comments on the guidance at any time. Two paper copies of mailed comments are to be submitted, 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. The guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: July 25, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–19590 Filed 7–31–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0228]

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 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: July 16, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–19622 Filed 7–31–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998N–1109]

Mercury Compounds in Drugs and Food; List

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is updating a list of drug and biologic products that contain intentionally introduced mercury compounds, e.g., phenylmercuric acetate, phenylmercuric nitrate, thimerosal. This list is part of the implementation of the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the document entitled ''Mercury in Drug and Biologic Products; 2003 Update'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Copies of the document are available on the Internet at *http://www.fda.gov/cder/fdama/mercury300.htm*. Submit written comments on the document 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*.

FOR FURTHER INFORMATION CONTACT: Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION:

I. Background

FDAMA (Public Law 105–115) was enacted on November 21, 1997. Section 413 of FDAMA, entitled ''Food and Drug Administration Study of Mercury Compounds in Drugs and Food,'' required FDA to: (1) Compile a list of drugs and foods that contain intentionally introduced mercury compounds, and (2) provide a quantitative and qualitative analysis of the mercury compounds in this list. The statute did not differentiate whether the mercury compound was present in the products as an active or an inactive ingredient and required FDA to compile the list and provide the analysis within 2 years after the date of its enactment.

FDA prepared this list and announced its availability in the **Federal Register** of November 19, 1999 (64 FR 63323). The list is entitled ''Mercury in Drug and Biologic Products'' and is available on the Internet at *http://www.fda.gov/cder/fdama/mercury300.htm*.

Five manufacturers and distributors subsequently informed FDA that 10 products had been reformulated to delete the mercury ingredients or were no longer being marketed. However, FDA did not update the list at that time.

II. Updating the List

In the **Federal Register** of February 3, 2003 (68 FR 5299), FDA published a notice requesting information to update this list. FDA was aware that other manufacturers or distributors with products on the list had reformulated their products since 1999. FDA requested any affected manufacturer or distributor to inform us which product(s) on the list had been reformulated and no longer contain mercury ingredients. Eleven manufacturers provided information, which resulted in 39 additional products being deleted from the list and one product being added to the list. The new list now includes 171 products. The list continues to provide information and does not set forth any requirements.

III. 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. A copy of the list and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 24, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–19620 Filed 7–31–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Agricultural Health Study—A Prospective Cohort Study of Cancer and Other Diseases Among Men and Women in Agriculture

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Agricultural Health Study—A Prospective Cohort Study of Cancer and Other Diseases Among Men and Women in Agriculture. *Type of Information Collection Request:* Extension of a currently approved collection (0925–0406, expiration 11/31/03). *Need and Use of Information Collection:* The Agricultural Health Study is in its fifth year of follow-up data collection for a prospective cohort of 89,658 farmers, their spouses, and commercial applicators of pesticides from Iowa and North Carolina. Follow-up is not yet