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.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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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