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 Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857;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 The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Paul J. Seligman, Center for Drug Evaluation and Research (HFD–030), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6276, or Miles Braun, Center for Biologics Evaluation and Research (HFM–220), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6090.

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 November 2003, the ICH Steering Committee agreed that a draft guidance entitled ''E2E Pharmacovigilance Planning'' should be made available for public comment. The draft guidance is the product of the Efficacy E2E Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Efficacy E2E Expert Working Group.

The draft guidance describes a method for summarizing the identified risks of a drug, the potential for important unidentified risks, and the potentially at-risk populations and situations that were not studied before the drug was approved. The draft guidance is intended to foster better and earlier planning of pharmacovigilance activities, especially in preparation for the early postmarketing period of a new drug.

The draft guidance proposes a structure for a pharmacovigilance plan and sets out principles of good practice for the design and conduct of observational studies. The draft guidance does not describe other methods to reduce risks from drugs, such as risk communication.

This 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 regarding this 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: March 24, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–7105 Filed 3–29–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0118]

International Conference on Harmonisation; Draft Guidance on Q5E Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process; 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 ''Q5E Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process.'' 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 purpose of the draft guidance is to provide principles for assessing the comparability of biotechnological/biological products before and after changes are made in the manufacturing process to ensure that the process changes did not have an adverse impact on the quality, safety, and efficacy of the

product. The draft guidance is intended to assist in the design and conduct of studies that establish the comparability of products following a change in the manufacturing process.

DATES: Submit written or electronic comments on the draft guidance by May 19, 2004.

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 draft guidance may also be obtained by mail by calling the CBER Voice Information System 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: Barry Cherney, Center for Drug Evaluation and Research (HFM–536), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–1795; or Andrew Chang, Center for Biologics Evaluation and Research (HFM–340), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–496–4833.

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 November 2003, the ICH Steering Committee agreed that a draft guidance entitled ''Q5E Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process'' should be made available for public comment. The draft guidance is the product of the Quality Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Quality Expert Working Group.

The purpose of the draft guidance is to provide principles for assessing the comparability of biotechnological/biological products before and after changes are made in the manufacturing process to ensure that the process changes did not have an adverse impact on the quality, safety, and efficacy of the product. The draft guidance is intended to assist in the design and conduct of studies that establish the comparability of products following a change in the manufacturing process.

The draft guidance applies to:

- Proteins and polypeptides, their derivatives, and products of which they are components (e.g., conjugates). These proteins and polypeptides are produced from recombinant or nonrecombinant cell-culture expression systems and can be highly purified and characterized using an appropriate set of analytical procedures;
- Products where changes are made by a single manufacturer, including those made by a contract manufacturer, who can directly compare results from the analysis of prechange and postchange products; and
- Products where process changes are made in development or for which a marketing authorization has been granted.

The principles outlined in the draft guidance might also apply to other product types, such as proteins and polypeptides isolated from tissues and body fluids.

This 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 regarding this 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.

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Dated: March 24, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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