GENERAL SERVICES ADMINISTRATION

Public Buildings Service; Notice of Availability of Final Environmental Impact Statement; Proposed Federal Courthouse and Office Building, Eugene/Springfield Metro Area, Lane County, Oregon

Pursuant to section 102(2)(C) of the National Environmental Policy Act (NEPA) of 1969, as amended, as implemented by the Council on Environmental Quality (40 CFR Parts 1500–1508), the General Services Administration (GSA) has filed with the Environmental Protection Agency, and made available to other government and interested private parties, the Final Environmental Impact Statement (FEIS) for the proposed construction of a 265,290 gross square feet Courthouse and office building including 80 secured parking spaces, located in the urban center of either Eugene/Springfield, Lane County, Oregon.

The FEIS is on file and a copy may be obtained from U.S. General Services Administration, Region 10, Attention: Michael D. Levine, 10PCP, 400 15th Street, SW., Auburn, Washington 98001 (206) 931–7263. A summary of the FEIS can be viewed at the following website: www.northwest.gsa.gov/eugeneusch/intro.htm.

Dated: December 4, 2000.

L. Jay Pearson,

Regional Administrator (10A).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1223]

International Conference on Harmonisation; Guidance on E11 Clinical Investigation of Medicinal Products in the Pediatric Population; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''E11 Clinical Investigation of Medicinal Products in the Pediatric Population.'' 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 sets forth critical issues in pediatric drug development and approaches to the safe, efficient, and ethical study of medicinal products in the pediatric population. The guidance is intended to encourage and facilitate the timely development of pediatric medicinal products internationally.

DATES: This guidance is effective December 15, 2000. Submit written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the 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), 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 that office in processing your requests. 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. Requests and comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section of this document for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: M. Dianne Murphy, Center for Drug Evaluation and Research (HFD–104), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2350, or Karen Weiss, Center for Biologics Evaluation and Research (HFM–570), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5093.

Regarding the 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.

In accordance with FDA's good guidance practices (GGP's) regulation (65 FR 56468, September 19, 2000), 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 of this document). Draft guidances will be left in the original ICH format. Final guidances will be reformatted to conform to the GGP style before publication.

In the **Federal Register** of April 12, 2000 (65 FR 19777), FDA published a draft tripartite guidance entitled ''E11: Clinical Investigation of Medicinal Products in the Pediatric Population.'' The notice gave interested persons an opportunity to submit comments by May 30, 2000.

After consideration of the comments received and revisions to the guidance,