

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D-0228]

DAB

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Medical Devices; Guidance for Industry and FDA Staff; Implantable Middle Ear Hearing Device; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Guidance for Industry and FDA Staff; Implantable Middle Ear Hearing Device." This guidance document represents the agency's current thinking on the technical content and clinical considerations for a premarket approval application (PMA) for an implantable middle ear hearing device (IMEHD). This guidance provides information to consider for developing the clinical studies and generating the scientific evidence that will provide reasonable assurance of safety and effectiveness of the IMEHD for its intended use.

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 "Guidance for Industry and FDA; Implantable Middle Ear Hearing Device" 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

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office in processing your request, or fax your request to 301-443-8818. 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. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Eric Mann, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2080, ext. 187.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 12, 2002 (67 FR 40318), FDA announced the availability of the draft guidance entitled “Guidance for Industry and FDA; Implantable Middle Ear Hearing Device.” FDA invited interested persons to comment on the draft guidance by September 10, 2002. On August 16, 2002, FDA held a meeting of the Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee to discuss the draft guidance.

FDA received seven comments. In general, most comments suggested various clarifications throughout the document. FDA revised the document accordingly. One comment stated that the standard entitled “ANSI/IEEE C63.19-2001 American National Standard for Methods of Measurement of Compatibility Between Wireless Communications Devices and Hearing Aids” was developed for air conduction hearing aids and that the standard requires measurements that have been difficult to reproduce in these conventional hearing aids. FDA agrees, however, the agency believes that portions of this

standard may be useful. Therefore, the guidance has been revised to recommend that manufacturers use test methods cited in this standard that are applicable to their device designs. There were two comments requesting a more precise definition for the “control condition” in the suggested clinical study design for IMEHDs. FDA agrees and will replace the term “state-of-the-art” with “appropriately fit conventional air conduction hearing aids.” Another comment suggested that measuring aided baseline performance is not necessary as a control condition. FDA disagrees. The agency believes that it is important to compare IMEHD performance to both appropriately fit conventional air conduction hearing aid performance and unaided performance for the benefit of clinicians and prospective IMEHD recipients.

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 approval applications for IMEHDs. 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 “Guidance for Industry and FDA Staff; Implantable Middle Ear Hearing Device” 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 (1406) 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. 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>.

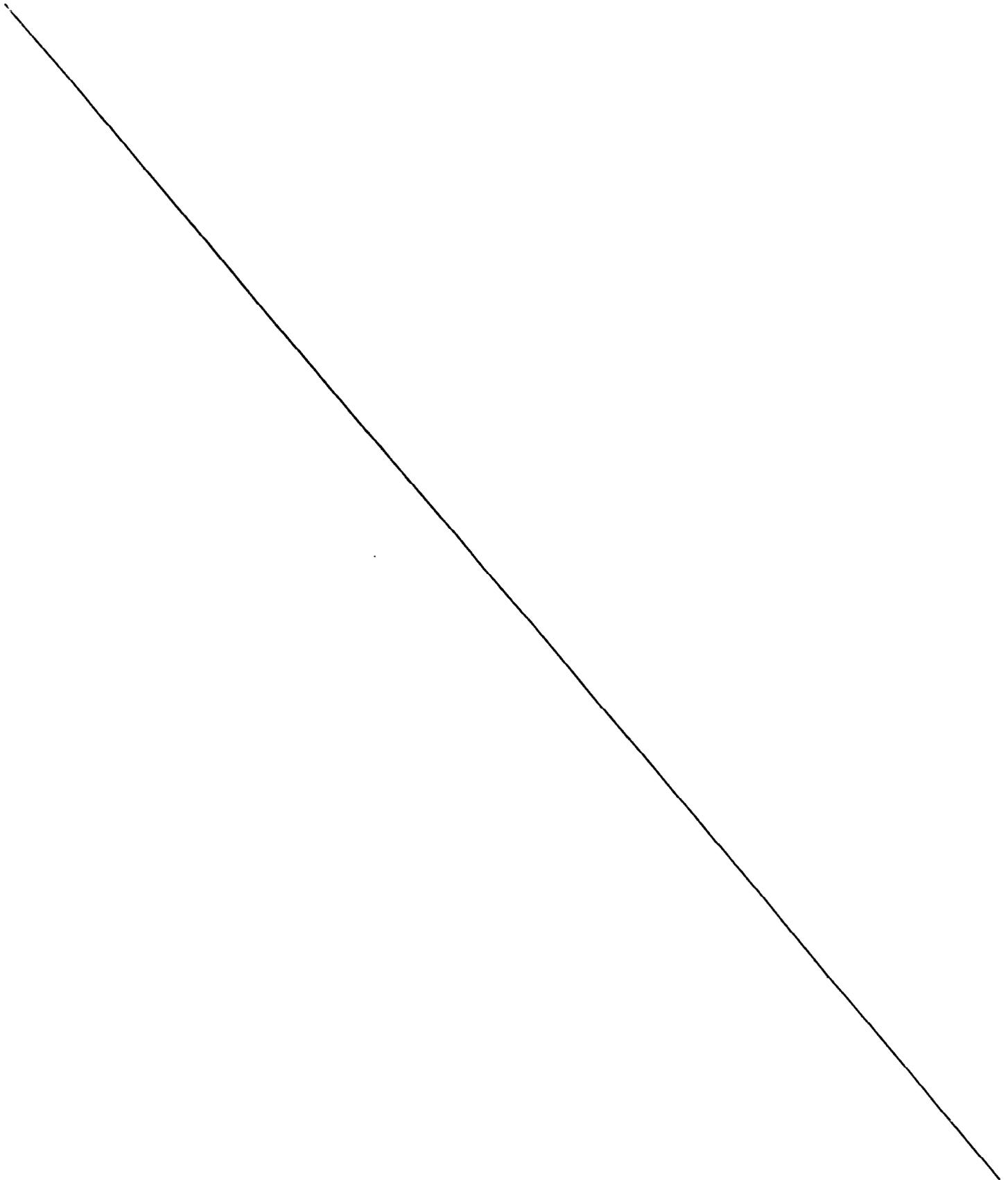
IV. Paperwork Reduction Act of 1995

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 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 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. 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



Dated: 7/16/03
July 16, 2003.

Linda S. Kahan

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Sept 16, 2003