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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 98D-0996]

Draft Guidance for Industry on General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products." This document is intended to assist applicants who plan to conduct pharmacokinetic (PK) studies in the pediatric population so that drugs and biological products can be labeled for pediatric use.

DATES: Written comments may be submitted on the draft guidance by *(insert date 60 days after date of publication in the Federal Register)*. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at "http://www.fda.gov/cder/guidance/index.htm" or "http://www.fda.gov/cber/guidelines.htm". Submit written requests for single copies of "General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products" to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 or Office of Communication, Training and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. Copies of this guidance may also be obtained by fax from 1-888-CBERFAX or 301-

827-3844 or by mail from the CBER Voice Information System at 800-835-4709 or 301-827-1800.

Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Leanne Cusumano, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2330.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled "General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products." The guidance is intended to assist applicants who plan to conduct pharmacokinetic (PK) studies in the pediatric population so that drugs and biological products can be labeled for pediatric use.

In the past few years, the agency has addressed the need for greater information on the use of drugs in the pediatric population. In the **Federal Register** of December 13, 1994 (59 FR 64240), FDA published a final rule that encouraged manufacturers to provide more information in the labeling on the use of a drug in the pediatric population. The rule recognized several methods of establishing substantial evidence to support pediatric labeling claims, including relying in certain cases on studies carried out in adults. Under the final rule, products may be labeled for pediatric use based on adequate and well-controlled studies in adults together with other information supporting pediatric use (e.g., pharmacokinetic data, safety data, pharmacodynamic data). In the **Federal Register** of August 15, 1997 (62 FR 43899), FDA published a proposed rule that would require new drugs and biological products to be labeled for use in the pediatric population. The enactment of the Food and Drug Modernization Act of 1997 (Pub. L. 105-111) (Modernization Act) on November 21, 1997, further addressed this need by providing incentives to sponsors for conducting pediatric studies (21 U.S.C. 355a). This draft guidance addresses general considerations for conducting PK studies in the pediatric population.

This draft level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on pediatric pharmacokinetic studies. 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 statute, regulations, or both.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). 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 are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1998

William B. Schultz

William B. Schultz
Deputy Commissioner for Policy

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Olga Enders