and product code HLJ, Ophthalmoscope, Battery-powered (see 21 CFR 886.1570—Ophthalmoscope). FDA has determined it is appropriate to add these product codes to the guidance because FDA has tentatively concluded they are sufficiently well understood and do not require premarket notification (510(k)) to assure their safety and effectiveness.

Seven comments also requested the removal or clarification of specific product codes in the draft guidance. The issues raised in these comments were addressed by the removal of certain product codes from the draft guidance, and the clarification of two product codes: Product code MRQ, Analyzer, Nitrogen Dioxide; and product code KKX, Drape, Surgical. Moreover, in response to the issues raised, FDA is clarifying that it is not the Agency's intent to exempt combination products or single entity products containing antimicrobial agents. For the remaining product codes identified in those comments, FDA believes that the product codes are sufficiently well understood and do not require premarket notification (510(k)) to assure their safety and effectiveness. Thus, FDA has not removed these products codes from the guidance.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the intent to exempt certain unclassified, class II, and class I reserved medical devices from premarket notification requirements. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Intent to Exempt Certain Unclassified, Class II, and Class I Reserved Medical Devices from Premarket Notification Requirements'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1300046 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120.

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.*

VI. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. FDA announced that it would exercise enforcement discretion for premarket notification for the following product codes, among others, if the devices meet the criteria set forth in guidance: OFX, OKF, OKG, OKH, OKI, LRO, and OJW. See Convenience Kits Interim Regulatory Guidance (May 1997), available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080217.pdf.*

Dated: August 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–20005 Filed 8–13–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2711]

Neurodiagnostics and Non-Invasive Brain Stimulation Medical Devices; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following two-day public workshop entitled, ''Neurodiagnostics and Non-Invasive Brain Stimulation Medical Devices Workshop''. The focus of the first day of the workshop will be cognitive assessment medical devices, which are intended to provide healthcare professionals with an evaluation of cognitive function through non-invasive measurements. The focus of the second day of the workshop will be non-invasive brain stimulation medical devices, which are medical devices that are intended to improve, affect, or otherwise modify the cognitive function of a normal individual (*i.e.,* without a treatment objective) by means of non-invasive electrical or electromagnetic stimulation to the head. The purpose of this workshop is to obtain public input and feedback on scientific, clinical, and regulatory considerations associated with medical devices for assessing and influencing cognitive function. Ideas generated during this workshop may facilitate further development of guidance regarding the content of premarket submissions for neurodiagnostics and non-invasive brain stimulation medical devices and help to speed development and approval of future submissions.

Dates and Times: The public workshop will be held on November 19 and 20, 2015, from 8:30 a.m. to 5 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 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;* 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,* 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* 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.* 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: 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).