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Research-based Dietary Ingredient Association
1722 Eye Street N.W.
Washington, DC 20006

June 7, 1999

via Fed Ex

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

RE: Docket No. 99N-1174
Dietary Supplements: Center for Food Safety and Applied Nutrition Strategy;
Public Meeting
Federal Register 64:25889 (1999)

Dear Sir or Madam:

The Research-based Dietary Ingredient Association is a recently-formed association of companies, including Cargill, Galagen, Monsanto, and Novartis, committed to championing the role of science in the development of functional food ingredients and related products. We believe it is essential for science based companies to take the lead in establishing and abiding by standards for scientific research to assure a product's safety, to substantiate its claims, and to assure consumer trust. Our mission is to catalyze a process to develop and obtain support for these standards.

Our comments are directed towards the Agency's request for input on its objectives to ensure consumer access to safe dietary supplements that are truthfully and not misleadingly labeled. We also address the Agency's request for guidance in developing implementation strategies that leverage its limited resources.

RDIA believes that FDA's overall objective in this area should be the development of public policies that serve consumers and promote public health by fostering the availability of safe nutritional products that deliver scientifically substantiated benefits.

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availability of safe nutritional products that deliver scientifically substantiated benefits. RDIA believes achieving this objective requires not only oversight by FDA to ensure that the safety and utility of products are documented, but also consideration of how the regulatory system affects the incentives for investment in innovative and truly beneficial products.

Thus, RDIA urges FDA to develop a regulatory framework for foods and dietary supplements that:

- has consistent and transparent standards for safety and claims substantiation
- has timely and predictable processes for regulatory acceptance
- rewards investment in research
- has meaningful enforcement options

RDIA would like to work collaboratively with FDA and others to help ensure that these concerns are taken into account in developing the optimal regulatory framework for the development and marketing of science-based nutritional products. We also recognize that, in the long run, this may require legislation, but we also believe that FDA should implement current law in a way that, to the maximum extent possible, protects and promotes public health.

I. Develop Policies that Promote Consistent and Transparent Standards for Safety and Claims Substantiation

A. Common Safety Standard

Consumers have the right to know that the foods and dietary supplements they consume are safe. Whether they are conventional foods, dietary supplements, or new dietary ingredients in dietary supplements, these products should meet a common safety standard that their consumption will not pose a significant or unreasonable risk to health when used as intended. Meeting this standard may require a scientific process that includes original research. For example, if the safety assessment of a new dietary ingredient in a dietary supplement indicates that the safety standard articulated above cannot be met through experience based on common use and published literature, then safety research will be required.

We believe there is a need for uniformity of understanding in the industry as to what this safety standard means and what information is required to be assured this standard is met. While DSHEA does not prescribe a specific safety assessment *process,* neither does it excuse any company from determining that its products are safe for the target population, at the specified level of ingestion. We urge FDA to work with industry to

help assure uniformity in understanding what information and science are required to meet the safety standard as indicated under the law.

B. Common Claims Substantiation Standard

RDIA believes that foods and dietary supplements whose benefits to health have been demonstrated via sound scientific research, to a reasonable certainty, should be able to describe these benefits on labeling and via other types of communications. We see no scientific rationale for differing standards of substantiation for labeling claims on either foods or dietary supplements made under FDAMA, NLEA or DSHEA. We believe all types of claims, whether they are structure/function claims, NLEA health claims, or FDAMA health claims, should meet the same standard of "reasonable certainty" that the claim is true. The nature of the science needed to support a claim likely will vary depending on the type of claim made, but the same standard of "reasonable certainty" that the claim is truthful and not misleading should be required. We encourage FDA to apply this standard evenly to all types of claims on both foods and dietary supplements.

One of the obstacles to developing responsible claims for products is the lack of clarity regarding the nature and extent of evidence constituting adequate substantiation. We realize it is not feasible or even desirable to prescribe a set of studies needed to substantiate every claim; however, we believe it is appropriate to establish a process for gathering, evaluating and weighting the evidence that may substantiate a claim and to require that this process be applied consistently. The Functional Foods Technical Committee of the International Life Sciences Institute is developing a proposal for such a process and is seeking scientific input and acceptance. RDIA supports this effort and believes it will help assure that claims are evaluated according to a consistent, scientifically sound process.

II Timely and Predictable Processes for Regulatory Acceptance

RDIA believes there should be mechanisms in place to assure that claims made on foods and dietary supplements do, in fact, meet a standard of reasonable certainty and that they can be used by manufacturers within a timely manner after their data evaluation is complete. The FDA Modernization Act essentially provides one avenue for this by allowing the use of labeling health claims based on appropriate authoritative statements under a timely notification process.

However, the food and dietary supplement industries are developing products with claims based on new data at a pace that appears to exceeds the abilities of the FDA, with its current limited resources, to review them expeditiously. RDIA believes this situation may be one where it makes sense for industry to participate actively in its own monitoring. The Presidential Commission on Dietary Supplements Labeling

recommended that the dietary supplement industry should monitor itself as a means of easing the burden on FDA to take action against fraudulent claims.

For example, industry could develop guidelines that would help its members perform appropriate and adequate studies to assure reasonable certainty of claimed benefits. In addition, an independent expert review process could be established to verify that claims are substantiated to a reasonable certainty. The Life Sciences Research Office, for example, or another organization of similar stature, could be considered to be an independent expert. Claims determined to be adequately supported could be distinguished on labeling. This option would take much of the burden of data evaluation off the FDA.

These measures are not meant to replace FDA's role and authority in taking action against claims; rather, they would limit the number of situations in which FDA would need to act. RDIA urges FDA to encourage the development of such self-monitoring processes.

III Incentives for Investing in Research

Adequate incentives for companies to invest in research are critical if society is to obtain the most benefit from what is learned about the relationship between diet and health. Research incentives are affected by intellectual property laws and other factors beyond FDA's control, but the regulatory system is also a powerful influence on investment decisions. RDIA believes the regulatory system should be designed and implemented in a way that encourages research. By encouraging scientific research and the development of products that provide benefits for people, the regulatory system can be a tool for promoting public health as well as protecting it.

For example, suppose a manufacturer of a dietary supplement invests significantly in well-conducted clinical studies to demonstrate its product reduces blood cholesterol consistently in subjects with moderately elevated cholesterol when taken as part of an overall dietary plan for managing cholesterol levels. The current petition and approval process for health claims under NLEA is too uncertain and time-consuming for manufacturers to be confident that their investment in research will be rewarded by timely use of the claim in the marketplace. In addition, the provisions that data supporting a health claim be publicly available and that any other company can use an approved claim are strong deterrents to research investment. Instead, the manufacturer should be rewarded for its investment by having the freedom to make a labeling claim, such as, "When taken as part of an overall dietary plan, this product can help lower moderately elevated cholesterol levels." Such a claim should be allowed because that it what the data, truthfully and not misleadingly, showed.

Manufacturers who invest in research should have the ability to make claims in a timely manner. In addition, they should be able to use proprietary data to support their claims, and they should have exclusive use of their claims for a period of time if the claim is based substantially on the company's research. We realize some of these objectives require legislative change. In the meantime, RDIA urges FDA to step back from its current views on claims and generate discussion within the scientific and public health communities and industry on how the results of scientific studies about products should be presented appropriately to consumers.

IV Meaningful Enforcement Options

We applaud the enforcement actions FDA has taken against several unsafe dietary supplements. We urge FDA to continue to focus its limited resources against unsafe products as well as against products with inadequate science to support their benefits. We also believe it would be useful for the industry to establish a self-monitoring program, and we ask the Agency to participate in, and support these efforts.

SUMMARY

RDIA believes FDA should direct its effort to developing the critical features of an optimal regulatory system, including: consistent and commonly applied standards for safety and claims substantiation, transparent, predictable and timely regulatory processes, acceptance of industry self-monitoring, and regulatory oversight focused primarily on identifying and removing unsafe products and/or products with inadequate science to support their claims.

Respectfully submitted,

Maureen Mackey

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Secretary, Research-based Dietary Ingredient Association

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