FOR FURTHER INFORMATION CONTACT: Michael B. Fauntleroy, CBER (HFM–25), Food and Drug Administration, 11400 Rockville Pike, RKWL rm. 4119, Rockville, MD 20857, 301–827–5132, e-mail: *michael.fauntleroy@fda.hhs.gov* or William H. Taylor, Office of the Commissioner (HFA–83), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–45, Rockville, MD 20857, 301–255–6734, e-mail: *william.taylor@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: FDA receives a variety of electronic submissions under 21 CFR 11.2(b), including biological license applications (BLAs), new drug applications (NDAs), drug master files (DMFs), investigational new drug applications (INDs), and investigational device exemptions (IDEs), as well as their associated correspondence and other types of regulatory submissions. The FDA ESG supports the receipt and processing of electronic submissions through the use of a single point of entry.

The increasing number of electronic submissions highlights a critical need to automate and standardize the receipt of these submissions and their delivery to the appropriate centers. The FDA ESG automates the receipt, acknowledgment (to the applicant/sponsor), routing, and notification (to a receiving center) of electronic submissions via the Internet and meets the standards for the electronic exchange of information adopted by the American National Standards Institute (ANSI) and the National Institute of Standards and Technology (NIST).

The FDA ESG offers two secure communication options for applicants that have established gateway systems. One utilizes simple mail transfer protocol (SMTP) with secure multi-purpose internet mail extensions (S/MIME) to provide secure e-mail communication and the other supports faster information exchange and utilizes hypertext transfer protocol secure (HTTPS) to provide real-time Internet communication. The FDA ESG also offers a secure WebTrader submission option for applicants who do not have gateway systems. The WebTrader is a no-cost applet which can be downloaded from FDA and requires only a standard security certificate to provide the applicants with a secure Internet connection to FDA. The WebTrader addresses the need to expand participation in electronic submissions without costly expenditures for infrastructure upgrades and gateway systems.

Use of the FDA ESG is voluntary. Electronic format submissions may be made through the gateway or may continue to be made on physical media. Information on the FDA ESG is available on the following Web site: *http://www.fda.gov/esg/*. Except where FDA has promulgated regulations requiring submission in electronic format, applicants/sponsors may also continue to make regulatory submissions on paper.

If you wish to use the FDA ESG, you should send an e-mail to *esgprep@fda.gov* to begin the registration process. Include your name, phone number, and the name of the company you represent. Please state whether you are using the WebTrader, SMTP, or HTTPS for submissions.

Dated: July 31, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–12808 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–0296]

International Conference on Harmonisation; Draft Guidance on Q4B Regulatory Acceptance of Analytical Procedures and/or Acceptance Criteria; 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 draft guidance entitled ''Q4B Regulatory Acceptance of Analytical Procedures and/or Acceptance Criteria; Annex 1: Residue on Ignition/Sulphated Ash General.'' 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 outcome of the ICH Q4B evaluation of the Residue on Ignition/Sulphated Ash 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 acceptance of the three pharmacopoeial methods by the three ICH regulatory regions and provides specific information regarding the acceptance. The draft guidance is intended to recognize the interchangeability between the local regional pharmacopoeias, thus avoiding redundant testing and different acceptance criteria 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 draft guidance entitled ''Q4B Regulatory Acceptance of Analytical Procedures and/or Acceptance Criteria.''

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

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, 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 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*. 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.

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]

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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