

7177, e-mail: [dgibson@oc.fda.gov](mailto:dgibson@oc.fda.gov). Application forms PHS 5161-1 are available via the Internet at: <http://www.hhs.gov/forms> (revised 7/00). Applications hand-carried or commercially delivered should be addressed to 5630 Fishers Lane (HFA-500), rm. 2131, Rockville, MD 20852. An application not received in time for orderly processing will be returned to the applicant without consideration."

On page 36091, in the second column, **FOR FURTHER INFORMATION CONTACT** is corrected to read:

**"FOR FURTHER INFORMATION CONTACT:**

*Regarding the administrative and financial management aspects of this notice:* Djuana Gibson (see **ADDRESSES**).

*Regarding the programmatic aspects of this notice:* Stephen Toigo, Division of Federal-State Relations (DFSR), Office of Regulatory Affairs, Food and Drug Administration (HFC-150), 5600 Fishers Lane, rm. 12-07, Rockville, MD 20857, 301-827-6906, or access the Internet at: [http://www.fda.gov/ora/fed\\_state/default.htm](http://www.fda.gov/ora/fed_state/default.htm). For general ORA program information contact your Public Affairs Specialists at [http://www.fda.gov/ora/fed\\_state/DFSR\\_Activities/](http://www.fda.gov/ora/fed_state/DFSR_Activities/)."

On page 36091, in the second column, under section I, the first paragraph is corrected to read: "FDA will support projects covered by this notice under title XVII of the Public Health Service Act (42 U.S.C. 1702). FDA's project program is described in the Catalog of Federal Domestic Assistance, No. 93.245, and applicants are limited to States that have an existing AIDS Health Fraud Task Force or States that are in the process of developing a Health Fraud Task Force."

On page 36092, in the first column, under section V.A, a sentence is added at the end of the paragraph that reads: "A Current Listing of SPOCs can be found at <http://www.whitehouse.gov/omb/grants/spoc.html>."

On page 36092, in the third column, under section VII, the paragraph is corrected to read: "Applicants are encouraged to apply electronically (see **ADDRESSES**). If not, the original and two copies of the completed grant application Form PHS-5161-1 (revised 7/00) for State and local governments should be delivered to the Grants Management Office. The receipt date is April 30, 2005. No supplemental material or addenda will be accepted after the receipt date."

On page 36092, in the third column, under section VIII.A, the section is corrected to read:

"A. *Submission Instructions*

Applications will be accepted during working hours, 8 a.m. to 4:30 p.m., Monday through Friday, on or before the established receipt date. Applications will be considered received on time if sent or mailed on or before the receipt date as evidenced by a legible U.S. Postal Service dated postmark or a legible date receipt from a commercial carrier, unless they arrive too late for orderly processing. Private metered postmarks shall not be acceptable as proof of timely mailing. Applications not received on time will not be considered for review and will be returned to the applicant. Applicants should note that the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on this method, applicants should check with their local post office.

Do not send applications to the Center for Scientific Research, NIH. Any application sent to NIH that is then forwarded to FDA and not received in time for orderly processing will be deemed unresponsive and returned to the applicant. FDA is able to receive applications via the Internet.

The outside of the mailing package and item 2 of the application face page should be labeled 'Response to FDA-ORA-04-2.' You must submit only one application, an original and two copies, per package."

Please note that the only change to section VIII.A is that FDA is now accepting applications via the Internet.

Dated: February 18, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05-3710 Filed 2-25-05; 8:45 am]

**BILLING CODE 4160-01-S**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

#### **General and Plastic Surgery 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:* General and Plastic Surgery 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 April 11, 2005, from 8 a.m. to 5:30 p.m., on April 12, 2005, from 8 a.m. to 6 p.m., and on April 13, 2005, from 8 a.m. to 6 p.m.

*Location:* Hilton Washington DC North/Gaithersburg, Grand Ballroom, 620 Perry Pkwy., Gaithersburg, MD.

*Contact Person:* David Krause, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-3090, ext. 141, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512519. Please call the Information Line or access the Internet address of <http://www.fda.gov/cdrh/panelmtg.html> for up-to-date information on this meeting.

*Agenda:* On April 11, 2005, the committee will hear oral presentations from the public. On April 12 and 13, 2005, the committee will discuss, make recommendations, and vote on two premarket approval applications for Silicone Gel-Filled Breast Prostheses. Background information, including the agenda and questions for the committee, will be available to the public on April 8, 2005, on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>.

*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 March 28, 2005. Oral presentations from the public will be scheduled on April 11, 2005, between approximately 8 a.m. and 5:30 p.m., and on April 12 and 13, 2005, between approximately 2:45 p.m. and 3:45 p.m. Time allotted for each presentation is limited. Those desiring to make formal oral presentations should notify the contact person before March 28, 2005, and submit a brief statement of the general nature of the comments they wish to present, and the names and addresses of proposed participants.

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 240-276-0450, 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: February 17, 2005.

**Sheila Dearybury Walcoff,**  
*Associate Commissioner for External Relations.*

[FR Doc. 05-3741 Filed 2-25-05; 8:45 am]

BILLING CODE 4160-01-S

## 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 March 17, 2005, from 8 a.m. to 4 p.m.

*Location:* Hilton Washington DC North/Gaithersburg, Crystals Ballroom, 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 and make recommendations regarding a premarket notification submission for use in the induction, maintenance, and reversal of mild hypothermia in the treatment of unconscious adult patients with spontaneous circulation after out-of-hospital cardiac arrest when the initial rhythm was ventricular fibrillation.

Background information for the topic, including the agenda and questions for the committee, will be available to the public one business day before the

meeting on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>.

*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 March 5, 2005. 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 March 5, 2005, 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 Shirley Meeks at 240-276-0450, ext. 105, 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: February 17, 2005.

**Sheila Dearybury Walcoff,**  
*Associate Commissioner for External Relations.*

[FR Doc. 05-3742 Filed 2-25-05; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of

proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer at (301) 443-1891.

Comments are invited on: (a) Whether the proposed 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 proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be 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.

#### Proposed Project: Evaluation of the Implementation and Outcomes of the Maternal and Child Health Bureau's National Healthy Start Program—Phase II (NEW)

The Health Resources and Service Administration's Maternal and Child Health Bureau (MCHB) initiated the Healthy Start Program in 1991 in response to concerns about high infant mortality rates. The Phase II evaluation includes a survey of Healthy Start Program participants designed to collect information that is important to understanding the implementation of Healthy Start and the program effects from a client perspective. Specifically, the goals of the survey are to: describe the participant population, assess the services they received during the prenatal and early postpartum periods, describe their experiences and satisfaction with the health system and services, and examine their health behaviors.

The survey will be administered to participants at eight grantee sites. The survey will use a mixed-mode approach: it will be conducted primarily by telephone using computer-assisted telephone interviewing (CATI) with in-person field follow up if the telephone attempts are unsuccessful.

Data gathered from the survey will be used to provide HRSA the information necessary to assess the grantees' achievement of MCHB's goal to improve perinatal outcomes among racial and ethnic minorities.

The estimated burden on respondents is as follows: