DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. FDA–2010–N–0001]

Town Hall Discussion With the Director of the Center for Devices and Radiological Health and Other Senior Center Management

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing a public meeting entitled: “Town Hall Discussion With the Director of the Center for Devices and Radiological Health and Other Senior Center Management.” The purpose of this meeting is to present the Center for Devices and Radiological Health (CDRH) fiscal year (FY) 2010 priorities. In addition, FDA is interested in engaging in discussions about issues that are of importance to the medical device industry.

Dates and Time: The public meeting will be held on May 18, 2010, from 9 a.m. to 4 p.m.

Location: The public meeting will be held at the Hilton Minneapolis, Saint Paul Airport, 3800 American Blvd. East, Bloomington, MN, 55425–1658. The meeting will not be videotaped or webcast.

Contact Person: Heather Howell, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66 (rm. 4320), Silver Spring, MD 20993, 301–796–5718, e-mail: heather.howell@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/ucm206671.htm. Provide complete contact information for each attendee, including: Name, title, company or organization, address, e-mail, and telephone number. Registration requests must be received by 5 p.m. on Wednesday, May 5, 2010.

If you wish to make an oral presentation during any of the sessions at the meeting (see section II of this document), you must indicate this at the time of registration. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their requests for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled 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 8 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan at 301–796–5661 or susan.monahan@fda.hhs.gov at least 7 days in advance of the meeting.

Comments: FDA is holding this public meeting to share information and discuss issues of importance to the medical device industry. CDRH is specifically interested in addressing the following question: What mechanism(s) would you prefer or suggest for FDA to engage with the industry? The deadline for responding to this question and for submitting other comments related to this public meeting is Wednesday, May 5, 2010.

Regardless of attendance at the public meeting, interested persons may submit electronic or written comments. 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. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments will be placed on file in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION:

I. Background

CDRH has announced four priority areas of activity for fiscal year 2010, each of which presents significant opportunities to improve the Center’s effectiveness in fulfilling our public health mission. More information, including specific goals and actions associated with each priority, is available under “CDRH Strategic Planning” at: www.fda.gov/AboutFDA/CentersOffices/CDRH.

II. Public Meeting

The objective of this public meeting is to present CDRH FY 2010 priorities. In addition, FDA is interested in engaging in discussions about issues that are of importance to the medical device industry. CDRH wishes to obtain feedback/ideas for facilitating two-way communication between CDRH and the medical device industry.

The meeting will open with an introduction of CDRH Senior Staff in attendance. Following introductions, Jeffrey Shuren, the Director of CDRH, will present the FY 2010 CDRH priorities. Industry representatives and other members of the public will then be given the opportunity to present comments to CDRH Senior Staff. Attendees from CDRH may respond to questions presented by industry and other members of the public.

In advance of the meeting, additional information, including a meeting agenda with a speakers’ schedule, 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/default.htm (select the appropriate meeting from the list).

III. Transcripts

Transcripts of the public meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane,.rm. 6–30, Rockville, MD 20857, approximately 15 working days after the public meeting at a cost of 10 cents per page. A transcript of the public meeting will be available on the Internet at http://www.regulations.gov.


Leslie Kux,
Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose

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