

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96D-0041]

International Conference on Harmonisation; Draft Guidance on Addendum to E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled “Addendum to E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs.” The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use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). In the **Federal Register** of May 19, 1997 (62 FR 27470), FDA published the guidance entitled “Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs” (ICH E2C guidance), which recommends a unified standard for the format, content, and reporting frequency for postmarketing periodic safety update reports for drug and biological products. This draft guidance, an addendum to the ICH E2C guidance of May 19, 1997, provides additional information on the content and format of PSURs, including clarification of the objectives, general principles, and model for PSURs. The draft guidance is intended to help harmonize collection and submission of postmarketing clinical safety data.

DATES: Submit written or electronic comments on the draft guidance by January 24, 2003.

ADDRESSES: You may submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857;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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Regarding the guidance: Min Chen, Center for Drug Evaluation and Research (HFD-430), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3159, or Miles Braun, Center for Biologics (HFM-220), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-6090.

Regarding the ICH: Janet 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, Japan, and the United States. The six ICH sponsors are the: European Commission; European Federation of Pharmaceutical Industries Associations; Japanese Ministry of Health, Labour, and Welfare; Japanese Pharmaceutical Manufacturers Association, Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and 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's Health Products and Food Branch, and the European Free Trade Area.

In accordance with FDA's good guidance practices 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. As of 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 style before publication.

In September 2002, the ICH Steering Committee agreed that a draft guidance entitled "Addendum to E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs" should be made available for public comment. The draft guidance is the product of the Efficacy Expert Working Group of the ICH focusing on pharmacovigilance topics. Comments about this draft will be considered by FDA and the Efficacy Expert Working Group.

The ICH E2C guidance of May 19, 1997, recommends a unified standard for the format, content, and reporting frequency for PSURs for drug and biological products. This draft guidance, an addendum to the ICH E2C guidance, provides additional information on the objectives, general principles, and model for PSURs. The draft guidance includes, for example, recommendations regarding:

- Synchronization of National Birthdates with the International Birthdates,
- Use of the latest version of the reference safety information,
- Submission of executive summaries as part of the PSUR,

- Options to submit summary bridging reports and addendum reports, and
- Handling of solicited reports.

The document should be used in conjunction with the E2C guidance.

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 Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance by January 24, 2003. 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 guidance and received comments may be seen in the Dockets Management Branch 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: December 23, 2002.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

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