

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0496]

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 public meeting in San Francisco, CA, is to engage in a dialogue about issues of importance to FDA's Center for Devices and Radiological Health (CDRH) and to members of the public, including the medical device industry, health care professionals, patients, and consumers.

Date and Time: The public meeting will be held on Thursday, September 22, 2011, from 8 a.m. to 12 noon PDT.

Location: The public meeting will be held at the Embassy Suites Hotel, San Francisco Airport, 250 Gateway Blvd., South San Francisco, CA 94080. Attendees requiring overnight accommodations should call 650-589-3400 and request the group rate for the "FDA/CDRH Town Hall Meeting" block of rooms.

Contact: Heather Howell, Center for Devices and Radiological Health, Food and Drug Administration, 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/ucm258228.htm>. Persons without Internet access may call Heather Howell at 301-796-5718 to register for the meeting.

Provide complete contact information for each attendee, including name, title, company or organization, address, e-mail, and telephone and fax number. Registration requests must be received by 5 p.m. EDT on Friday, September 9, 2011.

The meeting will not be videotaped or Web cast.

If you wish to make an oral presentation during the 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 the day of the public meeting will be provided on a space-available basis beginning at 7 a.m. PDT on September 22, 2011.

If you need special accommodations due to a disability, please contact Susan Monahan, 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 public, including the medical device industry, health care professionals, patients, and consumers.

Regardless of attendance at the public meeting, interested persons may submit either 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. 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

In 2010, CDRH held three Town Hall meetings in Minneapolis, MN, Boston, MA, and Los Angeles, CA, to provide the public with a new venue to discuss issues of interest with the Center. Any member of the public was invited to provide comments to or ask questions of CDRH participants. We received positive feedback on these meetings and are continuing this activity in 2011 in three new locations. This year we have held two meetings: one in Dallas, TX, and one in Orlando, FL. The meeting in

San Francisco will be our final meeting of 2011.

II. Public Meeting

The objective of this public meeting is to engage in a dialogue about issues that are of importance to the public.

The public meeting will open with an introduction of CDRH senior staff in attendance. Following introductions, Dr. Jeffrey Shuren, the Director of CDRH, will describe CDRH's strategic priorities for 2011. Members of the public will then be given the opportunity to present comments to CDRH senior staff followed by a question and answer session during which any member of the public may ask questions of the CDRH senior staff on any topic of interest.

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

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 20852. 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 (HF1-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

Dated: July 11, 2011.

Nancy K. Stade,

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

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