Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Lawrence Lesko, Center for Drug Evaluation and Research (HFD–850), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5690, or

Raj Puri, Center for Biologics Evaluation and Research (HFM–735), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0471.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Pharmacogenomic Data Submissions.'' Although the field of pharmacogenomics is in its infancy, the promise of pharmacogenomics lies in its potential to predict sources of interindividual variability in drug response (both efficacy and toxicity), thus allowing individualization of therapy to maximize effectiveness and minimize risk. Pharmaceutical sponsors have been reluctant to embark on programs of pharmacogenomic testing during the FDA-regulated phases of drug development, due to uncertainties in how FDA will react to the data being generated. This guidance is intended to facilitate scientific progress in the area of pharmacogenomics.

The guidance is one of several efforts under way to facilitate pharmacogenomic testing. FDA will make available soon a concept paper entitled ''Concept Paper on Pharmacogenomic Drug Diagnostic Co-Development.'' The concept paper is the first step in development of a draft guidance on that topic.

On November 4, 2003 (68 FR 62461), FDA announced a document announcing the availability of the draft version of this guidance. A number of comments were received. The agency considered them carefully as it finalized the guidance and made appropriate changes. For the most part, the changes clarified statements made in the draft version. The following changes are noteworthy: (1) Appendix D (examples of pharmacogenomic data submissions) is no longer part of the guidance and has been moved into a separate document that will be available with the final guidance so that additional examples can be added over time; (2) a new appendix E has been added, a voluntary submission cover sheet, which should be used when submitting a ''voluntary'' genomic data submission to clearly distinguish such a submission from regular IND, NDA, or BLA submissions; (3) two fundamental issues regarding the procedure of submitting and reviewing voluntary genomic data submissions and the function and responsibilities of the Interdisciplinary Pharmacogenomics Review Group were addressed by creating separate internal agency procedures (i.e., the Center for Drug Evaluation and Research Manual of Policy and Procedures or the Center for Biologics Evaluation and Research Manual of Standard Operating Procedures and Policies) rather than including the information in the guidance document.

II. The Paperwork Reduction Act of 1995

In the **Federal Register** of November 4, 2003 (68 FR 62461), FDA published a 60-day notice requesting public comment on the information collection provisions of this guidance. In the **Federal Register** of August 11, 2004 (69 FR 48876), the agency announced that it was submitting the collection of information to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. The information collection provisions related to this guidance have been approved under OMB control number 0910–0557. This approval expires December 31, 2007. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

This level 1 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 statute, regulations, or both.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of mailed 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. 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 guidance at either *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: March 10, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–5381 Filed 3–22–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Office of AIDS Research Advisory Council.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Office of AIDS Research Advisory Council.

Date: April 7, 2005.

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

Agenda: A Report of the Director addressing OAR initiatives. The meeting will focus on the burden of HIV disease on women.

Place: National Institutes of Health, Building 31, 31 Center Drive, Room 6C10, Bethesda, MD 20892.

Contact Person: Jack Whitescarver, Director, Office of AIDS Research, OD, National Institutes of Health, 9000 Rockville Pike, Building 2, Room 4E14, Bethesda, MD 20892, (301) 496–0357.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-

in at the security desk upon entering the building.

Information is also available on the Institute's/Center's home page: *www.nih.gov/od/oar/index.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: March 15, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–5665 Filed 3–22–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Alternative Medicine; Notice of 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 National Advisory Council for Complementary and Alternative Medicine (NACCAM) meeting.

This 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/or contract proposals and the discussion could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Complementary and Alternative Medicine.

Date: July 29, 2005.

Closed: 11 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: 6707 Democracy Boulevard, Two Democracy, Room 401, Bethesda, Maryland 20892, (Telephone Conference Call).

Contact Person: Jane F. Kinsel, PhD, M.B.A., Executive Secretary, National Center for Complementary and Alternative Medicine, National Institutes of Health, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, (301) 496–6701.

Copies of the meeting agenda and the roster of members will be furnished upon request by contacting Dr. Jane Kinsel, Executive Secretary, NACCAM, National Institutes of Health, 6707 Democracy Boulevard, Suite 401, Bethesda, Maryland 20892, 301–496–6701, Fax 301–480–0087, or via e-mail at *naccames@mail.nih.gov.*

Dated: March 16, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy, NIH.

[FR Doc. 05–5668 Filed 3–22–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Alternative Medicine; Notice of Meeting

Pursuant to Section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the National Advisory Council for Complementary and Alternative Medicine (NACCAM) meeting.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Advisory Council for Complementary and Alternative Medicine.

Date: April 4, 2005.

Open: 12:30 p.m. to 2:30 p.m.

Agenda: The agenda includes Opening Remarks by Director, NCCAM, and a Concept for Milk Thistle RFA.

Place: 6707 Democracy Boulevard, Two Democracy, Room 401, Bethesda, Maryland 20892, (Telephone Conference Call).

Contact Person: Jane F. Kinsel, Executive Secretary, National Center for Complementary and Alternative Medicine, National Institutes of Health, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, (301) 496–6701.

The meeting is being published less than 15 days prior to the meeting due to scheduling conflicts.

Copies of the meeting agenda and the roster of members will be furnished upon request by contacting Dr. Jane Kinsel, Executive Secretary, NACCAM, National Institutes of Health, 6707 Democracy Boulevard, Suite 401, Bethesda, Maryland 20892, 301–496–6701, Fax 301–480–0087, or via e-mail at *naccames@mail.nih.gov.*

Dated: March 16, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy, NIH.

[FR Doc. 05–5669 Filed 3–22–05; 8:45 am]

BILLING CODE 4140–01–M

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 the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, 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, Loan Repayment Program (L30 and L40s).

Date: April 8, 2005.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Jamie Varghese, PhD, Health Science Administrator, DHVD/HRP, NIH/NHLBI, Rockledge 2, Room 9204, 6701 Rockledge Drive, Bethesda, MD 20892–7950, 301–435–0510, *varghesej@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.

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

Dated: March 15, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–5660 Filed 3–22–05; 8:45 am]

BILLING CODE 4140–01–M