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Division of Dockets Management
(HFA-305)
Food and Drug Administration
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Rockville, MD 20852

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Please note the enclosed document supercedes the comment on the "Advance Notice of Proposed Rulemaking on Food Labeling: Health Claims; Dietary Guidance," submitted on February 25, 2004 by the American Association of Family and Consumer Science, American Cancer Society, American College of Preventive Medicine, Association of American Medical Colleges, Center for Science in the Public Interest, Consumer Federation f America, and National Consumers League.

Please call if there are any questions regarding this change at (202) 392-9110, x.362.

Sincerely,

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2003N-0496 CR1

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Advance Notice of Proposed Rulemaking) Food Labeling: Health Claims; Dietary) Guidance)	Docket No. 2003N-0496

Comments of

AMERICAN ASSOCIATION OF FAMILY AND CONSUMER SCIENCES
AMERICAN CANCER SOCIETY
AMERICAN COLLEGE OF PREVENTIVE MEDICINE
ASSOCIATION OF AMERICAN MEDICAL COLLEGES
CENTER FOR SCIENCE IN THE PUBLIC INTEREST
CONSUMER FEDERATION OF AMERICA
NATIONAL CONSUMERS LEAGUE

February 25, 2004

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Food and Drug Administration
5630 Fishers Lane
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Rockville, Maryland 20852

Re: Food Labeling: Health Claims; Dietary Guidance

I. Introduction

We, the undersigned organizations wish to respond to the request for comments on the Food and Drug Administration's (FDA) Advance Notice of Proposed Rulemaking (ANPRM) on Food Labeling: Health Claims; Dietary Guidance. 68 *Fed. Reg.* 66040 (Nov. 25, 2003). As discussed below, we believe that the FDA's policies regarding qualified health claims violate the Nutrition Labeling and Education Act (NLEA) and are otherwise contrary to law.

Prior to the NLEA, the Federal Food, Drug and Cosmetic Act specified that foods that made health claims were drugs and, as such, were required to file New Drug Applications prior to marketing. In the 1980s, a number of food companies began bypassing the drug approval process, and FDA decided to exercise its enforcement discretion to permit such claims. The market soon was overrun with false or misleading health claims that confused consumers and undermined the credibility of food labels. Louis Sullivan, who was then the Secretary of Health and Human Services, characterized these claims as a "Tower of Babel" for the consumer.[1] *Business* Week ran a cover story in 1989 asking *"Can Corn Flakes Cure Cancer?"* The subhead read "Of course not. But health claims for foods are becoming ridiculous."[2]

In 1990, Congress unanimously passed the NLEA, which specifically exempted foods making health claims from the definition of a drug so long as the claims were approved by FDA pursuant to a very high standard: significant scientific agreement. FDA's recent adoption of a policy permitting the use of qualified health claims will result in the same kind of consumer confusion that convinced the Congress of the necessity for permitting only those claims that were supported by "significant scientific agreement."

Contrary to FDA's current position, the decision in *Pearson v .Shalala*[3] does not require the agency to approve qualified health claims for foods to avoid violating the First Amendment. In *Pearson*, the court found that FDA violated the First Amendment by refusing to permit four health claims for dietary supplements simply because the evidence fell short of the significant scientific agreement standard. The court found that FDA could not prohibit those claims without first considering whether a disclaimer would prevent consumer deception. However, consumer fraud, not health, was at issue in that case. Furthermore, the case did not involve food products. Unlike dietary supplements, health claims for foods are subject to a specific legal standard

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[1] H.R. Rep. No. 538, 101st Cong. 2d Sess. 7-10.
[2] *Business Week,* Oct. 9, 1989.
[3] 164 F.3d 650, *reh'g en banc denied,* Apr. 2, 1999. U.S. app. LEXIS 5954.

written into the statute. The legislative history of the NLEA makes it abundantly clear that Congress was aware of particular abuses with respect to health claims for foods and, therefore, determined that the significant scientific agreement standard was the only standard that would be effective for those products.

Moreover, for more than two years, FDA concluded that it had no choice but to apply the significant scientific agreement standard to foods and could not approve qualified claims.[4] FDA maintained this position until shortly after the arrival of a new Chief Counsel. The FDA's decision to apply *Pearson* to foods, is now under legal challenge in the U.S. District Court for the District of Columbia.[5]

Pending the outcome of that decision, FDA should not approve any new qualified health claims for foods. Moreover, in the event the court determines that FDA must apply *Pearson* to foods, FDA should not issue any additional qualified health claims for foods until it has the results of consumer surveys addressing the most effective way of communicating health claim messages to consumers.

Our comments on the options set forth in the ANPRM are set forth below.

II. Health Claims

A. Option I: "to codify the current interim procedures and evidence-based ranking system into a regulation, or codify a variation of these."

This option violates the substantive and procedural requirements of the NLEA.

1. Substantive Violations of Law

The NLEA specifically provides that health claims may only be authorized after the FDA determines that a claim about the relationship between a nutrient and a disease or health-related condition is supported by "significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims." 21 U.S.C. § 343 (r)(3)(B). This determination must be based upon a review of the "totality of the publicly available scientific evidence." *Id.* This standard was enacted to control the exaggerated and unfounded health claims that had become rampant on food labels more than a decade ago. The FDA does not have administrative discretion to ignore this statutory standard.

2. Procedural Violations of Law

The NLEA specifies three procedural routes by which health claims may be authorized. First, the FDA may issue a regulation permitting a health claim after completing a notice and comment rulemaking proceeding. The FDA must issue a proposed rule for public comment,

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[4] Letter from FDA to Rep. David McIntosh (May 2000) FDA stated that "absent a court ruling finding the statute unconstitutional, FDA does not have authority to authorize health claims for conventional foods when such a claim would require a disclaimer to render it truthful and nonmisleading."

[5] Center for Science in the Public Interest and Public Citizen Health Research Group v. FDA (Case No. 03-cv-01962 (RBW) (filed Sept. 23, 2003).

evaluate such comments and complete a rulemaking procedure within 540 days after a petition has been filed. 21 U.S.C. § 343 (r)(4)(A). Second, a health claim may be based upon an "authoritative statement from a scientific body of the . . . Government with official responsibility for public health protection or research directly relating to human nutrition or the National Academy of Sciences." Such claims – which must also meet the significant scientific agreement standard – become lawful 120 days after a petition has been filed, unless the FDA formally objects to the evidence used to support that claim. 21 U.S.C. § 343 (r)(3)(C); FDA, *Guidance for Industry, Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body* (June 11, 1998). Third, in exceptional circumstances, the FDA may publish an interim final rule permitting the immediate use of a health claim supported by "significant scientific agreement," with a public comment period following publication of the interim rule. 21 U.S.C. § 343 (r)(7).

The FDA does not have administrative discretion to establish a new procedural process for authorizing health claims that is inconsistent with these statutory requirements. The FDA itself admits that Option I does not follow the letter of the law when it states that this approach is only "consistent with the *spirit* of the NLEA . . . " 68 *Fed. Reg.* 66042 (emphasis added) and that other options meet the "statutorily prescribed process for health claims." *Id.*

B. Option II: "to require each qualified health claim to undergo notice-and-comment rulemaking, which is the statutorily prescribed process for health claims for conventional foods."

Although this approach may satisfy the procedural requirements of the NLEA, the FDA still does not have the discretion to authorize health claims for conventional foods that do not meet the substantive requirements of the NLEA. As discussed in Part II-A (1), *supra,* Congress clearly established that health claims should not be authorized unless they satisfy the significant scientific agreement standard.

C. Option III: "to treat qualified health claims as wholly outside the NLEA and regulate them on a postmarket basis under section 403(a)(1) of the act, which provides that food is misbranded if its labeling is false or misleading."

This option is illegal both substantively and procedurally as discussed in Part II-A. This option bypasses both the significant scientific agreement standard and the notice and comment requirements that are clearly specified by the NLEA.

Under this approach, qualified claims would be able to be made at the sole discretion of the marketer. The FDA would not review petitions requesting approval of qualified health claims in advance of marketing. Consequently, the FDA would not be able to halt the distribution of products with false or misleading labeling prior to sale. Theoretically, the FDA could take enforcement action against false or misleading claims being made on currently marketed products if it could prove that the claims lack substantiation. However, as the FDA explains in the ANPRM, it cannot order companies to provide substantiation for their claims because, unlike the Federal Trade Commission, it lacks administrative subpoena power. This means that the FDA would have to build enforcement cases by first searching the literature,

consulting with experts and testing consumer perceptions about this claim. The FDA itself admits that "this option could be inefficient and too resource intensive for the FDA to be able to protect consumers from misleading claims that would already be in products in the marketplace." 63 *Fed. Reg.* 66043. For these reasons, Option III is not acceptable.

III. Task Force Report

The FDA has requested comment on a number of issues discussed in a Task Force Report issued on this matter. *Id.* All of the questions raised in the Task Force Report, however, are predicated on the assumption that qualified health claims are legal. Therefore, for the reasons stated above, we will not comment on these matters.

IV. Dietary Guidance

We oppose any efforts to re-characterize or redefine health claims as "dietary guidance" in order to avoid compliance with the requirements of the NLEA. The FDA should regulate dietary guidance statements in a manner that is fully consistent with the standards set out in the Act and the agency's existing regulations for health claims for foods. Such statements should be supported by significant scientific agreement. In addition, such statements should refer to a specific substance, be subject to nutrient disqualification levels, and be subject to public comment before being authorized for use on food labels. Furthermore, the agency should provide a comprehensive explanation in the *Federal Register* for any decision to allow such statements on food labels.

V. Conclusion

For the above reasons, the undersigned organizations oppose the FDA's proposal to permit qualified health claims and to expand the use of dietary guidance statements.

Sincerely,

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