## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–N–0062]**

### Medical Device Innovation Initiative; Public Meeting; Request for Comments

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

**ACTION:** Notice of public meeting; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting entitled "CDRH's Medical Device Innovation Initiative Public Workshop." The purpose of the public meeting is to solicit feedback on select actions outlined in the Center for Devices and Radiological Health's (CDRH) document, "Medical Device Innovation Initiative" (report). FDA is seeking input on a number of identified challenges associated with incentivizing innovation, and the proposed solutions. In addition, the Agency requests comments on the Innovation Pathway proposed under the report.

**DATES:** The public meeting will be held on March 15, 2011, from 8 a.m. to 5:30 p.m. Persons interested in attending and/or participating in the meeting must register by 5 p.m. on March 4, 2011.

**ADDRESSES:** The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 3502, Silver Spring, MD 20993. A live Webcast of this meeting will be viewable on the day of the meeting at *http://fda.yorkcast.com/webcast/Viewer/?peid=fae7c7ac49174d159e49e8d83aaf3b9d*. Closed captioning for this Webcast will be available at *http://www.speche.com/sbload.aspx?Load=Web,All,New&Height=90%&Width=100%&ClientID=31213*.

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.

*Contact Person:* Jonathan Sackner-Bernstein, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Avenue, Bldg. 66, Rm. 5410, Silver Spring, MD 20993, 301–796–5420, e-mail: *jonathan.sackner-bernstein@fda.hhs.gov*.

*Registration and Requests for Oral Presentations:* If you wish to attend the public meeting, you must register online at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm241095.htm*. Provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Registration requests should be received by March 4, 2011.

If you wish to make an oral presentation during any of the open comment sessions at the meeting, you must indicate this at the time of registration. FDA has included general discussion topics and specific questions for comment in this document. You should also identify which discussion topic you wish to address in your presentation. In order to keep each open session focused on the discussion topic at hand, each oral presentation should address only one discussion topic. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and to request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is to begin.

Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the public meeting will be provided on a space-available basis beginning at 7 a.m.

Non-U.S. citizens are subject to additional security screening, and they should register as soon as possible. If you need special accommodations due to a disability, please contact Susan Monahan, *susan.monahan@fda.hhs.gov,* 301–796–5661, at least 7 days in advance of the public meeting.

**SUPPLEMENTARY INFORMATION:**

## I. Background

The United States is the global leader in medical device innovation and CDRH is committed to assuring that American patients have timely access to important new technologies and next-generation products without compromising their safety. Each year, millions of American patients benefit from innovative medical devices that reduce suffering, treat previously untreatable conditions, extend lives, and improve public health.

CDRH is responsible for advancing public health and facilitating innovation to help bring novel technologies to market and make the medical devices that are already on the market safer and more effective. Recently, CDRH announced 25 actions it will take in 2011 to strengthen its most widely-used premarket review process—the 510(k) program—and increase its use of emerging science to foster innovation and improve the predictability, consistency, and transparency of its decisionmaking.[1] These actions will not only improve the safety of medical devices but also increase the ability of innovating companies to attract investors, estimate costs, and more quickly bring products to market.

The Medical Device Innovation Initiative proposes the following actions CDRH might take to help accelerate the development and regulatory evaluation of innovative devices safely and based on sound science:

- Facilitate the development and regulatory evaluation of innovative medical devices;
- Strengthen the U.S. research infrastructure and promote high-quality regulatory science; and
- Prepare for, and respond to, transformative innovative technologies and scientific breakthroughs.

Part of the Medical Device Innovation Initiative would consider the creation of a special Innovation Pathway intended to provide earlier investment of CDRH time and resources in devices that are true pioneering technologies and that have the potential to revolutionize patient care or health care delivery. By front-loading critical aspects, such as identifying clinical endpoints and key scientific questions, and seeking advice from external experts, the Innovation Pathway would facilitate a more efficient regulatory review process for transformative devices.

The objective of this public meeting is to receive public input on the proposals to facilitate medical device innovation as set forth in the report. The public meeting's focus includes the following areas:

- The Innovation Pathway and Horizon Scanning (morning session)
- Clinical Test Center Certification, Core Curriculum for Medical Device Development, and Regulatory Science (afternoon session)

During the meeting, FDA staff will present a brief overview of each of the previously listed areas. Each of the FDA presentations will be followed by an open comment session, during which members of the public may present oral comments related to the topic under

[1] See "*510(k) and Science Report Recommendations: Summary and Overview of Comments and Next Steps*." Available at *http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM239449.pdf*, and "Plan of Action for Implementation of 510(k) and Science Recommendations." Available at *http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM239450.pdf*.

discussion. As described previously in this document, individuals who are interested in making an oral presentation during any of the open comment sessions must indicate this at the time of registration, must identify which discussion topic they intend to address (*see Registration and Requests for Oral Presentations*), and must submit their presentations in advance. In order to keep each open session focused on the discussion topic at hand, each oral presentation should address only one discussion topic. Commenters are free to submit comments on any discussion topic(s) to the open docket (*see* II. Comments). FDA will schedule speakers for each open session as time permits.

After each of the open comment sessions, there will be a panel discussion between FDA staff and selected participants representing a range of constituencies. The participants in the panel discussions will reflect on the presentations and comments, engage in a dialogue with each other and FDA staff, and provide closing thoughts for each session. The participants will not be asked to develop consensus opinions during the discussion, but rather to provide their individual perspectives. Others in attendance at the meeting will have an opportunity to listen to the panel discussions.

In advance of the meeting, additional information, including a meeting agenda with a speakers' schedule for each open comment session, will be made available on the Internet. This information will be placed on file in the public docket (docket number found in brackets in the heading of this document), which is available at *http://www.regulations.gov*. This information will also be available at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm241095.htm*.

## II. Comments

FDA is holding this public meeting to obtain information on a number of questions regarding medical device innovation. The deadline for submitting comments related to this public meeting is March 15, 2011.

Regardless of attendance at the public meeting, interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments. 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 questions as outlined in 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.

## III. 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 hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, Rm. 6–30, Rockville, MD 20857.

Dated: February 4, 2011.

**Nancy K. Stade,**

*Deputy Director for Policy, Center for Devices and Radiological Health.*

[FR Doc. 2011–2915 Filed 2–8–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Advisory Committee on Organ Transplantation; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

*Name:* Advisory Committee on Organ Transplantation.

*Date and Times:* March 8, 2011, 7:30 a.m. to 5 p.m.

*Place:* Georgetown University Hotel and Conference Center, 3800 Reservoir Road, NW., Washington, DC 20057.

*Status:* The meeting will be open to the public.

*Purpose:* Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, and 42 CFR 121.12 (2000), ACOT was established to assist the Secretary in enhancing organ donation, ensuring that the system of organ transplantation is grounded in the best available medical science, and assuring the public that the system is as effective and equitable as possible, and, thereby, increasing public confidence in the integrity and effectiveness of the transplantation system. ACOT is composed of up to 25 members, including the Chair. Members are serving as Special Government Employees and have diverse backgrounds in fields such as organ donation, health care public policy, transplantation medicine and surgery, critical care medicine and other medical specialties involved in the identification and referral of donors, non-physician transplant professions, nursing, epidemiology, immunology, law and bioethics, behavioral sciences, economics and statistics, as well as representatives of transplant candidates, transplant recipients, organ donors, and family members.

*Agenda:* The Committee will hear reports from two ACOT Work Groups: Declining Rates of Donation/Geographical and Other Variations in Organ Distribution and Alignment of CMS Regulatory Requirements with OPTN. ACOT also will hear presentations on disease transmission and informed consent, transplant tourism, organ donation and transplantation alliance, a report on an intensive DMV outreach project demonstrating significant increases in Michigan donor registration, and OPO performance metrics for quality improvement. Agenda items are subject to change as priorities indicate.

After the presentations and Committee discussions, members of the public will have an opportunity to provide comments. Because of the Committee's full agenda and the timeframe in which to cover the agenda topics, public comment will be limited. All public comments will be included in the record of the ACOT meeting. Meeting summary notes will be made available on the Department's donation Web site at *http://www.organdonor.gov/acot.html.*

The draft meeting agenda is available on the Department's donation Web site at *http://www.organdonor.gov/acot.html* and at *http://www.team-psa.com/dot/spring2011/ACOT/.*

Registration can be completed electronically at *http://www.team-psa.com/dot/spring2011/ACOT/* or submitted by facsimile to HRM/Professional and Scientific Associates (PSA), the logistical support contractor for the meeting, at fax number (703) 234–1701 ATTN: Brittany Carey. Individuals without access to the Internet who wish to register may call Brittany Carey with HRM/PSA at (703) 889–9033.

**FOR FURTHER INFORMATION CONTACT:** Patricia A. Stroup, MBA, MPA, Executive Secretary, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 12–105, Rockville, Maryland 20857; telephone (301) 443–1127 or e-mail to *pstroup@hrsa.gov.*