notice announcing the availability of a draft tripartite guidance entitled “Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 9: Tablet Friability General Chapter.” The notice gave interested persons an opportunity to submit comments by October 13, 2009.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance entitled “Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 9: Tablet Friability General Chapter” was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in October 2009. The guidance provides the specific evaluation outcome from the ICH Q4B process for the Tablet Friability 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 made available in the Federal Register of February 21, 2008 (73 FR 9575). When implemented, this 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 submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding this document. 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 or http://www.fda.gov/Drugs/ComplianceEnforcement/ComplianceGuidance SOP/default.htm. See the 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, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4150, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development (HFM–25), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

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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 7447), 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 7: Dissolution 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 7: Dissolution Test General Chapter” was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in October 2009.

The guidance provides the specific evaluation outcome from the ICH Q4B process for the Dissolution 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 made available in the Federal Register of February 21, 2008 (73 FR 9575). 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.

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III. Electronic Access


Dated: March 31, 2010.

Leslie Kux,
Acting Assistant Commissioner for Policy.

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging: Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, NIA.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute on Aging, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIA.

Date: May 11–12, 2010.

Closed: May 11, 2010, 8 a.m. to 3:40 a.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Open: May 11, 2010, 8:30 a.m. to 12 p.m.

Agenda: Committee Discussion.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Closed: May 11, 2010, 12 p.m. to 1:15 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Closed: May 11, 2010, 4:15 p.m. to 4:30 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Open: May 11, 2010, 4:30 p.m. to 5 p.m.

Agenda: Committee Discussion.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Closed: May 12, 2010, 8 a.m. to 9 a.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Open: May 12, 2010, 9 a.m. to 11:30 a.m.

Agenda: Committee Discussion.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.