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CONSUMER HEALTHCARE PRODUCTS ASSOCIATION®

February 22, 2000

Docket No. 99D-5424
Docket Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 99D-5424: Comments on "Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements; Availability."

Dear Madam or Sir:

The Consumer Healthcare Products Association (CHPA)[1] submits these written comments in response to FDA's notice in the December 22, 1999 *Federal Register* concerning "Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements."

As stated in the Agency's guidance document, the document addresses the agency's current thinking on the significant scientific agreement standard, which FDA will use to evaluate the scientific evidence supporting health claim petitions about the relationship between a nutrient or food substance and a disease or health-related condition. When deciding to authorize a health claim, the agency plans to rely on five criteria that represent the agency's best judgment as to whether the significant scientific agreement standard is met. These five criteria are:

1. "Qualified experts would likely agree that the scientific evidence supports the substance/disease relationship that is the subject of a proposed health claim;"
2. It is "a strong standard that provides a high level of confidence in the validity of a substance/disease relationship;"

[1] CHPA membership includes over 200 Dietary Supplements and OTC companies involved in the manufacture, distribution and marketing of self-care products and their affiliated services (e.g., raw material suppliers, research testing companies, contract manufacturing companies, advertising agencies, etc.).

3. "The validity of the relationship is not likely to be reversed by new and evolving science, although the exact nature of the relationship may need to be refined;" and
4. The standard is objective … flexible … and responsive;"
5. The standard does not require a consensus or agreement based on unanimous and incontrovertible scientific opinion, but an area on the continuum of scientific discovery that extends from emerging evidence to consensus, that lies closer to the latter than to the former.

CHPA provides the following comments to FDA and asks that the agency revisit the conceptual framework of the guidance, in conformance with our comments, after it has first determined how it will proceed on Pearson v. Shalala.

First, FDA was directed by the Court of Appeals to "explain what it means by significant scientific agreement or, at a minimum, what it does not mean" (U.S. Court of Appeals for the District of Columbia Circuit in the matter of Pearson v. Shalala, January 15, 1999). As part of that proceeding, the Court of Appeals determined that FDA violated the First Amendment by denying the claims at issue. The Court further determined that FDA could have accomplished its goals with "the less draconian means" of allowing manufacturers to make unapproved health claims accompanied by a disclaimer, thereby letting consumers know that the claims were not "FDA approved." This is an extremely important issue, and one that has the attention of members of Congress (see letter to FDA Commissioner Dr. Jane Henney from selected members of the House of Representatives, dated February 25, 1999).

However, by publishing its "current thinking" in the form of a guidance which focuses on the established nature of a particular substance/disease relationship rather than truthfulness in the claims actually made about that relationship, FDA prejudges its approach to addressing *Pearson*, and thus its response to the Court suggested, i.e., a less draconian approach such as the use of a disclaimer on unapproved health claims. Hence, CHPA requests that FDA address *Pearson* in conjunction with a resolution of significant scientific agreement, not sequentially in a way that bifurcates the issues that brought *Pearson* to the Court of Appeals.

Alternatively, FDA could revisit the guidance and cast it in light of a definition of significant scientific agreement that focuses on whether the claim, and/or the manner in which the claim is being made, is truthful. Under section 403(r)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 343(r)(3)) and 21 CFR § 101.14(c), the fundamental criterion that establishes significant scientific agreement is that "the claim is supported by such evidence" (i.e., the "totality of publicly available scientific evidence"). If the claim reflects accurately what the totality of the publicly available scientific evidence is, then under 403 (r)(3) the claim should be allowed. If there is strong scientific support with little public disagreement, then the claim might appropriately be a definitive statement about a disease-food relationship. If, however, the evidence provides a reasonable expectation that there is a disease-food relationship, then the claim might in this case be appropriately clarified with a disclaimer, so that the "claim is appropriately

characterized and therefore linked to, and thus supported by the [totality of the publicly available scientific] evidence." The standard is thus the truthfulness of the claim, not the "validity" of the disease-food relationship.

Second, FDA cites as one of its five criteria a statement that can best be described as the "immutability criterion" –i.e., "The validity of the relationship is not likely to be reversed by new and evolving science, although the exact nature of the relationship may need to be refined" (emphasis added). This is too high a bar, and in fact flies in the face of another of the five criteria that the standard should be responsive to "re-evaluate data," as cited below:

> "Application of the significant scientific agreement standard is intended to be objective, in relying upon a body of sound and relevant scientific data; flexible, in recognizing the variability in the amount and type of data needed to support the validity of different substance/disease relationships; and responsive, in recognizing the need to re-evaluate data over time as research questions and experimental approaches are refined." (Emphasis supplied)

This aspect of FDA's standard is also further evidence that the agency has missed the mark in considering the First Amendment implications of significant scientific agreement and in recognizing, as surely it must, that science changes with evolving techniques, theories, facts, and approaches. New science can contradict old scientific beliefs. A recent example is saturated fat. Less that a decade ago scientists agreed that saturated fat was 'bad' and that excessive intakes of fat was a major dietary factor contributing to heart disease and some cancers. However, recent science does not continue to support this statement. We now know that not all saturated fats are 'bad', and that some saturated fats such as stearic acid are 'good' as they can lower blood cholesterol levels.

CHPA therefore requests that, as FDA reconsiders the guidance in light of the Association's comments and amends its "immutability criterion" to one grounded in "reasonable expectation." Coupled with a focus on the truthfulness of the claim about the disease-food relationship, a reasonable expectation that the "totality of the publicly available scientific evidence" supports the claim – given an ability to use a disclaimer – is itself a reasonable standard.

Finally, the Agency should not ignore the important public health implications of health claims. That is, the potential public health benefit(s) that would accrue from approving such claims. Both NLEA and DSHEA recognize the public health benefit of educating and encouraging consumers that certain nutrients will reduce their risk of certain chronic diseases such as, heart disease, cancer and osteoporosis --- the "E" or Education component of these Acts. Congress further recognized when passing these Acts, that these preventive health measures, "will limit the incidence of chronic disease and reduce long-term health care expenditures."

Please do not hesitate to contact us should you have questions or require clarification of these comments.

Sincerely yours,

R. William Soller, Ph.D.
Senior Vice President and
Director of Science & Technology

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No Attachments

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