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

May 7, 1999

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

RE: Docket No. 99N-0554
How to Use Health Claims and Nutrient Content Claims in Food
Labeling; Public Meeting
Federal Register 14178 (March 24, 1999)

Dear Sir or Madam:

The Research-based Dietary Ingredient Association (RDIA) is an organization of companies representing food, food ingredient, medical food, and dietary supplement industry segments. The members include Cargill, Galagen, General Nutrition, Monsanto, and Novartis.

Our companies came together because we feel that for the growing field of consumer health maintenance to develop responsibly, industry needs to help establish standards for scientific research and appropriate use of such research for substantiating product claims and safety. RDIA is committed to helping develop and promote these standards of scientific research and substantiation. We will work with appropriate scientific bodies to carry out this work.

We have made comments pursuant to the federal register request:

1e: How does the significant scientific agreement standard apply to health claims based on authoritative statements?

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

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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. We believe this standard is consistent with the standards for advertising claims substantiation applied by the FTC.

We also believe 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 for this by allowing the use of labeling health claims based on appropriate authoritative statements under a timely notification process.

At the same time, the food and dietary supplement industries are developing products with claims based on new data at a pace that exceeds the abilities of the FDA, with its current limited resources, to review them expeditiously. RDIA believes it could help FDA with this issue. For example, we believe a process similar to that used for private GRAS assessments could be applied to claims evaluation. A company could seek the evaluation of an independent body of experts to provide an unbiased opinion of the adequacy of the data supporting a claim. 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. If such a process were done voluntarily by manufacturers, we would ask FDA to exercise its authority under FDAMA to authorize use of a health claim at the time its regulation is proposed.

2b: What requirements of 21 CFR 101.14 should we apply to health claims based on authoritative statements?

We believe the field of nutritional science has made enormous strides in discovering the health benefits of foods and components in foods. We need to think more expansively about what are acceptable and desirable components to increase in our diets. Just as in the 1980's we realized that increasing our intake of fiber three-fold could benefit health, we are now discovering that increasing intake of other components in foods also may be beneficial. However, section 101.14(b)(3)(i) states that for a substance to be eligible for a health claim, it must “contribute taste, aroma, or nutritive value...”. We believe other components in foods should be viewed as providing “nutritive value,” once they have been shown through sound scientific research to have beneficial effects on human physiological processes, whether or not these processes are known to be associated with disease. We are encouraged by the Agency’s recent reaction to Lipton’s view that phytosterols contribute to the nutritive value of margarine. We hope this indicates an

open perspective in FDA's consideration of future products.

We also support the requirement under CFR 101.14(b)(3)(ii) that the substance about which a health claim is made should be demonstrated to be safe at the level necessary to justify the claim and also lawful under the applicable food safety provisions of the FDCA. We believe there is no scientific reason to support different standards of safety for foods and dietary supplements, even though the approval processes are different by statute. Consumers have the right to expect that both these types of products are safe. We encourage FDA to require that foods and dietary supplements, whether they have FDAMA health claims, any other type of claim, or no claim at all, meet a common safety standard that consumption of these products will not pose a significant or unreasonable risk to health when used as intended.

3b: Should we provide by regulation that health claims based on authoritative statements may be used in the labeling of dietary supplements?

RDIA encourages FDA to extend the opportunity to make health claims based on authoritative statements on the labeling of dietary supplements. As we have stated today, we believe FDA should adhere to a policy of uniform treatment for dietary supplements and foods. The claims should be subject to the same level of science for all products, but the level of the research needed depends on the nature of the claim.

In other words, the same ingredient, whether it goes into a dietary supplement or food should meet the same standard of safety and all claims, whether on foods or dietary supplements, should be required to meet the same standard of reasonable certainty that the claim is substantiated.

In summary, RDIA recognizes that FDAMA has provided a new, expeditious mechanism to allow health claims on products based on authoritative statements. We urge FDA to implement the provisions of this Act and also to work to make uniform the requirements for safety and substantiation for all types of products and claims.

Attached are the verbal comments I plan to make at the open meeting on May 11, 1999:

Thank you for the opportunity to present our views on FDAMA's provisions concerning labeling claims made on foods and dietary supplements.

The Research-based Dietary Ingredients Association is a recently-formed association of companies 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 submitted comments are responsive in detail to FDA's request for input regarding FDAMA; however, we wish to take this opportunity to provide our perspectives on several closely related matters pertaining to the broad area of the safety of functional foods and ingredients, dietary supplements, and the scientific support for their labeling claims. Such issues cut across product categories and types of claims, and their application laws and regulations.

Consumers have the right to know that the foods and dietary supplements they consume are safe and that the claims made about them are truthful and not misleading. RDIA believes that two fundamental principles should guide all aspects of research and development of ingredients and the food and supplement products in which they appear:

First, whether they are conventional foods, dietary supplements, or new dietary ingredients, 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* similar to that used to demonstrate that a product is Generally Recognized As Safe. 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, then some form of 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 the DSHEA does not require the GRAS *process* neither does it excuse any company from providing products that are safe for the target population, at the specified level of ingestion. RDIA's goal is to help establish within the industry, uniformity in understanding what information and science are required to meet the safety *standard* as indicated under the law.

Our second fundamental principle is that any type of labeling claim made about foods, ingredients or dietary supplements should be based on competent and reliable scientific evidence that establishes its truthfulness to a reasonable certainty.

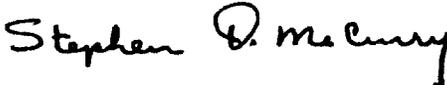
In addition, RDIA believes that products, whose benefits to health have been demonstrated via sound scientific research, to a reasonable certainty, should be able to describe these benefits in labeling and via other types of communications. We see no rationale for differing *standards* of substantiation for labeling claims on either foods or dietary supplements. 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 further believe that structure/function claims about the physiological effects of foods and supplements should be allowed, provided they do not state an ability to prevent, cure, or treat a disease, regardless of the "biomarker status" of the particular structure or function.

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Sincerely,

A handwritten signature in black ink that reads "Stephen D. McCurry". The signature is written in a cursive style with a large, looped initial "S".

Stephen D. McCurry

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