

**Contact Persons:** Hilda Scharen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm 3625, Silver Spring, MD 20993, 301-796-6815, [Hilda.Scharen@fda.hhs.gov](mailto:Hilda.Scharen@fda.hhs.gov); or Jay Gupta, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, [Jay.Gupta@fda.hhs.gov](mailto:Jay.Gupta@fda.hhs.gov), 301-796-2795.

**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 6, 2015, at 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, [susan.monahan@fda.hhs.gov](mailto:susan.monahan@fda.hhs.gov) or 301-796-5661 no later than November 5, 2015.

To register for the public workshop, please visit FDA's Medical Devices Workshops and 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. Those without Internet access should contact Susan Monahan to register (see *Contact for special accommodations*). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

**Streaming Webcast of the Public Workshop:** This public workshop will also be available via Webcast. Persons interested in viewing the Webcast must register online by 4 p.m., November 6, 2015. 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 10, 2015. 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](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](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:** 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 5, 2015.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments regarding this document 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. Identify comments with the docket number found in brackets in the heading of this document. In addition, when providing comments to the topics as outlined in section II of this document, 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. The address of the Division of Freedom of Information is available on the Agency's Web site at <http://www.fda.gov>. 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**

Cognitive assessment medical devices are intended to provide healthcare professionals with an evaluation of cognitive function through non-invasive measurements. Non-invasive brain stimulation medical devices are intended to improve, affect, or otherwise modify the cognitive function of a normal individual (*i.e.*, has no cognitive impairment) by means of non-invasive electrical or electromagnetic stimulation to the head. These medical

devices both present important safety and effectiveness questions as well as study design and data analysis challenges.

#### **II. Topics for Discussion at the Public Workshop**

The workshop seeks to involve industry and academia in addressing scientific, clinical, and regulatory considerations associated with medical devices for assessing and influencing cognitive function. 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.

This workshop is aimed to address scientific, clinical, and regulatory considerations associated with medical devices for assessing and influencing cognitive function; including, but not limited to, the following topic areas:

- Considerations for clinical study trial designs, patient populations, and patient selection methods;
- considerations for clinical study endpoints, *e.g.*, clinically relevant outcome measures and related statistical analyses;
- identification of risks and risk mitigation strategies; and
- evaluation of prior studies, current clinical research, and available scientific and clinical evidence.

Dated: August 10, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Food and Drug Administration**

[Docket No. FDA-2015-N-0001]

##### **Science Advisory Board to the National Center for Toxicological Research 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). At least one portion of the meeting will be closed to the public.

**Name of Committee:** Science Advisory Board (SAB) to the National Center for Toxicological Research (NCTR).

*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 November 3, 2015, from 12:30 p.m. to 5 p.m., and November 4, 2015, from 8 a.m. to 5 p.m.

*Location:* NCTR SAB, 3900 NCTR Rd., Conference rm. B-12, Jefferson, AR 72079. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

*Contact Person:* Donna Mendrick, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 2208, Silver Spring, MD 20993-0002, 301-796-8892; 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.

*Agenda:* On November 3, 2015, the SAB Chair will welcome the participants, and the NCTR Director will provide a Center-wide update on scientific initiatives and accomplishments during the past year. The SAB will be presented with an overview of the Division of Biochemistry Subcommittee and the Subcommittee Site Visit Report. Representatives from the Office of the Chief Scientist and Office of Medical Products and Tobacco will discuss research needs and opportunities for collaborations with NCTR.

On November 4, 2015, the Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research, Center for Tobacco Products, Center for Veterinary Medicine, and Office of Regulatory Affairs will each briefly discuss their Center-specific research strategic needs. Following the public session, the SAB will hear an update from each of NCTR's research divisions.

Following an open discussion of all the information presented, the open session of the meeting will close so the SAB members can discuss personnel issues at NCTR at the end of each day.

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:* On November 3, 2015, from 12:30 p.m. to 5 p.m., and November 4, 2015, from 8 a.m. to 4:15 p.m., the meeting is open to the public. 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 October 27, 2015. Oral presentations from the public will be scheduled between approximately 11:45 a.m. and 12:45 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 October 19, 2015. 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 October 20, 2015.

*Closed Committee Deliberations:* On November 4, 2015, from 4:15 p.m. to 5 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). This portion of the meeting will be closed to permit discussions of information concerning individuals associated with the research programs at NCTR.

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 Donna Mendrick 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 10, 2015.

**Jill Hartzler Warner,**  
*Associate Commissioner for Special Medical Programs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2004-N-0451; formerly Docket No. 2004N-0226]

### Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 040

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA Recognized Consensus Standards). This publication, entitled "Modifications to the List of Recognized Standards, Recognition List Number: 040" (Recognition List Number: 040), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

**DATES:** Submit electronic or written comments concerning this document at any time. See section VII for the effective date of the recognition of standards announced in this document.

**ADDRESSES:** An electronic copy of Recognition List Number: 040 is available on the Internet at <http://>