U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DIETARY SUPPLEMENTS; CENTER FOR FOOD SAFETY AND APPLIED NUTRITION STRATEGY; PUBLIC MEETING DOCKET NUMBER 99N-1174

STATEMENT OF

CENTER FOR SCIENCE IN THE PUBLIC INTEREST

Ilene Ringel Heller
Senior Staff Attorney

June 8, 1999
Washington, D.C.

The Center for Science in the Public Interest appreciates this opportunity to present our views on developing an overall strategy for achieving effective regulation of dietary supplements under the Dietary Supplement Health and Education Act (DSHEA). CSPI is a non-profit consumer organization supported by more than 1,000,000 members that has worked since 1971 to improve national health policies.

My presentation will focus on three recommendations: 1) the FDA should support the establishment of a research program at the National Institutes of Health (NIH) to evaluate the safety and efficacy of dietary supplement ingredients. The results of the research should be used as the basis for FDA determinations that particular supplement ingredients are safe or pose a significant or unreasonable risk and to specify appropriate and inappropriate labeling claims; 2) the research program should be funded by an industry user fee; and, 3) the FDA should coordinate its policies regarding dietary supplements and functional foods and take appropriate enforcement action.

INTRODUCTION

Recent scientific developments have shown that dietary supplements can play an important role in maintaining good health and can sometimes provide a valuable adjunct to conventional medical treatment. As Americans increasingly use supplements to promote their health, it is all the more important for Congress to ensure that such products are safe and that label claims are valid.

Unfortunately, DSHEA has made it difficult to achieve these objectives. In enacting that law, Congress changed the prevailing approach to product safety in the Federal Food, Drug and Cosmetic Act. Although manufacturers of food additives, drugs and medical devices must prove

that their products are safe before they can be sold, under DSHEA, dietary supplements are presumed safe until the FDA can prove that they may pose a significant or unreasonable risk. While assigning the FDA this new enforcement burden, Congress failed to provide the agency with any additional resources. Thus, as a practical matter, the FDA has not been able to effectively utilize its authority to remove dangerous products from the marketplace and instead has been forced to rely on inadequate remedies such as issuing public warnings and requesting voluntary recalls.

The wisdom of this approach must be seriously questioned. Since DSHEA became law, the FDA has had to issue numerous consumer alerts, industry alerts, public warnings, and requests for voluntary recalls of hazardous supplement ingredients. Such ingredients include:

- Chaparral - liver disease, possibly irreversible
- Comfrey - obstruction of blood flow to liver, possibly leading to death
- Dieter's teas - nausea, diarrhea, vomiting, stomach cramps, chronic constipation, fainting, possibly death
- Ephedra - high blood pressure, irregular heartbeat, nerve damage, injury, insomnia, tremors, headaches, seizures, heart attack, stroke and death
- Germander - liver disease, possibly leading to death
- Lobelia - breathing problems, rapid heartbeat, low blood pressure, coma and death
- Magnolia-stephania preparation - kidney disease, possibly leading to permanent kidney failure
- Willow bark - Reye's Syndrome, allergic reaction
- Wormwood - neurological symptoms, characterized by numbness of legs and arms, delirium, and paralysis
- Germanium - kidney damage, possibly death

- Herbal "Fen-Phen" - high blood pressure, heart rate irregularities, insomnia, nervousness, tremors, headaches, seizures, heart attacks, stroke and death
- Gamma butyrolactone (GBL) - loss of consciousness, coma, death, seizures, vomiting, slow breathing and heart rate.

Because of the enforcement burdens imposed by DSHEA, the FDA has been forced to "regulate by news release," warning the public of the dangers of particular dietary supplements but not actually removing them from the marketplace. This approach is woefully inadequate to protect the public's health.

DSHEA has also made it increasingly difficult to keep dietary supplements that make false and misleading claims off the market. DSHEA permits supplement producers to make structure/function claims, which are essentially implied health claims, without first demonstrating that such claims are valid. (A consumer survey should be conducted to confirm what has long been suspected: that consumers do not understand the difference between health claims, which are subject to pre-market approval procedures based on "significant scientific agreement," and structure/ function claims that do not require agency approval and do not need to meet any specific substantive requirements.) The distinction is crucial considering that structure/function claims often tout benefits based on anecdotal evidence, folklore or studies that were not conducted in accordance with modern scientific techniques.

Consumers deserve to know which supplements provide real health benefits and which are nothing more than placebos. Unfortunately, the current regulatory framework established by DSHEA leaves many consumers simply guessing about which supplements are truly beneficial.

I. The FDA Should Support the Establishment of a Research Program that Would Determine Whether Particular Supplement Ingredients Are Safe or Pose a Significant or Unreasonable Risk and that Would Specify Appropriate and Inappropriate Labeling Claims.

To address these problems, the FDA should support the establishment of a research program, paid for by industry, that would systematically review the safety and efficacy of dietary supplement ingredients. Vitamin and minerals known to be Generally Recognized as Safe and whose role in maintaining health is not the subject of controversy within the scientific community, could be exempted from such review. The results of the review will alert both the FDA and manufacturers to dietary supplement ingredients that should not be marketed or that should only be marketed subject to certain regulatory controls. The results of the review could also be used to support health claim petitions under the NLEA. The review could be modeled on elements of the Over-the-Counter Drug Review, which determined whether particular ingredients within a given class of drugs are Generally Recognized as Safe and Effective, or the GRAS Review of Food Additives, which was used by the FDA to affirm the safety of food additives. While those reviews were slow and far from perfect, they, nevertheless, demonstrated that comprehensive reviews of entire product categories are feasible.

The NIH would be the best entity to conduct and supervise this research. It is the premier research institution in the U.S. dedicated to helping prevent, detect, diagnose and treat disease and disability. It both conducts research in the laboratories of its 24 separate institutes, centers and divisions, and supports research of non-Federal scientists in universities, medical schools, hospitals, and research institutions. For all of these reasons, NIH is the logical choice to oversee dietary supplement research.

The specific NIH institute that has expertise relating to the particular dietary supplement ingredient to be tested should either test or supervise the testing of that substance. For example, The National Institute on Aging is currently working on a research project on the effect of gingko on memory. The National Institute of Arthritis and Musculoskeletal and Skin Diseases would be the appropriate agency to test dietary supplements designed to promote healthy bones. And, the National Heart, Lung and Blood Institute would be the logical choice for research relating to supplements aimed at maintaining healthy cholesterol levels and a healthy heart.

The Office of Dietary Supplements (ODS), which was established under DSHEA, should be given sufficient funding to coordinate dietary supplement research. Under DSHEA, ODS has been designated as the principal advisor to the FDA on dietary supplement issues including safety and claims. Congress specifically directed ODS to compile a database of scientific research on dietary supplements and individual nutrients, including foreign data and data from what is now the NIH Center for Complementary and Alternative Medicine, and to coordinate NIH funding concerning dietary supplement research. Despite the fact that Congress authorized a $5-million budget for ODS, funding was never appropriated. The Office of the Director of NIH funded ODS start up costs through a Discretionary Fund. Since that time, the operating and program funds have been a line item in the budget of the NIH Office of the Director. The funding level has not come close to the $5 million authorized by Congress.

II. Research Should be Funded by a User Fee.

The purpose of the dietary supplement review program would be to conduct and support research on the safety and efficacy of dietary supplement ingredients. The Secretary of the Department of Health and Human Services (HHS) could appoint an advisory council to provide advice in the development of the research program, the selection of research priorities, and the development of testing protocols.

Although a review of existing research would be part of the program, it is essential that the long-standing use of a supplement should not be considered as evidence of safety. Ephedra is a case in point. Ephedra (Ma Huang) is a Chinese herb that, in the U.S., has caused more than 38 deaths and 800 adverse effects. Because the reporting of adverse effects from dietary supplements used in developing countries may be limited, and in the U.S. is voluntary, the true number of adverse events is likely to be much higher. The fact that a product may have been on the market for hundreds of years in a less developed country is also no guarantee that the product is not mutagenic, carcinogenic, teratogenic or neurotoxic.

The research program would be funded through fees assessed on dietary supplement manufacturers. These fees would be based on an appropriate criterion (such as market share or annual sales), and waivers and fee reductions would be available for small businesses. The funds collected would be distributed in the form of research grants.

In developing such a program, Congress, the NIH and the FDA could look to other programs that were created whereby members of an industry jointly contribute to study the health effects of their industry's products. For example, under the Environmental Protection Agency's (EPA's) pesticide registration program, pesticide manufacturers pay fees, based on market share,

that fund the agency's review of pesticides. Under Congressionally enacted "check-off" programs administered by the U.S. Department of Agriculture, cattle ranchers, hog farmers, and egg and dairy producers pay into funds that conduct research on beef, pork, egg and dairy consumption.

None of these programs has operated perfectly; some have faced serious problems. Nevertheless, we urge the FDA to examine these programs, identify their best elements and support the establishment of a new program that requires the supplement industry to sponsor studies on the safety and efficacy of supplements.

III. The FDA Should Coordinate its Policies on Dietary Supplements and Functional Foods and Take Enforcement Action Against Foods that are Marketed as Dietary Supplements to Avoid More Stringent Regulatory Controls.

So-called functional foods -- foods with an ingredient added to provide a particular health benefit -- are becoming increasingly popular. For example, consumers can now purchase chicken soup with echinacea or pea soup with St. John's Wort. In the case of Benecol and Take Control, two margarines containing phytochemicals, the FDA required the manufacturers to submit a GRAS self-determination to which it did not object. Although there was no public review of the data supporting the claims, there was at least some assurance that the FDA felt that the data upon which McNeil and Lipton relied did not raise troublesome questions. However, the FDA has not taken similar actions with respect to other foods containing dietary supplement ingredients. The FDA should coordinate its policies and take enforcement action to demonstrate that merely calling a food product a dietary supplement does not except manufacturers from laws and regulations that apply to foods.

CONCLUSION

This is an exciting time in the dietary supplement and food industries, as new discoveries offer the promise of significant health benefits. But consumers need scientifically sound information about supplement ingredients if they are to make informed purchasing decisions. We, therefore, recommend the creation of an NIH research program that will study the safety and efficacy of dietary supplement ingredients and issue findings on which the government, industry and the consumer can rely.

CSPI Center for Science in the Public Interest

Publisher of *Nutrition Action Healthletter*
1875 Connecticut Avenue, N.W., Suite 300
Washington D.C., 20009-5728

Dockets Management Branch (HFA 305)
Food and Drug Administration
5600 Fishers Lane
Room 1061
Rockville, MD 20852

Do Not Fold