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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 91 N-0101,91 N-0098,91 N-0103, and 91 N-I OOH]

Food Labeling: Health Claims and Label Statements for Dietary Supplements; Strategy for Implementation of Pearson Court Decision

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice. .

SUMMARY: The Food and Drug Administration (FDA) is informing the public of its strategy to implement a recent court decision in ***Pearson*** v. *Shalala* ***(Pearson).*** The agency is taking this action to ensure that interested persons are aware of the steps it plans to follow to carry out the decision. FDA is also announcing how it plans to process petitions for dietary supplement health claims during the interim implementation period.

FOR FURTHER INFORMATION CONTACT: Marquita B. Steadman, Center for Food Safety and Applied Nutrition (HFS–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, 301–827–6733.

SUPPLEMENTARY INFORMATION:

I. Background

On January 15, 1999, the U.S. Court of Appeals for the D.C. Circuit issued its decision in ***Pearson v. Shalala***, 164 F.3d 650 (D.C. Cir. 1999). In ***Pearson, the*** plaintiffs had challenged FDA's health claim regulations for dietary supplements and FDA's decision not to authorize health claims for four specific nutrient-disease relationships: Dietary fiber and cancer, antioxidant vitamins and cancer, omega-3 fatty acids and coronary heart disease, and the claim that 0.8 mg of folic acid

in dietary supplement form is more effective in reducing the risk of neural tube defects than a lower amount in conventional food form.

The court held in ***Pearson*** that, on the administrative record compiled in the challenged rulemakings, the first amendment does not permit FDA to reject health claims that the agency determines to be potentially misleading unless the agency also reasonably determines that no disclaimer would eliminate the potential deception. Accordingly, the court invalidated the regulations prohibiting the four health claims listed above and directed the agency to reconsider whether to authorize the claims. The court further held that the Administrative Procedure Act requires FDA to clarify the "significant scientific agreement" standard for authorizing health claims, either by issuing a regulatory definition of significant scientific agreement or by defining it on a case-by-case basis.

The Government tiled a petition for rehearing en banc (reconsideration by the full court of appeals). The U.S. Court of Appeals for the D.C. Circuit denied the petition for rehearing on April 2, 1999.

After the petition for rehearing was denied, FDA's Center for Food Safety and Applied Nutrition updated its 1999 Program Priorities document to state that developing a strategy to implement the ***Pearson*** decision would be a high priority for calendar year 1999.

II. Components of the Implementation Strategy

The components of the strategy are to: (1) Update the scientific evidence on the four claims at issue in ***Pearson;*** (2) issue guidance clarifying the "significant scientific agreement" standard; (3) hold a public meeting to solicit input on changes to FDA's general health claim regulations for dietary supplements that may be warranted in light of the ***Pearson*** decision; (4) conduct a rulemaking to reconsider the general health claims regulations for dietary supplements in light of the ***Pearson*** decision; and (5) conduct rulemakings on the four ***Pearson*** health claims. Because of FDA's obligation to implement the court decision promptly, the agency intends to work on the components of the strategy concurrently whenever possible. As noted above, implementation

of ***Pearson*** is one of the items on the Center for Food Safety and Applied Nutrition's (CFSAN's) 1999 Program Priorities list, which constitutes CFSAN's priority work plan for the year, and CFSAN will include ***Pearson*** implementation as one of its high priority items for fiscal year 2000.

III. Updating the Scientific Evidence on the Four *Pearson* Claims

As a first step toward re-examining the evidence supporting the four claims at issue in ***Pearson,*** FDA published a notice in the **Federal Register** of September 8, 1999 (64 FR 48841), requesting that interested persons submit any available scientific data concerning the substance-disease relationships that are the subject of the four claims. In that notice, FDA requested that written comments be submitted to the agency by November 22, 1999. In addition, CFSAN entered into a contract with a nongovernment firm to conduct a literature review for the four claims to identify relevant scientific information that became available after the agency's initial 1990 to 1993 review of these claims. This data gathering and literature review is needed for FDA to determine the current nature of the scientific evidence relating to the four claims and is an essential step in re-considering the claims. The contracted literature review for the four claims is due to the agency this fall.

In response to a request from several of the ***Pearson*** plaintiffs, the agency has agreed to extend or reopen the comment period on the September 8, 1999, notice for 75 days after the agency issues its guidance on the significant scientific agreement standard (described below). The agency will give careful consideration to any additional data it receives during the second 75-day comment period.

IV. Guidance on the Significant Scientific Agreement Standard

The agency is preparing to issue guidance clarifying the meaning of the significant scientific agreement standard. FDA expects to issue such guidance before the end of calendar year 1999.

V. Rulemakings and Public Meeting

FDA is planning to initiate several rulemakings in response to ***Pearson.*** First, the court's decision requires the agency to reconsider whether to authorize the four claims that were at issue in the case. The agency intends to conduct four rulemakings, one for each claim. In each instance, the agency will first evaluate whether the evidence supporting the claim meets the significant scientific agreement standard; if not, the agency will then proceed to consider whether there is any qualifying language that could render the claim nonmisleading. If FDA believes that the answer to either question is yes, the agency will propose to authorize the claim; otherwise, the agency will propose not to authorize it.

Second, FDA intends to initiate rulemaking to consider changes to its general health claims regulations for dietary supplements that may be warranted in light of ***Pearson.*** A public meeting during the first quarter of calendar year 2000 will precede this rulemaking. FDA will publish a **Federal Register** notice announcing the date and location of the public meeting. In that notice, FDA will provide a list of topics or questions to focus public input on how the agency's approach to the regulation of health claims for dietary supplements could be changed in light of ***Pearson.***

Written comments received in response to the notice, and participation at the public meeting, will assist the agency in the rulemaking to reconsider its general health claims regulations for dietary supplements.

VI. Interim Process for Petitions

Until the rulemaking to reconsider the general health claims regulations for dietary supplements is complete, FDA intends to deny, without prejudice, any petition for a dietary supplement health claim that does not meet the significant scientific agreement standard in 21 CFR § 101.14(c). Once the rulemaking is complete, the agency will, on its own initiative, reconsider any petitions denied during the interim period. Petitions will be reconsidered in the order they were originally received. This process does not apply to the four claims at issue in ***Pearson,*** which will be handled as previously described.

FDA takes seriously its obligation to implement ***Pearson.*** The agency believes that the fastest and most efficient way to fully implement the decision is to conduct a rulemaking to reconsider the general procedures and standards governing health claims for dietary supplements before ruling on individual petitions that do not meet the current regulatory standard for health claim authorization. If the agency attempted to proceed case-by-case without establishing a regulatory framework applicable to all petitions, confusion among regulatees, inconsistent agency action, and waste of private and agency resources could result.

This practice is consistent with the practice FDA adopted immediately following the passage of the Nutrition Labeling and Education Act of 1990, which provided explicit statutory authority for health claims on conventional foods and dietary supplements. In a **Federal Register** notice

published March 14, 1991 (56 FR 10906), the agency announced that it would deny, without prejudice, any health claim petition that was submitted before issuance of final regulations concerning the submission and content of such petitions.

Dated: 11-23-99
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Margaret M. Dotzel
Acting Associate Commissioner for Policy

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

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