have been approved under OMB control number 0910–0130.

### III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

### IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: November 1, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–28726 Filed 11–4–11; 8:45 am]

**BILLING CODE 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 January 6, 2012.

*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 January 6, 2012. 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.*

[FR Doc. 2011–28722 Filed 11–4–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–N–0690]**

### Product Shortage Report; Availability; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a medical product shortage report entitled ''A Review of FDA's Approach to Medical Product Shortages.'' The Agency is making the report available by placing it in the docket opened for a previous public workshop on drug shortages. The report discusses the Agency's approach to product shortages, particularly those products regulated by the FDA Center for Drug Evaluation and Research (CDER). FDA requests comments, until December 23, 2011, on the report and its recommendations, including whether there are additional suggestions for recommendations and how we should prioritize work on these recommendations.

**DATES:** Submit either electronic or written comments by December 23, 2011.

**ADDRESSES:** 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.

**FOR FURTHER INFORMATION CONTACT:** Peter Lurie, Office of Policy and Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4220, Silver Spring, MD 20993–0002, (301) 796–4800.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

In the **Federal Register** of September 29, 2011 (76 FR 60505), FDA opened a comment period for a public workshop notice which published in the **Federal Register** of July 28, 2011 (76 FR 45268). This document announces the availability of a product shortage report by placing it in the docket of the public workshop on drug shortages. This report provides background information on product shortages, discusses four FDA product centers' various approaches to addressing product shortages, particularly those in CDER, and includes recommendations for FDA and others. FDA is requesting comment on the report and its recommendations, including whether there are additional suggestions for recommendations and how we should prioritize work on these recommendations.

#### II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm275051.htm* or *http://www.regulations.gov.*

Dated: October 31, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–28723 Filed 11–4–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Proposed Eligibility Criteria for the Centers of Excellence Program in Health Professions Education for Under-Represented Minority Individuals

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice requests comments on proposed eligibility criteria for the Centers of Excellence (COE) program in health professions education for under-represented minority (URM) individuals (See Title VII, Section 736 of the Public Health Service Act, 42 U.S.C. 293 (2011) as amended by the Patient Protection and Affordable Care Act, Public Law 111–148, § 5401 (2010)). When finalized, these eligibility criteria will be used to determine the eligibility of designated health professions schools to apply for COE funding in fiscal year (FY) 2012 and subsequent fiscal years. Funding is dependent on the availability of appropriated funds for the COE program. The designated health professions schools are schools of allopathic medicine, osteopathic medicine, dentistry, pharmacy, and graduate programs in behavioral or mental health. This does not apply to Historically Black Colleges and Universities (HBCUs) eligible to establish a COE, under PHS Act section 736(c)(2).

**DATES:** Interested persons are invited to comment within 30 days of the publication of this notice. All comments received on or before those 30 days complete will be considered.

**ADDRESSES:** All written comments concerning this notice should be submitted to Dr. Joan Weiss, Director, Division of Public Health and Interdisciplinary Education, at the contact information below.

**FOR FURTHER INFORMATION CONTACT:** Anyone requesting additional details should contact Dr. Joan Weiss, Bureau of Health Professions, Health Resources and Services Administration. Dr. Weiss may be reached in one of three following methods: (1) Via written request to: Dr. Joan Weiss, Designated Federal Official, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 9–36, 5600 Fishers Lane, Rockville, Maryland 20852; (2) via