General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 29 and 30, 2002, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Kathleen Reedy or LaNise Giles, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX 301–827–6776, or e-mail: reedyk@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12532. Please call the Information Line for up-to-date information on this meeting.

Agenda: On both days, the committee will discuss the clinical relevance of different classifications of pain as well as discussion of appropriate clinical trial models and designs for medications which would be indicated for each classification of pain.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 17, 2002. Oral presentations from the public will be scheduled on July 29, 2002, between approximately 1 p.m. and 3 p.m., and on July 30, 2002, between approximately 11 a.m. and 12 noon. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 17, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact LaNise Giles at 301–827–7001, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 3, 2002.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 02–14680 Filed 6–11–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0276]

Guidance for Industry: Channels of Trade Policy for Commodities With Vinclozolin Residues; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance document for industry entitled ''Channels of Trade Policy for Commodities With Vinclozolin Residues.'' This guidance presents FDA's policy for implementing, for the pesticide chemical vinclozolin, the channels of trade provision in the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Food Quality Protection Act (FQPA) of 1996. The guidance is intended to assist firms in understanding FDA's planned approach to the enforcement of this provision of the FQPA with regard to residues of vinclozolin in food.

DATES: Submit written or electronic comments concerning the guidance at any time.

ADDRESSES: Submit written comments concerning the guidance document 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. Submit written requests for single copies of the guidance document entitled ''Channels of Trade Policy for Commodities With Vinclozolin Residues'' to the Office of Plant and Dairy Foods and Beverages (HFS–305), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to this document.

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS–305), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–2022, FAX 301–436–2651, e-mail: mkashtoc@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of July 10, 2001 (66 FR 35990), FDA announced the availability of a draft guidance document entitled ''Channels of Trade Policy for Commodities With Vinclozolin Residues.'' The agency has finalized the draft guidance after receiving no comments on the document. In a notice published in the **Federal Register** of October 23, 2001 (66 FR 53614), FDA announced that it was submitting to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 the collection of information entitled ''Suggested Documentation for Demonstrating Compliance With the Channels of Trade Provision for Foods With Vinclozolin Residues.'' In the October notice, FDA estimated that the guidance entitled ''Channels of Trade Policy for Commodities With Vinclozolin Residues'' would create an estimated annual reporting burden of 921 hours and an estimated annual recordkeeping burden of 496 hours. The October notice also requested comments on these burden estimates. On March 25, 2002, OMB informed FDA that it had approved the information collection until March 31, 2005.

II. Guidance Document

This final guidance document is being issued as level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the channels of trade provision and how this provision relates to FDA-regulated products with residues of vinclozolin. 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

Copies of this guidance also may be downloaded to a personal computer with access to the Internet. The final guidance document may be accessed at http://www.cfsan.fda.gov under ''How to Obtain FDA Food & Cosmetic Guidance Documents.''

IV. Comments

Interested persons may, at any time, submit written comments concerning the guidance entitled ''Channels of Trade Policy for Commodities With Vinclozolin Residues'' to the Dockets Management Branch (see **ADDRESSES**). Two copies of any comments are to be submitted, 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. A copy of the guidance is available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 31, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–14840 Filed 6–11–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0228]

Medical Devices; Implantable Middle Ear Hearing Device; Draft Guidance for Industry and FDA; 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 ''Implantable Middle Ear Hearing Device; Draft Guidance for Industry and FDA.'' 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. This draft guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments on the guidance by September 10, 2002.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Implantable Middle Ear Hearing Device; Draft Guidance for Industry and FDA'' 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. 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. Identify comments with the docket number found in brackets in the heading of this document. Submit electronic comments to http://www.fda.gov/dockets/ecomments. 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

This draft guidance describes the kind of information needed to allow FDA to evaluate the safety and effectiveness of an IMEHD. It is based in part upon current scientific knowledge, current FDA review criteria, and discussions and recommendations resulting from an Ear Nose and Throat Devices Advisory Panel Meeting that was held on June 18, 1999.

II. Significance of Guidance

This draft 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 IMEHD. 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 statutes and regulations.

III. Electronic Access

In order to receive the ''Implantable Middle Ear Hearing Device; Draft Guidance for Industry and FDA,'' via your 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 draft guidance may also do so 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 manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Internet 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.

IV. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance by September 10, 2002. Two copies of any comments are to be submitted, 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. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 31, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–14839 Filed 6–11–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Maternal and Child Health Federal Set-Aside Program; Special Projects of Regional and National Significance; National Child Death Review Resource Center Demonstration Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that approximately $300,000 in fiscal year (FY) 2002 funds is