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In June 2006, the ICH Steering Committee agreed that a draft guidance entitled "Q4B Regulatory Acceptance of Analytical Procedures and/or Acceptance Criteria; Annex 1: Residue on Ignition/Sulfated Ash General Chapter" should be made available for public comment. The draft guidance is the product of the Q4B Quality Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Q4B Quality Expert Working Group.

The draft guidance provides the specific evaluation outcome from the ICH Q4B process for the Residue on Ignition/Sulphated Ash General Chapter harmonization proposal originating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 This draft guidance is in the form of an annex to the core ICH Q4B guidance.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**) written or electronic comments on the draft 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. The draft guidance and 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.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/publications.htm*.

Dated: July 31, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–12806 Filed 8–7–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0297]

International Conference on Harmonisation; Draft Guidance on Q4B Regulatory Acceptance of Analytical Procedures and/or Acceptance Criteria; 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 Regulatory Acceptance of Analytical Procedures and/or Acceptance Criteria." 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 describes a procedure to facilitate acceptance by regulatory authorities of pharmacopoeial test methods (referred to in the draft guidance as analytical procedures and/or acceptance criteria (APAC)) for use in the three ICH regions. The draft guidance is intended to facilitate regulatory acceptance of these proposed test methods and their interchangeability with test methods contained in the local regional pharmacopoeias, thus avoiding redundant testing and different acceptance criteria in favor of a common testing strategy in each ICH regulatory region. Elsewhere in this issue of the**Federal Register**, FDA is announcing the availability of a draft guidance entitled "Q4B Regulatory Acceptance of Analytical Procedures and/or Acceptance Criteria; Annex 1: Residue on Ignition/Sulphated Ash General."

DATES: Submit written or electronic comments on the draft guidance by October 10, 2006.

ADDRESSES: Submit written comments on the draft 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.fda.gov/dockets/ecomments*. 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, 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft 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, 10993 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, 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

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.

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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 2006, the ICH Steering Committee agreed that a draft guidance entitled "Q4B Regulatory Acceptance of Analytical Procedures and/or Acceptance Criteria" should be made available for public comment. The draft guidance is the product of the Q4B Quality Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Q4B Quality Expert Working Group.

The draft guidance provides information on a Q4B process for evaluating harmonization proposals for specific APAC topics originating principally from the three-party Pharmacopoeial Discussion Group (PDG). 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. Once finalized, the Q4B guidance will describe the process for formally conveying the evaluation outcomes 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.

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.

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Dated: July 31, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–12807 Filed 8–7–06; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2006–25528]

Chemical Transportation Advisory Committee

AGENCY: Coast Guard, DHS.

ACTION: Notice of meeting.

SUMMARY: The Chemical Transportation Advisory Committee (CTAC), its Subcommittee on Hazardous Cargo Transportation Security (HCTS), as well as its Working Groups on MARPOL Annex II, Barge Hazard Communication and Vapor Control Systems (VCS) will meet to discuss various issues relating to the marine transportation of hazardous materials in bulk. These meetings will be open to the public.

DATES: The Working Group on MARPOL Annex II will meet on Tuesday, August 22, 2006, from 8:30 a.m. to 12 p.m. and the HCTS Subcommittee will meet on Tuesday, August 22, 2006 from 12:30 p.m. to 5 p.m. The Working Group on VCS will meet on Wednesday, August 23, 2006 from 8:30 a.m. to 12 p.m. and the Working Group on Barge Hazard Communication will meet on Wednesday, August 23, 2006, from 12:30 p.m. to 5 p.m. CTAC will meet on Thursday, August 24, 2006, from 9 a.m. to 3:30 p.m. These meetings may close early if all business is finished. Written material and requests to make oral presentations should reach the Coast Guard on or before August 18, 2006. Requests to have a copy of your material distributed to each member of the Committee should reach the Coast Guard on or before August 18, 2006.

ADDRESSES: The HCTS Subcommittee and the Working Groups on MARPOL Annex II, VCS, and Barge Hazard Communication will be held at American Commercial Barge Lines LLC, 1701 East Market Street, Jeffersonville, IN 47130. The CTAC meeting will be held at The Ramada Inn Jeffersonville, 700 W. Riverside Drive, Jeffersonville, IN 47130. Send written material and requests to make oral presentations to Commander Richard Raksnis, Executive Director of CTAC, Commandant (G-