope that process will allow for more meaningful cooperation than mere participation in this forum, which was called on less than 30 days' notice and allows participants only five minutes to convey their views. We are hopeful that more extensive interaction will be possible on other occasions. At this time, we will present an overview of our key recommendations, and our full comments will be submitted at a later date.

OBJECTIVES

FDA says the objectives of its overall dietary supplement strategy are: to ensure consumer access to supplements that are safe and to ensure consumer access to label information that is truthful and not misleading. CRN fully endorses these, but urges FDA to add a third objective, namely **to fully implement DSHEA.** While this may be viewed as implicit, we believe it needs to be made explicit.

99N-1174

C14

FDA's main priority with regard to dietary supplements should be the same as its priority in other areas of food regulation, namely to maintain a credible FDA program that will help ensure consumer confidence in FDA regulated products.

ELEMENTS OF THE OVERALL STRATEGY

CRN believes the overall strategy can be compressed into four areas, with the understanding that implementation and enforcement are critical components of each of the first three. These are:

- **Safety**
- **Claims**
- **GMPs**
- **Stakeholder outreach and leveraging of resources**

SAFETY

Ensuring consumer access to safe dietary supplements is and should be a key objective of the FDA strategy. Two aspects of FDA regulation of dietary supplement safety involve the evaluation of notifications received on new ingredients and the management of an adverse event reporting system.

New dietary ingredients: CRN supports the need for careful and timely FDA review of the 75-day notices on safety of new dietary ingredients, and supports prompt enforcement action when FDA has made a determination that an ingredient is unsafe, as was the case with GBL. However, we were concerned in the case of GBL that FDA's grounds for action related to the argument that the products were unapproved new drugs, not to the fact that the products contained unsafe new dietary ingredients under DSHEA. We encourage the agency to rely upon and utilize the provisions of DSHEA in taking such enforcement actions.

Adverse event reporting system: CRN believes it is critical that a well-managed adverse event reporting system exist, in order to flag unexpected problems that may signal the need for action by FDA, the industry, health professionals, or consumers. In order to serve that purpose, the system needs to provide timely and relevant information, without exposing personal information about the person who suffered the adverse event and without falsely or inappropriately damaging the reputation of a responsible company or product. We have proposed a number of modifications in the current system which we believe would help accomplish these goals. These include:

- Posting adverse events, in summary form, as soon as FDA learns of them. (Summary form means listing only the product type and the event, not the company or product name.)

- Immediately sharing the report with the company implicated, and giving the company an opportunity to be involved in the evaluation process.
- Purging all case reports of personal information as soon as they are received, so the case can be shared with the company or with others who may request it.
- Evaluating the reports with regard to the strength of the association between the event that occurred and the product that was consumed.
- Establishing a system which permits FDA to correct any errors that may appear in the initial listing, regarding company or product identity or other aspects of the case, so that misinformation is not perpetuated.
- Carefully considering whether there is any value added to a report by listing the specific company and product names, even after evaluation has been done. Specific companies and products have not been identified in other adverse event reporting systems involving food products, such as the food additives aspartame or sulfite. Specifics are not listed in Poison Control Center reports and were not listed even in the CDC reports on serious adverse events related to L-tryptophan.

CLAIMS

In the area of label statements and claims, FDA should help ensure that all statements are truthful and not misleading, and are substantiated.

Statements of nutritional support: In areas where DSHEA provides ample guidance, there is no need for FDA to generate regulations interpreting that guidance, and it is entirely inappropriate for FDA to attempt by regulation to change the groundrules set forth in DSHEA. CRN believes the agency attempted in its proposed rule on structure/function claims to change the scope provided by DSHEA for such statements. The best course at this time would be for FDA to withdraw that proposal. The clear intent of DSHEA is that all statements that on their face are about effects on the structure or function of the body should be permitted, but specific disease claims should not. We believe FDA should give force to the prohibition against specific disease claims by taking enforcement action against statements that include such claims. When courtesy letters are not ultimately followed up with official action, the message is sent that courtesy letters can be ignored with impunity.

NLEA health claims: CRN urges FDA to favorably consider three health claims petitions submitted by the American Preventive Medical Association and other parties just last month, and an additional one to be submitted by the same group later this month. These four claims relate to vitamin E and heart disease, three B vitamins and cardiovascular disease, saw palmetto and benign prostatic hyperplasia, and some aspects of the psyllium claim. The petitioners request that FDA consider qualified claims on these topics, if the agency concludes the evidence does not yet support an unqualified claim.

FDAMA health claims: We encourage FDA to evaluate FDAMA health claims under the criteria outlined in the Act, without adding the additional conditions included in FDA's 1998 guidance document or the agency's response to a petition for nine claims filed early in 1998. This is another instance in which the law appears to provide ample guidance regarding the conditions under which a health claim may be made on the basis of an authoritative statement by a scientific body, and we believe it is inappropriate for the agency to expand those conditions.

GOOD MANUFACTURING PRACTICES (GMPs)

Dietary supplements are currently governed by the Good Manufacturing Practices for foods, which are intended to ensure that products are produced under sanitary and wholesome conditions. DSHEA specifically authorizes FDA to establish unique GMPs for dietary supplements, modeled after food GMP regulations. In order to facilitate FDA's work, the industry submitted a draft document to FDA in 1995 which the agency published as an Advance Notice of Proposed Rulemaking in 1997. That document would expand GMPs for this product category to encompass quality assurance procedures necessary to guarantee the identity and quality of dietary supplements. It is our understanding that FDA is now moving forward toward a formal proposal, based on the comments received on that notice. If there is anything CRN or its members can do to facilitate further progress on this matter, we are ready to provide assistance.

STAKEHOLDER OUTREACH AND LEVERAGING OF RESOURCES

Industry/FDA partnerships: CRN believes that the optimal approach to regulation is through private/public partnerships. We are prepared to work with FDA in any way possible to improve mutual communications and understanding, and to attempt to craft appropriate solutions to problems that arise. This is a relatively easy commitment to make, but seems difficult to deliver. When serious safety problems arise which need to be promptly addressed, we too often hear about it only hours in advance of an FDA public announcement. We want to be a more meaningful part of the solution, whenever possible.

Dietary supplement advisory committee: FDA relies periodically on advisory committees to leverage agency resources by providing outside expert advice on important policy issues. At the present time, the Food Advisory Committee is the primary resource available to advise FDA on food and dietary supplement issues. Over the past few years, almost half of the meetings of that committee have been entirely devoted to dietary supplement matters.

CRN continues to urge FDA to establish a Dietary Supplement Advisory Committee composed of experts who are familiar with the dietary supplement industry and its issues. In the absence of a Dietary Supplement Advisory Committee, the agency has

been relying on the Food Advisory Committee, which does not currently have the appropriate expertise in our product category. Recognizing the gaps in expertise, FDA has recently established working groups which include representatives from the dietary supplement industry and academics familiar with industry issues, to help the Food Advisory Committee in its evaluation of some key issues. These working groups are proving to be a valuable tool for incorporating appropriate expertise into the full committee's recommendations, but they are not a substitute for a properly constituted full committee of appropriate experts.

In the interest of stakeholder involvement, it would be an integral part of our proposal that the Dietary Supplement Advisory Committee should include liaison members from the major dietary supplement trade associations. In the interim, **we hereby request that dietary supplement industry liaison members be appointed** to the existing Food Advisory Committee.

CONCLUSION

On behalf of the dietary supplement industry, CRN wishes to express its appreciation to FDA in general and CFSAN in particular for its avowed commitment to open procedures and stakeholder involvement in arriving at science-based decisions regarding regulatory issues. We will be submitting expanded comments and responding to other questions raised by FDA in the notice provided for this meeting, at a later date.