DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96D–0028]

International Conference on Harmonisation; Draft Guideline on Stability Testing for New Dosage Forms; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a draft guideline entitled ''Stability Testing for New Dosage Forms.'' The draft guideline was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guideline addresses the generation of stability information for new dosage forms for submission to FDA by the owner of the original application. The draft guideline is an annex to the ICH guideline entitled ''Stability Testing of New Drug Substances and Products.''

DATES: Written comments by June 4, 1996.

ADDRESSES: Submit written comments on the draft guideline to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Copies of the draft guideline are available from the Division of Communications Management (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1012. An electronic version of this guideline is also available via Internet by connecting to the CDER file transfer protocol (FTP) server (CDVS2.CDER.FDA.GOV).

FOR FURTHER INFORMATION CONTACT:

Regarding the guideline: Guiragos K. Poochikian, Center for Drug Evaluation and Research (HFD–570), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1050.

Regarding 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.

At a meeting held on November 29, 1995, the ICH Steering Committee agreed that a draft guideline entitled ''Stability Testing for New Dosage Forms'' should be made available for public comment. The draft guideline 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. Ultimately, FDA intends to adopt the ICH Steering Committee's guideline.

In the Federal Register of September 22, 1994 (59 FR 48754), FDA published a guideline entitled ''Stability Testing of New Drug Substances and Products.'' The guideline addresses the generation of stability information for submission to FDA in new drug applications for new molecular entities and associated drug products. For biotechnological/biological products, see ''Quality of Biotechnological/Biological Products: Stability Testing of Biotechnological/Biological Products'' (60 FR 43501, August 21, 1995).

This draft guideline is an annex to that guideline and addresses the generation of stability information for new dosage forms for submission to FDA by the owner of the original application, after the original submission for new drug substances and products.

In the past, guidelines have generally been issued under § 10.90(b) (21 CFR 10.90(b)), which provides for the use of guidelines to state procedures or standards of general applicability that are not legal requirements but are acceptable to FDA. The agency is now in the process of revising § 10.90(b). Although this guideline does not create or confer any rights for or on any person and does not operate to bind FDA in any way, it does represent the agency's current thinking on stability testing for new dosage forms.

Interested persons may, on or before June 4, 1996, submit to the Dockets Management Branch (address above) written comments on the draft guideline. 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 draft guideline and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

The text of the draft guideline follows:

Stability Testing for New Dosage Forms

1. General

The ICH harmonized Tripartite Guideline on Stability Testing of New Drug Substances and Products was issued on October 27, 1993. This document is an annex to the ICH parent stability guideline and addresses what should be submitted regarding stability of new dosage forms by the owner of the original application, after the original submission for new drug substances and products. For biotechnological/biological products, see the guideline ''Quality of Biotechnological/Biological Products: Stability Testing of Biotechnological/Biological Products.''

2. New Dosage Forms

A new dosage form is defined as a drug product which is a different pharmaceutical product type but contains the same active substance as included in the existing drug product approved by the pertinent regulatory authority.

Such pharmaceutical product types include products of different administration route (e.g., oral to parenteral), new specific functionality/delivery systems (e.g., immediate release tablet to modified release tablet), and different dosage forms of the

same administration route (e.g., capsule to tablet, solution to suspension).

New dosage forms should follow the guidance in the parent stability guideline in principle; however, a reduced stability database at submission time, e.g., 6 months accelerated and 6 months long-term data from ongoing studies, may be acceptable in certain justified cases.

Dated: February 29, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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