Agenda: On May 9, 2002, at 8 a.m., the committee will receive updates of research programs in the Division of Therapeutic Proteins and the Division of Monoclonal Antibodies; at 9 a.m., the committee will discuss issues related to ooplasm transfer in assisted reproduction. On May 10, 2002, the committee will discuss issues related to inadvertent germline transmission of gene transfer vectors.

Procedure: On May 9, 2002, from 8 a.m. to 8:45 a.m. and from 9 a.m. to 6:30 p.m., the meeting is open to the public. 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 May 2, 2002. Oral presentations from the public are scheduled between approximately 3:35 p.m. and 4:05 p.m. on May 9, 2002, and from 11:40 a.m. to 12:10 p.m. on May 10, 2002. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 2, 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.

Closed Committee Deliberations. On May 9, 2002, from 8:45 a.m. to 9:00 a.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss reports of the review of research programs in the Division of Therapeutic Proteins and Division of Monoclonal Antibodies.

FDA regrets that it was unable to publish this notice 15 days prior to the May 9 and 10, 2002, Biological Response Modifiers Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Biological Response Modifiers Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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 accommodation due to a disability, please contact Gail Dapolito or Rosana L. Harvey 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: April 23, 2002.

Linda A. Suydam,

Senior Associate Commissioner for Communications and Constituent Relations.

[FR Doc. 02–10508 Filed 4–24–02; 3:29 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0311]

Medical Devices: Class II Special Controls Guidance Document: Endolymphatic Shunt Tube with Valve; Final Guidance for Industry Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Endolymphatic Shunt Tube with Valve; Guidance for Industry and FDA.'' This document describes a means by which the endolymphatic shunt tube with valve may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the**Federal Register**, FDA is publishing a final rule classifying endolymphatic shunt tubes with valve into class II (special controls).

DATES: Submit written or electronic comments on the 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 ''Class II Special Controls Guidance Document: Endolymphatic Shunt Tube with Valve; 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 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. 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.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 15, 2001 (66 FR 42809), FDA published a proposed rule to reclassify the endolymphatic shunt tube with valve from class III (premarket approval) into class II (special controls) based on new information regarding this device. E. Benson Hood Laboratories, Inc. (Hood Laboratories), submitted the new information in a reclassification petition. FDA also identified the document ''Class II Special Controls Guidance Document: Endolymphatic Shunt Tube with Valve; Draft Guidance for Industry and FDA'' as the special control capable of providing reasonable assurance of safety and effectiveness for this device.

Interested persons were invited to comment on the draft guidance by November 13, 2001. FDA received one comment. The comment, from the petitioner, Hood Laboratories, strongly supported the draft guidance as the proposed special control.

FDA has since revised the draft guidance to provide to manufacturers the option of submitting an abbreviated 510(k) to further reduce regulatory burden.

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 ''Class II Special Controls Guidance Document: Endolymphatic Shunt Tube with Valve; Guidance for Industry and FDA.'' 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

In order to receive the document ''Class II Special Controls Guidance Document: Endolymphatic Shunt Tube with Valve; 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. At the first voice prompt, press 1 to access DSMICA Facts, at second voice prompt press 2, and then enter the document number (791) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains a home page at http://www.fda.gov/cdrh on the Internet for easy access to information 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 manufacturers' assistance; information on video conferencing and electronic submissions; Mammography Matters, and other medical device oriented information. The CDRH home page also includes the document ''Class II Special Controls Guidance Document: Endolymphatic Shunt Tube with Valve; Guidance for Industry and FDA'' which may be accessed at http://www.fda.gov/cdrh/ode/guidance/791.html. A search capability for all guidance documents may be found 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: April 15, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–10427 Filed 4–26–02; 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; Sickle Cell Disease and Newborn Screening 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 $3.6 million in fiscal year (FY) 2002 funds is available to fund (1) a single cooperative agreement with a national sickle cell disease organization for a national coordinating center, and (2) up to 15 grants for community-based sickle cell disease projects to enhance the Sickle Cell Disease and Newborn Screening program through provision of outreach and counseling efforts. 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 U.S.C. 701(a)(2)), or ''SPRANS.'' Funds for these awards were appropriated under Public Law 107–116. Up to $750,000 will be available for one cooperative agreement; up to $2.87 million will be available for community-based grants. Awards are made for a grant period of one year.

DATES: Applicants for this program are expected to notify the Maternal and Child Health Bureau (MCHB) by May 20, 2002. Notification of intent to apply can be made in one of three ways: telephone: 301–443–1080; email *cdiener@hrsa.gov;* mail, MCHB, HRSA; Division for Children with Special Health Care Needs, Parklawn Building, Room 18A–19; 5600 Fishers Lane; Rockville, MD 20857. The deadline for receipt of applications is June 29, 2002. Applications will be considered ''on time'' if they are either received 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, applicants may telephone the HRSA Grants Application Center at 1–877–477–2123 (1–877–HRSA–123) beginning April 29, 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 appropriate Catalog of Federal Domestic Assistance (CFDA) number 93.110A 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 or delivered to: Grants Management Officer (MCHB), 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 Sickle Cell Disease and Newborn Screening grant program may be downloaded in either WordPerfect 6.1 or Adobe Acrobat format (.pdf) from the MCHB HomePage 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 are found by following instructions at: *http://www.access.gpo.gov/su_docs/aces/aces140.html.*

FOR FURTHER INFORMATION CONTACT: Michele A. Lloyd-Puryear, M.D., Ph.D. 301–443–1080, e-mail: *mpuryear@hrsa.gov* (for questions specific to project activities of the program, program objectives, or the Letter of Intent described above); and Jacquelyn Whitaker, 301/443–1440; e-mail, *jwhitaker@hrsa.gov* (for grants policy, budgetary, and business questions).

SUPPLEMENTARY INFORMATION:

Program Background and Objectives

Sickle cell disease (SCD) is an inherited red blood cell condition characterized primarily by chronic anemia and periodic episodes of pain. In affected individuals, the abnormal red blood cells break easily and clog blood vessels to block blood flow to organs and tissues. This process results in anemia, periodic pain episodes, and ultimately can damage tissues and vital organs and lead to increased infections and early death. In the United States, most cases of SCD occur among people of African ancestries. People of Mediterranean, Middle Eastern, and Indian background are also affected. It is estimated that more than 2 million Americans have the sickle cell trait and over 70,000 have the disease. Annually approximately 1,000 newborns are identified with the disease through state newborn screening programs.

Early diagnosis of SCD is critical so that children who have the condition can receive proper interventions. Newborn screening for SCD followed by parental health education, enrollment in comprehensive care, initiation of penicillin prophylaxis and anti-pneumococcal vaccination within the first two months of life can prevent death from severe infections.

The Federal MCHB has long recognized the significance of SCD. In the mid 1960s, MCHB developed and disseminated SCD educational materials nationally. Following passage of the National Sickle Cell Anemia Control Act in 1972, MCHB, with initial funding from the National Institutes of Health (NIH), provided support for community