that office in processing your requests. The draft guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance document entitled ''Guidance for Industry: In the Manufacture and Clinical Evaluation of *In Vitro* Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Virus Type 1.'' The draft guidance document outlines some of the major regulatory and scientific issues concerning gene based tests for Human Immunodeficiency Virus (HIV), these criteria also apply to tests for other transfusion transmitted viruses including Human Immunodeficiency Virus Type 2, Hepatitis C Virus, Hepatitis B Virus, Human T–cell Lymphotropic Virus Types I and II.

This draft guidance document represents the agency's current thinking with regard to the manufacture and clinical evaluation of in vitro testing to detect specific nucleic acid sequences of HIV type 1. 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 As with other guidance documents, FDA does not intend this draft guidance document to be all-inclusive and cautions that not all information may be applicable to all situations. The draft guidance document is intended to provide information and does not set forth requirements.

II. Comments

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the draft guidance document. Written comments may be submitted at any time; however, comments should be submitted by October 8, 1998, to ensure adequate consideration in preparation of the final guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft 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.

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 CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: June 30, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–18403 Filed 7–9–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review Collection; Comment Request; Individual National Research Service Award Application and Related Forms

Summary

Under the provisions of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of Extramural Research, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on April 2, 1998, pages 16268–16269 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: Individual National Research Service Award Application and Related Forms. *Type of Information Collection Request:* Revision, OMB 0925–0002, Expiration Date 9/30/98. *Form Numbers: PHS 416–1, 416–9, 416–5, 416–7, 6031, 6031–1. Need and Use of Information Collection:* The PHS 416–1 and PHS 416–9 are used by individuals to apply for direct research training support. Awards are made to individual applicants for specified training proposals in biomedical and behavioral research, selected as a result of a national competition. The other related forms (PHS 416–5, 416–7, 6031 and 6031–1) are used by these individuals to activate, terminate, and provide for payback of a National Research Service Award. *Frequency of Response:* Applicants may submit applications for published receipt dates. If awarded, annual progress is reported. Related forms are used at activation, termination, and to provide for payback of a National Research Service Award. *Affected Public:* Individuals or Households: Business or other for-profit; Not-for-profit institutions; Federal Government; and State, Local or tribal Government. *Type of Respondents:* Adult scientific trainees and professionals. The annual reporting burden is as follows: *Estimated Number of Respondents:* 29, 748; *Estimated Number of Responses per Respondent:* 1.0834; *Average Burden Hours Per Responses:* 2.658 hours; and *Estimated Total Annual Burden Hours Requested:* 85,679. The estimated annualized cost to respondents is $1,985,472 (Using a $35 physician/professor average hourly wage rate, and a $12 trainee average hourly wage rate.) There are no Capital Costs to report. There are no Operating or Maintenance costs to report.

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated,

electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, D.C. 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Charles MacKay, Ph.D., NIH Project Clearance Officer, Division of Grants Policy, Office of Policy for Extramural Research Administration, OER, NIH, Rockledge II, Rm. 2196, 6701 Rockledge Dr., Bethesda, MD 20892–7730, or call non-toll free at (301) 435–0978 or E-mail your request, including your address to: *mackayc@odrockm1.od.nih.gov*.

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received on or before August 10, 1998.

Dated: June 30, 1998.

Diana Jaeger,

Director, Division of Grants Policy, Office of Policy for Extramural Research Administration, OER, NIH.

[FR Doc. 98–18321 Filed 7–9–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; 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 section 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 Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel, Clinical Trials Musculoskeletal.

Date: August 3, 1998.

Time: 10:00 a.m. to 1:00 p.m.

Place: To review and evaluate grant applications.

Place: Natcher Bldg., 45 Center Drive, Room 5AS25N, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: John R. Lymangrover, Scientific Review Administrator, NIAMS, 45 Center Drive, Room 5AS 25, Bethesda, MD 20892–650, (301) 594–4952.

Name of Committee: National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel, Osteoporosis Center.

Date: August 10, 1998.

Time: 10 a.m. to 11:00 a.m.

Agenda: To review and evaluate grant applications.

Place: Natcher Bldg., 45 Center Drive, Room 5AS25N, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: John R. Lymangrover, Scientific Review Administrator, NIAMS, 45 Center Drive, Room 5AS 25, Bethesda, MD 20892–650, (301) 594–4952.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: July 2, 1998.

LaVeen Ponds,

Acting Committee Management Officer, NIH.

[FR Doc. 98–18317 Filed 7–9–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; 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 General Medical Sciences Special Emphasis Panel National Research Service Award.

Date: July 17, 1998.

Time: 9:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Bruce K. Wetzel, Scientific Review Administrator, Office of Scientific Review, NIGMS, Natcher Building, Room 1AS–19, Bethesda, MD 20892, (301) 594–3907.

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. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Phamacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: July 2, 1998.

LaVeen Ponds,

Acting Committee Management Officer, NIH.

[FR Doc. 98–18318 Filed 7–9–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program; Notice of International Workshop to ''Evaluate Research Needs on the Use and Safety of Medicinal Herbs''

The Workshop will be held at the National Institute of Environmental Health Sciences, Conference Facility in Research Triangle Park, North Carolina September 23 and 24 1998 from 8:30 to 5:00 each day.

Background

Herbal medicines and dietary supplements account for one of the fastest growing markets in U.S. pharmacies and constitute a multi-billion dollar industry. It is estimated that as many as 1,500 botanicals are sold in the U.S. as dietary supplements or ethnic traditional medicines. It is further estimated that greater than 50% of the U.S. population uses one or more dietary supplements including medicinal herbs. Medicinal herbs are not, however, subject to the same testing for efficacy or safety mandated for prescription or over-the-counter drugs. Given the increasing use of some medicinal herbs and the paucity of toxicological data, this workshop will bring together a panel of national and international experts to discuss the use of the medicinal herbs and dietary supplements and to establish research needs that address public health