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August 19, 1999

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

RE: FDA Docket No. 99N-1174

Comments of the American Cancer Society in response to the Food and Drug Administration's request for comments published in the Federal Register on May 13, 1999: Development of an overall strategy for achieving effective regulation of dietary supplements under the Federal Food, Drug and Cosmetic Act, as amended by the Dietary Supplement Health and Education Act.

The American Cancer Society is the nationwide, community-based, voluntary health organization dedicated to eliminating cancer as a major health problem by preventing cancer, saving lives and diminishing suffering from cancer, through research, education, advocacy, and service.

For patients undergoing treatment for cancer, cancer survivors worried about recurrence, and people hoping to prevent cancer, fear of this disease can be an overriding factor in making decisions regarding diet and health. The purchase and use of dietary supplements by people seeking to prevent or treat cancer represents a substantial expenditure of healthcare resources largely without proven value and not free of harm. Use of supplements based on implied disease claims may cause people with cancer to delay seeking medical care, resulting in delays in diagnosis and less effective treatment of the disease. Also, some dietary supplements contain substances that interact, reduce the efficiency, or increase the toxicity of conventional cancer treatment drugs. The Society encourages past, present, and future cancer patients to discuss with their doctors and other health care providers about any dietary supplements they may be taking.

The American Cancer Society is sensitive to the growing interest of the public, especially those living with cancer, in the use of dietary supplements. No matter what promises or claims are made for vitamins and other dietary supplements, none have been proven to cure cancer or any other disease. Dietary supplements have not been to slow or reverse growth or spread of cancers. However, misleading labeling and information has led the public to believe that these supplements are "magic pills." Therefore, the American Cancer Society strongly supports the need for stricter regulation of dietary supplements.

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And because the information on the label provides the most readily available information to the consumer about the product, we are particularly interested in regulating the labeling of such supplements.

Objectives: The American Cancer Society agrees with FDA's objective in regulating dietary supplements as "ensuring consumer access to safe dietary supplements that are truthfully and not misleadingly labeled." In pursuing this goal, the American Cancer Society believes that the driving force behind all dietary supplement regulation should be consideration of consumer protection and assistance to the consumer in making wise health choices.

ACS agrees with the criteria identified by FDA for priority ranking the tasks encompassed in the supplement strategy. Of the four criteria listed, the American Cancer Society believes that the first two – enhancement of consumer safety and development of health-related product labeling regulation – are the most important to protect consumers, and should be undertaken first.

Defining Boundaries: Clear boundaries need to be drawn between dietary supplements and conventional foods, drugs and cosmetic products. Because there are currently no boundaries, consumers have no way of knowing that the dietary supplements they purchase are not subjected to the same level of scrutiny as are foods or drugs. Many consumers incorrectly assume that all claims are supported by scientific evidence. Patients may have an inappropriately high level of trust in labeling claims on supplements they find on shelves of the same pharmacy from which they receive drugs prescribed by their physician.

The American Cancer Society supports the American Dietetic Association's recommendation that FDA establish categories for dietary supplements to delineate supplements that occur naturally in common foods from those that do not. Under this approach, vitamins and minerals that are relatively safe, have some requirements or formulation standards established by the Institute of Medicine or the United States Pharmacopoeia (USP), and for which there is a considerable research base, would be in one category along with components such as fiber and carotenoids that are either known nutrients or components of body function. Botanicals and hormones, of which less is known and therefore which present unknown or potentially greater risks, would be in a different category. The components in the latter category would require more scrutiny or limits. This approach would allow FDA to allocate more resources in ways that will better protect consumers.

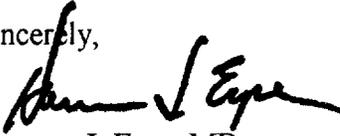
Claims: Because consumers rely primarily on product labels to provide all the information they have about dietary supplements, the American Cancer Society believes that all claims on dietary supplement labels should be pre-approved by FDA. Consumers neither know nor care whether a claim concerns a disease or structure or function of the body. This fine distinction appears to be irrelevant to the public. They tend to believe all claims. And most consumers probably do not realize that different types of claims

currently have different standards for approval. This inconsistency leaves the consumer without sufficient information to make knowledgeable choices. In addition, all allowed claims should be based on significant scientific agreement, which must incorporate the totality of available evidence published in respected, peer-reviewed journals.

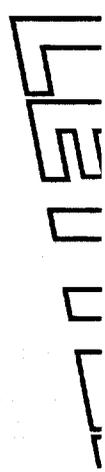
Adverse Event Reporting: The increased use of relatively unregulated dietary supplements by consumers points to the need for a more effective and user-friendly system for reporting adverse events.

The American Cancer Society appreciates the opportunity to provide comment on this important issue and looks forward to continuing to work with FDA to provide complete, accurate and nonmisleading information to help consumers make informed decisions about their health.

Sincerely,

A handwritten signature in black ink, appearing to read "Harmon J. Eyre". The signature is fluid and cursive, with a prominent downward stroke on the "E".

Harmon J. Eyre, MD
Executive Vice President for
Research and Medical Affairs



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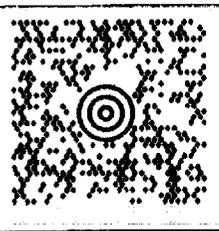
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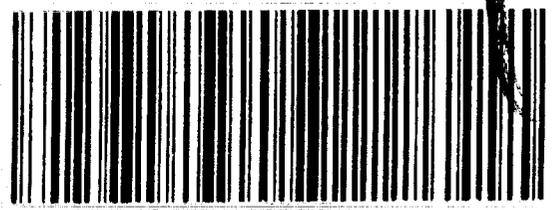
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