



# American Bakers Association

*Serving the Baking Industry Since 1897*

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February 22, 2000

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

Re: Docket Nos. 91N-0101, 91N-0098, 91N-0103 and 91N-100H;  
Food Labeling: Health Claims and Label Statements for Dietary  
Supplements; Strategy for Implementation of Pearson Court Decision  
64 Fed. Reg. 67289 (December 1, 1999)

Docket No. 99D-5424; Guidance for Industry: Significant Scientific  
Agreement in the Review of Health Claims for Conventional Foods  
and Dietary Supplements; Availability.  
64 Fed. Reg. 71794 (December 22, 1999)

Dear Sir/Madam:

These comments are submitted on behalf of the members of the American Bakers Association (ABA), the national trade association representing the wholesale baking industry. ABA membership consists of approximately 300 bakers and bakery suppliers who together are responsible for the manufacture of approximately 80 percent of the baked goods sold in the United States. ABA submits comments on several dockets that are inter-related. First, ABA comments on the strategy for implementation of the Pearson court decision. Second, ABA comments on its concerns over important policy implications related to FDA's significant scientific agreement standard as reflected in the agency's guidance document.

## Pearson Implementation Plan

The basis for the U.S. Court of Appeals for the District of Columbia in the Pearson v. Shalala decision, found that FDA's failure to consider whether the health claims at issue there could be stated in a qualified manner, violated the First Amendment. This decision fundamentally relates to the "significant scientific agreement" standard FDA has applied in the health claim approval process, since the NLEA was adopted. This standard governs FDA's approval of health claims for both conventional foods and

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dietary supplements, and the Pearson decision requires FDA to reform its standard to conform with the First Amendment.

ABA strongly believes that these reforms must not be limited to dietary supplements, as FDA's implementation plan suggests, but must extend fully to conventional foods. There is no reasonable legal basis for any other approach. In this regard, the American Bakers Association strongly objects to the implementation plan published on December 1, 1999.

Because of the substantial impact of the Pearson decision on bakery products, it is ABA's intention to fully participate in all policy development to implement Pearson. ABA will vigorously oppose any effort by FDA to shut out the conventional food industry, or sidetrack or delay consideration of health claims for conventional foods under Pearson. Moreover, any pending rulemaking process that predates the Pearson decision and impinges on health claim or nutrient content claim requirements cannot be brought to closure unless there has been a full opportunity for public comment in the light of the Pearson decision. ABA is concerned that, prior to Pearson, FDA did not take seriously the constitutional limits on its authority, and pending issues must be considered in the light of the Pearson decision.

#### Significant Scientific Agreement

First, ABA is very concerned that FDA's approach focuses on the "validity" of diet/disease relationships rather than the truthfulness of claims actually made in view of the weight of substantiating evidence. This position raises serious First Amendment concerns. ABA notes that the First Amendment violation found in Pearson stems directly from the "significant scientific agreement standard," which FDA applies to health claims for conventional foods and dietary supplements. It is obvious that while the NLEA provisions themselves raise serious First Amendment concerns under Pearson, FDA's misinterpretation of the NLEA has only aggravated the first amendment problems. The guidance FDA has issued in response to the Pearson mandate illustrates this core problem. While the NLEA applies the "significant scientific agreement standard" to the evaluation of specific claims, FDA has misapplied the standard to the generic question of whether a diet/disease relationship is "valid" before any claim can be made.

Second, FDA's approach does not adequately account for the dynamic nature of scientific investigation, which constantly refines our understanding of the diet/disease relationships that are considered "valid". Accordingly, FDA does not consider the text of specific labeling copy and pass judgment on whether experts would tend to agree that a claim is substantiated and accurately reflects the overall body of evidence. Instead, it engages in a determination of scientific validity of a diet/disease relationship. This

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precludes well-substantiated health claims that are meaningful to consumers, and are protected by the First Amendment.

As a corollary, FDA's embodiment of its standard in claim-by-claim regulations means that a huge burden is placed on the public and the agency to make changes as science changes.

ABA firmly believes that FDA cannot implement the Pearson decision without fundamentally reforming its application of the "significant scientific agreement standard."

In addition to the constitutional defects in FDA's approach, it yields health claims unlikely to contribute any significant public health benefit. The approved health claims are formulated to specify the elements of the diet/disease relationship FDA has deemed "valid" under its significant scientific agreement standard. This approach ignores consideration of real consumers, and the nature of the messages they will attend and find meaningful. Such FDA claims are of little value and are unattractive in a marketing context. Their complexity and lengthy wording can be confusing to consumers. In all cases, the rigid specifications rule out various communication approaches that truly impact consumers in meaningful ways.

ABA urges FDA in the strongest possible terms to fully embrace the Pearson decision and the Central Hudson principles on which it is founded. Protecting substantiated health claims from undue restriction not only is necessary to conform with the constitution, but is necessary for health claims in food labeling to advance public health. The necessary reform cannot be achieved under the "significant scientific agreement" standard FDA has applied, and is reflected in the Guidance issued in response to Pearson.

ABA appreciates this opportunity to comment on these notices, all of which are of interest to the wholesale baking industry. The technical contact for these comments is Lee Sanders, ABA Vice President, Regulatory and Technical Services, American Bakers Association, 1350 I Street, N.W., Suite 1290 Washington, D.C. 20005-3305 (telephone) 202-789-0300, (fax) 202-898-1164.

Respectfully submitted,



Paul C. Abenante  
President & CEO  
American Bakers Association

CROSS FILE SHEET

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