4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0580]

Battery-Powered Medical Devices Workshop: Challenges and Opportunities; 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 "Battery-Powered Medical Devices Workshop: Challenges and Opportunities". The purpose of this workshop is to create awareness of the challenges related to battery-powered medical devices and collaboratively develop solutions and best practices to improve the performance and reliability of these devices.

Date and Time: The public workshop will be held on July 30 and 31, 2013, from 8 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. 1503A), Silver Spring, MD 20993-0002. All visiting public workshop participants (non-FDA employees) must enter through Building 1 for routine security check procedures. For parking and security information, please visit the following Web site: http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

Contact: Iacovos Kyprianou, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3609, Silver Spring, MD 20993-0002, 301-796-2601, email: iacovos.kyprianou@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 5 p.m., July 19, 2013. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the workshop will be available beginning at 7 a.m.

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, and affiliation, address, email, and telephone number. Those without Internet access should contact Susan Monahan, susan.monahan@fda.hhs.gov or 301-796-5661, to register. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

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 5 p.m. on July 17, 2013.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by 5 p.m., July 19, 2013. 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 July 24, 2013. If you have never attended an Adobe 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.)

Requests for Oral Presentations: This public workshop includes public comment and topic-focused sessions. If you wish to present, please so indicate at time of registration. Please indicate whether you wish to present during a public comment session, or participate in a specific session. Please submit the topic and a short abstract of your presentation. FDA will do its best to accommodate requests to make public comment and participate in specific sessions. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in specific sessions. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by July 22, 2013. All requests to make oral presentations must be received by the close of registration at 5 p.m., July 19, 2013. If selected for presentation, any presentation materials must be emailed to Iacovos Kyprianou (see Contact) no later than July 24, 2013. No commercial promotional material will be permitted to be presented or distributed at the public workshop.

Comments: FDA is holding this public workshop to obtain information on battery-powered medical 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 and the issues discussed during the meeting is August 30, 2013.

Regardless of attendance at the public workshop, interested persons may submit either electronic or written comments. Submit electronic comments to http://www.regulations.gov. Submit 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 commenting on specific topics as outlined in section II of this document, please identify the topics 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

Batteries play a significant role in the overall safety, performance, and reliability of many life-saving and life-sustaining medical devices. As more medical devices become computerized, compact, and mobile, the number of battery-powered medical devices will continue to increase. While many different components can potentially impact the safety and effectiveness of medical devices, the battery can be one of the most critical components. Unexpected depletion or failure of the battery can cause the device to stop functioning properly, preventing the device from delivering life-sustaining or life-saving therapy. The Association for the Advancement of Medical Instrumentation has identified battery management as one of the top 10 challenges for hospitals' biomedical departments. In addition, the way that the battery is integrated into the overall device plays a critical role in the performance of the device. In many cases, the cause of the problem is identified as "battery failure" even when the battery is not the root cause of the problem. Improper charging of rechargeable batteries and inconsistent maintenance of batteries in general can adversely impact the effectiveness of the device, causing unexpected failure of devices at critical times, such as emergency situations where electrical power is unavailable or intermittent. While FDA has confidence that medical devices currently being marketed will continue to function as intended, there are opportunities to further improve their overall performance and safety. Therefore, FDA is organizing a Battery-Powered Medical Devices Workshop on July 30 and 31, 2013, to create awareness of the challenges related to battery-powered medical devices and collaboratively develop solutions and best practices to improve the performance and reliability of these devices. The forum will be held at the FDA's White Oak campus in Silver Spring, MD from 8 a.m. to 5 p.m. The participants would include a broad group

of stakeholders that are responsible for the design, testing, manufacturing, integration, regulation, selection, purchase, storage, maintenance, and use of batteries throughout the total product life cycle of battery-powered medical devices.

II. Topics for Discussion

At this meeting, participants will engage in open dialogue and discuss the following factors that contribute to battery-powered medical device performance and reliability:

- Identification of challenges,
- battery/device design and system integration,
- battery/device manufacturing process,
- battery/device maintenance,
- human factors,
- consistent labeling,
- user training,
- special considerations under extreme conditions,
- standardization,
- emerging technology and innovation, and
- mitigation of challenges.

Goals:

1. Create awareness of the challenges related to battery-powered medical devices and collaboratively develop solutions and best practices to improve the performance and reliability of these devices.

2. Create a forum for open dialogue among stakeholders to share lessons learned and best practices for overcoming battery-powered medical device challenges.

3. Promote better design, manufacturing, testing, system integration, maintenance and standardization of battery-powered medical devices.

4. Understand the challenges of hospitals, health care providers, and patients in selection, purchase, use, and maintenance of battery-powered medical devices.

5. Promote innovation in technology and processes to improve device performance and reliability.

6. Coordinate future collaboration in the development of educational materials, standards, and guidance.

Dated: May 30, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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