

collection. E-mail address:
grjohnson@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Officer for ACF, E-mail address: Katherine_T._Astrich@omb.eop.gov.

Dated: August 16, 2005.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 05-16641 Filed 8-19-05; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0153]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Fax written comments on the collection of information by September 22, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs,

OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT:

Karen L. Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

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.

Regulations For In Vivo Radiopharmaceuticals Used For Diagnosis and Monitoring—(OMB Control Number 0910-0409)—Extension

In response to the requirements of section 122 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105-115), FDA published a final rule (64 FR 26675, May 17, 1999) amending its regulations by adding provisions that clarify FDA's evaluation and approval of in vivo radiopharmaceuticals used in the diagnosis or monitoring of diseases. The regulation describes the kinds of indications of diagnostic radiopharmaceuticals and some of the criteria that the agency would use to evaluate the safety and effectiveness of a diagnostic radiopharmaceutical under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) and section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262). Information about the safety or effectiveness of a diagnostic radiopharmaceutical enables FDA to properly evaluate the safety and effectiveness profiles of a new diagnostic radiopharmaceutical or a new indication for use of an approved diagnostic radiopharmaceutical.

The rule clarifies existing FDA requirements for approval and evaluation of drug and biological products already in place under the authorities of the act and the PHS Act. The information, which is usually submitted as part of a new drug application (NDA), biologics license application, or as a supplement to an approved application, typically includes, but is not limited to, nonclinical and clinical data on the pharmacology, toxicology, adverse events, radiation safety assessments, and chemistry, manufacturing, and controls. The content and format of an

application for approval of a new drug are set forth in § 314.50 (21 CFR 314.50). Under 21 CFR part 315, information required under the act and needed by FDA to evaluate the safety and effectiveness of in vivo radiopharmaceuticals still needs to be reported.

Based on the number of submissions (that is, human drug applications and/or new indication supplements for diagnostic radiopharmaceuticals) that FDA receives, the agency estimates that it will receive approximately two submissions annually from two applicants. The hours per response refers to the estimated number of hours that an applicant would spend preparing the information required by the regulations. Based on FDA's experience, the agency estimates the time needed to prepare a complete application for a diagnostic radiopharmaceutical to be approximately 10,000 hours, roughly one-fifth of which, or 2,000 hours, is estimated to be spent preparing the portions of the application that would be affected by these regulations. The regulation does not impose any additional reporting burden for safety and effectiveness information on diagnostic radiopharmaceuticals beyond the estimated burden of 2,000 hours because safety and effectiveness information is already required by § 314.50 (OMB control number 0910-0001, approved by OMB until March 31, 2005). In fact, clarification in these regulations of FDA's standards for evaluation of diagnostic radiopharmaceuticals is intended to streamline overall information collection burdens, particularly for diagnostic radiopharmaceuticals that may have well-established, low-risk safety profiles, by enabling manufacturers to tailor information submissions and avoid unnecessary clinical studies. Table 1 of this document contains estimates of the annual reporting burden for the preparation of the safety and effectiveness sections of an application that are imposed by existing regulations. The burden totals do not include an increase in burden. This estimate does not include the actual time needed to conduct studies and trials or other research from which the reported information is obtained.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
315.4, 315.5, and 315.6	2	1	2	2,000	4,000

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Total					4,000

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

In the **Federal Register** of May 3, 2005 (70 FR 22887), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

Dated: August 17, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–16656 Filed 8–22–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0029]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Infant Formula Recall Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Infant Formula Recall Regulations” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 1, 2005 (70 FR 5188), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0188. The approval expires on July 31, 2008. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: August 17, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–16657 Filed 8–22–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0317]

Agency Information Collection Activities; Proposed Collection; Comment Request; Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the record retention requirement of the soy protein/coronary heart disease health claim.

DATES: Submit written or electronic comments on the collection of information by October 24, 2005.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug

Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim—21 CFR 101.82(c)(2)(ii)(B) (OMB Control Number 0910–0428)—Extension

Section 403(r)(3)(A)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(3)(A)(i)) provides for the use of food label statements characterizing a relationship of any nutrient of the type required to be in the label or labeling of the food to a disease or a health related condition only where that statement