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Medical Devices; Implantable Middle Ear Hearing Device; Draft Guidance for Industry and FDA; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Implantable Middle Ear Hearing Device; Draft Guidance for Industry and FDA.''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 This draft guidance is neither final nor is it in effect at this time.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for single copies on a 3.5″ diskette of the guidance document entitled ''Implantable Middle Ear Hearing Device; Draft Guidance for Industry and FDA'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health,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

available to fund a single competitive cooperative agreement to demonstrate the effectiveness of a National Child Death Review Resource Center (NCDRRC). The NCDRRC will assist States and localities in using the Child Death Review (CDR) process to promote improved health services delivery and risk reduction and public health prevention programs.

Eligibility is open to any public or private entity, including an Indian tribe or tribal organization (as defined at 25 U.S.C. 450(b)). Awards will be made under the program authority of section 501(a)(2) of the Social Security Act, the Maternal and Child Health (MCH) Federal Set-Aside Program (42 USC 701(a)(2)), or ''SPRANS.'' Funds for this award were appropriated under Public Law 107–116. The award will be made for a period of three years. Additional funding of up to $300,000 annually in the second and third years is contingent on the availability of funds and grantee performance. No matching funds are required.

DATES: Applicants for this program are requested to notify the Maternal and Child Health Bureau (MCHB) by June 25, 2002. Notification of intent to apply can be made in one of three ways: telephone: 301–443–2250; e-mail *dheppel@hrsa.gov;* mail, MCHB, HRSA; Division of Child, Adolescent and Family Health, Parklawn Building, Room 18A–39; 5600 Fishers Lane; Rockville, MD 20857. The deadline for receipt of applications is August 2, 2002. Applications will be considered ''on time'' if they are either received at the HRSA Grants Application Center on or before the deadline date or postmarked on or before the deadline date. The projected award date is September 1, 2002.

ADDRESSES: To receive a complete application kit which includes the number of copies of the application to be submitted and instructions on how to fill-out the application form, applicants may telephone the HRSA Grants Application Center at 1–877–477–2123 (1–877–HRSA–123) beginning June 1, 2002, or register on-line at: *http://www.hrsa.gov/,* or by accessing *http://www.hrsa.gov/g_order3.htm* directly. This program uses the standard Form PHS 5161–1 (rev. 7/00) for applications (approved under OMB No. 0920–0428). Applicants must use the Catalog of Federal Domestic Assistance (CFDA) number 93.110 when requesting application materials. The CFDA is a Government wide compendium of enumerated Federal programs, projects, services, and activities that provide assistance. All applications should be mailed: HRSA Grants Application Center, 901 Russell Avenue, Suite 450, Gaithersburg MD, telephone: 1–877–HRSA–123 (477–2123), e-mail: *hrsagac@hrsa.gov.*

This application guidance and the required form for the NCDRRC Demonstration Program may also be downloaded in either WordPerfect 6.1 or Adobe Acrobat format (.pdf) from the MCHB home page at *http://www.mchb.hrsa.gov/.* Please contact Joni Johns at 301–443–2088 or *jjohns@hrsa.gov/,* if you need technical assistance in accessing the MCHB home page via the Internet.

This announcement will appear on the HRSA home page at: *http://www.hrsa.gov/.* **Federal Register** notices can be accessed electronically by following instructions at: *http://www.access.gpo.gov/su_docs/aces/aces140.html.*

FOR FURTHER INFORMATION CONTACT: David Heppel or Peter Conway, 301–443–2250, e-mail: *pconway@hrsa.gov* (for questions specific to project activities of the program, program objectives, or the Letter of Intent described above); and Curtis Colston, 301–443–1440; e-mail, *ccolston@hrsa.gov* (for grants policy, budgetary, and business questions).

SUPPLEMENTARY INFORMATION:

Program Background and Objectives

For more than a decade the Maternal and Child Health Bureau has been deeply involved in supporting States and localities in the process of conducting Fetal and Infant Mortality Reviews (FIMR). A significant component of that support has been through the establishment of a National Fetal and Infant Mortality Review Resource Center. The intent of NCDRRC is to establish a similar resource center for CDR, to assist States and localities in examining factors contributing to poor child health outcomes from a broad public health perspective.

CDR is a community-based action process aimed at helping communities identify and solve problems contributing to poor child health outcomes. Specifically, using death as a sentinel event, CDR involves a systematic examination of personal characteristics such as age, race/ethnicity, and gender, and factors that play a role in death, integrating information about the health and safety of individuals with information descriptive of medical care and community health and social/welfare systems.

Information from the CDR process can then be used to focus planning and policy development, to direct health systems development, and to enhance efforts to develop and maintain risk reduction and prevention programs for children. The CDR process enhances the ability of State and local health departments to carry out the core public health functions of assessment, policy development, and quality assurance.

The CDR process, while focused on death, also has the potential to be adapted for use in examining *nonfatal* adverse events affecting maternal and child health and safety. A few States have begun to expand into this broader area.

Authorization

Section 501(a)(2) of the Social Security Act (42 U.S.C. 701(a)(2)).

Purpose

The purpose of this cooperative agreement is to demonstrate the effectiveness of developing an NCDRRC to assist States and localities in using the CDR process to promote improved health services delivery and risk reduction and public health prevention programs. Specifically, this cooperative agreement will determine how an NCDRRC could:

(1) Serve as a technical support to States, particularly State Title V agencies, and communities as they develop, implement, and sustain CDR as a community-based process to assess and improve services and systems for children and adolescents;

(2) Refine the methodology for CDR through continuous assessment of the state of the field, trends, and feedback from States and communities;

(3) Support expanded use of the CDR process to address other adverse events (e.g., morbidity) affecting the MCH population, and

(4) Promote collaboration with other MCH related mortality/morbidity review processes to increase effectiveness and reduce duplication of effort.

Eligibility

Under SPRANS project grant regulations at 42 CFR 51a.3, any public or private entity, including an Indian tribe or tribal organization (as defined at 25 U.S.C. 450(b)), is eligible to apply for grants and cooperative agreements covered by this announcement. Under the President's initiative, community-based and faith-based organizations that are otherwise eligible and believe they can contribute to HRSA's program objectives are urged to consider this initiative.

Funding Levels/Project Periods

The administrative and funding instrument to be used for the NCDRRC will be a cooperative agreement, in which substantial MCHB scientific and/or programmatic involvement with the awardee is anticipated during the performance of the project. Under the terms of this cooperative agreement, in addition to the required monitoring and technical assistance, Federal responsibilities will include:

(1) Participation in meetings conducted during the period of the cooperative agreement.

(2) Ongoing review of activities and procedures to be established and implemented.

(3) Review of project information prior to dissemination.

(4) Review of information on project activities.

(5) Assistance with the establishment of contacts with Federal and State agencies, MCHB grant projects, and other contacts that may be relevant to the project's mission; and referrals to these agencies.

One project will be approved for three years. Up to $300,000 in fiscal year 2002 funds will be used to fund the first year. Additional funding of up to $300,000 annually in years two and three will be contingent on the availability of funds, and grantee performance.

Review Criteria

Applications that are complete and responsive to the guidance will be evaluated by an objective review panel specifically convened for this solicitation and in accordance with HRSA grants management policies and procedures.

Applications will be reviewed using the following criteria:

1. Knowledge and Understanding of the Issues relating to CDR (Weight: 20%)

- The degree of understanding of the beginnings of CDR and the evolution of the CDR process as a public health model
- The degree of thoroughness in describing the CDR process and the challenges involved in creating and sustaining it in States and localities
- The extent of applicant knowledge of community-based systems in child and adolescent health and safety
- The extent of applicant knowledge of the individuals and organizations involved in the CDR process and the relationship of CDR and FIMR

2. Soundness and Adequacy of Project Plan (Weight: 30%)

- The extent to which the project objectives address the program purpose and are measurable, time-framed, and appropriate in relation to both the program requirements and identified needs.
- The degree to which the program areas outlined in the grant guidance have been addressed, prioritized and justified.
- The quality and feasibility of the project plan or methodology and its relation to the project's goals and objectives.
- The extent to which the proposed approach identifies the resources that will be used to implement the strategies.
- The degree to which the approaches are technically sound and appropriate to the project goals and objectives.

3. Soundness of Evaluation Plan (Weight: 10%)

- The soundness of the plan for evaluating the process and outcome of this project.
- The extent to which the applicant describes how the project staff will determine the degree to which proposed activities are being successfully conducted and completed, based on the objectives outlined.

4. Applicant's Capability and Capacity (Weight: 30%)

- The extent to which the applicant has demonstrated expertise and its capability to oversee and successfully carry out the project.
- Evidence that a sufficient number of project personnel and resources are proposed. Biographical sketches/curricula vitae document education, skills and experience that are relevant and necessary for the proposed project.

5. Appropriateness of Budget (Weight: 10%)

- The extent to which the proposed budget is realistic, adequately justified, and consistent with the proposed project plan.
- The extent to which the costs of administration and monitoring/evaluation are reasonable and proportionate to the costs of service provision.
- The degree to which the costs of the proposed project are economical in relational to the proposed service utilization.

Additional criteria may be used to review and rank applications for this competition. Any such criteria will be identified in the program guidance included in the application kit. Applicants should pay strict attention to addressing these criteria, in addition to those referenced above. Also, to the extent that regulatory review criteria generally applicable to all Title V programs (at 42 CFR 51a) are relevant to this specific project, such factors will be taken into account.

Paperwork Reduction Act

OMB approval for any data collection in connection with this cooperative agreement will be sought, as required under the Paperwork Reduction Act of 1995.

Executive Order 12372

The MCH Federal Set-Aside program has been determined to be a program which is not subject to the provisions of Executive Order 12372 concerning intergovernmental review of Federal programs.

Dated: May 16, 2002.

Elizabeth M. Duke,

Administrator.

[FR Doc. 02–14681 Filed 6–11–02; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Host-Tumor Cell Interactions in Myeloma: Therapeutic Applications.

Date: July 1–3, 2002.

Time: 7 p.m. to 11 a.m.

Agenda: To review and evaluate grant applications.

Place: The Inn at Longwood Medical, 342 Longwood Avenue, Boston, MA 02115.

Contact Person: William D. Merritt, PhD, Scientific Review Administrator, Grants Review Branch, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8034, MSC 8328, Bethesda, MD 20892–8328, 301–496–9767.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention