VII. Agency Contacts

Program Office Contact: Dr. Margaret Washnitzer, Department of Health and Human Services (HHS), Administration for Children and Families, Office of Community Services Operations Center, 1815 Fort Meyer Drive, Suite 300, Arlington, Virginia 22209, E-Mail: *OCS@lcgnet.com,* Phone: 1–800–281–9519.

Grants Management Office Contact: Barbara Ziegler Johnson, Team Leader, Office of Grants Management, Division of Discretionary Grants, Department of Health and Human Services (HHS), Administration for Children and Families, Office of Community Services Operations Center, 1815 Fort Meyer Drive, Suite 300, Arlington, Virginia 22209, E-Mail: *OCS@lcgnet.com,* Phone: 1–800–281–9519.

VIII. Other Information

Additional information about this program and its purpose can be located on the following Web site: *http://www.acf.hhs.gov/programs/ocs.*

Dated: May 7, 2004.

Clarence H. Carter,

Director, Office of Community Services.

[FR Doc. 04–10967 Filed 5–13–04; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

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 June 8, 2004, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Geretta Wood, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8320, ext. 143, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512625. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for a left ventricular assist system. The system is intended for use as a short or long term bridge to transplantation in cardiac transplant patients, and in patients with relative contraindication to transplantation who are expected to become transplant candidates with mechanical circulatory support, at risk of imminent death from nonreversible left ventricular failure. The device is indicated for use both inside and outside of the hospital. Background information for the topics, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at *http://www.fda.gov/cdrh/panelmtg.html.* Material will be posted on June 7, 2004.

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 May 25, 2004. On June 8, 2004, oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of committee deliberations and for approximately 30 minutes near the end of the deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 25, 2004, 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 AnnMarie Williams, Conference Management Staff, at 301–594–1283, ext. 113, 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: May 8, 2004.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 04–11029 Filed 5–13–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0319]

Guidance for Industry and Food and Drug Administration Staff; Premarket Assessment of Pediatric Medical Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Premarket Assessment of Pediatric Medical Devices.'' This guidance presents FDA's current thinking on the type of safety and effectiveness information needed to support marketing of pediatric devices and on measures to be used to help protect this vulnerable patient population during the course of clinical trials involving such products.

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 ''Premarket Assessment of Pediatric Medical Devices'' 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 one self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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.

FOR FURTHER INFORMATION CONTACT:

For device issues contact: Joy

Samuels-Reid, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1287.

For biologics issues contact: Edward Tabor, Center for Biologics Evaluation and Research (HFM–300), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3518.

SUPPLEMENTARY INFORMATION:

I. Background

On October 26, 2002, the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), Public Law 107–250, was signed into law. Among other things, MDUFMA amends the Federal Food, Drug, and Cosmetic Act (the act) by adding several new provisions concerning devices intended for pediatric use. MDUFMA requires FDA, within 270 days of enactment, to issue guidance on the safety and effectiveness information needed to support marketing of pediatric devices and on measures to be used to help protect this vulnerable patient population during the course of clinical trials involving such products.

On February 4, 2003, FDA published a **Federal Register** document entitled, ''Medical Device User Fee and Modernization Act of 2003, Establishment of a Public Docket'' (68 FR 5643) (hereinafter referred to as the MDUFMA Docket). In this **Federal Register** document, the agency identified several statutory provisions for which FDA was particularly interested in receiving stakeholder input, and this pediatric provision was one of them. No comments were submitted to the MDUFMA Docket on this topic. In the **Federal Register** of July 24, 2003 (68 FR 43729), FDA announced the availability of a draft of this guidance document and invited interested persons to comment by October 22, 2003. Three comments were submitted in response to the draft guidance, and the agency considered the comments while finalizing the document.

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 assessment of pediatric medical devices. 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 ''Premarket Assessment of Pediatric Medical Devices'' by fax, call the Center for Devices and Radiological Health (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 (1220) 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 with Internet access. 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 (44 U.S.C. 3501–3520) (the PRA). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120) and 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 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 at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 5, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–11028 Filed 5–13–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Collection: Comment Request

In compliance with the requirement for opportunity for public comment on data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the project or to obtain a copy of the data collection methods and instruments, call the HRSA Reports Clearance Officer on (301) 443–1891.

Comments are invited on: (a) Whether the continued collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Project: Evaluation of the Health Care for the Homeless Respite Pilot Initiative (OMB No. 0915–0269)—Extension

The Bureau of Primary Health Care (BPHC), Health Resources and Services Administration, is conducting an extension of an evaluation of the Health Care for the Homeless (HCH) Respite Pilot Initiative. Data are being collected from the ten HCH grantees participating in the Pilot Initiative. The National Health Care for the Homeless Council is conducting the evaluation through a cooperative agreement with the BPHC. The evaluation focuses on assessing the effect of respite services on the health of homeless people as well as examining any differences in outcomes based on client or program characteristics. The evaluation is being conducted