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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on this topic.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]

BILLING CODE 4160–01–S

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]

BILLING CODE 4140–01–P

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

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*. 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*.

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*. 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*. 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.

[FR Doc. 2010–17068 Filed 7–13–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number NIOSH 141–A]

Preventing Deaths and Injuries of Fire Fighters Using Risk Management Principles at Structure Fires

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of issuance of Final Guidance Publication.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the availability of the publication entitled "Preventing Deaths and Injuries of Fire Fighters Using Risk Management Principles at Structure Fires."

The final document can be found at: *http://www.cdc.gov/niosh/docs/2010-153/*.

Background and Summary of Document: NIOSH has developed this publication to assist the U.S. fire service in preventing fire fighter injuries and deaths at structure fires. Established fire service risk management principles suggest that caution should be exercised in abandoned, vacant and unoccupied structures and in situations where there is no clear evidence indicating that people are trapped inside the structure and can be saved. This publication summarizes fatality statistics from the National Fire Protection Association as well as the NIOSH Fire Fighter Fatality Investigation and Prevention Program (FFFIPP) databases. The publication describes four case studies on the deaths of five fire fighters and injuries to 10 others during fire suppression operations in and around structures with considerable fire involvement where there were indications that the structures were unoccupied. The publication presents a number of recommendations for preventing similar occurrences of fire fighter injuries and deaths. The primary audiences are expected to be fire commissioners, fire chiefs, fire department and municipal managers, fire fighters, labor unions, safety and health professionals, trainers, fire investigators, State fire marshals, and other interested parties.

This guidance publication does not have the force and effect of law.

Document Review Process: Following development of the initial draft, the document was reviewed by peers and external stakeholders within the fire service and revisions were made based upon these reviews. The revised draft document was posted in the **Federal Register** for public review and comment from January 5 to March 9, 2009. Public comments submitted to NIOSH Public Docket 141 can be viewed at the Web site *http://www.cdc.gov/niosh/docket/nioshdocket0141.html*. The draft document was revised to address these public comments. The most substantive revisions were to change the title and focus of the document from fighting fires in unoccupied structures to using established risk management principles at all structure fires, regardless of the occupancy status. The majority of comments received during the public comment period made it clear that the U.S. fire service would not support the recommendation that fire fighters avoid entering unoccupied structures, the focus of the original draft. A final draft containing revisions made to address comments received during the public comment period was reviewed by representatives from both the International Association of Fire Chiefs (IAFC) and the International Association of Fire Fighters (IAFF).

FOR FURTHER INFORMATION CONTACT: Timothy R. Merinar, Safety Engineer, Division of Safety Research, CDC/