

unapproved products, and supplements to certain drug product applications.

DATES: Written comments on the draft guidance document may be submitted by December 1, 1998. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/cber/guidelines.htm>. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Leanne Cusumano, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance entitled "Submitting Debarment Certification Statements." Section 306(k) of the act (21 U.S.C. 335a(k)) states that drug product applications are to include a certification that the applicant did not and will not use in any capacity the services of any person who has been debarred under sections 306(a) or (b) of the act. Additionally, section 306(k) of the act requires that abbreviated new drug applications (ANDAs) and supplements to ANDAs providing for a different or additional use and submitted on or after June 1, 1992, contain a list of all convictions of the applicant and affiliated persons responsible for the development or submission of such application that have occurred within the last 5 years and for which a person can be debarred.

Since section 306(k) of the act became effective in 1992, FDA has received a number of requests for clarification. This draft guidance addresses the most commonly asked questions about the certification and information requirements and should be helpful to those submitting the following drug product applications to FDA: (1) New drug applications, (2) ANDAs, (3) new animal drug applications, (4) abbreviated new animal drug applications, (5) export applications for certain unapproved products, (6) biological license applications, and (7) supplements to certain drug product applications. The draft guidance was prepared by the Debarment Task Force at FDA.

This draft level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on debarment certification statements. 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.

Submit written requests for single copies of the draft guidance entitled "Submitting Debarment Certification Statements" to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448; or the Communications and Education Branch (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Requests should be identified with the docket number found in brackets in the heading of this document. Send one self-addressed adhesive label to assist the office in processing your request.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). 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. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 4, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98-26424 Filed 10-1-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Research and Demonstration Projects for Indian Health

AGENCY: Indian Health Service, HHS.

ACTION: Notice of single source cooperative agreement with the Center for Native American Health, College of

Medicine/Arizona Prevention Center, University of Arizona.

SUMMARY: The Indian Health Service (IHS) announces the award of a cooperative agreement to the Center for Native American Health (CNAH), College of Medicine/Arizona Prevention Center, University of Arizona, for a demonstration project to build and expand on a unique collaborative partnership that currently exists among the CNAH, the IHS, and the Indian tribes located in the southwestern part of the country. The project is for a 2-year period, effective September 1, 1998, through August 31, 2000. Funding for the first year of the project is \$243,075, plus an annual in-kind contribution by the University of \$100,390.

The award is issued under the authority of the Public Health Service Act, Section 301. A general program description is contained in the *Catalog of Federal Domestic Assistance*, number 93.933.

The specific goals of the project are to increase opportunities for sub-specialty medical care at reservation health care facilities, to increase the availability of telemedicine at reservation health care facilities, to enhance community health planning and prevention activities, to facilitate counseling of high school level Indian students for entry into health careers, and to investigate the possibilities of replication of this collaborative project at other sites.

Justification for Single Source: The CNAH is a unique organization within the University that is guided by an Advisory Council composed of leaders from 13 Indian tribes and tribal organizations located in the southwestern part of the country and health professionals from the Arizona Department of Health, the IHS, and the University of Arizona.

Award of a Cooperative Agreement: The Project Director for this cooperative agreement is an IHS employee who is serving as the Director of CNAH; therefore, he will provide substantial on-going IHS programmatic involvement in the development and direction of this demonstration project. Also, the IHS has health professionals providing project guidance as members of the Advisory Council.

Contacts: For programmatic information, please contact Ms. Jan Frederick, Acting Chief, Nutrition and Dietetics, Phoenix Area IHS, Two Renaissance Square, 40 North Central Avenue, Phoenix, Arizona 85004, (602) 364-5197. For grants administration or business information, contact Ms. M. Kay Carpentier, Grants Management

Officer, IHS, Suite 100, Twinbrook Metro Plaza Building, 12300 Twinbrook Parkway, Rockville, Maryland 20852, (301) 443-5204.

Dated: September 25, 1998.

Michael H. Trujillo,

Assistant Surgeon General Director.

[FR Doc. 98-26343 Filed 10-1-98; 8:45 am]

BILLING CODE 4160-16-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Deafness and Other Communication Disorders Advisory Council, October 7, 1998, 8:30 AM to 3 PM, National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, Conference Room 6, Bethesda MD 20892, which was published in the **Federal Register** on September 9, 1998, 63 FR 48236.

The meeting was scheduled to be open to the public from 8:30 AM to 12 PM and closed to the public from 1 pm to 3 pm. The meeting will now be open to the public from 8:30 AM to 11 AM and closed to the public from 11 AM to 3:30 PM. The additional time in the closed session will be used to hear a report on the Division of Intramural Research, NIDCD.

Dated: September 25, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, National Institutes of Health.

[FR Doc. 98-26344 Filed 10-1-98; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 on Aging Special Emphasis Panel, Early events in Alzheimer Pathogenesis.

Date: October 15, 1998.

Time: 1 pm to 4 pm.

Agenda: To review and evaluate grant applications.

Place: 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

Contact person: Louise L. Hsu, PHD, Scientific Review Administrator, Office of Extramural Affairs, National Institute on Aging, Gateway Building, 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892.

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. 93.866, Aging Research, National Institutes of Health, HHS).

Dated: September 25, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, National Institutes of Health.

[FR Doc. 98-26345 Filed 10-01-98; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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/or 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 grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, Education Projects.

Date: November 18, 1998.

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

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Hotel, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Kesinee Nimit, MD, Health Scientist Administrator, Office of Extramural Program Review, National Institute on Drug Abuse, National Institutes of Health, DHHS, 5600 Fishers Lane, Room 10-22, Rockville, MD 20857, (301) 443-9042.

(Catalogue of Federal Domestic Assistance Program Nos. 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs; 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards, National Institutes of Health, HHS)

Dated: September 25, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, National Institutes of Health.

[FR Doc. 98-26346 Filed 10-1-98; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 Mental Health Initial Review Group Services Research Review Committee.

Date: October 13-14, 1998.

Time: 8 am to 5 pm.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Capitol, 550 C Street, SW, Washington, DC 20024.

Contact Person: Gerald E. Calderone, PHD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Parklawn Building, 5600 Fishers Lane, Room 9C-18, Rockville, MD 20857, 301-443-1340.

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. 93.242, Mental Health Research Grants; 93-281, Scientist Development