FOR FURTHER INFORMATION CONTACT: Sharon O'Callaghan, Center For Biologics Evaluation and Research (CBER) (HFM–650), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–1191.

SUPPLEMENTARY INFORMATION:

I. Background

CBER issued a memorandum to blood establishments on December 10, 1993, that provided guidance concerning process control procedures that should be established and maintained for the receipt, evaluation, investigation, and followup of post donation information reports. Post donation information includes information provided by the donor or other source and received or obtained following a donation, or at a subsequent donation during the health history screening process that relates to the suitability of the donor or of the blood or blood component. This CPG provides regulatory guidance relative to the evaluation and processing of this information.

This Level 2 guidance document is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on the evaluation and processing of post donation reports. 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 statutes, regulations, or both.

II. Request for Comments

Written comments concerning the guidance may be submitted to the Dockets Management Branch (address above) at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Written comments and requests for copies are to be identified with the docket number found in brackets in the heading of this document. A copy of the CPG and received comments are available for public examination in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

An electronic version of the CPG (section 230.140) is also available on the Internet by connecting to the ORA home page at ''http://www.fda.gov/ora/compliance__ref/default.htm''.

Dated: August 9, 1999.

Dennis E. Baker,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 99–21255 Filed 8–16–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2405]

Draft ''Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act.'' This draft guidance is intended to provide guidance to industry on the use of certain types of letters by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) as part of the review of marketing applications for certain drug and biological products.

DATES: Written comments may be submitted at any time, however, comments should be submitted by November 15, 1999, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self addressed adhesive label to assist the office in processing your request. 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document. Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Murray M. Lumpkin, Center for Drug Evaluation and Research (HFD–2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400; or

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–10), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act.'' In a November 1997 letter to Congress regarding the reauthorization of the Prescription Drug User Fee Act (PDUFA) as part of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115), the Secretary of Health and Human Services (the Secretary) committed FDA to certain user fee performance goals and additional procedures related to the review of products in human drug applications as defined in section 735(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g(1)) (PDUFA products). As one of the additional procedures intended to help expedite the development of drugs and biologics, the Secretary specified that FDA intends to provide early agency thoughts on possible deficiencies to applicants in a letter as each discipline finishes its initial review of its portion of the pending application. The procedures and policies described in this draft guidance are intended to explain how the agency will issue and use information request letters and discipline review letters during the review of PDUFA products.

This draft guidance document represents the agency's current thinking on information request letters and discipline review letters under PDUFA. 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, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide

information and does not set forth requirements.

II. Comments

This draft document is being distributed for comment purposes only, and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this guidance document. Written comments may be submitted at any time, however, comments should be submitted by November 15, 1999, to ensure adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance document using the World Wide Web (WWW). For WWW access, connect to CDER at ''http://www.fda.gov/cder/guidance/index.htm'', or CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: August 9, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–21254 Filed 8–16–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of September 1999.

The National Advisory Committee on Rural Health will convene its thirty-third meeting at the time and place specified below:

Name: National Advisory Committee on Rural Health

Date and Time: September 13, 1999; 8:30 a.m.– 5:00 p.m.; September 14, 1999; 8:30 a.m.–5:00 p.m.; September 15, 1999; 8:30–11:30 a.m.

Place: Omni Shoreham Hotel, 2500 Calvert Street, NW, Washington, DC 20008, Phone: (202) 234–7000.

Purpose: The National Advisory Committee on Rural Health provides advice and recommendations to the Secretary with respect to the delivery, research, development, and administration of health care services in rural areas.

Agenda: The plenary session on Monday morning, September 13, at 8:30 a.m., will include Office of Rural Health Policy update, legislative updates, NRHA Policy Institute overview, and presentation on the rural public health infrastructure project. After lunch, the Committee will begin formulating recommendations and review committee process and organization. Tuesday morning, September 14, will be spent exploring future committee options, topics and issues for the Committee. After lunch, a presentation on the Medicare Reform and its Implication for Rural: A Review of the Premium Support and the Administration proposal will be followed by panelist and Committee discussion. Late afternoon the Committee will continue formulating recommendations.

The final plenary session will be convened on Wednesday, at 8:30 a.m. During this session the Committee will conclude discussions on recommendations, Committee structure and future activities. The meeting will adjourn at 11:30 a.m.

Anyone requiring information regarding the subject Committee should contact Wayne W. Myers, M.D., Executive Secretary, National Advisory Committee on Rural Health, Health Resources and Services Administration, Room 9A–55, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, telephone (301) 443–0835, FAX (301) 443–2803.

Persons interested in attending any portion of the meeting should contact Sandi Lyles or Lilly Smetana, Office of Rural Health Policy, (301) 443–0835.

Agenda items are subject to change as priorities dictate.

Dated: August 11, 1999.

James J. Corrigan,

Associate Administrator for Operations and Management.

[FR Doc. 99–21256 Filed 8–16–99; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood 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 meeting.

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

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; PA–98–052 ''Mentored Patient-Oriented Research Career Development Award'' also PA–98–053 ''Midcareer Investigator Award in Patient-Oriented Research''.

Date: September 28–29, 1999.

Time: September 28, 1999, 7 pm to 9 pm.

Agenda: To review and evaluate grant applications.

Place: Chevy Chase Holiday Inn, 5520 Wisconsin Ave., Chevy Chase, MD 20815.

Time: September 29, 1999, 8:30 am to 5 pm.

Agenda: To review and evaluate grant applications.

Place: Chevy Chase Holiday Inn, 5520 Wisconsin Ave., Chevy Chase, MD 20815.

Contact Person: Diane M. Reid, MD, Scientific Review Administrator, NIH, NHLBI, DEA, Two Rockledge Center, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892–7924, (301) 435–0277.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research, 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: August 10, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99–21219 Filed 8–16–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; 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 meeting.

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

Name of Committee: National Institute of Nursing Research Special Emphasis Panel, Individual National Research Service Award Applications (NRSA).