no longer manufacture any animal feed. Section 515.30(c) details requirements for filing a request for a hearing by a sponsor to give reasons why a medicated feed mill license application should not be refused or revoked and § 510.305(b) (21 CFR 510.305 (b)), requires maintenance of approved labeling for each Type B and/or Type C medicated feed being manufactured on the premises of the manufacturing establishment or the facility where the feed labels are generated.

Description of Respondents: Respondents to this collection of information are individuals or firms that manufacture medicated animal feed. In the **Federal Register** of July 26, 2000 (65 FR 45987), FDA published a 60-day notice concerning the proposed extension of this collection of information and requested comments. In response to this notice, no comments were received on the estimated annual reporting and recordkeeping burden. We therefore believe that the total burden estimate of 72 hours for the annual reporting and recordkeeping burden should remain unchanged.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
515.10(b)	100	1	100	0.25	25
515.11(b)	25	1	25	0.25	6.25
515.23	50	1	50	0.25	12.25
515.30(c)	0.15	1	0.15	24	3.6
Total burden hours					47.10

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
510.305(b)	100	1	100	.25	25

[1]There are no capital cost or operating and maintenance cost associated with this collection of information.

The estimate for the number of respondents is derived from agency data, i.e. the number of medicated feed manufacturers entering the market each year, change in ownership or address, requests for voluntary revocation of a medicated feed mill license, revocation and/or suspension of a license. The estimate of the time required for the reporting and recordkeeping requirements is based on the agency communication with industry.

Dated: October 2, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–25699 Filed 10–5–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1309]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Suggested Documentation for Demonstrating Compliance With the Channels of Trade Provision

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by November 6, 2000.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Suggested Documentation for Demonstrating Compliance With the Channels of Trade Provision

Description: Under the pesticide tolerance reassessment process that the Environmental Protection Agency (EPA) was mandated to carry out under the Food Quality Protection Act (FQPA), EPA has proposed to revoke the tolerances for the pesticide chemical methyl parathion on several food commodities. The FQPA includes a provision in section 408(l)(5) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 346a(l)(5)), referred to as the ''channels of trade provision,'' that addresses the circumstances under which a food is not unsafe solely due to the presence of a residue from a pesticide chemical whose tolerance has been revoked, suspended, or modified by EPA. These circumstances are met if the party responsible for the food can demonstrate to FDA that the residue in the food resulted from application of the pesticide chemical to the food commodity at a time and in a manner that was lawful under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA).

In general, FDA anticipates that the party responsible for food found to contain methyl parathion residues (within the former tolerance) after the

tolerance for the pesticide chemical has been revoked, will be able to demonstrate that the residue resulted from a lawful application under FIFRA by providing appropriate documentation to the agency showing that such food was packed or processed on or prior to December 31, 2000, as discussed in the draft guidance that was announced in a notice that FDA published in the **Federal Register** of June 2, 2000 (65 FR 35376) (the June notice). FDA is not suggesting that firms maintain a certain set list of documents where anything less or different would likely be considered unacceptable. Rather, the agency is leaving it to each firm's discretion to maintain appropriate documentation to demonstrate that the food was so packed or processed.

Examples of documentation that FDA anticipates will serve this purpose include but are not limited to packing codes, batch records, and inventory records; it is anticipated that most food processors routinely generate this documentation as part of their basic food-production operations.

Description of Respondents: The likely respondents to this collection of information are firms in the produce and food-processing industries who handle food products that may contain residues of methyl parathion after the tolerances for this pesticide chemical in those foods have been revoked.

In the June notice, the agency requested comments on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
67	1	67	3	201

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours	Total Capital Costs
83	1	83	16	1,328	$500

[1]There are no operating and maintenance costs associated with this collection of information.

Estimates for the annual reporting burden were determined by using the maximum number of samples collected throughout a year that FDA believes may be found to contain methyl parathion residues. Because all residues are expected to have dissipated from nonfrozen foods by the time FDA intends to question firms about when a food product was packed or processed (i.e., after December 31, 2000), FDA included only frozen food in its estimate (i.e., processors of foods stored under refrigerated and ambient conditions were excluded). Although residues within the former tolerance resulting from legal application of methyl parathion are not expected to be found in nonfrozen foods after December 31, 2000, under the channels of trade provision, firms will have an opportunity to make a showing that any such food was packed or processed on or before this date.

Considering the variation in and effects of food handling, particularly with regard to the time between pesticide application and freezing, FDA estimated that potentially half of all frozen food products sampled may contain methyl parathion residues, and therefore, the responsible party, under the approach set forth in this guidance, would be subject to the reporting requirement since it would be the burden of the responsible party to demonstrate that food found to contain methyl parathion residues within the former tolerance was packed or processed on or before December 31, 2000.

When determining the annual recordkeeping burden, importers and domestic processors of frozen food commodities affected by the revocation of the pesticide chemical methyl parathion were considered. FDA estimated that most firms (at least 90 percent) maintain (or maintain access to) documentation such as packing codes, batch records, and inventory records as part of their basic food production and/or import operations. Therefore, the recordkeeping burden was calculated as the time required for the 10 percent of firms which may not currently be maintaining this documentation, to develop and maintain (or maintain access to) documentation such as batch records and inventory records. It was estimated that with $500 or less, the necessary software and/or hard copy filing systems could be obtained to implement a system.

Because all residues are expected to have dissipated from nonfrozen foods by the time FDA intends to ask for a showing under section 408(l)(5) of the act (i.e., after December 31, 2000), FDA used the number of frozen food processors when determining the annual recordkeeping burden. In the June notice, this burden was originally determined to be 6,600 hours. However, due to revisions that FDA will include in the final guidance document, the proposed information collection was refined, and the annual recordkeeping burden decreased to 1,328 hours. The ''Category II Documentation,'' which consisted of documentation relating to the institution of auditing programs and supplier verification, will be removed from the final guidance as suggested documentation to be provided to demonstrate compliance with the channels of trade provision.

As with the annual reporting burden estimate, although nonfrozen food processors are entitled to make a showing under the channels of trade provision, they were excluded from this estimate because based upon residue dissipation estimates provided by EPA, methyl parathion residues within the former tolerance resulting from legal application are not expected to be found in nonfrozen commodities after December 31, 2000.

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.