

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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A. Corbin

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Draft Guidance for Industry and FDA Staff; Premarket Assessment of Pediatric Medical Devices; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Premarket Assessment of Pediatric Medical Devices." This draft guidance presents FDA's current thinking on the type of safety and effectiveness information needed to support marketing of pediatric devices and on measures to be used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. This draft guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments on this guidance by [*insert date 90 days after date of publication in the Federal Register*].

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "Premarket Assessment of Pediatric Medical Devices" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220),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 two 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 ext. 177.

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. This guidance, as well as a collateral guidance on procedures for ensuring appropriate pediatric expertise on FDA Advisory Panels, "Pediatric Expertise for Advisory Panels" (<http://www.fda.gov/cdrh/ode/guidance/1208.html>), will help the agency achieve the intent of the pediatric provisions of MDUFMA.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft 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 machine, call the 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 draft 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. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. 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 (the PRA) (44 U.S.C. 3501–3520). 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 the PRA under OMB No. 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit two paper copies of any mailed comments, 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. Comments received may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 7/18/03
July 18, 2003.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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