review or funding decisions, but it will enable CDC to plan the review more efficiently and will ensure that each applicant receives timely and relevant information prior to application submission.

B. Application

The original and two copies of the application PHS Form 5161–1 (Revised 7/92, OMB Number 0937–0189) must be submitted Victoria Sepe, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Mailstop E–13, 255 East Paces Ferry Road, NE., Room 300, Atlanta, GA 30305, on or before July 15, 1997.

1. *Deadline:* Applications will be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date, or

(b) Sent on or before the deadline date and received in time for submission to the objective review group. (The applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks will not be acceptable as proof of timely mailing.)

2. Late Applicants: Applications that do not meet the criteria in 1.(a) or 1.(b) above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicants.

Where To Obtain Additional Information

To receive additional written information call (404) 332–4561. You will be asked to leave your name, address, and telephone number and will need to refer to NIOSH Announcement Number 754. You will receive a complete program description, information on application procedures, and application forms. If you have any questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Victoria Sepe, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 321, Mailstop E–13, Atlanta, GA 30305, telephone (404) 842–6804, Internet: vxw1.cdc.gov.

Programmatic technical assistance may be obtained from Steven L. Sauter, Ph.D., Chief, Applied Psychology and Ergonomics Branch, Division of Biomedical and Behavioral Science, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC), Mailstop C–24, 4676 Columbia Parkway, Cincinnati, OH 45226–1998, telephone (513) 533–8157, Internet: sls4.cdc.gov; or from Michael Colligan, Ph.D., Director Scientist, Training Evaluation Team, Education and Information Division, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC), Mailstop C–11, 4676 Columbia Parkway, Cincinnati, OH 45226–1998, telephone (513) 533–8222, Internet: mlc4.cdc.gov.

Please refer to Announcement Number 754 when requesting information on this program.

This and other CDC announcements are available through the CDC homepage on the Internet. The address for the CDC homepage is: http://www.cdc.gov.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report, Stock No. 017–001–00473–1) referenced in the Introduction section through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

The National Occupational Research Agenda: copies of this publication may be obtained from The National Institute for Occupational Safety and Health, Publications Office, 4676 Columbia Parkway, Cincinnati, OH 45226–1998 or telephone 1–800–356–4674.

Dated: May 23, 1997.

Diane D. Porter,

Acting Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–14182 Filed 5–29–97; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0182]

Agency Information Collection Activities: Proposed Collections; Comment Request; Reinstatements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collections of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection provisions relating to the regulation that samples and protocols of biological products may be required to be submitted to the agency, and Transmittal of Labels and Circulars, Form FDA 2657.

DATES: Submit written comments on the collections of information by July 29, 1997.

ADDRESSES: Submit written comments on the collections of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collections of information listed below.

With respect to each of the following collections of information, FDA invites comments on: (1) Whether the proposed collections of information are necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimates of the burdens of the proposed collections 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 burdens of the collections of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

1. Requests for Samples and Protocols: Official Release—(OMB Control Number 0910–0206 Reinstatement)

Under section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262), FDA has the responsibility to issue regulations that prescribe standards designed to assure the safety, purity, and potency of biological products and to ensure that licenses for such products are only issued when a product meets the prescribed standards.

Since January 8, 1948, there has been a regulation, now codified under § 610.2 (21 CFR 610.2), that gives authority to FDA to require manufacturers of licensed biological products to submit lot samples and protocols prior to marketing the lot of product. These lot samples and protocols are required by FDA when necessary for the safety, purity, or potency of the product. This requirement remains essential because of the potential lot-to-lot variability of a product produced from living organisms. In cases of certain biological products (e.g., Albumin, Plasma Protein Fraction, and specified biotechnology and specified synthetic biological products) that are known to have lot-to-lot stability, official lot release is normally not required. In addition to § 610.2, there are other regulations that require additional standards for the submission of samples and protocols for specific licensed biological products: §§ 640.101(f) (21 CFR 640.101(f)) (Immune Globulin (Human)), 660.6 (21 CFR 660.6) (Antibody to Hepatitis B Surface Antigen), 660.36 (21 CFR 660.36) (Reagent Red Blood Cells), and 660.46 (21 CFR 660.46) (Hepatitis B Surface Antigen).

Respondents to this collection of information are manufacturers of licensed biological products that are subject to lot release. Approximately 80 manufacturers are subject to lot release. Previously, 90 firms were subject to lot release, however, 10 of those firms have been exempted from this reporting requirement because the firms manufacture specified biotechnology and/or specified synthetic biological products. FDA estimates are based on data on lot releases submitted in fiscal year 1995. The estimated burdens for §§ 640.101(f), 660.6, 660.36, and 660.46 are included in the estimated annual reporting burden for § 610.2.

FDA estimates the burden of this information collection as follows:

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
610.2	80	75	6,500	1	6,500

There are no capital costs or operating and maintenance costs associated with this collection of information.

2. Transmittal of Labels and Circulars, Form FDA 2567—21 CFR 601.2(a) and 601.12(a) (OMB Control Number 0910–0039—Reinstatement)

Under section 351 of the PHS Act, FDA has the responsibility to ensure the safety, purity, potency and effectiveness of biological products. Part of this responsibility includes the review and approval of all labeling for biological products prior to marketing of the licensed product and when changes to labeling are proposed. Section 601.2(a) (21 CFR 601.2(a)) requires manufacturers of biological products to submit an establishment and product, or biologics license application for review and approval to the Center for Biologics Evaluation and Research (CBER) prior to marketing a biological product in interstate commerce. Specimens of the label are required to be submitted as part of the approval process. Section 601.12(a) (21 CFR 601.12(a)) requires proposed changes to labeling to be submitted to CBER for approval. For these labeling requirements, Form FDA 2567 is used to determine the type of labeling being submitted (container label, package label, diluent label and/or circular) and the type of change(s) to the labeling. This form is also used for the submission of advertising and promotion labeling. The form is composed of two parts: Part I is for the submission of draft and preliminary proof labeling and is completed by manufacturers of biological products, and Part II of the form is submitted upon implementation of final printed labeling. Parts I and II of the form are submitted separately. Respondents to this collection of information are manufacturers of biological products.

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN

Form No.	21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA Form 2657 Transmittal of Labels and Circulars	60l.2(a) and 601.12(a)	387	7.2	2,800	.16	448

There are no capital costs or operating and maintenance costs associated with this information collection of information.

Dated: May 23, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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

BILLING CODE 4160–01–F

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.

[FR Doc. 97–14141 Filed 5–29–97; 8:45 am]

BILLING CODE 4160–01–F

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