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

U.S. Food & Drug Administration

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[Notices]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0321]

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.
Date and Time: The public meeting will be held on October 7, 2010, from 8 a.m. to 12 noon.
Location: The public meeting will be held at the Hilton Irvine/ Orange County Airport Hotel, 18800 MacArthur Blvd., Irvine, CA 92612. The meeting will not be videotaped or webcast.
Contact: Heather Howell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg.

66, rm. 4320, Silver Spring, MD 20993, 301-796-5718, email: heather.howell@fda.hhs.gov [1].
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/ucm215113.htm [2]. Those without Internet access may contact Heather Howell (see Contact).
Provide complete contact information for each attendee, including name, title, company or organization, address, email, telephone and fax number. Registration requests must be received by 5 p.m. on Wednesday, September 22, 2010.
If you wish to make an oral presentation during any of the discussions at the meeting (see section II of this document, Public Meeting), 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 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 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 7 a.m.
If you need special accommodations due to a disability, please contact Susan Monahan at 301-796-5661 or by email: susan.monahan@fda.hhs.gov [3] at least 7 days in advance.
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

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engage with industry? The deadline for responding to this question and for submitting other comments related to this public meeting is September 22, 2010.
Regardless of attendance at the public meeting, interested persons may submit either electronic or written comments regarding this document. Submit electronic comments to http://www.regulations.gov [5]. 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. 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. Background

CDRH has announced four priority areas of activity for FY 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 [6].

II. Public Meeting

The objective of this public meeting is to present the 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, Dr. 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 [5]. This information will also be available at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm [7] (select the appropriate meeting from the list).

III. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at http://www.regulations.gov [5]. The transcript 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 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: July 8, 2010.
Nancy Stade,

Acting Associate Director for Regulations and Policy, Center for
Devices and Radiological Health.
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SOURCE [8]

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[8] http://edocket.access.gpo.gov/2010/2010-17068.htm