

authority to approve and issue regulations.

This delegation became effective upon date of signature. In addition, I affirm and ratify any actions taken by the Director, Centers for Disease Control and Prevention, or his/her subordinates which involved the exercise of authorities delegated herein prior to the effective date of the delegation.

**Kathleen Sebelius,**

*Secretary.*

[FR Doc. 2010-17196 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-0344]

#### International Conference on Harmonisation; Draft Guidance on Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 13 on Bulk Density and Tapped Density of Powders General Chapter; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 13: Bulk Density and Tapped Density of Powders General Chapter." The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance provides the results of the ICH Q4B evaluation of the Bulk Density and Tapped Density of Powders General Chapter harmonized text from each of the three pharmacopoeias (United States, European, and Japanese) represented by the Pharmacopoeial Discussion Group (PDG). The draft guidance conveys recognition of the three pharmacopoeial methods by the three ICH regulatory regions and provides specific information regarding the recognition. The draft guidance is intended to recognize the interchangeability between the local regional pharmacopoeias, thus avoiding redundant testing in favor of a common testing strategy in each regulatory region. This draft guidance is the thirteenth annex to the core Q4B

guidance, which was made available in the **Federal Register** of February 21, 2008 (73 FR 9575).

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 13, 2010.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance 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.

**FOR FURTHER INFORMATION CONTACT:**

*Regarding the guidance:* Robert H. King, Sr., Center for Drug Evaluation and Research (HFD-003), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4150, Silver Spring, MD 20993-0002, 301-796-1242; or Christopher Joneckis, Center for Biologics Evaluation and Research (HFM-25), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-0373.

*Regarding the ICH:* Michelle Limoli, Office of International Programs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4480.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international

harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In June 2010, the ICH Steering Committee agreed that a draft guidance entitled "Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 13: Bulk Density and Tapped Density of Powders General Chapter" should be made available for public comment. The draft guidance is the product of the Q4B Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Q4B Expert Working Group.

The draft guidance provides the specific evaluation results from the ICH Q4B process for the Bulk Density and Tapped Density of Powders General Chapter harmonization proposal originating from the three-party PDG. This draft guidance is in the form of an annex to the core ICH Q4B guidance. Once finalized, the annex will provide guidance to assist industry and regulators in the implementation of the

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](mailto: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](mailto: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](mailto: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