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 Ideas and suggestions generated during this workshop may facilitate development of draft guidance to provide our initial thoughts regarding the content of premarket submissions for emerging BCI technologies to help speed development and approval of future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.

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