submitted for approval;

- The agency and the regulated industry agree to explore opportunities for exchange of information regarding the characteristics of a new animal drug, and to identify safety and effectiveness issues as early as possible in the drug development process; and
- The agency and regulated industry commit to work together to explore shorter timeframes commensurate with the magnitude of submitted pharmacokinetic/pharmacodynamic and other new animal drug characteristic data/information.

C. Improving the Information Technology (IT) Infrastructure for Animal Drug Review

In the recommended IT performance goals for ADUFA II, FDA will develop an electronic submission tool for industry submissions and online review capability within 24 months of appropriated ADUFA funds for FY 2009. The agency will consult with the sponsors in the development of this tool.

III. What Information Should You Know About the Meeting?

A. When and Where Will the Meeting Occur? What Format Will FDA Use?

Through this document, FDA is announcing the convening of a public meeting to hear stakeholder views on the recommendations we propose to provide to Congress on the reauthorization of ADUFA.

FDA will conduct the meeting at 1 p.m. on March 11, 2008, at 7519 Standish Pl., third floor, rm. A, Rockville, MD 20855. In general, the meeting format will include presentations by FDA and an open comment period for the public. FDA will also give organizations and individuals an opportunity to submit written comments to the docket after the meeting.

B. Will Meeting Transcripts Be Available?

FDA will prepare a meeting transcript and make it available on the agency's Web site (*www.fda.gov*) after the meeting. FDA anticipates that transcripts will be available approximately 30 business days after the meeting.The transcript will also be available for public examination at the Division of Dockets Management (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 14, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–3267 Filed 2–20–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0081 (formerly Docket No. 2006D–0297)]

International Conference on Harmonisation; Guidance on Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; 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.'' 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 describes a process for the evaluation and recommendation by the ICH Q4B Expert Working Group (EWG) of selected pharmacopeial texts to facilitate their recognition by regulatory authorities for use as interchangeable in the ICH regions. Following favorable evaluations, ICH will issue topic-specific annexes with information about these texts and their implementation (the Q4B Outcomes). Implementation of the Q4B annexes is intended to avoid redundant testing by industry in favor of a common testing strategy in each ICH regulatory region.

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

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, 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. 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. 21, rm. 3542, Silver Spring, MD 20993–0002, 301–796–1242;or

Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–20), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–435–5681.

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

FDA is announcing the availability of a guidance entitled ''Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions.'' 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 August 8, 2006 (71 FR 45059), FDA published a notice announcing the availability of a draft guidance entitled ''Q4B Regulatory Acceptance of Analytical Procedures and/or Acceptance Criteria.'' The notice gave interested persons an opportunity to submit comments by October 10, 2006.

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'' was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in November 2007.

The guidance provides information on a Q4B process for evaluating harmonization proposals for specific pharmacopeial topics originating from the three-party Pharmacopoeial Discussion Group (PDG) or from individual PDG pharmacopeias. The PDG consists of representatives from the European Directorate for the Quality of Medicines in the Council of Europe; the Japanese Ministry of Health, Labour and Welfare, and the United States Pharmacopeial Convention, Inc. The results of the individual Q4B evaluations will move forward as topic-specific annexes to the core Q4B guidance. Each annex will be issued separately following the ICH step process, providing guidance to assist industry and regulators in the implementation of the specific topic evaluated by the ICH Q4B process. Following the receipt of comments on the draft guidance, the Q4B EWG made no substantive changes to the Q4B process or the use of annexes to convey the results of Q4B evaluations. The title of the guidance, as well as some of the text, was revised to more closely reflect the actual workings and process of the Q4B EWG.

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 Q4B evaluation and recommendation of pharmacopoeial texts for use in the ICH regions. 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.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

III. Electronic Access

Persons with access to the Internet may obtain the document at*http://www.fda.gov/ohrms/dockets/default.htm, http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/publications.htm*.

Dated: February 12, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–3186 Filed 2–20–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0083 (formerly Docket No. 2006D–0296)]

International Conference on Harmonisation; Guidance on Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex on Residue on Ignition/Sulphated Ash 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 1: Residue on Ignition/Sulphated Ash 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 Residue on Ignition/Sulphated Ash General Chapter harmonized text from each of the three pharmacopeias (United States, European, and Japanese) represented by the Pharmacopoeial Discussion Group (PDG). The guidance conveys recognition of the three pharmacopeial methods by the three ICH regulatory regions and provides specific information regarding the recognition. The guidance is intended to recognize the interchangeability among these texts from the local regional pharmacopeias, thus avoiding redundant testing in favor of a common testing strategy in each regulatory region. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of 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, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training and Manufacturers Assistance (HFM–40),