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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-2734]

Physiological Closed-Loop Controlled 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 public workshop entitled ``Physiological Closed-Loop Controlled (PCLC) Devices.'' The topic to be discussed is challenges related to the design, development, and evaluation of critical care PCLC devices. FDA considers PCLC devices an emerging technology and aims to hold a workshop focusing on design, development and performance evaluation of PCLC systems intended for use in critical care environments. Such devices include closed-loop anesthetic delivery, closed-loop vasoactive drug and fluid delivery, and closed-loop mechanical ventilation.

Dates and Times: The public workshop will be held on October 13 and 14, 2015, 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., Building 31 Conference Center, Rm. 1503 (The Great Room), Silver Spring, MD 20993.

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: Bahram Parvinian, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2534, Silver Spring, MD 20993, 301-796-6445, email: Bahram.Parvinian@fda.hhs.gov; and Allison Kumar, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5402, Silver Spring, MD 20993, 301-796-6369, email: Allison.Kumar@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 4 p.m., October 1, 2015. 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 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, Office of Communication and Education (OCE), Center for Devices and Radiological Health, Food and Drug Administration, 301-796-5661, email: susan.monahan@fda.hhs.gov no later than September 29, 2015.

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, address, email, and telephone number. Those without Internet access should contact Susan Monahan to register. 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 Webcast. Persons interested in viewing the Webcast must register online by 4 p.m., October 1, 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 October 7, 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

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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 a public comment session and topic-focused sessions. During online registration you may indicate if you wish to present during a public comment session or participate in a specific session, and which topics you wish to address. FDA has included general topics in this document. FDA will do its best to accommodate requests to make public comments. 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 the focused 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 September 15, 2015. All requests to make oral presentations must be received by September 1, 2015. If selected for presentation, any presentation materials must be emailed to Bahram Parvinian and Allison Kumar (see Contact Persons) no later than October 1, 2015. No commercial or 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 challenges related to the design, development, and evaluation of critical care PCLC 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 September 1, 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 responding to specific questions 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

PCLC medical devices are an emerging technology in the intensive care and emergency medicine settings that provides autonomous therapy adjustments to manipulate a physiological variable. For example, a closed-loop oxygen delivery device may automatically adjust the fraction of inspired oxygen when an individual's oxygen saturation level drifts too high or too low. PCLCs could benefit patients and practitioners by automating a number of tasks including adjustments to mechanical ventilation, anesthetic delivery, and fluid resuscitation. These devices may provide practitioners more resources to consider the course of treatment for an individual patient and improve resource allocation during times of medical surge (e.g., from mass casualty incidents). PCLC medical devices may also allow additional therapeutic and diagnostic capabilities by providing precise control of physiological variables by continuous manipulation of therapy that is impractical for a medical practitioner to perform.

Recent advances in medical device technology and control systems science have increased the development of PCLC medical devices. PCLCs shift specific assignments of data interpretation and therapy manipulation from a practitioner to a medical device. This may or may not introduce new risks to patients, but could introduce new medical device hazards that, considered during design and development, can be mitigated throughout the device life-cycle. Addressing technical and clinical challenges for a PCLC medical device to be robust, stable, and effective in its environment of use will ensure patient safety and promote innovation and development of PCLC medical devices.

This workshop seeks to involve industry, academia, medical societies, patient groups, standard bodies, and other relevant stakeholders in addressing the challenges in the development and implementation of PCLC medical devices in critical care environments. Participants in the workshop will include scientists and engineers developing PCLC medical devices, as well as end users including physicians, nurses, and patients. The intent of the workshop is to discuss benefit-risk considerations, design strategies, pre-clinical testing, and clinical evaluation for specific product areas of PCLC medical devices. Ideas generated during this workshop may facilitate development of new draft guidances and/or standards for PCLC medical devices.

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. Benefit-risk considerations at varying levels of closed-loop medical device autonomy
2. Challenges related to the design and development of critical care PCLC devices
 - a. System performance analysis for different controller types (e.g., rule based/knowledge based, proportional-integral derivative, fuzz logic, adaptive predictive, neural networks)
 - b. Fault detection and fallback modes
 - c. User interfaces and operational transparency
3. Knowledge gap between clinicians and system engineers
 - a. Clinician involvement in system design
 - b. Control system terminology
4. Pre-clinical evaluation
 - a. Evidence needed to demonstrate a stable and robust controller
 - b. Use of computer simulations including verification, validation and uncertainty quantification of physiological models used for design and evaluation of PCLC systems.
 - c. Real time bench testing
5. Clinical evaluation (e.g., study design, clinical endpoints, outside the U.S. data)
 - a. Clinical validity of sensors
 - b. Patient populations
 - c. Environments of use
 - d. User related level of expertise.

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6. Human factors of autonomous medical devices (e.g., usability, training, clinical decisionmaking)

Dated: August 11, 2015.

Leslie Kux,
Associate Commissioner for Policy.
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