

## FDA PUBLIC MEETING ON REGULATION OF DIETARY SUPPLEMENTS

### STATEMENT OF THE SOCIETY FOR NUTRITION EDUCATION

June 8, 1999

The Society for Nutrition Education (SNE) welcomes the opportunity to provide FDA with some thoughts for its goal to achieve the effective regulation of dietary supplements. SNE is a professional organization of some 1500 members interested and active in promoting healthful and sustainable food choices through science-based research, communication, and education. We acknowledge the growing role that supplements play in American life. We also recognize the need for authoritative information about these products so consumers can make more informed, sensible decisions about supplement use.

But making such decisions can be hard in the present environment. Thousands of supplement products are available, and not only vitamins and minerals about which a good deal is known. Supplements now also include the far less well-characterized botanicals, metabolites, enzymes, phytochemicals, extracts, and concentrates sold singly and in combination. Their use is growing. It's only natural that many consumers would be confused about supplements, given the large number of products available and the plethora of information from advertising, product promotions, media reporting of single studies, word-of-mouth from supplement sellers. It can be very hard even for experts to separate the science from the pseudoscience without a good bit of personal research.

FDA has asked about other objectives to add to its dietary supplement strategy beyond ensuring access to truthfully and not misleadingly labeled supplements. FDA has also asked what research on dietary supplements it should allocate some of its research resources to. SNE recommends that FDA consider adding a strong consumer research and information component to its overall strategy. Specifically, we request that FDA consider the following three suggestions.

#### *Suggestion 1*

FDA should take the lead in conducting—and encouraging others to conduct—both qualitative and quantitative consumer research on the use of supplements. Last year, FDA asked its Food Advisory Committee to help identify questions to ask consumers in future surveys and focus groups that target dietary supplements. FDA's Alan Levy stated that while half the population takes supplements—with one third of them characterized as heavy users—very little is known about consumer understanding and use of dietary supplement product labeling. He added that FDA's current research on supplements focuses on who uses them, how many are used, and reasons for use. Dr. Levy acknowledged

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that more research is needed where consumers are asked their thoughts about supplements.

We agree! Clearly, more research is needed on how the labeling, advertising, and various promotions of supplements shape consumer perceptions of them and their willingness to try such products. We need detailed studies—both qualitative and quantitative in nature and theory based—that explore how consumers come to decisions about whether or not to supplement and details of the decisionmaking process itself. Do consumers make meaningful distinctions between health claims and nutritional support claims? Do they evaluate advertising copy and label information on supplements in the same way or differently. What do consumers recommend that FDA do to regulate supplements? The research needs to get beyond the simple surveys and small numbers of focus groups that have been the most frequent methodologies to date.

FDA should use its Food Advisory Committee as appropriate to help define the questions that need to be asked and do what it can to stimulate the needed research. FDA might also develop a workshop or conference to get advice from the scientific community on developing a consumer-focused research agenda on supplements. Some SNE members would undoubtedly want to participate.

#### *Suggestion 2*

At present, manufacturers of dietary supplements do not have to provide FDA with substantiation of their claims of nutritional support for their products, even though DSHEA says the manufacturer must have substantiation that the claims are truthful and not misleading. We believe FDA should require that the evidence on which the manufacturer is relying be provided to the agency and made publicly available. As a result, more claims of nutritional support would likely be investigated by scientists, investigative journalists, and perhaps even FDA itself. The results of these investigations would help consumers become more savvy users of supplements.

#### *Suggestion 3*

Consumers and health-care professionals need easily accessible and authoritative information about supplements without having to search too many diverse sources or to conduct their own literature reviews using, for example, the IBIDS database from the National Institute of Health's Office of Dietary Supplements (ODS). ODS, for example, is preparing fact sheets on selected vitamins, minerals, and botanicals. The U.S. Pharmacopoeia has produced short monographs on various botanicals. And recently, the American Society of Anesthesiologists issued a warning regarding the use of certain herbal products just before undergoing surgery. Authoritative information such as this should be accessible from a single source that is frequently updated. The FDA website might be the right source, or perhaps the ODS website. Irrespective of

placement, FDA could do more to encourage the development of a central source of authoritative statements regarding supplements and then promoting it.

Again, SNE thanks you for the opportunity to comment on FDA's efforts to develop an overall strategy for regulating dietary supplements. Consumers need easy access to good, authoritative information to make sensible decisions about these products. And more consumer research is needed to develop better policies and regulations that will allow the dietary supplements industry to thrive but not at the expense of consumer misunderstanding and confusion about the benefits and limitations of its products.

Society for Nutrition Education

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**SNE** facsimile transmittal**To:** Gloria Ortego**Fax:** 301-827-6870**From:** Mary Bresnahan**Date:** August 11, 1999**Re:** SNE Statement on Regulation Pages: 4 , including cover  
of Dietary Supplements:  
Docket # 99N-1174**CC:** Urgent  For Review  Please Comment  Please Reply  Please Recycle

Ms. Ortego:

Attached is a copy of SNE's full statement on Dietary Supplements.

Reference: Docket # 99N-1174.

If you require additional information or have questions about the attachment,  
please feel free to contact me at 301-656-4938.Gloria, thank you very much for all of your much needed assistance. I truly  
appreciated your help.

Best regards,

Mary Bresnahan  
Executive Director

82-11-508-66-613

**Join us for SNE's 32nd Annual Meeting in Baltimore, MD July 24th-July 28th.  
For more information contact us at 301-656-4938 or via email at info@sne.org.**