Atlantic salmon and a preliminary FONSI for those specific conditions of use. Comments on the draft EA and FONSI will inform FDA's decision whether to require an environmental impact statement (EIS) or finalize the EA and FONSI for this NADA.

The Agency has received a request for a 60-day extension of the comment period for the draft EA and FONSI. The request conveyed concern that the current 60-day comment period does not allow sufficient time to respond.

FDA has considered the request and is extending the comment period for the draft EA and FONSI for 60 days, until April 26, 2013. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying the Agency's decision on whether to finalize these documents or prepare an EIS.

II. Request for Comments

Interested persons may submit either electronic comments regarding these documents 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: February 11, 2013.

Leslie Kux,

Assistant Commissioner for Policy.
[FR Doc. 2013–03445 Filed 2–13–13; 8:45 am]
BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; 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 of General Medical Sciences Initial Review Group; Training and Workforce Development Subcommittee A.

Date: March 12, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard by Marriott Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD

Contact Person: John J. Laffan, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.18J, Bethesda, MD 20892, 301-594-2773, laffanjo@mail.nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: February 8, 2013.

Melanie J. Grav,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–03361 Filed 2–13–13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; 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 materials, 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 Minority Health and Health Disparities Special Emphasis Panel; NIMHD Conference Grant Review (R13).

Date: March 15, 2013.

Time: 12:00 p.m. to 5:00 p.m. Agenda: To review and evaluate grant applications. Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Hui Chen, M.D., Scientific Review Officer, National Institute on Minority Health and Health Disparities, 6707 Democracy Blvd., Suite 800, Bethesda, MD 20892, (301) 594–7784, chenhui@mail.nih.gov.

Dated: February 7, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–03357 Filed 2–13–13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; 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: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; NIDCD Vestibular Prosthesis Research Application. Date: March 25, 2013.

Time: 4:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Andrea B. Kelly, Ph.D., Scientific Review Officer Division of Extramural Activities, National Institutes of Health/NIDCD 6120 Executive Blvd.—MSC 7180, Rockville, MD 20892, (301) 496–8683, kellya2@nidcd.nih.gov.

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; NIDCD Outcome Research Application.

Date: March 26, 2013.

Time: 12:30 p.m. to 1:30 p.m. Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852, (Telephone Conference Call). Contact Person: Andrea B. Kelly, Ph.D., Scientific Review Officer Division of Extramural Activities, National Institutes of Health/NIDCD, 6120 Executive Blvd.—MSC 7180, Rockville, MD 20892, (301) 496–8683, kellya2@nidcd.nih.gov.

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Hearing and Balance Clinical Trial Review.

Date: March 29, 2013.

Time: 10:30 a.m. to 12:30 p.m. Agenda: To review and evaluate grant

Place: National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Christine A. Livingston, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institutes of Health/NIDCD, 6120 Executive Blvd.—MSC 7180, Bethesda, MD 20892, (301) 496–8683, livingsc@mail.nih.gov.

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; NIDCD VSL Clinical Trial Applications Review.

Date: April 9, 2013.

Time: 11:30 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Andrea B. Kelly, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institutes of Health/NIDCD, 6120 Executive Blvd.—MSC 7180, Rockville, MD 20892, (301) 496–8683, kellya2@nidcd.nih.gov.

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; LRP Applications Review.

Date: April 9, 2013.

Time: 12:00 p.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Sheo Singh, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, Executive Plaza South, Room 400C, 6120 Executive Blvd., Bethesda, MD 20892, 301– 496–8683, singhs@nidcd.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: February 8, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–03360 Filed 2–13–13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 a meeting of the Board of Scientific Counselors for Basic Sciences National Cancer Institute.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Cancer Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors for Basic Sciences National Cancer Institute, NCI Board of Scientific Counselors Meeting (Basic Sciences).

Date: March 12, 2013.

Time: 9:00 a.m. to 1:30 p.m.

Agenda: To review and evaluate personal qualifications and performance, and, competence of individual investigators.

Place: National Institutes of Health, Building 31, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Florence E. Farber, Ph.D., Executive Secretary, Office of the Director, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 2205, Bethesda, MD 20892, 301–496–7628, ff6p@nih.gov.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: February 8, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–03358 Filed 2–13–13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 a meeting of the Board of Scientific Counselors for Clinical Sciences and Epidemiology National Cancer Institute.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL CANCER INSTITUTE, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors for Clinical Sciences and Epidemiology, National Cancer Institute; NCI Board of Scientific Counselors Meeting (Clinical Sciences and Epidemiology).

Date: March 11, 2013.

Time: 9:30 a.m. to 1:30 p.m.

Agenda: To review and evaluate personal qualifications and performance, and

competence of individual investigators.

Contact Person: National Institutes of
Health, Building 31, Conference Room 6, 31
Center Drive, Bethesda, MD 20892.

Contact Person: Brian E. Wojcik, Ph.D., Senior Review Administrator, Institute Review Office, Office of The Director, National Cancer Institute, 6116 Executive Boulevard, Room 2201, Bethesda, MD 20892, (301) 496–7628, wojcikb@mail.nih.gov.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)