4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Bridging the Idea Development Evaluation Assessment and Long-Term Initiative and Total Product Life Cycle Approaches for Evidence Development for Surgical Medical Devices and Procedures; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Bridging the IDEAL and TPLC Approaches for Evidence Development for Surgical Medical Devices and Procedures." The purpose of the public workshop is to provide a forum for discussion among FDA, governmental agencies, academia, physicians, and various stakeholders to further refine and advance the Idea Development Evaluation Assessment and Long-Term (IDEAL) initiative and Total Product Life Cycle (TPLC) frameworks related to evidence generation and evaluation for surgical devices and procedures.

Date and Time: The meeting will be held on December 2, 2011, from 8 a.m. to 5:30 p.m. Participants are encouraged to arrive early to ensure time for parking and security screening before the meeting. Submit electronic and written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Location: The public workshop will be held at the FDA 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 Bldg.

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: Samantha Jacobs, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4113, Silver Spring, MD 20993, 301-796-6897, email: Samantha.jacobs@fda.hhs.gov; or Danica Marinac-Dabic, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4113, Silver Spring, MD 20993, 301-796-6689, email: danica.marinac-dabic@fda.hhs.gov.

Registration: There is no fee to attend the public workshop, but attendees must register in advance. Registration will be on a first-come, first-served basis. Persons interested in attending this workshop must register online at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ by November 25, 2011. Non-U.S. citizens are subject to additional security screening, and they should register as soon as possible. For those without Internet access, please call the contact person to register. Onsite registration is not available.

If you need special accommodations due to a disability, please contact Susan Monahan at susan.monahan@fda.hhs.gov at least 7 days in advance.

Comments: Regardless of attendance at the public workshop, interested persons may submit either electronic or written comments until [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. 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. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific topics as outlined in section III of this document, please identify the topic 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.

SUPPLEMENTARY INFORMATION:

I. Why Are We Holding This Public Workshop?

The purpose of the public workshop is to facilitate discussion among FDA, governmental agencies, academia, clinicians, and the key stakeholders in the scientific community on issues related to evidence generation and evaluation for surgical devices and procedures. Based on complementary methodological frameworks of the IDEAL and TPLC initiatives, more comprehensive and applicable models and methodologies will be developed.

II. Who Is the Target Audience for This Public Workshop? Who Should Attend This Public Workshop?

This workshop is open to all interested parties. The target audience is comprised of professionals in the scientific community interested in advancing the infrastructure and methodology for evaluating surgical devices and procedures.

III. What Are the Topics We Intend to Address at the Public Workshop?

We intend to discuss a large number of issues at the workshop, including, but not limited to, the following:

- The IDEAL and the FDA TPLC approach for evaluation of new medical devices, surgical operations, and invasive medical procedures;
- Unique study designs and reporting methods for evaluation of medical devices and surgeries;
- Innovative methodologies and scientific infrastructure to promote innovation;
- The role of registries and observational studies during device life cycle; and
- Integrating innovation, evaluation, and dissemination pathways for medical devices, surgical operations, and invasive medical procedures.

IV. Where Can I Find Out More About This Public Workshop?

Background information on the public workshop, registration information, the agenda, information about lodging, and other relevant information will be posted, as it becomes available, on the Internet at http://www.fda.gov/cdrh/meetings.html.

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 (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. 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.

Dated: November 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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