

specific topic evaluated by the ICH Q4B process.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

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 <http://www.regulations.gov>, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>.

Dated: July 8, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-17055 Filed 7-13-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant

applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel, HIV/AIDS Intervention Development.

Date: July 22, 2010.

Time: 9 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call)

Contact Person: Enid Light, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6132, MSC 9608, Bethesda, MD 20892-9608. 301-443-0322. elight@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: July 8, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-17129 Filed 7-13-10; 8:45 am]

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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.

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>. 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 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