DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
(Docket No. 99N-1174)

Dietary Supplements; Center for Food Safety and Applied Nutrition Strategy; Public Meeting

The Association of Food and Drug Officials (AFDO) is a non-profit, professional association consisting of state, federal, and local regulatory officials as members, with industry representatives participating as associate members. From its very inception almost 103 years ago, AFDO has recognized the need for uniform laws and regulations and have actively promoted uniformity and cooperation within the regulatory arena. AFDO strongly supports FDA's desire to develop effective strategies for achieving proper regulation of dietary supplements.

With respect to the enhancement of consumer safety, FDA needs to follow the recommendations of the President's Committee on Dietary Supplement Labeling and address areas where labeling is inadequate for safe use.

Many of the botanical dietary supplements have potent pharmacological activity that has the potential for drug interactions with both OTC and prescription drugs along with other incompatibilities such as alcohol consumption. In other cases, there is a potential for abuse, such as with the sedating type products, and consumers need to be aware of not only the interactions, but that exceeding dosages can be harmful. Women who are pregnant, trying to conceive, or are on other estrogen therapies should not consume products that contain phytoestrogens. Should monoamine oxidase inhibitors bare information as to their interactions? Certainly someone on anti-depressive therapy should not consume St. John's Wrote. In addition, many products are contraindicated by persons with underlying medical conditions like hypertension and diabetes. FDA, with industry input, must answer the question, where is the appropriate place for consumers to receive this type of accurate information to insure safe use--ad hoc from print media and advertising, from manufacturers of OTC and prescription drugs which may interact with botanicals, or from manufacturers of dietary supplements in the form of additional labeling information? A label is misbranded if it fails to disclose pertinent facts. Do these issues fall into the category of pertinent facts?

Many consumers, including many senior citizens, consume a wide variety of dietary supplements without full understanding of interactions, contraindications, or symptoms of adverse reactions. Somehow, they have to be provided this information to ensure safe use. The President's Commission pointed to labeling as the appropriate mechanism. FDA has identified AEnhancement of Consumer Safety as its first priority for dietary supplement safety and the ADevelopment of Health-related Product Labeling Regulations, its second priority. AFDO concurs with this important emphasis and hopes that the issues raised by the President's Commission with respect to additional label information for botanicals remains the highest priority.

AFDO has praised FDA's new labeling regulations, but they really don't go far enough. If a

product is to be used in a fashion similar to an OTC drug, which many supplements are, then an accurate statement of the potency of the active ingredient must be disclosed. Knowing the quantity of the botanical present does not necessarily bear any declaration of the amount of active ingredient, which is the overriding issue for appropriate use.

In addition, AFDO feels that some products should not be provided to infants. Florida had one death associated with an infant being given Echinecea instead of traditional therapies. Some of the Aherbal books declare that Echinecea should not be used by children under the age of two. Again, whose responsibility is it to provide consumers this information, which incidentally is not uniform source to source?

AFDO previously testified to, and continues to believe, that FDA and the industry need to jointly approach these issues from a stance that solutions in this area will benefit industry by maintaining educated access to consumers that does not unnecessarily expose product liability due to inadequate label information for safe use. One mechanism that we previously mentioned would be the development of a compendium for herbals with pharmaceutical properties, important interactions, adverse reactions, and contraindications delineated. The compendium could also provide information as to expected level of active ingredients. Currently FDA is referring consumers with questions to the NIH database, but this is not a viable option for most of the public, particularly elderly persons. Canada is also developing a program to address dietary supplements that the FDA should examine for improvements to the current US system. Eventually harmonization will be necessary, and provisions that enhance safety from the Canadian system may be included now in the FDA system thereby facilitating harmonization in the future.

While it is essential for consumers to have access to dietary supplements, it is incumbent on government with industry's input to ensure, as best as possible, that consumers have accurate and appropriate information on products to enable safe and knowledgeable use.

AFDO believes that the FDA should make finalization of Good Manufacturing Practices regulations a high priority. While the industry has provided guidance through voluntary GMPs, it is important that the FDA finalize uniform standards for GMPs, which can be adopted by states to ensure national uniformity. These GMPs should give special emphasis to quality of raw ingredient, impurities or contaminants, and levels of active ingredients. This is essential since much of the raw material is produced outside of this country and therefore outside the oversight of FDA.

FDA also needs to actively enforce its laws and regulations relating to dietary supplements that protect consumer health and lives. AFDO understands the tremendous workload that DSHEA created for the agency at the same time other critical issues were on the table. However, the explosion of the use of dietary supplements, which is projected to increase even more, mandates that resources to address thee issues be given a very high priority within the Center. AFDO pledges its support to agency with respect to integrating dietary supplement activities with state programs.

The following is provided in response to specific questions:

1. Are there other objectives that the FDA strategy should include?

AFDO feels that particularly with dietary supplements a strong educational component is required. This educational component should have emphasis for medical and health professionals as well as consumers.

2. Are the criteria for prioritizing the tasks within the supplement strategy appropriate?

AFDO has strongly responded to this in its opening remarks that adequate product labeling information to ensure safe use in conformance with the recommendations of the Presidentσ Commission on Dietary Supplement Labeling has to be the highest priority.

3. What factors should FDA consider in determining how best to implement a task?

The mechanism for implementing a task will depend on the task. If it is a task, which necessitates national uniformity in application by other state and local programs, then FDA must choose the regulation route so that states can adopt them as state rules. If, on the other hand, the task is interpretive, guidance documents will suffice. The industry can assist the FDA in determining where uniformity will be needed.

4. What tasks should be included under the various dietary supplement program elements in the CFSAN 1999 Program Priorities document?

Adequate label information for safe use of products, good manufacturing practices, and education of medical and health professionals, as well as consumers, are the tasks AFDO feels are most important and are listed in our priority order.

5. Are there current safety, labeling, or other marketplace issues that FDA should address quickly through enforcement actions to ensure...products on the market are safe and truthfully and not misleadingly labeled?

AFDO has responded to this question in the body of its opening remarks. Clearly the issue of current inadequate label information for safe, informed use is paramount.

6. Toward what type of area of research on dietary supplements should FDA allocate its research resources?

Research resources should be directed toward product integrity and safety.

7. Given FDA's limited resources, what mechanisms are available, or should be developed, to leverage FDA's resources to meet effectively the objective of the strategy?

FDA can leverage resources by use of JIFSAN and by utilizing industry and state programs where appropriate to provide input on issues, extend enforcement strategies, and provide information on prioritization of problem areas.

AFDO appreciates the opportunity to comment on this important matter.

Submitted By: Joseph Corby, President
Association of Food and Drug Officials

STATE OF NEW YORK
DEPARTMENT OF AGRICULTURE AND MARKETS
1 Winners Circle
ALBANY, N.Y. 12235-0001

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