



Council for Responsible Nutrition

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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 (formerly 98N-0359)
Program Priorities in the Center for
Food Safety and Applied Nutrition, FY 2007

The Council for Responsible Nutrition (CRN) is pleased to submit these comments on the FY 2007 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 2006:

- (1) Ensuring Food Defense
- (2) Ensuring Food Safety
- (3) Improving Nutrition
- (4) Improving Dietary Supplement Safety
- (5) Ensuring Cosmetic Safety

CRN and its member companies believe FDA should put a high priority on the following activities for FY 2007:

1. **GMPs:** Publish the Final Ruling for GMPs for dietary supplements, and assist industry with implementation through guidance documents and stakeholder meetings. CRN and its members have 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. **NDIs:** Provide a draft guidance on the new dietary ingredient (NDI) notification process.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.
3. **Improved communication:** We strongly urge the Agency to improve its communication and coordination between regional control/enforcement offices to improve efficiency and reduce delays. For example, many companies experience significant and needless delays in getting imported dietary supplement product and ingredients through customs. This is a direct result of poor communication between regional Agency offices. This might be accomplished in part by improving the 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