Administration, suite 200N, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, suite 200N, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples From Donors of Whole Blood and Blood Components to Adequately and Appropriately Reduce the Risk of Transmission of HIV–1 and HCV,'' dated October 2004. FDA's final rule (66 FR 31146, June 11, 2001) entitled ''Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Diseases'' became effective on December 10, 2001. The regulations under § 610.40(b) (21 CFR 610.40(b)) require that establishments that collect or manufacture Whole Blood and blood components ''must perform one or more screening tests to adequately and appropriately reduce the risk of transmission of communicable disease agents'' (66 FR 31146 at 31162). As we noted in the preamble to the final rule, the standard for adequate and appropriate testing will change as new testing technology is approved by FDA. We explained, ''* * * we intend to regularly issue guidance describing those tests that we believe would adequately and appropriately reduce the risk of transmission of communicable disease agents'' (66 FR 31146 at 31149).

The guidance announced in this notice finalizes the draft guidances entitled ''Use of Nucleic Acid Tests on Pooled Samples From Source Plasma Donors to Adequately and Appropriately Reduce the Risk of Transmission of HIV–1 and HCV,'' dated December 2001, and ''Use of Nucleic Tests on Pooled and Individual Samples From Donors of Whole Blood and Blood Components for Transfusion to Adequately and Appropriately Reduce the Risk of Transmission of HIV–1 and HCV,'' dated March 2002. This guidance recommends that establishments implement these recommendations as soon as feasible, but not later than 6 months after publication of this notice.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. 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 and regulations.

II. The Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 601.12 and § 610.40 of this guidance were approved under OMB control numbers 0910–0315 and 0910–0472.

III. Comments

Interested persons may, at any time, submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: October 20, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–24067 Filed 10–27–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0462]

Draft Guidance for Industry: Criteria for Safety and Efficacy Evaluation of Oxygen Therapeutics as Red Blood Cell Substitutes; 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 entitled Criteria for Safety and Efficacy Evaluation of Oxygen Therapeutics as Red Blood Cell Substitutes'' dated October 2004. The draft guidance provides sponsors or investigators, with criteria for testing the efficacy and safety of oxygen therapeutics as substitutes for red blood cells, and guidance on the design of clinical trials to assess risk/benefit ratio of such use. The draft guidance, when finalized, would supercede the ''Points to Consider on the Safety Evaluation of Hemoglobin-Based Oxygen Carriers,'' dated August 27, 1990, and replaces the draft ''Guidance for Industry: Efficacy Evaluation of Hemoglobin- and Perfluorocarbon-Based Oxygen Carriers'' dated September 1997.

DATES: Submit written or electronic comments on the draft guidance by January 26, 2005 to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance 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 the office in processing your requests. The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics

Evaluation and Research (HFM–17), Food and Drug Administration, suite 200N, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry entitled Criteria for Safety and Efficacy Evaluation of Oxygen Therapeutics as Red Blood Cell Substitutes'' dated October 2004. The draft guidance, when finalized, would supercede the ''Points to Consider on the Safety Evaluation of Hemoglobin-Based Oxygen Carriers,'' dated August 27, 1990, and replaces the draft ''Guidance for Industry: Efficacy Evaluation of Hemoglobin- and Perfluorocarbon-Based Oxygen Carriers'' dated September 1997. The draft guidance provides you, as a sponsor or investigator, with criteria for testing the efficacy and safety of oxygen therapeutics as substitutes for red blood cells, and guidance on the design of clinical trials to assess risk/benefit ratio of such use. While the draft guidance is restricted to use of oxygen therapeutics as substitutes for red blood cells, this may not be the only indication being evaluated for these investigational new drugs. The draft guidance should not discourage innovation in the development of appropriate endpoints for and the design of clinical trials for other uses of oxygen therapeutics.

The draft guidance was revised based on, in part, presentations and discussions obtained at a workshop entitled ''Criteria for Safety and Efficacy Evaluation of Oxygen Therapeutics as Red Cell Substitutes'' held on September 27 and 28, 1999, and public comments received on the September 1997 draft guidance. The workshop was sponsored by CBER, FDA, and co-sponsored by the National Heart, Lung, and Blood Institute, National Institute of Health, the Department of Defense, U.S. Army Medical and Material Command, and the Armed Services Blood Program Office.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. 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 requirement of the applicable statutes and regulations.

II. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management 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 at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: October 20, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–24066 Filed 10–27–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on Migrant Health; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: National Advisory Council on Migrant Health.

Dates and Times: November 17, 2004, 9 a.m. to 5 p.m.; November 18, 2004, 9 a.m. to 5 p.m.

Place: Adam's Mark Denver, 1550 Court Place, Denver, Colorado 80202, Phone: (800) 444–2326; Fax: (303) 626–2544.

Status: The meeting will be open to the public.

Agenda: The agenda includes an overview of the Council's general business activities. In addition, the Council will hear presentations from experts on farmworker issues, including the status of farmworker health at the local and national level.

The Council meeting is being held in conjunction with the 14th Annual Midwest Farmworker Stream Forum sponsored by the National Center for Farmworker Health, Inc., which is being held in Denver, Colorado, during the same period of time.

Agenda items are subject to change as priorities indicate.

For Further Information Contact: Anyone requiring information regarding the Council should contact Gladys Cate, Office of Minority and Special Populations, staff support to the National Advisory Council on Migrant Health, Bureau of Primary Health Care, Health Resources and Services Administration, 4350 East-West Highway, Bethesda, Maryland 20814, Telephone (301) 594–0367.

Dated: October 20, 2004.

Steven A. Pelovitz,

Associate Administrator, Office of Administration and Financial Management.

[FR Doc. 04–24069 Filed 10–27–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 meetings.

The meetings 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 commerical 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 Mental Health Special Emphasis Panel Services Conflicts 3.

Date: November 2, 2004.

Time: 3:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Marina Broitman, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6153, MSC 9608, Bethesda, MD 20892–9608, 301–402–8152, *mbroitma@mail.nih.gov.*

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

Name of Committee: National Institute of Mental Health Special Emphasis Panel Advanced Centers for MH Disparities Research (SEP II).

Date: November 30, 2004.

Time: 9 a.m. to 5 p.m.