

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,

a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in July 2000.

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 addresses the following clinical study issues: (1) Considerations when initiating a pediatric program for a medicinal product; (2) timing of initiation of pediatric studies during medicinal product development; (3) types of studies (pharmacokinetic, pharmacokinetic/pharmacodynamic, efficacy, safety); (4) age categories for studies; and (5) ethics of pediatric clinical investigation. The guidance is not comprehensive, but is intended to be used in conjunction with other ICH guidances and documents from regional regulatory authorities and pediatric societies. The guidance is intended to encourage and facilitate the timely development of pediatric medicinal products internationally.

This guidance represents the agency's current thinking on clinical investigation of medicinal products in the pediatric population. 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 guidance at any time. 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Electronic Access

Copies of the guidance are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/cber/publications.htm>.

Dated: December 7, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00P-1554]

Medical Devices; Exemptions From Premarket Notification; Class II Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a notice announcing that it has received a petition requesting exemption from the premarket notification requirements for pharmacy compounding systems classified within the intravascular administration set, a class II device (special controls). FDA is publishing this notice in order to obtain comments on this petition in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit written comments by January 16, 2001.

ADDRESSES: Submit written comments on this notice to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ-404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1190.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (the 1976 amendments (Public Law 94-295)), as amended by the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101-629)), devices are to be classified into class I (general controls) if there is information showing that the general controls of the act are sufficient to ensure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such

assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use that is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices), are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations (21 CFR part 807) require persons who intend to market a new device to submit a premarket notification report containing information that allows FDA to determine whether the new device is "substantially equivalent" within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Public Law 105-115). Section 206 of FDAMA, in part, added a new section 510(m) to the act. Section 510(m)(1) of the act requires FDA, within 60 days after enactment of the FDAMA, to publish in the **Federal Register** a list of each type of class II device that does not require a report under section 510(k) of the act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published that list in the **Federal Register** of January 21, 1998 (63 FR 3142). In the **Federal Register** of November 3, 1998 (63 FR 59222), FDA published a final rule codifying these exemptions.

Section 510(m)(2) of the act provides that, 1 day after date of publication of the list under section 510(m)(1), FDA may exempt a device on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a