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**Comments  
Of the  
International Center for Environmental Technology (INTERCET, Ltd.)  
And  
Center for Research Information, Inc.  
On  
Dietary Supplements; Center for Food Safety and Applied Nutrition  
Strategy; Public Meeting  
Federal Register: June 18, 1999 (Volume 64, Number 117)  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration  
[Docket No. 99N-1174]  
Submitted August 20, 1999**

My name is Dr. Richard D. Thomas and I am the President and Chief Executive Officer for the International Center for Environmental Technology (INTERCET, Ltd.) in McLean, Virginia. On behalf of our center and that of the Center for Research Information, Inc., I am pleased to present our written comments to the FDA on some of the questions posed in the June 8, 1999 Federal Register Notice regarding assistance for the Center for Food Safety and Applied Nutrition (CFSAN) to develop an overall strategy for achieving effective regulation of dietary supplements under the Dietary Supplement Health and Education Act (DSHEA).

INTERCET, Ltd. advises industry, government, local, and rural communities through contract research, consultation, and technology transfer. The Center for Research Information, Inc., of Washington D.C. is an information services firm, with which we have worked, that has specialized skills in Toxicology, Pharmacology, Pharmacognosy, and Information Sciences. Together we have assembled an excellent team of scientists with backgrounds in toxicology, pharmacology, pharmacognosy and analytical chemistry that we believe will allow us to assist clients in scientific information support arena for the ever expanding dietary supplement market. Hence the purpose for our written testimony to FDA is to provide suggestions on possible strategies that could assist in attaining the FDA stated objective of ensuring consumer access to safe dietary supplements that are truthfully and not misleadingly labeled.

I am a diplomat of the American Board of Toxicology with over 25 years experience in environmental and human health, risk assessment, toxicology and pathology. My research interests concern the mechanisms of toxic chemical actions and the related ultra-structural changes in tissues, such as lung tissue. For twelve years, I directed various risk assessment studies at the National Academy of Sciences on topics such as: the assessment of contaminants in drinking water and pesticides in children, the use of pharmacokinetics in risk assessment, and the recommendation of acceptable levels of chemical exposure for military and NASA personnel. In addition, I have directed toxicologic studies at Borriston Laboratories, the MITRE Corporation, SRI International, and CIBA-GEIGY Corporation. International experience includes work with the United Nations, U.S. Agency for International Development, the World Health Organization, and the World Bank.

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Many Americans are supplementing and replacing traditional prescription and over-the-counter medicines with alternative and complementary preparations such as herbs, vitamins, and minerals. A burgeoning manufacturing industry has arisen where approximately 800 U.S. companies (*Time*, November 1998) compete in the marketplace producing a large variety of nutritional products. Sales of these products reached \$14 billion in 1998, according to the *Nutrition Business Journal*. We believe this trend will continue into the future.

Dietary Supplements represent a new and fast growing market posing new challenges mostly associated with scientific information. Historically, regulations have driven the need for scientific information for consumer product safety, worker health, environmental concern and pharmaceuticals and related products. The major difference in the herbal supplement market is that since Congress deregulated the industry in 1994, the FDA's interest in these substances has been as a lightly regulated foodstuff. This association is partially misleading - particularly with the incredible and sometimes miraculous claims of life improving results.

This situation has created a new challenge for the general public and pharmaceutical companies. Because the data on safety and efficacy of these preparations is often difficult to retrieve and analyze, a need arises for a strategy of new regulations and guidelines that is able to provide the environment for the development, accumulation and dissemination of accurate and dependable scientific data about dietary supplements to meet the needs of the professional and general public. Companies and associations that are involved in this industry must be knowledgeable about the scientific properties and potential side effects of their products and discriminate between good science and unfounded claims.

Our suggestions to a few of the specific questions the Agency posed in the June 8, 1999 Federal Register notice follow, with questions one and three being commented on together:

**1. In addition to ensuring consumer access to safe dietary supplements that are truthfully and not misleadingly labeled, are there other objectives that an overall dietary supplement strategy should include?**

**3. What factors should FDA consider in determining how best to implement a task (i.e., use of regulations, guidance, etc.)?**

We recommend that the FDA consider requiring, through regulation, that dietary supplements contain dietary supplemental material safety data sheets (DS MSDS) at the point of purchase. Specifically we recommend the FDA examine carefully the successful experience and record of accomplishment with the OSHA Hazard Communication Standard (29 CFR 1910.1200).

A major factor in the DSHEA is education. We believe an effective strategy for the FDA would be to keep safety and efficacy (if available) information in one place for easy availability and access to the public and to separate and prioritize the scientific tasks required to accumulate the information, with immediate safety the highest priority, to answer the needs by pharmacists, health care providers and consumers of dietary supplements and efficacy, second.

The FDA could issue a performance-based regulation similar to the OSHA Hazard Communication Standard with minimum requirements as to the types of safety information for a sheet but with flexibility and guidance as to format and preferred types of statements. In this way it would provide the public with the information it needs to make choices and decisions, especially regarding safety.

The experience of the OSHA Hazard Communication Standard has provided some measure of liability protection to manufacturers by its required disclosure indicating transparency and allowed greater informed decisions about working with chemical substances. This has assisted in fostering an environment of good product stewardship, causing a climate where knowledge is generated and disseminated about products and chemicals, what they can do and how they should be safely used.

An FDA regulation of this type would provide a minimum level of safety information, a level playing field and provide clear direction to manufacturers about required sets of information. An atmosphere would be created to allow competition to provide more and better information about the safe and optimal use of their products. An aspect of the Right to Know regulations are that they have been evolutionary and improve over time, allowing for priorities to continually be reset to meet new societal informed choice expectations. FDA would thus set in motion a process for accurate scientific safety information, assisting with labels, yet going beyond.

Another strategy for FDA to consider in DSHEA is novel educational outreach directly to the public. We suggest seminars, sponsored jointly with other relevant stakeholders about dietary supplements to help educate about dietary supplement label interpretation, and if adopted interpretation of a Dietary Supplement Safety Data Sheet. The seminars could be targeted both to consumers and to professionals, such as pharmacists and physicians to discuss work completed on the major areas outlined in this Federal Register notice. The effect would be two fold, conveyance of what to expect from a label and DS MSDS, in essence conveyance of the official FDA regulatory and any voluntary guideline perspective and second to hear from consumers and customer first hand about their experiences, concerns and what they want and need. Seminars as part of the strategy with continual direct contact with consumers will keep FDA, and other stakeholders, in a learning mode and benefit everyone in the process. This type of an addition to the strategy would require resources of time and travel but it could be very popular and useful.

We believe such direct consumer outreach on simple aspects of dietary supplement labeling or safety data sheets to the CFSAN strategy may be necessary as we enter an age marked by increased information, emphasis on health preservation, prevention of negative medical outcome and increased consumer control of their medical destinies.

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

We recommend that Dietary Supplement Material Safety Data Sheets, with sections for safety information valuable to consumers, in a format agreed upon between FDA, industry and consumers be prepared and supplied at the point of sale with all dietary supplements that make health related claims. Consumers have a right to know as much safety information about over the counter dietary supplements, as can be provided to them to immediately protect themselves and use the products safely. Even if this information is not known, this should be communicated so that they may make an informed choice.

In strict safety terms users need to know what materials they are ingesting (e.g. % active and % inactive ingredients), what the immediate and long term effects may be with normal use, what the recommended use is for the claim made, and what negative effects of overexposure or a sensitive individual could be. There are other categories of information that could be useful but this we believe would be the minimum.

The experience of the OSHA Hazard Communication Standard (29 CFR 1910.1200) and EPA SARA Title III, "Community Right to Know" (40 CFR Parts 350-372) regulations have been very helpful in instructing workers and the public on the safe use of chemicals and possible effects where workers or the public may be voluntarily or involuntarily exposed to chemicals. Experience with these standards has shown that scientific information can be written in lay terms so as to be easily understood by the public.

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

Ensure no public harm should be the first priority with dietary supplement research resources available. The FDA should allocate resources towards safety first, with the consuming public in mind and exercising

good science and the precautionary principle, meaning if there is a possibility a supplement will do harm, err in the side of citizen safety.

Research areas could be prioritized by acute toxicity, irreversible adverse reaction, reversible adverse reaction, side effects, synergistic adverse reaction with prescription medicines or other foods, medical contraindication and chronic toxicological research. Efficacy research with verification of recommended dosage for health effect claimed would be next.

Research priorities could be determined by a matrix that would compare the availability, or lack of, scientifically credible research information on prioritized toxicological endpoints for consumers, such as acute toxicity, about a specific dietary supplement, against the volume of these supplements that are consumed annually, available from industry sales data. We suggest this to help the FDA fairly decide research priorities.

We support a comment that appeared in the public record on June 8, 1999 that an extension of a safety claim would include efficacy if a health effect claim were implied for a serious disease such as cancer or heart disease where a person may use a dietary supplement instead of seeking standard treatment. We would suggest FDA consider an estimate of the risk of disease and death that may occur from patients shunning traditional treatment in favor of an unsubstantiated claim from a dietary supplement as a fair means to establish higher and lower priorities for dietary supplement efficacy research.

We also believe, with a number of the commentors, that the health claim made is the distinguishing factor of dietary supplements from other foodstuffs. In noting that substantiation of health related claims is a close second to safety, Dr. Paul Thomas of the Society for Nutrition Education said at the June 8, 1999 hearing, these substances are being purchased "largely on the basis of hoping for some kind of effect" and went on to say "unlike with foods that you might eat because they taste good, they're crunchy--you know, that sort of thing--you're taking dietary supplements for specific health-related types of effects, and here the labeling and the information that is available about them is critical." We would concur with this comment. The hopeful health expectation generated about certain dietary supplements within the consuming public make FDA directives about communication in simple terms of scientific certainty, or the honest lack of it, concerning efficacy of the health related claims of grave or serious medical implication a high priority. We hope our suggestions here assist the Agency in making decisions when Federal research dollars should be spent in efficacy research versus safety and when these lines cross.

**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?**

The FDA should use private sector voluntary standard mechanisms and incentives to encourage development of safety information for dietary supplement material safety data sheets. Suggestions put forth in the June 8, 1999 public record included developing monographs, establishing advisory committees (FACA) or usage of some non-profit organization such as the United States Pharmacopeia or the Herbal Pharmacopeia as a means to achieve this end. We would support these suggestions.

We have had good experience with the American National Standards Institute (ANSI) and the American Society for Standards and Materials (ASTM) and would suggest FDA look into their processes as a possible means to reach consensus. These organizations are well known for consensus standards and employ a process that could involve all relevant stakeholders, including users or consumers of supplements. ANSI is also the U.S. voting member to the International Standard Organization (ISO) and instituting national voluntary standards could provide a useful platform in case the scientific information and labeling issues enter the global arena in the future.

Processes, such as voluntary standard committees could be established within these organizations involving all the stakeholders. ANSI and ASTM can employ a canvass method that allow voluntary standards to be

developed through the mail or electronically, thus using modern electronic communication reducing travel cost, involving more stakeholders and could expedite the production of the guidelines or standards needed.

Maximum usage of voluntary consensus and other non-profit and professional resources would allow FDA to focus on issues that require Agency decision or must remain in a government regulatory context (e.g. mandating a dietary supplemental material safety data sheet or final decision about the definition of a disease) where guidance or voluntary consensus is not sufficient. However, even in these cases, the maximum use of the voluntary consensus standards, guidelines and non-profit scientific and professional resources available to the Agency provides a platform to regulate if necessary.

The FDA should consider separating safety issues from efficacy ones and develop standards simultaneously using voluntary standard setting organizations, such as USP or ANSI. This would allow safety information, on which there appears to be a consensus of opinion about the need for and even a fair amount of agreement as to the subjects, to be developed quickly and made available to the public. If gaps exist they will be quickly identified and filled. Animal acute toxicity data can be developed rather quickly.

Earlier we suggested on going educational dietary supplement seminars with the public, possibly jointly sponsored with other stakeholder and some specifically focused on stakeholder issues such as pharmacists and other health care providers. Interactive long distance learning on the internet would be an inexpensive means to conduct such educational outreach. Internet outreach would allow wide participation, easy and unintrusive access, greater focus, seminars for specific issues and achieve the CFSAN objectives.

Thank you for the opportunity to provide these comments. If we can help clarify our comments, please contact me at:

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