

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 03D-0181]

*AMS*

Display Date 6-2-03

Publication Date 6-3-03

Certifier *Dr. [Signature]*

**Guidance for Industry and FDA on Pediatric Expertise for Advisory Panels;  
Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “Pediatric Expertise for Advisory Panels; Guidance for Industry and FDA.” The guidance defines pediatric subpopulations by age and specifies when we would seek pediatric expertise on our advisory panels. This guidance document is immediately in effect, but it remains subject to comment in accordance with the agency’s good guidance practices (GGPs).

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies on a 3.5” diskette of the draft guidance document entitled “Pediatric Expertise for Advisory Panels; Guidance for Industry and FDA” to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health (CDRH), 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.

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**NAD**

Submit written comments concerning this guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Comments are to be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:** Nancy J. Pluhowski, Center for Devices and Radiological Health (HFZ- 400), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2022, ext. 133

**SUPPLEMENTARY INFORMATION:**

**I. Background**

This guidance describes internal office procedures to ensure that an advisory panel reviewing a premarket submission or other regulatory documents includes or consults with one or more pediatric experts, when appropriate.

FDA is making this guidance effective immediately because there is a statutory requirement that requires immediate implementation, and guidance is needed to help effect such implementation. On October 26, 2002, the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) was signed into law. MDUFMA amended section 515(c) (21 U.S.C. 360e(c)) Application for Premarket Approval of the Federal Food, Drug, and Cosmetic Act to read in part, “Where appropriate, the Secretary shall ensure that such panel includes, or consults with, one or more pediatric experts.” The guidance describes circumstances where FDA believes that pediatric expertise on the

advisory panel is appropriate as well as the steps FDA will take to ensure pediatric expertise is available.

## **II. Significance of Guidance**

This guidance is being issued consistent with FDA's GGP's regulation (21 CFR 10.115). The guidance represents the agency's current thinking on pediatric expertise in FDA advisory panels. 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. Comments**

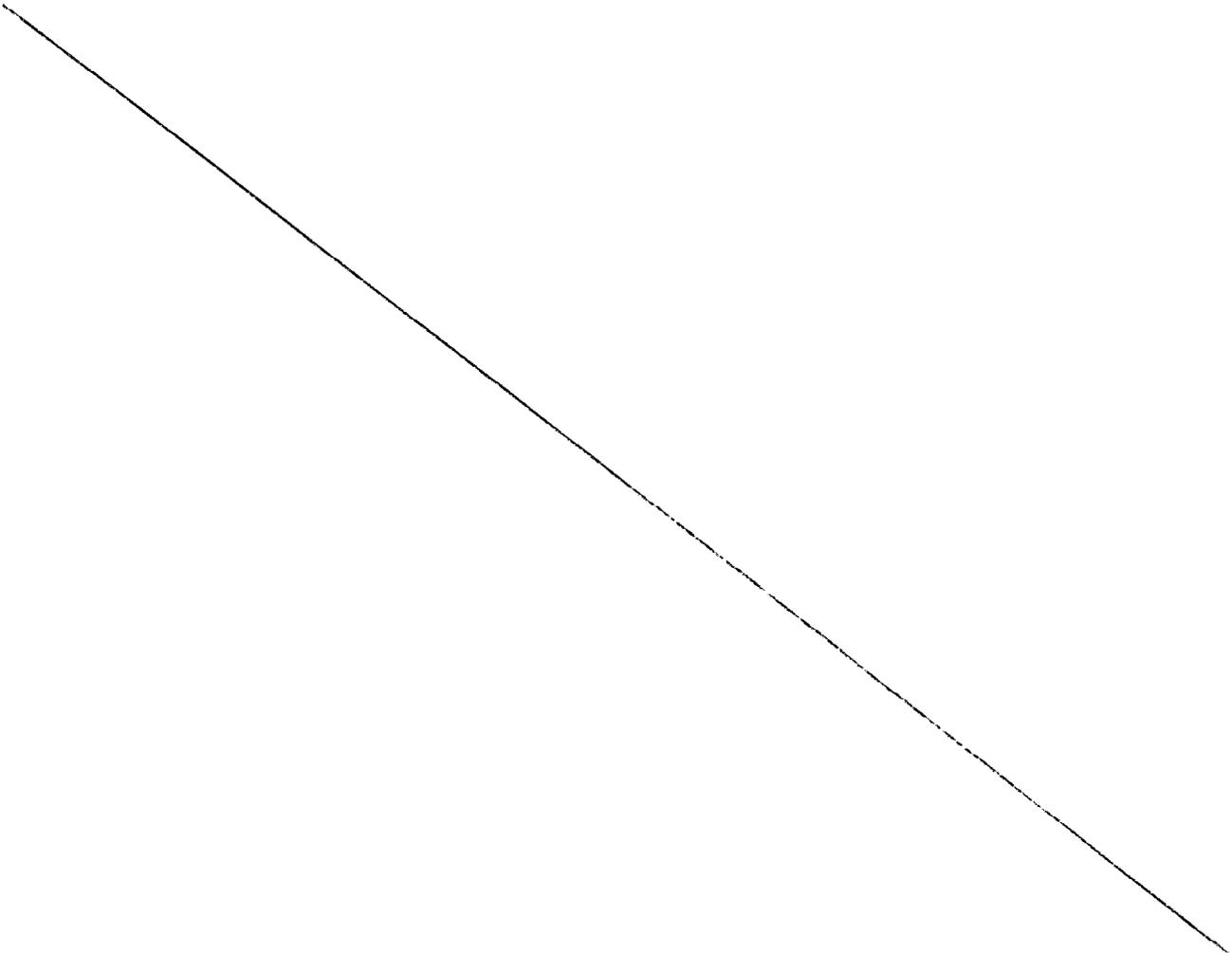
Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified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

## **IV. Electronic Access**

You may obtain a copy of "Pediatric Expertise for Advisory Panels; Guidance for Industry and FDA" via your fax machine, by calling 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, then enter the document number (1208) followed by the

pound sign (#). Then follow the remaining voice prompts to complete your request.

You may also obtain a copy of the guidance through 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: (1) Device safety alerts; (2) **Federal Register** reprints; (3) information on premarket submissions (including lists of approved and cleared applications and submissions, and manufacturers' addresses); (4) small manufacturer's assistance; (5) information on video conferencing and electronic submissions; (6) mammography matters; and (7) 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 Dockets Management Branch Internet site at <http://www.fda.gov/ohrms/dockets>.

Dated: 5/23/03  
May 23, 2003.



Jeffrey Shuren,  
Assistant Commissioner for Policy.

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