and support systems. CMS currently requires grantees to report on a quarterly, semi-annual, and or annual basis depending upon the grant type. CMS requires the information obtained through web-based grantee reporting for two reasons: (1) In order to effectively monitor the grants; and, (2) To report to Congress and other interested stakeholders the progress and obstacles experienced by the grantees. The grantees are the respondents to the web-based reporting system. *Form Number:* CMS–10161 (OMB# 0938–0979); *Frequency:* annually, semi-annually, and quarterly; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 171; *Total Annual Responses:* 428; *Total Annual Hours:* 3,764.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Request for Certification as a Supplier of Portable X-ray Services and Portable X-ray Survey Report Form under the Medicare/Medicaid Program and Supporting Regulations in 42 CFR 486.100–486.110; *Use:* The Medicare program requires portable X-ray suppliers to be surveyed for health and safety standards. The CMS–1882 is the survey form that records survey results. The CMS–1880 is used by the surveyor to determine if a portable X-ray applicant meets the eligibility requirements. *Form Numbers:* CMS–1880/1882 (OMB# 0938–0027); *Frequency:* Occasionally; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 544; *Total Annual Responses:* 68; *Total Annual Hours:* 4,760.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Rehabilitation Hospital Criteria Worksheet and Rehabilitation Hospital Criteria Worksheet; *Use:* The rehabilitation hospital and rehabilitation unit criteria worksheets are necessary to verify that these facilities/units comply and remain in compliance with the exclusion criteria for the Medicare prospective payment system. *Form Number:* CMS–437A and 437B (OMB# 0938–0986); *Frequency:* Annually; *Affected Public:* Business or other for-profit; *Number of Respondents:* 1,227; *Total Annual Responses:* 1,227; *Total Annual Hours:* 307.

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Survey Report Form for Clinical Laboratory Improvement Amendments (CLIA) and Supporting Regulations in 42 CFR 493.1–493.2001; *Use:* This form is used by the State to determine a laboratory's compliance with CLIA. This information is needed for a laboratory's CLIA certification and recertification. *Form Number:* CMS–1557 (OMB# 0938–0544); *Frequency:* Biennially; *Affected Public:* Business or other for-profit, Not-for-profit institutions, State, Local or Tribal Governments and Federal Government; *Number of Respondents:* 21,000; *Total Annual Responses:* 10,500; *Total Annual Hours:* 5,248.

5. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF–PAI) data and Supporting Regulations in 42 CFR 412 Subpart P; *Use:* This instrument with its supporting manual is needed to permit the Secretary of Health and Human Services, and CMS, to implement Section 1886(j) of the Social Security Act. The statute requires the Secretary to develop a prospective payment system for inpatient rehabilitation facility services for the Medicare program. This payment system is to cover both operating and capital costs for inpatient rehabilitation facility services. It applies to inpatient rehabilitation hospitals as well as rehabilitation units of acute care hospitals. CMS implemented the inpatient rehabilitation facility prospective payment system for cost reporting periods beginning on or after January 1, 2002.

Form Number: CMS–10036 (OMB# 0938–0842); *Frequency:* Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions, State, Local or Tribal Governments and Federal Government; *Number of Respondents:* 1,202; *Total Annual Responses:* 396,660; *Total Annual Hours:* 337,161.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *February 13, 2009:* OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395–6974.

Dated: January 8, 2009.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E9–687 Filed 1–13–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0544]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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 February 13, 2009.

ADDRESSES: 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: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0428. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

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.

Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim—(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 meets the requirements of the regulations issued by the Secretary of Health and Human Services to authorize the use of such a health claim. Section 101.82 (§ 101.82) of FDA's regulations authorizes a health claim for food labels about soy protein and the risk of coronary heart disease. To bear the soy protein/coronary heart disease health claim, foods must contain at least 6.25 grams of soy protein per reference amount customarily consumed. Analytical methods for measuring total protein can be used to quantify the amount of soy protein in foods that contain soy as the sole source of protein. However, at the present time there is no validated analytical methodology available to quantify the amount of soy protein in foods that contain other sources of protein. For these latter foods, FDA must rely on information known only to the manufacturer to assess compliance with the requirement that the foods contain the qualifying amount of soy protein. Thus, FDA requires manufacturers to have and keep records to substantiate the amount of soy protein in a food that bears the health claim and contains sources of protein other than soy, and to make such records available to appropriate regulatory officials upon written request. The information collected includes nutrient databases or analyses, recipes or formulations, purchase orders for ingredients, or any other information that reasonably substantiates the ratio of soy protein to total protein.

In the **Federal Register** of October 23, 2008 (73 FR 63157), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
101.82(c)(2)(ii)(B)	25	1	25	1	25

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

Based upon the agency's experience with the use of health claims, FDA estimates that only about 25 firms would be likely to market products bearing a soy protein/coronary heart disease health claim and that only, perhaps, one of each firm's products might contain non-soy sources of protein along with soy protein. The records required to be retained by § 101.82(c)(2)(ii)(B) are the records, e.g., the formulation or recipe, that a manufacturer has and maintains as a normal course of its doing business. Thus, the burden to the food manufacturer is that involved in assembling and providing the records to appropriate regulatory officials for review or copying.

Dated: January 7, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–573 Filed 1–13–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0653]

Agency Information Collection Activities; Proposed Collection; Comment Request; Filing Objections and Requests for a Hearing on a Regulation or Order

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 requirements for filing objections and requests for a hearing on a regulation or order.

DATES: Submit written or electronic comments on the collection of information by March 16, 2009.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. 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: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

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