DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0013]

International Conference on Harmonisation; Guidance on Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 8 on Sterility Test General Chapter; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 8: Sterility Test General Chapter.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance provides the results of the ICH Q4B evaluation of the Sterility Test General Chapter harmonized text from each of the three pharmacopoeias (United States, European, and Japanese) represented by the Pharmacopoeial Discussion Group (PDG). The guidance conveys recognition of the three pharmacopoeial methods by the three ICH regulatory regions and provides specific information regarding the recognition. The 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. In the **Federal Register** of February 21, 2008 (73 FR 9575), FDA made available a guidance on the Q4B process entitled ''Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions.''

DATES: Submit written or electronic comments on agency guidance at any time.

ADDRESSES: Submit written requests for single copies of the 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, suite 200N, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send two self-addressed adhesive labels to assist the office in processing your requests. Requests and comments should be identified with the docket number found in brackets in the heading of this document. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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 the **Federal Register** of February 17, 2009 (74 FR 7446), FDA published a notice announcing the availability of a draft tripartite guidance entitled ''Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 8: Sterility Test General Chapter.'' The notice gave interested persons an opportunity to submit comments by April 20, 2009.

After consideration of the comments received and revisions to the guidance, a final draft guidance entitled ''Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 8: Sterility Test General Chapter'' was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in June 2009.

The guidance provides the specific evaluation outcome from the ICH Q4B process for the Sterility Test General Chapter harmonization proposal originating from the three-party PDG. This guidance is in the form of an annex to the core ICH Q4B guidance. When implemented, the annex will provide guidance for industry and regulators on the use of the specific pharmacopoeial texts evaluated by the ICH Q4B process. Following receipt of comments on the draft, no substantive changes were made to the annex.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written comments on the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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/Guidances/default.htm*.

Dated: December 16, 2009.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning, and Budget.

[FR Doc. E9–30326 Filed 12–21–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; 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 material, 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 Center for Research Resources Special Emphasis Panel; SBIR Contract.

Date: January 21, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Hilton, 620 Perry Parkway, Gaithersburg, MD 20877.

Contact Person: Guo Zhang, PhD, Scientific Review Officer, National Center For Research Resources, or National Institutes of Health, 6701 Democracy Blvd., 1 Democracy Plaza, ROOM 1064, MSC 4874, Bethesda, MD 20892–4874, 301–435–0812, *zhanggu@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93.333; 93.702, ARRA Related Construction Awards, National Institutes of Health, HHS)

Dated: December 16, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–30391 Filed 12–21–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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 material, 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Nephrolithiasis Program Project.

Date: February 25, 2010.

Time: 1 p.m. to 5 p.m.

*Agenda:*To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Atul Sahai, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 759, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–2242, *sahaia@niddk.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: December 16, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–30393 Filed 12–21–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, January 6, 2010, 1 p.m. to January 6, 2010, 3 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on December 8, 2009, 74 FR 64703.

The starting time of the meeting on January 6, 2010 has been changed to 11 a.m. until adjournment at 1p.m.

The meeting date and location remain the same. The meeting is closed to the public.

Dated: December 16, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–30395 Filed 12–21–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.