locations to be determined. This draft Plan will serve as the basis for the development of the updated National Vaccine Plan and based on this range of input, indicators of measurable outcomes will be determined and priorities will be presented. In addition, an implementation plan will be drafted that identifies specific actions that will be undertaken by government and other vaccine and immunization enterprise stakeholders to achieve the objectives and strategies in the plan and milestones will be established that will allow progress to be measured. The draft Plan has a ten-year horizon, and thereby balances a strategic vision, which requires development and implementation of new initiatives, with the recognition that changing circumstances and new opportunities and challenges will occur over the next decade. The ten-year horizon also allows incorporation of the HealthyPeople 2020 objectives once those are established by the Department of Health and Human Services (see *http://www.healthypeople.gov*). Annual monitoring of progress and a mid-course review will promote both accountability and flexibility. The updated National Vaccine Plan is expected to be completed by early 2010.

Through this Request for Information, HHS is seeking broad comment from stakeholders and the general public. Comments received will be available for public viewing and will be summarized in an open meeting on February 6, 2009, to the NVAC in Washington, DC. If you wish to attend the meeting in person or by audioconference, please reply to *nvpo@hhs.gov*, or to 202–690–5566.

II. Information Request

NVPO, on behalf of the NVAC requests information in four broad areas. Responders may address one or more of the areas below.

(1) *Comments on priorities for the National Vaccine Plan for a ten-year period:* What do you recommend be the top priorities for vaccines and the immunization enterprise in the United States and globally? Why are those priorities most important to you? [Provide up to 3 pages for an answer to these questions].

(2) *Comments on the goals, objectives, and strategies for the National Vaccine Plan for a ten-year period:* Please comment on the existing goals, objectives, and strategies in the draft Plan, and suggest specific goals, objectives, or strategies to be added to it, if the existing ones do not address your concerns. Are there any goals, objectives or strategies in the draft strategic Plan that should be discarded or revised? Which ones, and why? [Provide up to 3 pages for an answer to these questions].

(3) *Comments on the indicators for the National Vaccine Plan for a ten-year period:* Please comment on the existing indicators in the draft Plan, and suggest target estimates for them. Please suggest new indicators to be added to it, if the existing ones do not address your concerns. Are there any indicators in the draft strategic Plan that should be discarded or revised? Which ones, and why? [Provide up to 3 pages for an answer to these questions].

(4) *Comments on stakeholders' roles in the National Vaccine Plan:* Please identify which stakeholders you believe should have responsibility for enacting the objectives and strategies listed in the draft Plan, as well as for any new objectives and strategies you suggest. Specifically identify roles your organization can play in the Plan. [Provide up to 3 pages for an answer to these questions].

III. Potential Responders

HHS invites input from a broad range of individuals and organizations that have interests in vaccines and the immunization enterprise. Some examples of these organizations include, but are not limited to, the following:

- General public.
- Advocacy groups and public interest organizations.
- State, local, and tribal governments and public health agencies.
- State and local public health departments.
- Vaccine manufacturing industry, distributors, investors, and other businesses.
- Health care professional societies and organizations.
- Academic researchers and groups.
- Health care payers and plans.
- International organizations.
- Non-governmental organizations.
- Philanthropic organizations.
- Travel industry.

The submission of written materials in response to the RFI should not exceed 12 pages (3 pages for each of the four broad topics), not including appendices and supplemental documents. Responders may submit other forms of electronic materials to demonstrate or exhibit concepts of their written responses. Any information you submit will be made public. Consequently, do not send proprietary, commercial, financial, business confidential, trade secret, or personal information that you do not wish to be made public. Information and comments will not be considered nor made publicly available, if it is not signed by, or attributed to, an individual, or an individual representing an organization.

Public Access: Responses to this RFI will be available to the public on the NVPO Web site at *http://www.hhs.gov/nvpo/vacc_plan/*. You may access public comments received from this RFI by going to the above Web site.

Dated: January 7, 2009.

Bruce Gellin,

Deputy Assistant Secretary for Health, Director, National Vaccine Program Office, U.S. Department of Health and Human Services.

[FR Doc. E9–495 Filed 1–13–09; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10161, CMS–1882, CMS–437A and B, CMS–1557 and CMS–10036]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), 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 function; (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.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* New Freedom Initiative—Web-based Reporting System for Grantees; *Use:* CMS currently awards competitive grants to States and other eligible entities for the purpose of designing and implementing effective and enduring improvements in community-based long-term services

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]

BILLING CODE 4120–01–P

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.