

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0231]

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Certifier G. Pressley

International Conference on Harmonisation; Stability Data Package for Registration in Climatic Zones III and IV; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Q1F Stability Data Package for Registration in Climatic Zones III and IV." The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use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). This draft guidance, an annex to an ICH guidance entitled "Q1A(R) Stability Testing of New Drug Substances and Products," defines an approach for broader use of Q1A(R) for territories in climatic zones III and IV.

DATES: Submit written or electronic comments on the draft guidance by August 20, 2002.

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. 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 Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857;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, 301-827-3844, FAX 888-CBERFAX. Send two self-addressed adhesive labels to assist the office in processing your requests. Requests and comments should

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be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Chi-wan Chen, Center for Drug Evaluation and Research (HFD-830), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2001; or Andrew Shrake, Center for Biologics Evaluation and Research (HFM-345), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1148, 301-402-4635.

Regarding the ICH: Janet J. Showalter, Office of International Programs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0864.

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 (EU), 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 (WHO), Health Canada's Health Products and Food Branch, and the European Free Trade Area.

In accordance with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115), this document is being called a guidance, rather than a guideline.

To facilitate the process of making ICH guidances available to the public, the agency has changed its procedure for publishing ICH guidances. Beginning April 2000, we no longer include the text of ICH guidances in the **Federal Register**. Instead, we publish a notice in the **Federal Register** announcing the availability of an ICH guidance. The ICH guidance will be placed in the docket and can be obtained through regular agency sources (see **ADDRESSES**). Draft guidances are left in the original ICH format. The final guidance is reformatted to conform to the GGP style before publication.

In February 2002, the ICH Steering Committee agreed that a draft guidance entitled "Q1F Stability Data Package for Registration in Climatic Zones III and IV" 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.

This draft guidance, an annex to an ICH guidance entitled "Q1A(R) Stability Testing of New Drug Substances and Products" (66 FR 56332, November 7, 2001), defines an approach for broader use of Q1A(R) for territories in climatic zones III and IV.

There are four climatic zones in the world that are distinguished by their characteristic prevalent annual climatic conditions, based on the concept described by P. Schumacher (*Pharmazeutische Zeitung*, 119:321–324, 1974). The Q1A(R) guidance defines the stability data package for the ICH tripartite regions (the EU, Japan, and the United States), which are in climatic

zones I or II. The WHO has published a guideline entitled “Stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms” (WHO technical report series, no. 863, annex 5), updated in the “Report of the thirty-seventh meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations,” Geneva, October 22–26, 2001. The WHO guideline defines stability testing recommendations, including storage conditions for all four climatic zones.

Harmonized global stability testing recommendations have been established in this draft guidance based on Q1A(R) and the WHO guideline. For territories in climatic zones III and IV, the data package as described in Q1A(R) can be considered applicable except for the defined long-term storage condition. The draft guidance recommends the long-term storage condition for a stability data package for registration of drug substances and products intended to be marketed in climatic zones III and IV.

When this draft guidance is finalized, Q1A(R) will be revised to harmonize the intermediate storage condition for zones I and II with the long-term storage condition for zones III and IV.

This draft guidance, when finalized, will represent the agency’s current thinking on a stability data package for registration in climatic zones III and IV. 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 Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance by August 20, 2002. 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 office above 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: 6/6/02

June 6, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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