

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0022]

International Conference on Harmonisation; Guidance on S8 Immunotoxicity 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 guidance entitled “S8 Immunotoxicity Studies for Human Pharmaceuticals.” 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 provides recommendations on nonclinical testing approaches to identify compounds that have the potential to be immunotoxic and guidance on a weight-of-evidence decisionmaking approach for immunotoxicity testing. The guidance is intended to provide recommendations on nonclinical testing for immunotoxicity induced by human pharmaceuticals. The guidance applies to unintended immunosuppression and immunoenhancement, excluding allergenicity or drug-specific autoimmunity.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this 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. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD, 20857. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Requests and comments should 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 guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Kenneth L. Hastings, Center for Drug Evaluation and Research (HFD-024), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6480, Silver Spring, MD 20993-0002, 301-796-0169.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4480.

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, 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, Health Canada, and the European Free Trade Area.

In the **Federal Register** of February 8, 2005 (70 FR 6697), FDA published a notice announcing the availability of a draft tripartite guidance entitled “S8 Immunotoxicity Studies for Human Pharmaceuticals.” The notice gave interested persons an opportunity to submit comments by April 11, 2005. 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 in August 2005.

The guidance provides the following information: (1) Recommendations on nonclinical testing approaches to identify compounds which have the potential to be immunotoxic, and (2) guidance on a weight-of-evidence decisionmaking approach for immunotoxicity testing. The guidance is intended to provide recommendations on nonclinical testing for immunotoxicity induced by human pharmaceuticals. The guidance applies to immunosuppression and immunoenhancement, excluding allergenicity or drug-specific autoimmunity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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 Division of Dockets Management (see **ADDRESSES**) written comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management 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: April 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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