



*Producers of Quality
Nonprescription Medicines and
Dietary Supplements for Self-Care*

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION[®]

1150 Connecticut Avenue, N.W., Washington, D.C. 20036-4193 • Tel: 202-429-9260 • Fax: 202-223-6835 • www.chpa-info.org

August 20, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**RE: Docket No. 98N-0359: 2003 Program Priorities for Dietary
Supplements in the Center for Food Safety and Applied Nutrition**

Dear Madam or Sir:

The Consumer Healthcare Products Association (CHPA)¹ submits these
comments in response to FDA's notice in the *Federal Register* of June 21, 2002

¹ CHPA is a 121-year-old trade organization representing the manufacturers and distributors of national and store brand dietary supplements and nonprescription medicines. CHPA's membership includes over 200 companies involved in the manufacture and distribution of these self-care products and their affiliated services (e.g., raw material suppliers, research testing companies, contract manufacturing companies, advertising agencies, etc.).

concerning Program Priorities in the Center for Food Safety and Applied Nutrition (CFSAN) fiscal year 2003 (FY03).

As articulated in previous comments to FDA, CHPA strongly supports CFSAN's outreach to stakeholders in developing its yearly program of work, as well as reports on the progress made on its program of work and re-prioritization of goals. Overall, CHPA encourages further development of the regulatory environment for dietary supplements, consistent with the 1994 Dietary Supplement Health Education Act (DSHEA) and FDA's ample enforcement authority under the Food Drug & Cosmetic (FD&C) Act.

CHPA submitted comments on September 17, 2001 in relation to CFSAN's Program Priorities for FY02. At that time, CHPA agreed with the strategic approach taken by CFSAN to ask the question, "*Where do we do the most good for consumers?*" and urged FDA to place safety, including enforcement of ingredient safety issues and labeling, issuance of the GMPs, and development of an effective AER management system within CFSAN.

In 2000-2002, some progress has been made in the area of safety, and FDA has successfully exercised its authority under the FD&C Act to remove certain dietary ingredients from the marketplace, e.g., aristolochic acid and comfrey. However, notwithstanding such activities, we believe that the FDA is far from realizing a comprehensive quality and safety program for dietary supplements that encompasses all the requisite elements, including:

- Issuing a final regulation on Good Manufacturing Practices (GMPs) for dietary supplements, that has languished inexplicably within the Administration;
- Implementing a framework for evaluating the safety of dietary supplements, which is now under development by the Institute of Medicine (IOM);
- Implementing a reasonable enforcement program consistent with DSHEA that includes an appropriate level of inspections, which are dependent on issuance of GMPs and adequate appropriations for field activities;
- Implementing a well-developed adverse experience monitoring system with adequate staffing for electronic-based collection activities, competent medical reviews, training, etc., which has yet to be fully developed;
- Developing a framework for potential public health interventions by FDA, based on CFSAN-initiated safety reviews (e.g., labeling, product withdrawal, education), and this includes an articulated labeling policy that has yet to be defined in the context of “failure to reveal a material fact” [i.e., 201(n) of the Act].

Quality and safety of dietary supplements are very important issues for the consumer, and therefore for the industry. Although, certain elements of a comprehensive safety system for dietary supplements are under development, issuance of the proposed GMPs

appears to be in limbo. Both these items require #1 and #2 priority attention by CFSAN, as this is where CFSAN can do the most good for consumers as it relates to dietary supplements.

CHPA'S DETAILED COMMENTS AND RECOMMENDATIONS

- **Good Manufacturing Practices:** GMP regulations specific for dietary supplements products, are important, as it will provide reassurance to consumers that these products are being manufactured to comply with FDA quality standards. The absence of dietary supplement specific GMPs, has led consumers and experts to mistakenly believe that these products lack quality. This is not the case and there are several GMP standards in use. This in turn, has lead to a lack of uniformity in how these products are manufactured and evaluated by third-party certification programs, such as that by National Nutritional Foods Association, NSF International, and US Pharmacopeia. FDA GMPs specific for dietary supplements would bring uniformity within the industry and raise the level of awareness among suppliers, manufacturers, and distributors regarding the need for quality operations. Without these GMPs, it is difficult for FDA to demonstrate its seriousness towards the quality and its obligation to regulate these products. As a #1 “priority A” activity, CFSAN should actively seek ways within the Administration to obtain publication of the GMPs.

Furthermore, CHPA has written to CFSAN requesting an opportunity to work with CFSAN to develop at least two industry-wide briefing sessions for the proposed

GMPs when they are issued. CHPA again requests the opportunity to work with CFSAN to help plan and implement these sessions.

- **Enforcement of Dietary Ingredient Safety Issues:** CHPA urges CFSAN to initiate the appropriate scientific review of dietary supplement ingredients for which there is a scientifically sound consensus with regard to their safety. CFSAN can begin this process by implementing the framework for evaluating the safety of dietary supplements under development by IOM and consistent with CHPA's comments on this framework which will be sent to IOM shortly. While CHPA agrees with the need for a well-articulated Dietary Supplement Ingredient Safety Review (DSIR) (see CHPA's comments to IOM dated October 5, 2001), there remains a significant issue with the method of prioritization proposed by IOM. This prioritization scheme requires resolution before implementation by FDA. Because of our selected concerns with the IOM draft framework, CHPA urges FDA to initiate the standard notice and comment process through publication of the framework in the Federal Register.

In addition, CHPA urges FDA to issue guidance on appropriate safety information to include in the 75-day notifications. This activity was initially ranked as a priority "A" goal for FY02 by the agency, but it was changed to priority "B" in the mid-year accomplishments report issued June 15 by the agency. CHPA encourages the Agency to change this back to a priority "A" activity in FY03.

Finally, CHPA urges CFSAN to continue to take action on known toxicants and contaminants which should not be marketed as or in dietary supplements and publish its findings as a means to further build the safety base of the industry and raise awareness among manufacturers and the public.

- **Adverse Event Reports (AER)**: Consistent with our FY02 comments, CHPA asks FDA to create an AER Ad Hoc Working Group, which would provide recommendations to FDA on how they could reengineer the current or create a new AER system for dietary supplements. An effective AER system for dietary supplements is important to ensure that safe products continue to remain in the marketplace. This group should include representation from industry, and provide a review of and recommendations for changes to FDA's existing AER system to better serve the needs of consumers, professionals, the industry and the agency.
- **Needed Policy Framework for Labeling**: Under DSHEA, a dietary supplement is adulterated if it or one of its ingredients presents “a significant or unreasonable risk of illness or injury” when used as directed on the label, or under normal conditions of use. It is the dietary supplement manufacturer’s responsibility to ensure that its products are safe, effective, and properly labeled. This responsibility includes ensuring dietary supplement labels bear all facts that are material in light of consequences that may result from use of the product or representations made about

it.² However, CFSAN has taken no specific steps to help manufacturers understand what safety information represents a material fact finding or to provide guidance to manufacturers on the scope and extent of specific label language relating to a safety issue that would meet the requirement of revealing a material fact. Clearly the matter of defining a dietary supplement labeling policy should be placed in the “priority A” list for immediate attention and action by CFSAN. The timing is right to begin this activity in view of CFSAN’s sponsored project with IOM to create a scientific framework for safety evaluations of dietary supplements and IOM’s review of six supplements. When that work is completed, CFSAN may be faced with certain “findings of material fact” relating to the safety of these six ingredients. Without a clear labeling policy in place, the agency will be caught flat-footed.

- **Bioterrorism Regulations:** As requested in Mr. Levitt’s letter to the industry of July 17, 2002, CHPA stands ready to provide CFSAN with the assistance it may seek in drafting and implementing the regulations as required under four provisions outlined in Title III, Subtitle A of the Bioterrorism Act. Under these provisions, FDA is to issue regulations on 1) Registration of Food Facilities, 2) Establishment and Maintenance of Records, 3) Prior Notice of Imported Food Shipments, and 4)

² CFSAN’s policy relating to material fact labeling has been put forth in part in the preamble to the structure/function final rule as follows: “FDA agrees that it is important to inform consumers about potential adverse effects or drug interactions for specific dietary supplement ingredients. In fact, dietary supplement labeling, like the labeling of other FDA-regulated products, is required to include all facts that are material in light of consequences that may result from use of the product or representations made about it (sections 403(a)(1) and 201(n) of the act). This provision is not intended in any way to preclude truthful adverse event or drug interaction information from appearing in a dietary supplement’s labeling.” [Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body; Final Rule; 65 *Federal Register* 999-1050 (1/6/2000)]

Administrative Detention. As requested by CFSAN, CHPA will submit initial comments by August 30, to assist the agency in drafting the proposed regulations.

Conclusion

As outlined in these comments, CHPA asks FDA to continue to place quality and safety as “priority A” items for dietary supplements in FY03. In doing so, the Agency will have addressed the one central question the Agency uses in its priority-setting process, i.e., “*Where do we do the most good for consumers?*”

The attached appendix highlights specific areas CHPA would like CFSAN to focus on in FY03, with priority levels. Contents of table in this appendix were excerpted from CFSAN’s 2002 Program Priorities areas list and a new item related to the need for a “material facts” labeling policy added.

Sincerely yours,



Leila Saldanha, Ph.D., R.D.
Vice President, Nutritional Sciences



R. William Soller, Ph.D.
Senior Vice President and
Director of Science & Technology

APPENDIX

CFSAN 2003 Program Priorities

Specific areas CHPA would like CFSAN to focus on in FY03, with priority levels.

Contents of table were excerpted from CFSAN's 2002 Program Priorities areas list.

| STRATEGY | SUB STRATEGY | GOAL DESCRIPTION | PRIORITY LEVEL |
|----------|--------------|---|-------------------------------------|
| 2.3 | 2.3.5 | Enforcement/Compliance a. Continue to identify dietary supplement ingredients/products that raise safety problems, and take appropriate enforcement actions. | #2 A |
| 2.3 | 2.3.3 | Protecting and Promoting Public Health with Agency Initiated Actions a. Publish proposed rule for dietary supplement GMPs and conduct outreach. b. Continue to develop mechanisms to enhance timely clinical assessment of dietary supplement adverse event investigations. | #1 A A |
| 2.3. | 2.3.1 | Review of Industry Submissions/Statutory Requirements a. Continue to review premarket (75-day) notifications for new dietary ingredients within statutory timeframe b. Continue to review 30-day postmarket notifications for supplement claims in a timely manner. | A Change from B to A in FY03 |
| 3.5 | 3.5.1 | CFSAN Adverse Events Reporting System (CAERS): a. Develop standard operating procedures and pilot test new systems for the processing of adverse events. | Change from B to A in FY03 |

| STRATEGY | SUB STRATEGY | GOAL DESCRIPTION | PRIORITY LEVEL |
|----------|--------------|--|-------------------------------------|
| 3.5 | 3.5.2 | Compliance/Enforcement: Improve CFSAN's response time to recommended regulatory actions through the development of better-defined roles and responsibilities across the Program Offices. | A |
| 2.2 | 2.2.5 | Enforcement/Compliance a. Continue to conduct enforcement activities to clarify boundaries between conventional foods and other product categories. | Change from B to A in FY03 |
| 2.3. | 2.3.4 | Improve Efficiency/Responsiveness a. Issue "Regulatory Guidebook" for industry d. Work to develop guidance on appropriate safety information to include in 75-day notifications. | A Change from B to A in FY03 |
| 3.3 | 3.3.1 | Codex Committees and Working Group: Participate in and raise visibility in the Codex committees, ad hoc task forces, and related drafting and working groups and scientific advisory committees meeting in FY 2002 that are of relevance to the FDA. The most visible efforts are the following committees/task force where CFSAN provides the Delegate: | A |
| New item | | Dietary supplements "material facts" labeling policy | A |