



Council for Responsible Nutrition

1875 Eye Street, N.W., Suite 400
Washington, D.C. 20006-5409
(202) 872-1488 • Fax (202) 872-9594
www.cmusa.org

1 3 9 1 '00 FEB 28 A9 :42

February 22, 2000

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

[Docket No. 99D-5424] Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements
64 Federal Register 71794, December 22, 1999

Dear Sir or Madam:

The Council for Responsible Nutrition ("CRN")¹ submits the following comments on the above-referenced docket.

The First Amendment violations found in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) arise fundamentally from the "significant scientific agreement" standard which FDA applies to health claims for dietary supplements, as well as conventional foods.² While no specific statutory standard applies to health claims for dietary supplements,³ invoking the discretion provided under the Nutrition Labeling and Education Act of 1990 ("NLEA"), FDA has applied the same standard specified in the statute for conventional foods to dietary supplements, and it is this standard which was subjected to scrutiny under the First Amendment in *Pearson*.⁴ Since there is no statutory requirement for the agency to apply the significant scientific agreement standard to dietary supplement claims, CRN urges FDA to revisit its decision to do so. In any case, *Pearson* makes clear that the standard cannot be invoked to block truthful claims that are well substantiated in view of the weight of the relevant scientific evidence.

¹ CRN is a trade association representing approximately 100 companies in the dietary supplement industry.

² 21 C.F.R. § 101.14(c) (1999).

³ 21 U.S.C. § 343(r)(5).

⁴ The court's First Amendment critique of the application of the "significant scientific agreement" standard to dietary supplements impliedly applied to conventional foods as well. *See* 164 F.3d at 653, n.3.

99D-5424

ct

Even in its attempt to maintain parity between policies governing dietary supplements and conventional foods, FDA has failed to interpret this standard in accordance with the statutory language. Section 403(r)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 343(r)(3)(B)(i)) specifies that the standard be interpreted in the context of the “claim” a manufacturer wishes to make:

The Secretary shall promulgate regulations authorizing claims of the type described in subparagraph (1)(B) only if the Secretary determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that *the claim* is supported by such evidence. (emphasis added)

There is no statutory basis for FDA's focus on whether the validity of the diet/disease relationship to which the specific claim relates has been established generally in the scientific community to such a point as to be embraced by “significant scientific agreement.” As the draft Guidance indicates, FDA will preclude a health claim entirely unless the diet/disease relationship to which the claim refers has been established as scientifically “valid.” *See* Guidance at page 16. Yet, the statute expressly requires that “the claim” be subject to significant scientific agreement, not the diet/disease relationship. *Id.* Specifically, the statute requires (1) that the weight of the scientific evidence support the likelihood that the diet/disease relationship exists and (2) that the language of the claim reflect the general agreement of the scientific community regarding the strength of the evidence for the diet/disease relationship and do so in a manner which is truthful and non-misleading. Under this scenario, the claim would be based on “significant scientific agreement” regarding the evidence.

FDA's failure to comply with the Federal Food, Drug, and Cosmetic Act has resulted in several severe and unjustifiable consequences for both manufacturers and consumers. First, it deprives consumers of truthful, non-misleading information to which they are entitled. Under its unduly restrictive policy, FDA refuses to approve any health claim unless and until the scientific evidence relating to the diet/disease connection reaches some level arbitrarily chosen by FDA at which the agency decides that the diet/disease relationship is “valid.” This scheme necessarily creates a significant disparity between the type, content and number of fully substantiated health claims that should be available, and the few, narrowly circumscribed health claims FDA would actually approve.⁵ Indeed, even the few claims that FDA has approved contain such onerous

⁵ There has been for some time a serious disconnect between the types of validly supported health claims that can be made in advertising and the type that can be made in product labeling under FDA's restrictive scheme. The proposed Guidance in no way diminished this chasm.

specifications that the claims become virtually useless in a real-world setting. In order to communicate validly substantiated health information *effectively* to consumers, manufacturers must have the leeway to use language and graphics creatively to catch the consumer's interest and foster his or her comprehension of the health message.

FDA's policy also violates the First Amendment rights of manufacturers to make truthful and non-misleading claims about their products. As the court recognized in *Pearson*, "[t]ruthful advertising related to lawful activities is entitled to the protections of the First Amendment."⁶ Indeed, FDA's Guidance ignores both the holding and the admonitions of the court in the *Pearson* case. The court decried FDA's overly repressive policy of suppressing health claims if the supporting evidence was inconclusive for one reason or another when any potential for the resulting claim to be misleading could be cured by an appropriate disclaimer. The court additionally rejected FDA's position that there is no general First Amendment preference for disclosure over suppression, and characterized as "clear" the notion that, "when government chooses a policy of suppression over disclosure--at least where there is no showing that disclosure would not suffice to cure misleadingness--government disregards a 'far less restrictive' means."⁷ To the extent that FDA's implementation blocks consumer access to truthful and nonmisleading information about a variety of diet/disease relationships, the intent of NLEA is frustrated.

FDA's policy also has the effect of "freezing in time" the current scientific thought with respect to such claims. By its very nature, science and scientific evidence expand, evolve and advance over time. What are held to be universally agreed-upon truths in one decade are recognized to be fallacious in the next. Thus, the diet/disease relationships FDA has concluded are valid can be invalidated as new evidence comes to light. These scientific "facts of life" demonstrate the weaknesses in FDA's concept of the "significant scientific agreement" standard. It is impossible to conclude with absolute certainty that any diet/disease relationship is valid when that relationship could be shown to be false with the publication of the next significant research study.⁸ This approach requires FDA to possess a prescience it does not and cannot have about the future course of science, which is not only impractical, but sets an impossibly high standard for both FDA and manufacturers.

⁶ 164 F.3d at 655.

⁷ *Id.* at 658.

⁸ For example, in sharp contrast to the 1995 edition of *Dietary Guidelines for Americans*, the Year 2000 edition does not state that a low-fat diet may be important in reducing the risk of cancers. Instead, the new Guideline recommends that diets should be moderate in total fat. This new message to consumers is based on the research that has evolved over the five years between the publications. Yet, the relationship between a diet low in fat and the potential for a reduction in the risk of cancer is one of the handful of health claims already approved by FDA.

Dockets Management Branch
Docket No. 99D-5424
February 22, 2000
Page 4

For the reasons articulated above, under the *Pearson* decision and the huge body of First Amendment case law upon which the decision is founded, FDA no longer can hold truthful, substantiated health claims hostage to the "significant scientific agreement standard" articulated in its Guidance document. CRN urges FDA to fully embrace the *Pearson* decision by adopting flexible procedures and standards for health claim approval, so as to protect truthful health claims from undue regulation to the full extent required by the First Amendment. This kind of policy reform is fundamental to any genuine effort to implement the *Pearson* decision.

Respectfully submitted,



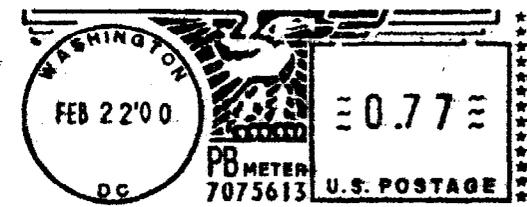
Annette Dickinson, Ph.D.
Vice President, Scientific and Regulatory Affairs
Council for Responsible Nutrition

Of counsel:

Eugene I. Lambert, Esq.
Jeannie Perron, JD, DVM
Covington & Burling
1201 Pennsylvania Avenue, NW
Washington, DC 20044
(202) 662-6000
(202) 662-6291 (fax)

Council for Responsible Nutrition

1875 Eye Street, N.W., Suite 400
Washington, D.C. 20006-5409



FIRST CLASS MAIL

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