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*michelle.consolazio@hhs.gov.* Please email Michelle Consolazio for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice.

*Agenda:* The committee will hear reports from its workgroups and updates from ONC and other Federal agencies. ONC intends to make background material available to the public no later than 24 hours prior to the meeting start time. If ONC is unable to post the background material on its Web site prior to the meeting, it will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on ONC's Web site after the meeting, at <http://www.healthit.gov/FACAS/health-it-standards-committee>.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. Written submissions may be made to the contact person prior to the meeting date. Oral comments from the public will be scheduled prior to the lunch break and at the conclusion of each meeting. Time allotted for each presentation will be limited to three minutes. If the number of speakers requesting to comment is greater than can be reasonably accommodated during the scheduled open public session, ONC will take written comments after the meeting.

Persons attending ONC's advisory committee meetings are advised that the agency is not responsible for providing wireless access or access to electrical outlets.

ONC welcomes the attendance of the public at its advisory committee meetings. Seating is limited at the location, and ONC will make every effort to accommodate persons with physical disabilities or special needs. If special accommodations are required, please contact Michelle Consolazio at least seven (7) days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (Pub. L. No. 92-463, 5 U.S.C., App. 2).

Dated: December 6, 2013.

**Michelle Consolazio,**

*FACA Program Director, Office of Policy and Planning, Office of the National Coordinator for Health Information Technology.*

[FR Doc. 2013-30102 Filed 12-17-13; 8:45 am]

**BILLING CODE 4150-45-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-1204]

#### Draft Risk Profile on Pathogens and Filth in Spices: Availability; Extension of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; Extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or we) is extending the comment period for the notice entitled "Draft Risk Profile on Pathogens and Filth in Spices: Availability" that appeared in the **Federal Register** of November 4, 2013 (78 FR 66010). In the notice, FDA requested comments that can help improve the data and information used; the analytical analyses employed; and the clarity and transparency of the draft risk profile. We are taking this action in response to a request for an extension to allow interested persons additional time to submit comments, scientific data, and information.

**DATES:** We are extending the comment period for the draft risk profile. Submit either electronic or written comments by March 3, 2014.

**ADDRESSES:** Submit electronic comments and scientific data and information to <http://www.regulations.gov>. Submit written comments and scientific data and information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Jane Van Doren, Center for Food Safety and Applied Nutrition (HFS-06), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2927.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of November 4, 2013 (78 FR 66010), we published a notice entitled "Draft Risk Profile on Pathogens and Filth in Spices: Availability." The notice provided a 60-

day comment period for comments that can help improve (1) the data and information used; (2) the analytical analyses employed; and (3) the clarity and transparency of the draft risk profile.

We have received one request for an extension of the comment period for the notice. The request conveyed concern that the current 60-day comment period is not adequate to develop a response to the notice.

We have considered the request and are extending the comment period for the notice for 60 days, until March 3, 2014. We believe that a 60-day extension allows adequate time for interested persons to submit comments, scientific data, and information without significantly delaying the risk profile.

#### II. Request for Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: December 11, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-30055 Filed 12-17-13; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0308]

#### Centers for Medicare and Medicaid Services

[CMS-3180-N3]

#### Pilot Program for Parallel Review of Medical Products; Extension of the Duration of the Program

**AGENCIES:** Food and Drug Administration, Centers for Medicare and Medicaid Services, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) (the Agencies) are announcing the extension of the "Pilot Program for Parallel Review of Medical Products."

The Agencies have decided to continue the program as currently designed for an additional period of 2 years from the date of publication of this notice.

**DATES:** This notice is effective December 18, 2013.

**FOR FURTHER INFORMATION CONTACT:** John Burke, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5460, Silver Spring, MD 20993-0002, 301-796-5738, [John.Burke@fda.hhs.gov](mailto:John.Burke@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of October 11, 2011 (76 FR 62808), the Agencies announced the procedures and guiding principles for the Parallel Review Pilot Program and solicited nominations for the pilot. To date, there has been significant interest in the pilot and the Agencies are currently working through the parallel review process with the approved pilot program participants. We believe that interest in the pilot has also facilitated mutually informative discussions between additional sponsors and the Agencies.

In the October 11, 2011 (76 FR 62808), Parallel Review Pilot Program notice, the Agencies stated their intent to accept requests for a 2-year period, followed by an announcement in the **Federal Register** as to the future of the pilot. The Agencies have decided to continue the program as currently designed for an additional 2 years from the date of publication of this notice.

Once a representative group of participants have completed the pilot process the Agencies will formally evaluate the program for best practices and will announce any future revisions and/or enhancements in a future **Federal Register** notice.

Dated: December 5, 2013.

**Marilyn Tavenner,**  
*Administrator, Centers for Medicare & Medicaid Services.*

Dated: December 6, 2013.

**Margaret A. Hamburg,**  
*Commissioner of Food and Drugs.*

[FR Doc. 2013-29822 Filed 12-17-13; 8:45 am]

**BILLING CODE 4120-01-M; 4160-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### The National Children's Study, Vanguard (Pilot) Study; Submission for OMB Review; 30-Day Comment Request

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of

the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on August 23, 2013, page 52548 and allowed 60-days for public comment. Two public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The Eunice Kennedy Shriver, National Institute of Child Health and Human Development (NICHD), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

**Direct Comments to OMB:** Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974, Attention: Desk Officer for NIH.

**Comment Due Date:** Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

**FOR FURTHER INFORMATION CONTACT:** To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Sarah L. Glavin, Deputy Director, Office of Science Policy, Analysis and Communication, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 31 Center Drive, Room 2A18, Bethesda, Maryland 20892, or call a non-toll free number (301) 496-7898 or Email your request, including your address to [glavins@mail.nih.gov](mailto:glavins@mail.nih.gov). Formal requests for additional plans and instruments must be requested in writing.

**Proposed Collection:** The National Children's Study, Vanguard (Pilot) Study, 0925-0593, Expiration 8/31/2014—Revision, Eunice Kennedy Shriver National Institute of Child Health and Human Development

(NICHD), National Institutes of Health (NIH).

#### *Need and Use of Information*

**Collection:** The purpose of this request is to continue data collection activities for the NCS Vanguard Study and receive a renewal of the Vanguard Study clearance. The NCS also proposes the initiation of a new enrollment cohort, the addition of new Study visits, revisions to existing Study visits, and the initiation of methodological substudies. The NCS Vanguard Study is a prospective, longitudinal pilot study of child health and development that will inform the design of the Main Study of the National Children's Study.

**Background:** The National Children's Study is a prospective, national longitudinal study of the interaction between environment, genetics on child health, and development. The Study defines "environment" broadly, taking a number of natural and man-made environmental, biological, genetic, and psychosocial factors into account. Findings from the Study will be made available as the research progresses, making potential benefits known to the public as soon as possible. The National Children's Study (NCS) has several components, including a pilot or Vanguard Study, and a Main Study to collect exposure and outcome data.

The NCS Vanguard Study continues to follow the children and families enrolled in the Vanguard Study, conducting Study visits in participants' homes and over the telephone. Data Collection visits may include the administration of questionnaires, neurodevelopmental assessments, physical measures, and the collection of biospecimens and environmental measures. The Vanguard Study has yielded valuable data and field experience related to participant recruitment, the conduct of Study assessments, and operational requirements associated with NCS infrastructure and field efforts. The purpose of the proposed data collection is to obtain further operational and performance data on processes and administration Study visit measures.

**Research Questions:** The primary research goal is to systematically pilot additional study visit measures and collections for scientific robustness, burden to participants and study infrastructure, and cost for use in the Vanguard (Pilot) Study and to inform the Main Study. A secondary goal is to increase enrollment in the Vanguard Study through the identification of subsequent pregnancies among enrolled women.

**Methods:** The NCS Vanguard Study data collection schedule currently