V. 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: August 13, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–19577 Filed 8–18–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Food Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Food Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 16–17, 2014, from 8:30 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Karen Strambler, Center for Food Safety and Applied Nutrition (HFS–024), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2589 or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). 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. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

If you are unable to attend in person, FDA encourages you to watch the free Web cast. Visit the Food Advisory Committee Web site at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/FoodAdvisoryCommittee/default.htm.* The link will become active shortly before the open session begins on December 16, 2014, at 8:30 a.m.

Agenda: The committee will discuss science issues surrounding susceptible life stages or populations and the circumstances under which FDA might decide to conduct a separate risk assessment for these populations. Also, FDA is requesting advice from the Food Advisory Committee on how to integrate concern for susceptible populations into its risk assessment procedures and methodologies including under what conditions a separate risk assessment should be conducted.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

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 on or before December 8, 2014. Oral presentations from the public will be scheduled for December 17, 2014, between approximately 11 a.m. to 12 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 25, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by December 1, 2014.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Karen Strambler at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 13, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–19601 Filed 8–18–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1130]

Brain-Computer Interface Devices for Patients With Paralysis and Amputation; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Brain-

Computer Interface (BCI) Devices for Patients With Paralysis and Amputation.'' BCI devices include neuroprostheses that interface with the central or peripheral nervous system to restore lost motor or sensory capabilities in paralyzed and amputee patients. The purpose of this workshop is to obtain public feedback on scientific, clinical, and regulatory considerations associated with BCI devices. Ideas and suggestions generated during this workshop may facilitate development of draft guidance to provide our initial thoughts regarding the content of premarket submissions for emerging BCI technologies to help speed development and approval of future submissions.

Dates and Times: The public workshop will be held on November 21, 2014, from 8:30 a.m. to 5:30 p.m.

Location: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to: *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact Person: Hilda Scharen, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, rm. 3625, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–6815, email: *Hilda.Scharen@fda.hhs.gov.*

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by November 12, 2014, by 4 p.m. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4321, Silver Spring, MD 20993–0002, 301–796–5661, email: *susan.monahan@fda.hhs.gov* no later than November 7, 2014.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this meeting/public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number. If you are unable to register online, please contact Susan Monahan (see *Registration.*) Registrants will receive confirmation after they have been accepted and will be notified if they are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by Wednesday, November 12, 2014, by 4 p.m. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after November 14, 2014. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Comments: FDA is holding this public workshop to obtain information on the technical challenges of BCI devices. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is December 22, 2014.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Please identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section II, please identify the question you are addressing. 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.*

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.)

SUPPLEMENTARY INFORMATION:

I. Background

BCI devices have the potential to restore functional movement and sensory capabilities to individuals disabled by paralysis or amputation. BCI devices interface with the central and/or peripheral nervous system to detect neural control commands for real or virtual prosthetic or assistive devices. Investigational studies of BCI devices have revealed both device potential effectiveness and implementation challenges. Advancement of BCI devices from the laboratory to patients may be impeded by gaps in scientific and clinical data regarding long-term device reliability and safety; uncertainty in the regulatory, reimbursement, and commercialization pathways; and the need for increased patient input in the device development process.

The workshop seeks to involve industry and academia in addressing the challenges in the development of BCI devices. By bringing together relevant stakeholders, which include scientists, patient advocates, clinicians, researchers, industry representatives, and regulators, to this workshop, we hope to facilitate the improvement of this rapidly evolving product area.

II. Topics for Discussion at the Public Workshop

This workshop is aimed to address the scientific, clinical, and regulatory considerations associated with these devices, including but not limited to, the following topic areas:

1. Challenges, needs, and benefit/risk profiles for target patient populations.

2. Device interoperability for complex, multi-component systems.

3. Technological metrics for invasive and non-invasive neural interfaces (i.e., reliability, biocompatibility, electromagnetic compatibility, software evaluation, and safety).

4. For different stages of device development, considerations regarding appropriate selection of preclinical (bench and animal) testing methods, and patient-centered outcome metrics in clinical and ''real world'' use settings.

Dated: August 13, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–19576 Filed 8–18–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; 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/contract proposals 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 Alcohol Abuse and Alcoholism Special Emphasis Contract Proposal-Discovering Control Variables for Maladaptive Drinking Behavior.

Date: August 28, 2014.

Time: 2:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: NIAAA, 5635 Fishers Lane; Room 2098, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Ranga Srinivas, Ph.D., Chief, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, NIH, 5365 Fishers Lane; Room 2085, Rockville, MD 20852, (301) 451–2067, *srinivar@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Review of RFP NIH–NIAAA–2014–04; Biomarkers for Alcohol and ALD.

Date: September 3, 2014.

Time: 2:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NIAAA, 5635 Fishers Lane, Rockville, MD 20852, Telephone Conference Call).

Contact Person: Ranga Srinivas, Ph.D., Chief, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, NIH, 5365 Fishers Lane; Room 2085, Rockville, MD 20852, (301) 451–2067, *srinivar@mail.nih.gov*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 92.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Supports Awards, National Institutes of Health, HHS)

Dated: *August 13, 2014.*

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–19598 Filed 8–18–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 Allergy and Infectious Diseases Special Emphasis Panel Clinical Trial Implementation and Planning Grants-Program Project Grant.

Date: September 30–October 1, 2014.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 3121, 6700 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Paul A. Amstad, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–402–7098, *pamstad@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: August 13, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–19596 Filed 8–18–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, September 30, 2014, 08:00 a.m. to October 01, 2014, 05:00 p.m., Hilton Rockville Hotel, Rockville, MD, 20852 which was published in the **Federal Register** on July 17, 2014, 79 FR 41701.

Meeting location has been changed to the Doubletree Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814. The meeting is closed to the public.

Dated: August 13, 2014.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–19597 Filed 8–18–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

AGENCY: National Institute of Mental Health (NIMH), HHS.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the NIH Reform Act of 2006 (42 U.S.C. 281(d)(4)), notice is hereby given that the National Institute of Mental Health (NIMH) will host a meeting to enable public discussion of the Institute's proposal to merge the Division of Adult Translational Research with the Division of Translational Research. The proposal seeks to capitalize on emerging scientific opportunities, while reducing