



# Council for Responsible Nutrition

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August 29, 2007

Dockets Management Branch, HFA-305  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852  
<http://www.fda.gov/dockets/>

**RE: Request for Comments**  
**Docket No. 1998N-0359, CFSAN 200720**  
**Program Priorities in the Center for**  
**Food Safety and Applied Nutrition, FY 2008**

The Council for Responsible Nutrition (CRN) is pleased to submit these comments on the FY 2008 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.

Within, or in addition to the priorities outlined by the Agency for 2008:

- (1) Food Defense
- (2) Food Safety
- (3) Nutrition and Labeling
- (4) Dietary Supplements and Cosmetics
- (5) Priority On-Going Activities

CRN and its member companies believe FDA should put a high priority on the following activities for FY 2008:

1. **GMPs:** Now that the dietary supplement GMP Final Rule has been published, FDA should provide further resources toward collaborating with industry on the implementation of the rule through guidance documents and stakeholder meetings. CRN and its members will be conducting various educational programs to help ensure that the industry is fully informed of the provisions and are

provided ample opportunity for meaningful analysis and comment. We invite the Agency to partake in these discussions, both formally and informally.

2. **AERs:** Add additional qualified reviewers to expedite the Agency's evaluation of incoming AERs/SAERs. Improvements are needed on the ability of MedWatch to gather detailed information to make meaningful assessments possible. FDA should amend form 3500A to allow the reporter the choice to provide approval to his/her physician to speak with a medical representative of the product manufacturer to facilitate adequate assessment of the facts. In addition, resources should be committed toward the development of a reporting system that would allow AERs and accompanying information (such as product labels) to be submitted electronically.
3. **NDIs:** Provide a draft guidance on the new dietary ingredient (NDI) notification process. The Agency held a public meeting on this topic in October of 2004 during which there was substantial industry interest and involvement. The Agency has yet to issue guidance or comments of any kind resulting from the proceedings of this meeting. The confusion and lack of clarity that currently surrounds the NDI notification process is cause for significant concern in the industry. As a result, many firms are choosing to forego the process entirely, resulting in more ingredients that are not grandfathered and are not the subject of 75-day notifications. Further continuance of this pattern is not in the best interests of the responsible members of the dietary supplement industry, FDA or consumers. Further resources should also be allocated to the review and assessment of notifications received, in order to better expedite the process.
4. **Improved communication:** We urge the Agency to continue to improve its communication and coordination between regional control/enforcement offices. Many companies still experience significant and needless delays with the importation of dietary supplement product and ingredients through Customs. This is a direct result of poor communication between regional Agency offices or a misunderstanding of the laws and regulations that govern dietary supplements. We believe these delays can be avoided by continued training of field staff and State officials on regulatory provisions and safety issues relating to dietary supplements.

CRN urges FDA to commit to the activities highlighted above, with the full support and cooperation of industry.

Sincerely,



Andrew Shao, Ph.D.  
VP, Scientific & Regulatory Affairs