Dated: October 2, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–25700 Filed 10–5–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 91N–0101, 91N–0098, 91N–0103, and 91N–100H]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: :Notice.

SUMMARY: The Food and Drug Administration (FDA) is updating its strategy for implementation of the court of appeals decision in *Pearson* v. *Shalala* (*Pearson*). The updated implementation strategy includes an interim enforcement strategy for dietary supplement health claims that do not meet the ''significant scientific agreement'' standard of evidence by which the health claims regulations require FDA to evaluate the scientific validity of claims. It also includes changes in the process that will be used for reconsidering the four *Pearson* health claims and for responding to future petitions for dietary supplement health claims. The agency is taking this action to inform interested persons of the latest developments in FDA's plans for implementation of *Pearson*.

FOR FURTHER INFORMATION CONTACT: James E. Hoadley, Center for Food Safety and Applied Nutrition (HFS–832), 200 C St. SW., Washington, DC 20204, 202–205–5372.

SUPPLEMENTARY INFORMATION:

I. Background

After the enactment of the Nutrition Labeling and Education Act of 1990 (the NLEA) and the Dietary Supplement Act of 1992, FDA issued regulations applying the general requirements for health claims for conventional foods to dietary supplements (59 FR 395, January 4, 1994). Under these regulations, a health claim is authorized for use only if FDA determines that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by the totality of publicly available scientific evidence, including evidence from well-designed studies conducted in a manner that is consistent with generally recognized scientific procedures and principles § 101.14 (21 CFR 101.14). FDA also undertook rulemaking to consider specific health claims, including the four health claims at issue in the *Pearson* case.

In *Pearson*, the plaintiffs challenged FDA's general health claims regulation for dietary supplements and FDA's decision not to authorize health claims for four specific substance/disease relationships: Dietary fiber and cancer, antioxidant vitamins and cancer, omega-3 fatty acids and coronary heart disease, and the comparative claim that 0.8 milligram of folate[1] in dietary supplement form is more effective in reducing the risk of neural tube defects[2] than a lower amount in conventional food form. Although the district court ruled for FDA in all respects (14 F. Supp. 2d 10 (D.D.C. 1998)), the U.S. Court of Appeals for the D.C. Circuit reversed the lower court's decision (164 F.3d 650 (D.C. Cir. 1999)). The appeals court held 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 codifying FDA's decision not to authorize the four health claims listed above and directed the agency to reconsider the four 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.

On March 1, 1999, the Government filed 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 (172 F.3d 72 (D.C. Cir. 1999)).

[1] In its original health claim evaluation, FDA used the term ''folic acid'' to describe this B vitamin. Later, the agency decided that the broader term ''folate'' was more scientifically accurate because that term encompasses both synthetic and naturally occurring forms of the vitamin, whereas folic acid refers only to the synthetic form (see 58 FR 53254 at 53257–58, and 53280, October 14, 1993). Accordingly, this notice uses the term ''folate.'' The two terms may be used interchangeably in food labeling.

[2] Neural tube defects are birth defects of the brain or spinal cord. Spinabifida and anencephaly are the most common types of neural tube defects.

II. Strategy for Implementation of the Pearson Court Decision

A. The December 1999 Implementation Strategy Notice

In the **Federal Register** of December 1, 1999 (64 FR 67289), FDA published a notice entitled ''Food Labeling: Health Claims and Label Statements for Dietary Supplements; Strategy for Implementation of *Pearson* Court Decision'' to inform the public of the steps FDA planned to follow to carry out the *Pearson* decision. The strategy included five components: (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 what changes to FDA's general health claim regulations for dietary supplements 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. In addition, the implementation strategy notice stated that, until the rulemaking to reconsider the general health claims regulations for dietary supplements was complete, FDA would deny, without prejudice, any petition for a dietary supplement health claim that does not meet the significant scientific agreement standard in § 101.14(c). The notice further explained that, once the rulemaking was complete, the agency would, on its own initiative, reconsider any petitions denied during the interim period.

Since the December 1999 **Federal Register** notice was published, FDA has completed the first three steps in the implementation strategy. The agency entered into contracts with two nongovernment firms to conduct a literature review for the four claims to identify relevant scientific information that became available after the agency's initial 1991 to 1993 review of these claims. FDA also 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 December 1999, FDA issued a guidance clarifying the significant scientific agreement standard. A notice of availability of the guidance was published in the **Federal Register** of December 22, 1999 (64 FR 71794). The guidance is available on the Internet at http://vm.cfsan.fda.gov/~dms/ssaguide.html.

In response to a request from several of the *Pearson* plaintiffs, the agency agreed to reopen the comment period for scientific data on the four claims after the agency issued its guidance on the significant scientific agreement standard. Accordingly, in the **Federal Register** of January 26, 2000 (65 FR 4252), FDA reopened the comment period for an additional 75 days, until April 3, 2000.

On April 4, 2000, FDA completed the third step in the *Pearson* implementation strategy by convening a public meeting to solicit input on changes to the general health claims regulations for dietary supplements in light of the *Pearson* decision. Information on the public meeting, including the agenda and transcripts, are available on the Internet at http://vm.cfsan.fda.gov/dms/ds-0400.html.

B. Modifications to the December 1999 Implementation Strategy

1. Interim Enforcement Strategy for Dietary Supplement Health Claims

In the NLEA, Congress made health claims for dietary supplements subject to a procedure and standard to be established by FDA (see section 403(r)(5)(D) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(5)(D)). By regulation, FDA adopted the same procedure and standard for health claims in dietary supplement labeling that Congress had prescribed in the NLEA for health claims in the labeling of conventional foods (see section 403(r)(3) and (r)(4) of the act). The procedure requires the evidence supporting a health claim to be presented to FDA for review before the claim may appear in labeling (§§ 101.14(d) and (e), and 101.70 (21 CFR 101.70)). The standard requires a finding of ''significant scientific agreement'' before FDA may authorize a health claim by regulation (§ 101.14(c)). Unless and until FDA adopts a regulation authorizing use of the claim, a dietary supplement bearing the claim is subject to regulatory action as a misbranded food (see section 403(r)(1)(B) of the act), a misbranded drug (see section 502(f)(1) of the act (21 U.S.C. 352(f)(1))), and as an unapproved new drug (see section 505(a) of the act (21 U.S.C. 355(a))). Under FDA's current general health claim regulations, the agency cannot authorize use of a health claim that does not meet the significant scientific agreement standard.

Pending reconsideration of the general health claim regulations in response to *Pearson*, FDA is modifying its approach to processing new health claim petitions for dietary supplements. Absent this modification, FDA would have to deny all petitions that do not meet the significant scientific standard pending completion of the general rulemaking. Such an approach could lead to additional First Amendment challenges prior to completion of the rulemaking process.

Rather than denying all petitions that do not meet the significant scientific agreement standard pending completion of the general rulemaking, FDA intends to exercise enforcement discretion in appropriate circumstances. Specifically, the agency will consider exercising enforcement discretion for a dietary supplement health claim when the following conditions are met: (1) The claim is the subject of a health claim petition that meets the requirements of § 101.70; (2) the scientific evidence in support of the claim outweighs the scientific evidence against the claim, the claim is appropriately qualified, and all statements in the claim are consistent with the weight of the scientific evidence; (3) consumer health and safety are not threatened; and (4) the claim meets the general requirements for health claims in § 101.14, except for the requirement that the evidence supporting the claim meet the significant scientific agreement standard and the requirement that the claim be made in accordance with an authorizing regulation.

To the extent possible, FDA will consider these criteria while it is evaluating the petition and will state its conclusions in a letter to the petitioner; however, some criteria will have to be evaluated after-the-fact, because they involve information or circumstances that cannot be determined from the petition. For example, FDA will not be able to determine whether the entire claim appears in one place without intervening material, as required by § 101.14(d)(2)(iv), until it actually sees the claim on products in the marketplace. Some provisions of § 101.14 may not be relevant to a particular claim. The agency intends to identify any such provisions in its letter to the petitioner.

As discussed below, FDA will consider exercising enforcement discretion only if a petition to authorize the health claim has been submitted; the agency has filed the petition; the agency has completed its scientific evaluation of the claim and communicated that evaluation by letter to the petitioner; and the conditions previously described, as well as any others stated in the letter to the petitioner, are met.

2. Interim Process for Responding to New Dietary Supplement Health Claim Petitions and Reconsidering the Four *Pearson* Health Claims

FDA intends to respond to the four health claims at issue in the *Pearson* case and, pending rulemaking to implement *Pearson*, to new dietary supplement health claim petitions that have been filed for comprehensive review (see § 101.70(j)(2)) in one of the following three ways:

(1) If FDA determines that the significant scientific agreement standard is met, the agency will propose to authorize the health claim. FDA will consider using its interim final rule authority under section 403(r)(7)(A)(iii) of the act to allow use of the health claim immediately upon publication of the proposal.

(2) If FDA determines that the significant scientific agreement standard is not met, but that the scientific evidence in support of the claim outweighs the scientific evidence against the claim and the other threshold criteria listed above are met, FDA will consider exercising enforcement discretion with regard to dietary supplements that bear the health claim with appropriate qualifying language. The petitioner will be notified in writing of this intention. The letter to the petitioner will outline the agency's rationale for its determination that the evidence does not meet the significant scientific agreement standard set forth in § 101.14(c) and then state the conditions under which the agency would ordinarily expect to exercise enforcement discretion for the claim.

(3) If FDA determines that the significant scientific agreement standard is not met and that the evidence supporting the claim is outweighed by evidence against the claim (either qualitatively or quantitatively), or the substance poses a threat to health, or that any of the other criteria listed in section II.B.1 of this document are not met, FDA intends to deny the petition. The denial letter to the petitioner will: (1) Outline the agency's rationale for its determination that the evidence does not meet the significant scientific agreement standard set forth in § 101.14(c); and (2) explain why FDA believes that the scientific evidence for the claim is outweighed by the evidence against the claim, that the claim would be otherwise misleading even if qualified, or that authorizing a health claim would pose a threat to consumer health or safety.

This process is consistent with case law holding that FDA has wide latitude in matters of enforcement discretion.

(See, e.g., *Heckler* v. *Chaney*, 470 U.S. 821 (1985); *Schering* v. *Heckler*, 779 F.2d 683 (D.C. Cir. 1985).) It is also consistent with the *Pearson* decision, which described several circumstances in which FDA might be justified in banning certain health claims outright —e.g., where consumer health and safety are threatened, or where FDA can demonstrate that a health claim would be misleading even if qualified (see *Pearson*, 164 F.3d at 650, 657–60). For example, the court said that FDA could prohibit a health claim where the evidence in support of the claim is outweighed by evidence against the claim, either quantitatively or qualitatively (164 F.3d at 659 & n.10). The agency is adopting this modified process on an interim basis to minimize any burden on speech pending consumer research and rulemaking to complete the implementation of the *Pearson* decision.

3. Timing of FDA's Decisions on Health Claims for Dietary Supplements

FDA will complete its reconsideration of the four *Pearson* claims and issue a final decision on each of the claims within 190 days after the close of the comment period seeking scientific data on the claims, i.e., by October 10, 2000. For new health claim petitions for dietary supplements, FDA will continue to follow the applicable deadlines in § 101.70(j), as with past health claim petitions.

Dated: October 2, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–10011]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: New Collection;

Title of Information Collection: Stages of Change Survey for Informed Choice in the Medicare Population;

Form No.: HCFA–10011 (OMB# 0938–NEW);

Use: This is a survey of Medicare beneficiaries in the first step in the application the Transtheoretical Model (the ''stage model'') to informed choice in the Medicare population. The Transtheoretical Model has been applied and proven effective in facilitating behavior change in a wide range of health behaviors including smoking cessation, mammography screening, and safe sex. This work will yield psychometrically sound and externally valid measures of beneficiaries' readiness to make informed choices about health plans, and provide information to HCFA to assist with its national educational campaign to inform beneficiaries about their choices. Stages of Change measures will be administered to 560 Medicare beneficiaries and initial enrollees. This survey research will yield psychometrically sound measures of beneficiaries' readiness to make informed choices about health plans, and provide information to guide HCFA's National Medicare Education Program (NMEP);

Frequency: Other: One-time survey;

Affected Public: Individuals or Households;

Number of Respondents: 560;

Total Annual Responses: 560;

Total Annual Hours: 327.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Melissa Musotto, HCFA–10011, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: September 26, 2000.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–9044]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, OHHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Provider Reimbursement Manual, Part 1—Chapter 27, Section 2721, 2722 and 2725, Request for Exception to ESRD Composite Rates and Supporting Regulations in 42 CFR 413.170 and 413.184; *Form No.:* HCFA–9044 (OMB# 0938–0296); *Use:* Sections 2721, 2722 and 2525 of the Provider Reimbursement Manual describe the information ESRD facilities must submit