

Dated: May 23, 1997.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

[FR Doc. 97-14140 Filed 5-29-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D-0200]

Control of Pharmaceutical Production; Out-of-Specification Guidance for Laboratory Testing; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting sponsored by the Office of Regulatory Affairs (ORA), FDA. This meeting will involve representatives from ORA's Division of Field Science, the Center for Drug Evaluation and Research, and other representatives from FDA. The topic of this public meeting is out-of-specification (OOS) laboratory test results used in pharmaceutical production. This meeting will provide guidance in appropriate evaluation of, and response to, out-of-specification test results.

DATES: The public meeting will be held on Friday, June 20, 1997, from 10 a.m. to 12 m.

ADDRESSES: The meeting will be held at the Westin Rio Mar Beach Resort, 6000 Rio Mar Blvd., Rio Grande, PR 00745. A conference room will be announced in the hotel lobby before the session.

FOR FURTHER INFORMATION CONTACT: Len P. Valenti, Office of Regulatory Affairs, Division of Field Science (HFC-141), Food and Drug Administration, 5600 Fishers Lane, rm. 12-41, Rockville, MD 20857, 301-443-3320, FAX 301-443-6388.

Questions related to this meeting should be directed to Len P. Valenti or Richard A. Baldwin, Director, Division of Field Sciences (address above) or by calling 301-443-3320, between 8 a.m. and 4:30 p.m.

SUPPLEMENTARY INFORMATION:

The purpose of this meeting is to continue a dialogue with members of trade, technical, and professional organizations, and other interested persons in order to discuss issues associated with the pharmaceutical laboratory practices and procedures.

On November 20, 1996, FDA held a public meeting to informally address

and outline ways to discuss problems associated with the development and monitoring of pharmaceutical products. The meeting explored issues of concern to the agency and industry laboratories. As a result of the meeting, industry members asked FDA to provide guidance in two control aspects of pharmaceutical production: (1) Evaluating OOS test results, and (2) system suitability requirements in measuring performance of a chromatographic system.

Interested persons who are unable to attend this meeting may contact the Division of Field Science (address above) regarding plans for a second meeting on this topic. A second OOS seminar is currently being planned for late August or early September 1997, in the Mid-Atlantic region. A **Federal Register** notice will be issued to notify all interested parties to announce its availability.

In addition to the OOS meeting in Rio Grande, PR, a system suitability workshop, scheduled for Monday, June 9, 1997, at the Hoffman-La Roche facility in Nutley, NJ was announced in the **Federal Register** of May 13, 1997 (62 FR 26320).

Dated: May 23, 1997.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[OPL-015-N]

Medicare Program; June 16, 1997, Meeting of the Practicing Physicians Advisory Council

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the Practicing Physicians Advisory Council. This meeting is open to the public.

DATES: The meeting is scheduled for June 16, 1997, from 9 a.m. until 5 p.m. e.d.t.

ADDRESSES: The meeting will be held in the Auditorium, 1st Floor, Health Care Financing Administration Building, 7500 Security Boulevard, Baltimore, Maryland 21224.

FOR FURTHER INFORMATION CONTACT: Jeffrey Kang, M.D., Executive Director, Practicing Physicians Advisory Council, Room 435-H, Hubert H. Humphrey Building, 200 Independence Avenue, S.W., Washington, DC 20201, (202) 690-7418.

SUPPLEMENTARY INFORMATION: The Secretary of the Department of Health and Human Services (the Secretary) is mandated by section 1868 of the Social Security Act to appoint a Practicing Physicians Advisory Council (the Council) based on nominations submitted by medical organizations representing physicians.

The Council meets quarterly to discuss certain proposed changes in regulations and carrier manual instructions related to physicians' services, as identified by the Secretary. To the extent feasible and consistent with statutory deadlines, the consultation must occur before publication of the proposed changes. The Council submits an annual report on its recommendations to the Secretary and the Administrator of the Health Care Financing Administration not later than December 31 of each year.

The Council consists of 15 physicians, each of whom has submitted at least 250 claims for physicians' services under Medicare or Medicaid in the previous year. Members of the Council include both participating and nonparticipating physicians, and physicians practicing in rural and underserved urban areas. At least 11 members must be doctors of medicine or osteopathy authorized to practice medicine and surgery by the States in which they practice. Members have been invited to serve for overlapping 4-year terms. In accordance with section 14 of the Federal Advisory Committee Act, terms of more than 2 years are contingent upon the renewal of the Council by appropriate action before the end of the 2-year term.

The Council held its first meeting on May 11, 1992.

The current members are: Richard Bronfman, D.P.M.; Wayne R. Carlsen, D.O.; Gary C. Dennis, M.D.; Catalina E. Garcia, M.D.; Mary T. Herald, M.D.; Ardis Hoven, M.D.; Sandral Hullett, M.D.; Jerilynn S. Kaibel, D.C.; Marie G. Kuffner, M.D.; Marc Lowe, M.D.; Katherine L. Markette, M.D.; Derrick K. Latos, M.D.; Susan Schooley, M.D.; Maisie Tam, M.D.; and Kenneth M. Viste, Jr., M.D. The chairperson is Kenneth M. Viste, Jr., M.D.

Council members will receive an update on legislation involving HCFA, the Medicaid program, and the Medicare physician fee schedule. The

agenda will provide for discussion and comment on the following items:

- Current Directions in Performance Measurement and Quality Improvement
- Uniform Procedure Coding

Individuals or organizations who wish to make 5-minute oral presentations on the agenda issues should contact the Executive Director by 12:00 noon, June 6, 1997, to be scheduled. The number of oral presentations may be limited by the time available. A written copy of the oral remarks should be submitted to the Executive Director no later than 12:00 noon, June 11, 1997. Anyone who is not scheduled to speak may submit written comments to the Executive Director by 12:00 noon, June 11, 1997. The meeting is open to the public, but attendance is limited to the space available.

(Section 1868 of the Social Security Act (42 U.S.C. 1395ee) and section 10(a) of Public Law 92-463 (5 U.S.C. App. 2, section 10(a)); 45 CFR part 11)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: May 23, 1997.

Bruce C. Vladeck,
Administrator, Health Care Financing Administration.

[FR Doc. 97-14186 Filed 5-29-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

[0917-ZA04]

American Indians Into Psychology Program

AGENCY: Indian Health Service, HHS.

ACTION: Notice of competitive grant applications for American Indians Into Psychology Program.

SUMMARY: The Indian Health Service (IHS) announces that competitive grant applications are now being accepted for the American Indians Into Psychology Program. These grants are established under the authority of section 217 of the Indian Health Care Improvement Act, Public Law 94-437, as amended. There will be only one funding cycle during fiscal year (FY) 1997. This program is described at 93.970 in the Catalog of Federal Domestic Assistance. Costs will be determined in accordance with applicable Office of Management and Budget Circulars. Executive Order 12372 requiring intergovernmental review is not applicable to this program.

The PHS is committed to achieving the health promotion and disease prevention objectives of *Health People 2000*. *Health People 2000*, the full report, is currently out of print. You may obtain the objectives from the latest *Health People 2000 Review*. A copy may be obtained by calling the National Center for Health Statistics, telephone (301) 443-8500.

Smoke Free Workplace

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products, and Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

DATES: a. Application Receipt Date: An original and two copies of the completed grant application must be submitted with all required documentation to the Grants Management Branch, Division of Acquisition and Grants Management, Twinbrook Metro Plaza, 12300 Twinbrook Parkway, Suite 100, Rockville, Maryland 20852, by close of business July 2, 1997.

Applications shall be considered as meeting the deadline if they are either: (1) Received on or before the deadline with hand carried applications received by close of business 5 p.m.; or (2) postmarked on or before the deadline and received in time to be reviewed along with all other timely applications. A legibly dated receipt from a commercial carrier or the U.S. Postal Service will be accepted in lieu of a postmark. Private metered postmarks will not be accepted as proof of timely mailing. Late applications not accepted for processing will be returned to the applicant and will not be considered for funding.

Additional Dates

1. *Application Review:* July 15, 1997. The review will be conducted by field readers.

2. *Applicants Notified of Results:* on or about July 17, 1997 (approved, recommended for approval but not funded, or disapproved).

3. *Anticipated Start Date:* August 1, 1997.

CONTACTS FOR ASSISTANCE: For American Indians Into Psychology program information, contact Ms. Pat Lee-McCoy, Office of Management Support, Division of Health Professions Support, Scholarship Branch, Indian Health Service, 12300 Twinbrook

Parkway, Suite 100, Rockville, MD 20852, (301) 443-6197. For grant application and business management information, contact Mrs. M. Kay Carpentier, Grants Management Branch, Indian Health Service, Twinbrook Metro Plaza, 12300 Twinbrook Parkway, Suite 100, Rockville, MD 20852, (301) 443-5204.

SUPPLEMENTARY INFORMATION: This announcement provides information on the general program purpose, eligibility and documentation, program requirements, required affiliations, funds available, limitations, period of support, and application procedures for FY 1997.

A. General Program Purpose

The purpose of the American Indians Into Psychology program is to develop and maintain American Indian psychology career recruitment programs as a means of encouraging Indians to enter the mental health field.

B. Eligibility and Documentation

Public and non-profit private colleges and universities are eligible to apply for a grant, however, only one grant will be awarded and funded to a college or university per funding cycle.

C. Program Requirements

Each proposal must address the following objectives to be considered for funding:

1. Provides outreach and recruitment for health professions to Indian communities including elementary, secondary and community colleges located on Indian reservations that will be served by the program.

2. Incorporates a program advisory board comprised of representatives from the tribes and communities that will be served by the program.

3. Provides summer enrichment programs to expose Indian students to the varied fields of psychology through research, clinical, and experiential activities.

4. Provides stipends to undergraduate and graduate students to pursue a career in psychology. Stipends for individuals will not be funded during the first year of the project because the first year will involve recruiting individuals. Stipends must be included in the budget and narrative for the second and third years of the project.

5. Develops affiliation agreements with tribal community colleges, the IHS, university affiliated programs, and other appropriate entities to enhance the education of Indian students.

6. To the maximum extent feasible, utilizes existing university tutoring,