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