

Wilma G. Johnson,

*Acting Associate Director for Policy Planning
And Evaluation, Centers for Disease Control
and Prevention (CDC).*

[FR Doc. 97-19893 Filed 7-28-97; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93N-0453]

Guidance for Screening and Testing of Donors of Human Tissue Intended for Transplantation; Availability

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled "Guidance for Screening and Testing of Donors of Human Tissue Intended for Transplantation." The purpose of the guidance document is to assist facilities involved in recovery, infectious disease testing, screening, processing, storing, or distributing human tissue intended for transplantation. The guidance document provides information on procedures and practices for donor screening and testing. FDA prepared the guidance document after receiving public input. The topics included in the guidance document were contained in a draft document "Screening and Testing of Donors of Human Tissue Intended for Transplantation" made available for discussion at a public workshop on human tissue held on June 20 and 21, 1995.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the "Guidance for Screening and Testing of Donors of Human Tissue Intended for Transplantation" to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844.

Persons with access to the Internet may obtain the document using File

Transfer Protocol (FTP), the World Wide Web (WWW), or bounce-back e-mail. For FTP access, connect to CBER at "ftp://ftp.fda.gov/cber/". For WWW access, connect to CBER at "http://www.fda.gov/cber/publications.htm". To receive the document by bounce-back e-mail, send a message to "tissue2@a1.cber.fda.gov".

Submit written comments on the guidance document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Two copies of any comments are to be submitted, except individuals may submit one copy. Requests and comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM-630), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-594-3074.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 14, 1993 (58 FR 65514), FDA published an interim rule on human tissue intended for transplantation to reduce the risk of transmission of human immunodeficiency virus (HIV) and hepatitis through human tissue intended for transplantation. The interim rule was issued under the authority of sections 215, 311, 361, and 368 of the Public Health Service Act (42 U.S.C. 216, 243, 264, 271) because of an immediate need to protect the public health from the transmission of communicable diseases through the transplantation of human tissue. The interim rule established requirements for the testing of donors of human tissue for HIV Type 1 virus, HIV Type 2 virus, hepatitis B virus, and hepatitis C virus. The interim rule also required that donors be screened for medical history, including behaviors that carry an increased risk of exposure to these viruses (behavioral and high risk information) and for signs and symptoms of infection with these viruses.

In the **Federal Register** of June 20, 1995 (60 FR 32128), FDA announced the availability for public comment of a draft document entitled "Screening and Testing of Donors of Human Tissue Intended for Transplantation." The availability of the draft document coincided with the workshop on Human

Tissue for Transplantation and Human Reproductive Tissue: Scientific and Regulatory Issues and Perspectives which was held on June 20 and 21, 1995. Comments received on this draft document and the issues discussed at the workshop were considered in the development of the guidance document being announced in this notice.

This guidance document provides general information on the following procedures: (1) Determination of donor suitability, (2) evaluation of screening test performance, (3) application of a plasma dilution algorithm to determine the acceptability of the blood specimen used for testing, (4) screening for behavioral and high risk information, and (5) evaluation of clinical and physical evidence of infection with HIV or hepatitis.

As technical standards change over time due to an increased understanding of infectious diseases and improved technology for testing, FDA may issue future guidance to help ensure that the regulatory process reflects the current level of knowledge. The recommendations in this guidance document should be considered in addition to voluntary standards developed and used by human tissue organizations.

This document is not being issued under the authority of 21 CFR 10.90(b) because FDA is in the process of revising this section. As with other guidance documents, FDA does not intend this document to be all-inclusive. This document does not bind the agency and does not create or confer any rights, privileges, or benefits for or on any person. Tissue facilities may follow the guidance document or may choose to use alternative procedures not provided in the guidance document. If a tissue facility chooses to use alternative procedures, the facility may wish to discuss the matter further with the agency to prevent expenditure of resources on activities that may be unacceptable to FDA.

Interested persons may, at any time, submit written comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Continued comment by the human tissue industry is encouraged, and comments will be continuously accepted by the Dockets Management Branch.

FDA periodically will review written comments on the guidance document to

determine whether future revisions to the guidance document are warranted.

Dated: January 21, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97-19821 Filed 7-28-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-P-15A]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.

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 comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Current Beneficiary Survey (MCBS) Rounds: 20-32; *Form No.:* HCFA-P-15A (OMB# 0938-0568); *Use:* The MCBS is a continuous, multipurpose survey of a nationally representative sample of aged and disabled persons enrolled in Medicare. The survey provides a comprehensive source of information on beneficiary characteristics, needs, utilization, and satisfaction with Medicare-related activities; *Frequency:* Other (3 times a year per respondent); *Affected Public:* Individuals and households; *Number of Respondents:* 16,000; *Total Annual Responses:* 48,000; *Total Annual Hours:* 48,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections

referenced above, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards Attention: John Rudolph, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: July 9, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, Division of HCFA Enterprise Standards, Health Care Financing Administration.

[FR Doc. 97-19924 Filed 7-28-97; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Cancer Institute Special Emphasis Panel (SEP) meeting:

Name of SEP: Genetic Epidemiology of Lung Cancer I and II.

Date: August 4, 1997.

Time: 11:00 a.m. to 12:30 p.m.

Place: Teleconference, National Cancer Institute, Executive Plaza North, Room 635G, 6130, Executive Boulevard, Bethesda, MD 20892.

Contact Person: Sally A. Mulhern, Ph.D., Scientific Review Administrator, National Cancer Institute, NIH, Executive Plaza North, Room 635G, 6130 Executive Boulevard, MSC 7410, Bethesda, MD 20892-7410, Telephone: 301/496-7413.

Purpose/Agenda: To evaluate and review grant applications.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. Applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Numbers: 93.393, Cancer Cause and

Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control)

Dated: July 22, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97-19848 Filed 7-28-97; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Cancer Institute Special Emphasis Panel (SEP) meetings:

Name of SEP: Pivotal Clinical Trials for Chemoprevention Agent Development.

Date: August 18-19, 1997.

Time: August 18—7:00 a.m.-5:00 p.m.; August 19—8:00 a.m.-5:00 p.m.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, Md 20852.

Contact Person: Ray Bramhall, Ph.D., Scientific Review Administrator, National Cancer Institute, NIH, Executive Plaza North, Room 636, 6130 Executive Boulevard, MSC 7410, Bethesda, Md 20892-7410, Telephone: 301/496-3428.

Purpose/Agenda: To evaluate and review grant applications.

Name of SEP: Chemoprevention in Genetically-Identified High-Risk Groups: Interactive Research and Development Project.

Date: August 25-26, 1997.

Time: August 25—8:30 a.m.-5:00 p.m.; August 26—8:00 a.m.-5:00 p.m.

Place: Hyatt Regency Bethesda, 1 Bethesda Metro Center, Bethesda, Md 20814.

Contact Person: Ray Bramhall, Ph.D., Scientific Review Administrator, National Cancer Institute, NIH, Executive Plaza North, Room 636, 6130 Executive Boulevard, MSC 7410, Bethesda, Md 20892-7410, Telephone: 301/496-3428.

Purpose/Agenda: To evaluate and review grant applications.

These meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Numbers: 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395,