anticipate manufacturing these tobacco products and are estimated to take approximately 5 hours each to conduct a review of their records, draft and send a letter to FDA indicating that they do not have documents to submit. Total burden hours for this portion of the collection are expected to be 595 hours.

Dated: October 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–25638 Filed 10–28–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1575]

Best Practices for Communication Between the Food and Drug Administration and Investigational New Drug Sponsors During Drug Development; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket, request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a docket to receive suggestions, recommendations, and comments from interested parties, including academic institutions, regulated industry, and other interested organizations on best practices for communication between FDA and investigational new drug application (IND) sponsors during drug development. These comments will help FDA identify and ultimately establish best practices to be included in a draft guidance for industry and review staff.

DATES: Submit either electronic or written comments by December 29, 2014.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel E. Hartford, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6312, Silver Spring, MD 20993–0002, 301–796–0331, email: *ONDEnhancedComm@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

One of FDA's performance commitments made as part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA) under Title I of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), related to promoting innovation through enhanced communication between FDA and sponsors during drug (including biological product) development, is for FDA to publish draft guidance for industry and review staff describing best practices for communication between FDA and IND sponsors during drug development. (A copy of the PDUFA Reauthorization Performance Goals and Procedures; Fiscal Years 2013 Through 2017 is available on the FDA Web site at *http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf.*)

The guidance will describe FDA's philosophy regarding timely interactive communication with IND sponsors as a core activity and the scope of appropriate interactions between the review team and the sponsor, outline the types of advice that are appropriate for sponsors to seek from FDA in pursuing their drug development program, describe the general expectations for the timing of FDA response to IND sponsor inquiries of simple and clarifying questions or referral of more complex questions to the formal meeting process, and describe best practices and communication methods (including the value of person-to-person scientific dialogue) to facilitate interactions between the FDA review team and the IND sponsor during drug development. We anticipate that the best practices will include expectations and agreement on appropriate methods (e.g., when teleconferencing or secure email may be the most appropriate means of communication) and frequency of such communications.

II. Establishment of a Docket and Request for Comments

To help FDA identify and ultimately establish best practices to be included in a draft guidance, FDA is requesting public suggestions, recommendations, and comments for each aspect of the best practices mentioned above. FDA will consider all comments submitted. FDA generally will not respond directly to the person or organization submitting the comment.

III. 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: October 22, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–25641 Filed 10–28–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Solicitation of Information and Recommendations for Revising OIG's Non-Binding Criteria for Implementing Permissive Exclusion Authority Under Section 1128(b)(7) of the Social Security Act

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice; Extension of comment period.

SUMMARY: This document announces an extension of the public comment period for the OIG **Federal Register** notice published on July 11, 2014 (79 FR 40114). The notice solicited input from the public on revising the criteria used by OIG in implementing its permissive exclusion authority under Section 1128(b)(7) of the Social Security Act. Due to a technical problem, the public may have been unable to submit comments at *http://www.regulations.gov* during the comment period. Accordingly, we are extending the comment period to ensure that the public has an opportunity to provide input.

DATES: To ensure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on December 29, 2014.

ADDRESSES: In commenting, please refer to file code OIG–1271–N. Because of staff and resource limitations, we cannot

accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific recommendations and proposals through the Federal eRulemaking Portal at *http://www.regulations.gov.*

2. *By regular, express, or overnight mail.* You may send written comments to the following address: Patrice Drew, Office of Inspector General, Department of Health and Human Services, Attention: OIG–1271–N, Room 5296, Cohen Building, 330 Independence Avenue SW., Washington, DC 20201. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver, by hand or courier, your written comments before the close of the comment period to Patrice Drew, Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue SW., Washington, DC 20201. Because access to the interior of the Cohen Building is not readily available to persons without Federal Government identification, commenters are encouraged to schedule their delivery with one of our staff members at (202) 619–1368.

For information on viewing public comments, please see the Supplementary Information section.

FOR FURTHER INFORMATION CONTACT: Patrice Drew, Department of Health and Human Services, Office of Inspector General, Office of External Affairs, at (202) 619–1368.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the end of the comment period are available for viewing by the public. All comments will be posted on *http://www.regulations.gov* as soon as possible after the closing of the comment period. Comments received timely will also be available for public inspection as they are received at Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue SW., Washington, DC 20201, Monday through Friday of each week from 10 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (202) 619–1368.

Background: The OIG published on a notice entitled, ''Solicitation of Information and Recommendations for Revising OIG's Non-Binding Criteria for Implementing Permissive Exclusion Authority Under Section 1128(b)(7) of the Social Security Act,'' on July 11, 2014 (79 FR 40114). The notice solicited input from the public on the revision of the criteria used by OIG in implementing its permissive exclusion authority under Section 1128(b)(7) of the Social Security Act. Due to a technical problem, the public may have been unable to submit comments during the comment period at *http://www.regulations.gov.* Accordingly, we are extending the comment period to ensure that the public has an opportunity to provide input.

Dated: October 22, 2014.

Daniel R. Levinson,

Inspector General.

[FR Doc. 2014–25681 Filed 10–28–14; 8:45 am]

BILLING CODE 4152–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Effect of Exercise Modality During Weight Loss on Bone Health in Older Adults.

Date: December 11, 2014.

Time: 11:00 a.m. to 12:00 p.m.

Agenda: To Review and Evaluate Grant Applications.

Place: National Institute on Aging, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Ramesh Vemuri, Ph.D., Chief, Scientific Review Branch, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Suite 2C–212, Bethesda, MD 20892, 301–402–7700, *rv23r@nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.866, Aging Research, National Institutes of Health, HHS).

Dated: October 23, 2014.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–25649 Filed 10–28–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, November 14, 2014, 12:00 p.m. to November 14, 2014, 02:00 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on October 22, 2014, 78 FR 63136.

The meeting will be held on November 11, 2014 instead of November 14, 2014. The meeting time and location remains the same. The meeting is closed to the public.

Dated: October 23, 2014.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–25648 Filed 10–28–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel Population Sciences and Epidemiology Area Review.

Date: November 13, 2014.

Time: 1:00 p.m. to 4:00 p.m.