



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-2655]

Center for Devices and Radiological Health Veteran Amputee 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 "Center for Devices and Radiological Health Veteran Amputee Devices." The purpose of this workshop is to engage all stakeholders involved in the research, development, and marketing of prosthetic limb medical devices used by veteran amputees. A specific goal is to engage veteran amputees who use prosthetic limb medical devices and hear their views on these devices so that these perspectives may be considered in the total product life cycle of prosthetic limb devices.

DATES: The public workshop will be held on October 31, 2016, from 9 a.m. to 4 p.m. Submit either electronic or written comments on the public workshop by November 30, 2016.

ADDRESSES: 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. 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>.

You may submit comments as follows:

### Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

### Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-N-2655 for "Center for Devices and Radiological Health Veteran Amputee Devices." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For

more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Fabienne Santel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3502, Silver Spring, MD 20993, 301-796-9644, email: [Fabienne.santel@fda.hhs.gov](mailto:Fabienne.santel@fda.hhs.gov).

SUPPLEMENTARY INFORMATION:

#### I. Background

The Center for Devices and Radiological Health (CDRH) is committed to including views of patients on the total product life cycle of medical devices. To better understand their needs, CDRH plans to engage patients throughout our regulatory process. CDRH is interested in patients contributing their views, data, and resources to improve the total product life cycle for medical devices, reduce adverse events, and improve communication about the risks and benefits that matter most to them.

Together with other centers and offices across FDA, we are testing and developing ways to engage patients and capture their views through public workshops. The CDRH Veteran Amputee Devices is one such workshop intended to engage veteran amputees, such as those

patients from the Walter Reed National Military Medical Center, Warrior Clinic, who use prosthetic limb medical devices.

## II. Topics for Discussion at the CDRH Veteran Amputee Devices Public Workshop

Topics to be discussed at the public workshop include, but are not limited to the following:

- Introduce the CDRH Total Product life Cycle (TPLC) for prosthetic limb devices.
- A focus group to obtain information on priorities for upper-limb prosthetics from the perspective of upper-limb amputees.
- Presentations from prosthetic limb device manufacturer.
- Question and answer session where patients, their caregivers and other interested parties have an opportunity to present their views and ask questions about the total product life cycle of medical devices.

Registration: Registration is free and available on a first-come, first-served basis.

Persons interested in attending the CDRH Veteran Amputee Devices public workshop must register online by October 24, 2016. 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 public workshop will be begin at 8 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Office of Communication, Education (OCE), 301-796-5661 email: Susan.Monahan@fda.hhs.gov no later than October 17, 2016.

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 Fabienne Santel to register (see FOR FURTHER INFORMATION CONTACT). 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. The Webcast link will be available on the registration Web page after October 21, 2016. Organizations are requested to view using one connection per location. 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, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

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 or give presentations during the focused 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 the focused sessions. 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 October 17, 2016. All requests to make oral presentations

must be received by October 10, 2016. If selected for presentation, any presentation materials must be emailed to Fabienne Santel (see FOR FURTHER INFORMATION CONTACT) no later than October 28, 2016. If you are a manufacturer and wish to have a display table, please submit this request by October 17, 2016. Space is limited; therefore, FDA will select and notify manufacturers by October 24, 2016. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

FDA is holding this public workshop to obtain views from patients on prosthetic limb devices so that these perspectives may be considered in the total product life cycle of prosthetic limb 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 patient workshop is November 30, 2016.

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 ADDRESSES). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address 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).

Dated: September 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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