

meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: February 2, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96-2664 Filed 2-7-96; 8:45 am]

BILLING CODE 4160-01-F

#### Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1-800-741-8138 or 301-443-0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

**MEETING:** The following advisory committee meeting is announced:

#### Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee

**Date, time, and place.** February 26, 1996, 9 a.m., Holiday Inn—Gaithersburg, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 301-948-8900 and reference FDA's Panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Sociometrics, Inc., 301-608-2151. The availability of appropriate accommodations cannot be assured unless prior written notification is received.

**Type of meeting and contact person.** Open public hearing, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 1 p.m.; closed presentation of data, 1 p.m. to 2 p.m.; open committee discussion, 2 p.m. to 4 p.m.; Cornelia B. Rooks, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1243, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Clinical Chemistry and Clinical Toxicology Devices Panel, code 12514.

**General function of the committee.** The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

**Agenda—Open public hearing.** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before February 12, 1996, 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 required to make their comments.

**Open committee discussion.** The committee will discuss a premarket notification submission (510(k)) for a noninvasive transcutaneous glucose monitor intended for the quantitative determination of blood glucose in diabetics.

**Closed presentation of data.** The sponsor of the 510(k) will present to the committee trade secret and/or confidential commercial information.

This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing

from the Freedom of Information Office (HFI-35), Food and Drug Administration, rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: February 2, 1996.  
Michael A. Friedman,  
*Deputy Commissioner for Operations.*  
[FR Doc. 96-2689 Filed 2-7-96; 8:45 am]  
BILLING CODE 4160-1-F

#### [Docket No. 96N-0026]

#### **Peripheral Blood Stem Cells: Discussion of Procedures for Collection, Processing, and Product Characterization; Notice of Public Workshop**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public workshop to discuss procedures for preparation, processing, and characterization of human peripheral blood stem cells. The purpose of this scientific workshop, sponsored by FDA and the National Heart, Lung, and Blood Institute, National Institutes of Health, is to identify and discuss the steps for the collection, processing, and storage of peripheral blood stem cells for transplantation and to identify areas in need of further research. The scientific information presented at this workshop will aid FDA in regulating peripheral blood stem cells and identifying product standards.

**DATES:** The public workshop will be held on February 22 and 23, 1996, from 8 a.m. to 4:30 p.m. Preregistration is recommended because seating is limited. Registration is requested by February 16, 1996.

**ADDRESSES:** The public workshop will be held at the National Institutes of

Health, Bldg. 10, Masur Auditorium, 9000 Rockville Pike, Bethesda, MD.

#### **FOR FURTHER INFORMATION CONTACT:**

Regarding information on registration: Dawn Apple, KRA Corp., 1010 Wayne Ave., suite 850, Silver Spring, MD 20910, 301-495-1591, or FAX 301-495-9410.

Regarding information on the workshop agenda: Richard Lewis, Center for Biologics Evaluation and Research (HFM-380), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-3524.

**SUPPLEMENTARY INFORMATION:** The purpose of this workshop is to identify and discuss steps for collection, processing, and storage of peripheral blood stem cells for transplantation and to identify what additional scientific data is needed in this area.

Topics to be discussed include the following: Product viability testing, donor leukopheresis, donor testing, product storage/transfer conditions, definition of cell types and numbers in the product, and differences between allogeneic and autologous use of peripheral blood stem cells.

FDA intends to make available at this workshop a draft document discussing the regulatory approach FDA believes is appropriate for human peripheral blood stem cell products for transplantation and, shortly thereafter, will publish in the Federal Register a notice of availability for the draft document. FDA will solicit written comments on its draft document. Written comments received will be reviewed and considered in determining whether amendments to, or revisions of, the approach are warranted.

Dated: February 5, 1996.  
William K. Hubbard,  
*Associate Commissioner for Policy Coordination.*  
[FR Doc. 96-2845 Filed 2-6-96; 11:47 am]  
BILLING CODE 4160-01-F

#### **Health Care Financing Administration**

#### **Public Information Collection Requirements Submitted for Public Comment and Recommendations**

**AGENCY:** Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summaries of proposed collections for public comment. Interested persons are invited to send