proposed project or to obtain a copy of the data collection reports and instrument, contact Kathy Kranzfelder, Director, NIDDK Office of Communications and Public Liaison, Building 31, Room 9A06, MSC2560, Bethesda, MD 20852 or e-mail your request, including your address to: KranzfelderK@mail.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: July 6, 2010.

Lynell Nelson, NIDDK, Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2010–17581 Filed 7–16–10; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0343]


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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled “Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 14: Bacterial Endotoxins Test General Chapter.” The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use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 The draft guidance provides the results of the ICH Q4B evaluation of the Bacterial Endotoxins Test General Chapter harmonized text from each of the three pharmacopoeias (United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 The draft guidance conveys recognition of the three pharmacopoeial methods by the three ICH regulatory regions and provides specific information regarding the recognition. The draft guidance is intended to recognize the interchangeability between the local regional pharmacopoeias, thus avoiding redundant testing in favor of a common testing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 This draft guidance is the 14th annex to the core guidance on the Q4B process entitled “Q4B Evaluation and Recommendation of Pharmaceutical Texts for Use in the ICH Regions” (the core ICH Q4B guidance).

DATES: Although you can comment on any guidance at any time (see 21 CFR 418.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 14, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm.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 (HF–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label tape 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.


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 14: Bacterial Endotoxins Test 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 Bacterial Endotoxins Test 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 made available in the Federal Register of February 21, 2008 (73 FR 9575). 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. Interested persons may sign up for electronic mail notifications of new filings. The document can be accessed by searching for Docket Number HFD-001-09.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Child Health and Human Development Special Emphasis Panel, July 16, 2010, 10 a.m. to July 16, 2010, 12 p.m., National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852 which was published in the Federal Register on June 28, 2010, 75 FR 36662.

The date of the meeting has been changed from July 16, 2010 to August 9, 2010. The meeting is closed to the public.

Dated: July 12, 2010.

Jennifer Spaeth,
Director, Office of Federal Advisory Committee Policy.