

OMB

Display Date	8-2-00 @ 3:33pm
Publication Date	8-7-00
Certifier	W. Reese

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1407]

International Conference on Harmonisation; Draft Guidance on Safety Pharmacology Studies for Human Pharmaceuticals; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "S7 Safety Pharmacology Studies for Human Pharmaceuticals." The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use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 The draft guidance describes general principles and recommendations for safety pharmacology evaluations. The draft guidance is intended to help protect clinical trial participants and patients receiving marketed products from potential adverse reactions to pharmaceuticals and to avoid unnecessary use of animals and other resources.

DATES: Submit written comments on the draft guidance by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the draft guidance are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/cber/publications.htm>. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the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), 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.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Joseph J. DeGeorge, Center for Drug Evaluation and Research (HFD-24), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5476.

Regarding the ICH: Janet J. Showalter, Office of International Programs (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 accordance with FDA's good guidance practices (GGP's) (62 FR 8961, February 27, 1997), 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 is changing its procedure for publishing ICH guidances. Beginning April 2000, we will no longer include the text of ICH guidances in the **Federal Register**. Instead, we will 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 the **ADDRESSES** section). The draft guidance will be left in the original ICH format. The final guidance will be reformatted to conform to GGP style before publication.

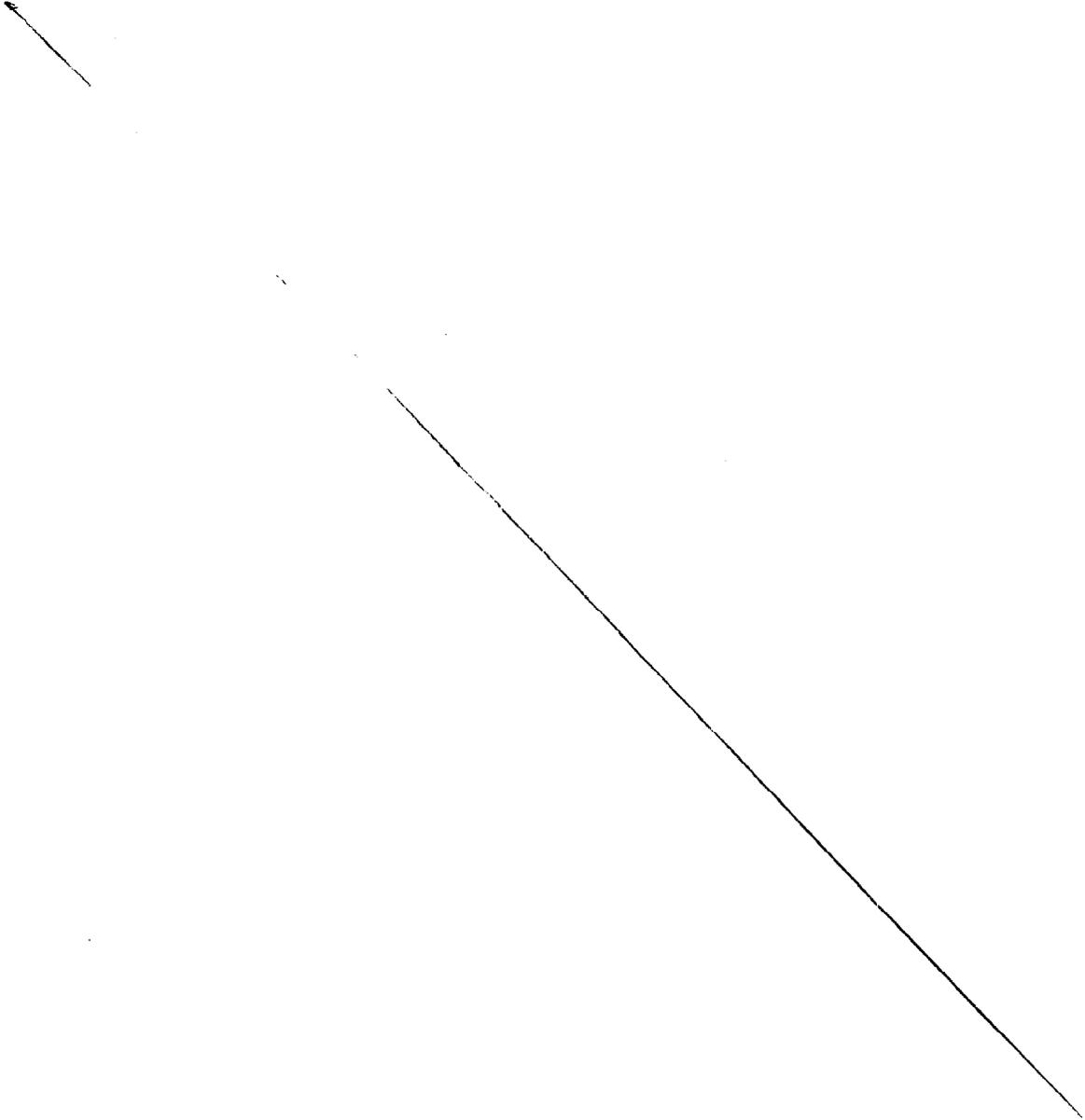
In March 2000, the ICH Steering Committee agreed that a draft guidance entitled "S7 Safety Pharmacology Studies for Human Pharmaceuticals" should be made available for public comment. The draft guidance is the product of the Safety Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Safety Expert Working Group.

The draft guidance describes general principles and recommendations for safety pharmacology evaluations. The draft guidance is intended to help protect clinical trial participants and patients receiving marketed products from potential adverse reactions to pharmaceuticals and avoid unnecessary use of animals and other resources. The draft guidance generally applies to new chemical entities and biotechnology-derived products for human use. The draft guidance may be applied to marketed pharmaceuticals when appropriate. For example, adverse clinical events, a new patient population, or a new route of administration may raise concerns not previously addressed.

This draft guidance represents the agency's current thinking on safety pharmacology studies for human pharmaceuticals. 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, regulations, or both.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance by *[insert date 30 days after date of publication in the **Federal Register**]*. 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 office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 7/31/00
July 31, 2000



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

BILLING CODE 4160-01-F

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

