

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DDM

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Certifier A. Corbin

[Docket No. 2003D-0319]

Guidance for Industry and Food and Drug Administration Staff; Premarket Assessment of Pediatric Medical Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Premarket Assessment of Pediatric Medical Devices." This guidance presents FDA's current thinking on the type of safety and effectiveness information needed to support marketing of pediatric devices and on measures to be used to help protect this vulnerable patient population during the course of clinical trials involving such products.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "Premarket Assessment of Pediatric Medical Devices" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For device issues contact: Joy Samuels-Reid, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1287.

For biologics issues contact: Edward Tabor, Center for Biologics Evaluation and Research (HFM–300), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3518.

SUPPLEMENTARY INFORMATION:

I. Background

On October 26, 2002, the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), Public Law 107–250, was signed into law. Among other things, MDUFMA amends the Federal Food, Drug, and Cosmetic Act (the act) by adding several new provisions concerning devices intended for pediatric use. MDUFMA requires FDA, within 270 days of enactment, to issue guidance on the safety and effectiveness information needed to support marketing of pediatric devices and on measures to be used to help protect this vulnerable patient population during the course of clinical trials involving such products.

On February 4, 2003, FDA published a **Federal Register** document entitled, “Medical Device User Fee and Modernization Act of 2003, Establishment of a Public Docket” (68 FR 5643) (hereinafter referred to as the MDUFMA Docket). In this **Federal Register** document, the agency identified

several statutory provisions for which FDA was particularly interested in receiving stakeholder input, and this pediatric provision was one of them. No comments were submitted to the MDUFMA Docket on this topic. In the **Federal Register** of July 24, 2003 (68 FR 43729), FDA announced the availability of a draft of this guidance document and invited interested persons to comment by October 22, 2003. Three comments were submitted in response to the draft guidance, and the agency considered the comments while finalizing the document.

II. Significance of Guidance

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 premarket assessment of pediatric medical devices. 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 and regulations.

III. Electronic Access

To receive "Premarket Assessment of Pediatric Medical Devices" by fax, call the Center for Devices and Radiological Health (CDRH) Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1220) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. The CDRH web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance

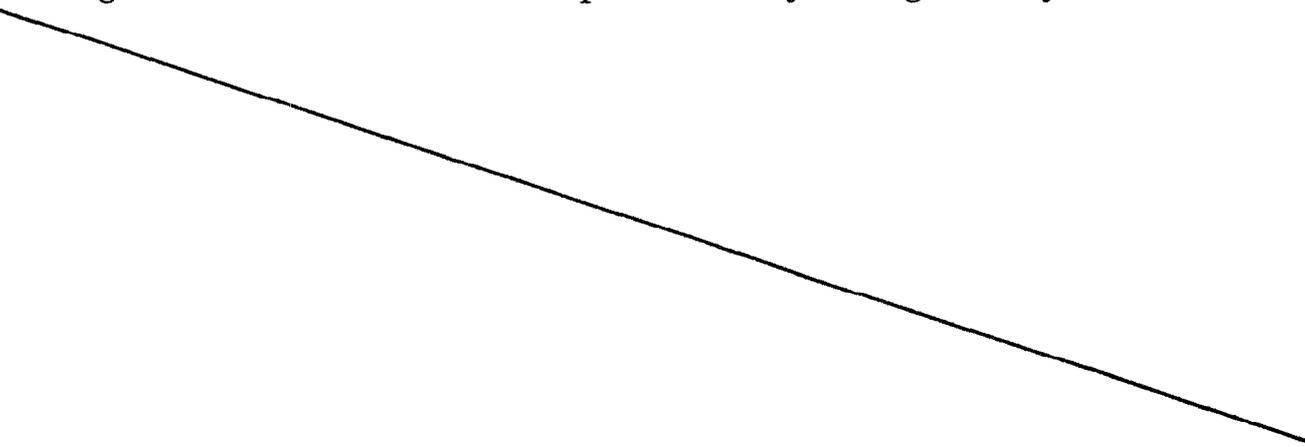
documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (the PRA). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120) and premarket approval applications (21 CFR part 814, OMB control number 0910–0231). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



Dated: 5/5/04
May 5, 2004.

SR 5-11-04

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Jeffrey Shuren,
Assistant Commissioner for Policy.

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