GUIDANCE DOCUMENT

Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances

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Final

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Center for Drug Evaluation and Research

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[Notices]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D-0448]

International Conference on Harmonisation; Guidance on Q6A

Specifications: Test Procedures and Acceptance Criteria for New Drug

Substances and New Drug Products: Chemical Substances

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a

guidance entitled ``Q6A Specifications: Test Procedures and Acceptance

Criteria for New Drug Substances and New Drug Products: Chemical

Substances.'' 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 or provides recommendations concerning the selection of test procedures and the setting and justification of acceptance criteria for new chemical drug substances and new drug products produced from them. The guidance is intended to assist in the establishment of a single set of global specifications for new drug substances and new drug products.

DATES: Submit written comments by March 29, 2001.

ADDRESSES: Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the guidance are available from the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4573.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Eric B. Sheinin, Center for Drug Evaluation and Research (HFD-003), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2847, or Neil D. Goldman, Center for Biologics Evaluation and Research (HFM-20), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0377.

Regarding the ICH: Janet J. Showalter, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0864.

SUPPLEMENTARY INFORMATION: 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 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, the Canadian Health Protection Branch, and the European Free Trade Area.

In the Federal Register of November 25, 1997 (62 FR 62890), FDA published a draft tripartite guidance entitled ``Q6A Specifications: Test Procedures and

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Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances." The notice gave interested persons an opportunity to submit comments by January 26, 1998.

After consideration of the comments received and revisions to the

guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies on October 6, 1999.

In accordance with FDA's good guidance practices regulation (65 FR 56468, September 19, 2000), this document has been designated a guidance, rather than a guideline.

The guidance provides recommendations on the selection of test procedures and the setting and justification of acceptance criteria for new drug substances of synthetic chemical origin, and new drug products produced from them, that have not been registered previously in the United States, the European Union, or Japan. This guidance is intended to assist in the establishment of a single set of global specifications for new drug substances and new drug products.

This guidance represents the agency's current thinking on the selection of tests procedures and the setting and justification of acceptance criteria for new chemical drug substances and new drug products. 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.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the guidance at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. An electronic version of this guidance is available on the Internet.

The text of the guidance follows:

Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances \1\

\1\ This guidance represents the Food and Drug Administration'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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