Seleda Perryman,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. E9–8818 Filed 4–16–09; 8:45 am]

BILLING CODE 4150–30–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the National Vaccine Advisory Committee (NVAC) will hold a meeting, to be held by teleconference. This meeting will be equivalent to an in-person meeting and will be open to the public. Pre-registration is required for both public attendance by phone as well as public comment. Any individual who wishes to attend the meeting and/or participate in the public comment session should e-mail *nvpo@hhs.gov.*

DATES: The Committee will meet by teleconference on May 7, 2009, from 3 p.m. to 4:30 p.m., Eastern Daylight Time (EDT).

ADDRESSES: The meeting will occur by teleconference. To attend, please call 1–800–369–1957, passcode ''NVAC''. International callers must dial 1–630–395–0286.

FOR FURTHER INFORMATION CONTACT: Ms. Andrea Krull, Public Health Advisor, National Vaccine Program Office, Department of Health and Human Services, Room 715–H, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201. Phone: (202) 690–5566; Fax: (202) 260–1165; e-mail: *nvpo@hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to Section 2101 of the Public Health Service Act (42 U.S.C. 300aa–1), the Secretary of Health and Human Services was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The National Vaccine Advisory Committee was established to provide advice and make recommendations to the Director of the National Vaccine Program, on matters related to the Program's responsibilities. The Assistant Secretary for Health serves as Director of the National Vaccine Program.

This is a special meeting of the NVAC. Discussions will surround the draft recommendations on the draft ISO Scientific Agenda contained in the document titled ''NVAC Vaccine Safety Working Group Draft Report'' prepared at the request of the Assistant Secretary for Health by the Committee's Vaccine Safety Working Group. The NVAC Vaccine Safety Working Group was initially established to (1) undertake and coordinate a scientific review of the draft Centers for Disease Control and Prevention (CDC) Immunization Safety Office (ISO) Scientific Agenda, and (2) review the current vaccine safety system. The draft report may be found at *http://www.hhs.gov/nvpo/nvac/reports.html.* The draft ISO Scientific Agenda can be found at: *http://www.cdc.gov/vaccinesafety/00_pdf/draft_agenda_recommendations_080404.pdf* and the addendum at *http://www.cdc.gov/vaccinesafety/00_pdf/draft_recommendations_add_080410.pdf.* The Committee will review the draft document and discuss the proposed recommendations in preparation for an upcoming vote on these recommendations at the June 2009 NVAC meeting.

For this special meeting, members of the public are invited to attend by teleconference via a toll-free call-in phone number. The call-in number will be operator assisted to provide members of the public the opportunity to provide comments to the Committee. Public participation and ability to comment will be limited to space and time available. Public comment will be limited to no more than three minutes per speaker. Pre-registration is required for both public attendance and comment. Individuals who plan to attend and need special assistance, such as accommodation for hearing impairment or other reasonable accommodations, should notify the designated contact person at least one week prior to the meeting.

Any members of the public who wish to have printed material distributed to NVAC should submit materials to the Executive Secretary, NVAC, through the contact person listed above prior to close of business April 30, 2009. A draft agenda and any additional materials will be posted on the NVAC Vaccine Safety Working Group Web site (*http://www.hhs.gov/nvpo/nvac/*) prior to the meeting.

Dated: April 14, 2009.

Raymond A. Strikas,

Medical Officer, National Vaccine Program Office, U.S. Department of Health and Human Services.

[FR Doc. E9–8825 Filed 4–16–09; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Solicitation for Nominations for Members of the U.S. Preventive Services Task Force (USPSTF)

Correction

In notice document E9–8040 beginning on page 16408 in the issue of Friday, April 10, 2009, make the following corrections:

1. On page 16409, in the first column, in the fifth line from the top, ''indMduals'' should read ''individuals''.

2. On the same page, in the **ADDRESSES** section, in the eighth and ninth lines, ''*http://dreamless.keenspot.com/comic.rss*'' should read ''*uspstaskforce@ahrq.hhs.gov*''.

3. On the same page, in the **FOR FURTHER INFORMATION CONTACT** section, in the second line, ''*uspstaskforce@ahrg.hhs.gov*'' should read ''*uspstaskforce@ahrq.hhs.gov*''.

4. On the same page, in the last full paragraph, in the second line from the bottom, ''*http://preventiveservices.ahrg.gov*'' should read ''*http://preventiveservices.ahrq.gov*''.

[FR Doc. Z9–8040 Filed 4–16–09; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0657]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use

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 May 18, 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 0910–0583. 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.

Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use—(OMB Control Number 0910–0583)—Extension

Since May 29, 1992 (57 FR 22984), when FDA issued a policy statement on foods derived from new plant varieties, FDA has encouraged developers of new plant varieties, including those varieties that are developed through biotechnology, to consult with FDA early in the development process to discuss possible scientific and regulatory issues that might arise. The guidance entitled ''Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use'' continues to foster early communication by encouraging developers to submit to FDA their evaluation of the food safety of their new protein. Such communication helps to ensure that any potential food safety issues regarding a new protein in a new plant variety are resolved early in development, prior to any possible inadvertent introduction into the food supply of material from that plant variety.

FDA believes that any food safety concern related to such material entering the food supply would be limited to the potential that a new protein in food from the plant variety could cause an allergic reaction in susceptible individuals or could be a toxin. The guidance describes the procedures for early food safety evaluation of new proteins in new plant varieties, including bioengineered food plants, and the procedures for communicating with FDA about the safety evaluation.

The respondents to this collection of information are developers of new plant varieties intended for food use.

In the **Federal Register** of January 9, 2009 (74 FR 906), 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 REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
First four data components	20	1	20	4	80
Two other data components	20	1	20	16	320
Total					400

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

FDA estimates the annual total hour burden for this collection of information to be 400 hours. This estimate is based on early food safety evaluations submitted in the past 3 years. FDA's estimate of the time that it would take a respondent to prepare the data components of the early food safety evaluation submission is based on the agency's experience with similar submissions.

Completing an early food safety evaluation for a new protein from a new plant variety is a one-time burden (one evaluation per new protein). Based on its experience over the past 3 years, FDA estimates that approximately 20 developers will choose to complete an early food safety evaluation for their new plant protein. Many developers of novel plants may choose not to submit an evaluation because the field testing of a plant containing a new protein is conducted in such a way (e.g., on such a small scale, or in such isolated conditions, etc.) that cross-pollination with traditional crops or commingling of plant material is not likely to be an issue. Also, other developers may have previously communicated with FDA about the food safety of a new plant protein, for example, when the same protein was expressed in a different crop.

The early food safety evaluation for new proteins includes six main data components. Four of these data components are easily and quickly obtainable, having to do with the identity and source of the protein. FDA estimates that completing these data components will take about 4 hours per evaluation. In table 1 of this document, row 1 shows that for 20 evaluations, the total burden for these 4 data components is 80 hours.

Two data components ask for original data to be generated. One data component consists of a bioinformatics analysis which can be performed using publicly available databases. The other data component involves ''wet'' lab work to assess the new protein's stability and the resistance of the protein to enzymatic degradation using appropriate in vitro assays (protein digestibility study). The paperwork burden of these two data components consists of the time it takes the company to assemble the information on these two data components to submit to FDA. We estimate that these two data components will take 16 hours to complete (8 hours for each component). In table 1 of this document, row 2 shows that for 20 evaluations, the total burden for these two data components is 320 hours.

Dated: April 10, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–8773 Filed 4–16–09; 8:45 am]

BILLING CODE 4160–01–S