



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 26 2000

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The Honorable David M. McIntosh
Chairman
Subcommittee on National Economic Growth,
Natural Resources, and Regulatory Affairs
House of Representatives
Washington, D.C. 20515-6134

Dear Mr. Chairman:

Thank you for your interest in the Food and Drug Administration's (FDA or the Agency) December 22, 1999, "Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements." This is in response to your letter of February 22, 2000, addressed to Jane E. Henney, M.D., Commissioner of Food and Drugs. We apologize for the delay.

The January 1999 court of appeals decision in *Pearson v. Shalala* (*Pearson*) held in part that the Administrative Procedure Act requires FDA to explain what it means by "significant scientific agreement." The FDA guidance document, *Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements*, was issued in response to this part of *Pearson*.

You asked FDA to explain how the guidance's application of the significant scientific agreement standard reconciles with the First Amendment, Nutrition Labeling and Education Act of 1990 (NLEA), Dietary Supplement Health and Education Act of 1994 (DSHEA), Food and Drug Administration Modernization Act of 1997 (FDAMA), and the *Pearson* case. The guidance is consistent with *Pearson* in that it fulfills the court's directive to clarify the meaning of significant scientific agreement. We are unaware of any inconsistency between the significant scientific agreement guidance and NLEA, DSHEA, FDAMA or the First Amendment, and neither did your letter point out any such inconsistency. This guidance does not purport to respond to the First Amendment holding of *Pearson* or to address the use of qualified health claims, however, these issues were addressed in a public meeting held April 4, 2000 and will be addressed in a subsequent rulemaking ~~to reevaluate~~ our general health claim regulations, as was explained in the Federal Register (FR) notice announcing FDA's *Pearson* implementation strategy (Volume 64 FR 67289).

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At the public meeting we heard comments representing a wide range of viewpoints on implementing the requirements of *Pearson*. We are now carefully considering how best to incorporate these comments into appropriate rulemaking to implement the *Pearson* decision. We will also consider the meeting comments in developing an interim policy on qualified health claims pending finalization of rulemaking.

You also questioned FDA's rationale for applying the significant scientific agreement standard to the overall substance-disease relationship, rather than to a proposed specific health claim. You are correct that FDA applies the significant scientific agreement standard to the validity of the substance-disease relationship that is the subject of the claim, not to the wording of the claim. This approach derives from the NLEA, which provides that FDA shall authorize a health claim to be used on conventional foods only when the Agency "determines, based on the totality of the 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." Title 21, United States Code (U.S.C.) § 343(r)(3)(B)(i). Thus, the statute requires there be significant scientific agreement that the claim is supported by the totality of the publicly available scientific evidence.

FDA extensively discussed the validity of science needed to support a health claim, as well as significant scientific agreement as the standard of validity, in the preambles to the general health claim requirements proposal and final rule (Volume 56 FR 60537 at 60539 and 60547 - 60548, November 27, 1991; Volume 58 FR 2478 at 2503 - 2505, January 6, 1993). In these discussions, FDA indicated that significant scientific agreement addressed the validity of the scientific support for the claim (e.g., see Volume 56 FR 60537 at 60540 and 60547). FDA inferred from Congress' definition of a health claim as a statement of a relationship between a substance and a disease or health-related condition, that the significant scientific agreement should apply to the relationship. The Agency stated that a health claim is to describe the scientifically established relationship between a substance and a disease, and

not the state of evidence that might support such a claim (Volume 58 FR 2478 at 2505). The Agency also cited legislative history in support of these conclusions (e.g., Volume 56 FR 60537 at 60540 and 60547 - 60548; Volume 58 FR 2478 at 2504 - 2505).

In light of the foregoing considerations, FDA concluded that the significant scientific agreement standard should apply to the validity of the substance-disease relationship, not to the specific wording of the claim (see Volume 58 FR 2478 at 2504 - 2505).

Applying the significant scientific agreement standard to the substance-disease relationship, rather than to the specific claim is also consistent with *Pearson*. The court said that FDA might be justified in rejecting a proposed health claim outright where the evidence for a claim is outweighed by evidence against the claim. If the court had focused on significant scientific agreement for a claim rather than for the relationship, there would not be any need for the weighing of evidence because the petitioner (or FDA) could always adjust the wording of the claim to reflect the available evidence, however limited or contrary.

In summary to the points you raise in your letter, we believe our guidance on significant scientific agreement is consistent with the *Pearson* decision and other applicable law. As another element in implementing *Pearson*, we are working towards the development of criteria to allow qualified health claims for dietary supplements when evidence supporting a relationship between a substance in the supplement and a disease or health-related condition does not meet the significant scientific agreement standard.

Thank you again for your comments. We trust this responds to your questions. If you have further questions, please let us know.

Sincerely,



Melinda K. Plaisier
Associate Commissioner
for Legislation

cc: The Honorable Dan Burton
Chairman
Committee on Government Reform

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The Honorable Dennis J. Kucinich
Ranking Minority Member
Subcommittee on National Economic Growth,
Natural Resources, and Regulatory Affairs

The Honorable Helen Chenoweth-Hage
Member, Subcommittee on National Economic Growth,
Natural Resources, and Regulatory Affairs

Dockets Management Branch
(Docket No. 99D-5424)

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February 22, 2000

BY FACSIMILE

The Honorable Jane E. Henney
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: FDA Docket No. 99D-5424

Dear Dr. Henney:

I am writing to comment on and ask questions about the Food and Drug Administration's (FDA) December 22, 1999 draft "Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements."

By enacting the Nutrition Labeling and Education Act of 1990 (NLEA), Dietary Supplement Health and Education Act of 1994 (DSHEA), and the Food and Drug Modernization Act of 1997 (FDAMA), Congress provided that FDA encourage increased consumer access to new nutritional information as long as such information is truthful and adequately substantiated. In 1999, the United States Court of Appeals for the District of Columbia Circuit found that, under the First Amendment, FDA may not continue to apply the "significant scientific agreement" standard to ban health claims based on emerging scientific evidence where the claim may be stated using qualifying language and/or disclaimers to accurately reflect its supporting scientific substantiation (*Pearson v. Shalala*, 164 F.3d 650 D.C. Cir. 1999).

However, in section II. E. of the draft guidance, FDA apparently plans to apply the "significant scientific agreement" standard to the overall substance-disease relationship, rather than to a proposed, specific health claim. The level of scientific agreement for a specific claim, which may include qualified language and disclaimers, is likely to be less than that required to prove the overall substance-disease relationship. For example, the scientific evidence needed to substantiate a specific health claim (e.g., "emerging research indicates that consumption of three

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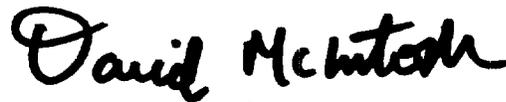
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servings a day of a particular food may reduce the risk of contracting a certain disease for people over fifty”) is likely to be less than that needed to conclusively establish the entire substance-disease relationship. The approach employed in the draft guidance ignores the reality that scientific progress establishing diet-disease relationships is incremental. Thus, applying the “significant scientific agreement” standard to the proposed claim, as opposed to the entire substance-disease relationship, properly implements the Congressional goal of providing increased nutritional information to the public.

Therefore, pursuant to the Constitution and Rules X and XI of the United States House of Representatives, I request that you answer the following two questions. First, please explain how the guidance’s application of the “significant scientific agreement” standard reconciles with the First Amendment, NLEA, DSHEA, FDAMA, and the *Pearson* case. Second, will the guidance’s application of the “significant scientific agreement” standard allow the communication to consumers of properly qualified health claims (or those with disclaimers) explaining new and emerging scientific findings?

Please deliver your response to the Subcommittee majority staff in B-377 Rayburn House Office Building and the minority staff in B-350A Rayburn House Office Building not later than noon on Friday, March 10, 2000. If you have any questions about this request, please call Subcommittee Counsel Bill Waller on 226-2067. Thank you for your attention to this request.

Sincerely,



David M. McIntosh

Chairman

Subcommittee on National Economic Growth,
Natural Resources, and Regulatory Affairs

cc: The Honorable Dan Burton
The Honorable Dennis Kucinich
The Honorable Helen Chenoweth-Hage