



## AMERICAN OSTEOPATHIC ASSOCIATION

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April 4, 2005

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

To Whom It May Concern:

On behalf of the American Osteopathic Association (AOA), which represents the nation's 54,000 osteopathic physicians, practicing in 23 specialties and subspecialties, I write to provide our comments on the areas of the regulatory strategy for the Dietary Supplement Health and Education Act (DSHEA), docket number 2004N-0458.

The AOA continues to evaluate the impact of increased use of dietary supplements and other "natural" products on the patients we serve. Over the last ten years, we have seen a steady increase in the utilization of dietary supplements by consumers. We remain concerned about the unregulated manner in which many of these products are produced, marketed, and sold. We urge you to examine and address the issues we have put forth in this letter.

### Safety

The safety of our patients is our primary concern. We particularly are concerned about the numerous health dangers posed by many dietary supplements and the risks to those who use them. Since a majority of these products have not undergone independent evidence-based research or clinical trials, the benefits and risks are unknown. Additionally, many patients fail to inform their physician when they use one or more of these products. This leads to potential interactions with prescribed medications and may also obscure an accurate diagnosis of an underlying condition or disease.

It is essential that dietary supplements be scrutinized and held to the same standards as prescription medications in order to minimize risks to consumers. This includes quality control, monitoring of the manufacturing process, product review, etc.

We support FDA's effort to improve the evidentiary base for safety and enforcement through collaboration with other Federal agencies and organizations. We also think it is essential to have in place a process to evaluate safety concerns. We would be interested to learn more about the safety process when details become available.

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Another important part of the strategy is the area which refers to adverse events. You state that you will encourage manufacturers, marketers, and distributors to report adverse events associated with their products. This language is simply not strong enough to invoke any major change – FDA needs to require that adverse events be reported. If those in the dietary supplement industry are not required to report this information, they simply will not do so.

### **Quality**

Another important concern that we have is the current lack of manufacturing standards within the industry. Manufacturers of dietary supplements have taken advantage of a “loophole” or “lack of clarification” in the law to produce, market, and sell their products independent of pre-market regulatory scrutiny.

We are encouraged to see that the FDA is taking steps to address this issue, the first being development of a forthcoming proposed rule on current good manufacturing practice (CGMP) guidelines for dietary supplements. We urge you to publish this rule as soon as possible, since it is the first step in the development of your long-term plan in the area. The other steps you have proposed of outreach, implementation, and compliance simply cannot occur until this rule is published.

### **Labeling**

We continue to remain concerned by an environment which permits false and misleading product claims, few limitations on advertising, and allows for companies to market their products through unscrupulous means.

We approve of your efforts to continue to identify and take action against those that make claims which are not supported by scientific evidence. It is important that any claims, which are made as to the efficacy of a particular product be evaluated scientifically and approved by the FDA.

There is one segment in this area which we feel does need additional thought before the agency proceeds. FDA states that it will obtain dietary supplement samples to analyze them to determine if the contents are consistent with the product labeling. While this is a noble goal, we see potential problems emerging. This simply would take a significant amount of time, effort, and money. The cost of doing this could be quite prohibitive, and the sample size of what the agency could actually test would be only a small portion of the market.

In the case of herbal products, the same herb may be obtained from different sources and therefore, be of different quality. We believe it would be of dubious value to test an herb against a standard product label. How would the FDA know whether the herb came from a single source and is of uniformly high quality?

The AOA appreciates this opportunity to provide comments on this strategy. If you have questions with regard to our comments, please contact the AOA Department of Government Relations at (202) 414-0140.

Sincerely,

A handwritten signature in cursive script that reads "George Thomas D.O.".

George Thomas, D.O.  
President

C: President-Elect, AOA, Members, Board of Trustees, AOA, Chairman, Department of Government Affairs, AOA, Council on Federal Health Programs, Executive Director, AOA, Council on Scientific Affairs