guidance be replaced by two new statistical approaches termed ''population'' and ''individual'' bioequivalence.

In contrast to the standard bioequivalence approach, which focuses on assessing and comparing only population averages for a bioavailability metric of interest for a test and reference product, the population and individual bioequivalence approaches assess and compare both population averages and population variances for the metric.

This preliminary draft guidance recommends that the population bioequivalence approach be used by NDA sponsors who wish to assess bioequivalence during the investigational phase of drug development. The preliminary draft guidance recommends that the individual bioequivalence approach be used by sponsors of ANDA's and AADA's to assess bioequivalence between a generic and reference listed drug, or by sponsors of NDA's, ANDA's, and AADA's who, during the postapproval period, wish to reassess in vivo bioequivalence when a change of sufficient magnitude occurs in the formulation and/or manufacturing of the drug product. If finalized, this guidance would replace the 1992 guidance.

Because transition to the approaches delineated in this preliminary draft will require careful consideration, FDA is publishing it as a preliminary draft guidance. The agency hopes to engage the public in a discussion of the justification for and implications of the recommendations that are presented. This public discussion may include a number of activities, such as holding a public workshop, creating an expert panel, and other discussions and deliberations as appropriate. At the conclusion of this public discussion, which is expected to take at least several months, FDA may release the draft document for a second round of public comment. Despite the possibility that the draft guidance may be released again for comment, the public is encouraged to comment now on this preliminary version and, specifically, to provide information that supports or refutes the importance of its proposals.

Given the need for careful consideration of some of the recommendations in the preliminary draft, FDA does not recommend implementation of any of its provisions at this time.

This preliminary draft guidance for industry represents the agency's current thinking on in vivo bioequivalence studies based on population and individual bioequivalence approaches. 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.

Interested persons may, at any time, submit written comments on the preliminary 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. A copy of the preliminary draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 17, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–33795 Filed 12–29–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–667]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Alternate Quality Assessment *Survey; Form No.:* HCFA–667 (OMB# 0938–0650); *Use:* The HCFA–667 is used in lieu of an onsite survey for those Clinical Laboratories Improvement Amendment (CLIA) laboratories with good performance as determined by their last onsite survey. This form is designed to determine current CLIA compliance as well as prepare laboratories for future onsite surveys. This system rewards good performance and facilitates quality assurance. *Frequency:* On occasion; *Affected Public:* Business or other for-profit, Not-for-profit institutions, Federal Government, State, Local or Tribal Government; *Number of Respondents:* 4,000; *Total Annual Responses:* 4,000; *Total Annual Hours:* 10,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards Attention: Louis Blank, Room C2–26–17, 7500 Security Boulevard Baltimore, Maryland 21244–1850.

Dated: December 18, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, Office of Information Services Information Technology Investment Management Group Division of HCFA Enterprise Standards.

[FR Doc. 97–33819 Filed 12–29–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1034–N]

Medicare Program; Request for Nominations for Members for the Practicing Physicians Advisory Council

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

ACTION: Notice.

SUMMARY: In accordance with section 1868(a) of the Social Security Act, this notice requests nominations from medical organizations representing physicians for individuals to serve on the Practicing Physicians Advisory Council. There will be four vacancies on February 28, 1998.

DATES: Nominations from medical organizations representing physicians will be considered if we receive them at the appropriate address, provided below, no later than 5 p.m. on January 30, 1998.

ADDRESSES: Mail or deliver nominations for membership to the following address: Health Care Financing Administration, Center for Health Plans and Providers, Office of Professional Relations, Attention: Jeffrey Kang, M.D., Executive Director, Practicing Physicians Advisory Council, Room 435–H, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Jeffrey Kang, M.D., Executive Director, Practicing Physicians Advisory Council, (202) 690–7418.

SUPPLEMENTARY INFORMATION: Section 4112 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508), enacted on November 5, 1990, added a new section 1868 to the Social Security Act (the Act), which established the Practicing Physicians Advisory Council (the Council). The Council advises the Secretary (the Secretary) of the Department of Health and Human Services on proposed regulations and manual issuances related to physicians' services. An advisory committee created by the Congress, such as this one, is subject to the provisions of the Federal Advisory Committee Act (5 U.S.C. App. 2).

Section 1868(a) of the Act requires that the Council consist of 15 physicians, each of whom must have submitted at least 250 claims for physicians' services under Medicare in the previous year. At least 11 Council members must be physicians as defined in section 1861(r)(1) of the Act; that is, State-licensed physicians of medicine or osteopathy. The other four Council members may include dentists, podiatrists, optometrists, and chiropractors. The Council must include both participating and nonparticipating physicians, as well as physicians practicing in rural and under served urban areas. In addition, section 1868(a) of the Act provides that nominations to the Secretary for Council membership must be made by medical organizations representing physicians.

This notice is an invitation to all organizations representing physicians to submit nominees for membership on the Council. Current members whose terms expire in 1998 will be considered for reappointment, if renominated. The Secretary will appoint new members to the Council from among those candidates determined to have the expertise required to meet specific agency needs and in a manner to ensure appropriate balance of membership.

Each nomination must state that the nominee has expressed a willingness to serve as a Council member and must be accompanied by a short resume or description of the nominee's experience. To permit evaluation of possible sources of conflict of interest, potential candidates will be asked to provide detailed information concerning financial holdings, consultant positions, research grants, and contracts.

Section 1868(b) of the Act provides that the Council meet once each calendar quarter, as requested by the Secretary, to discuss proposed changes in regulations and manual issuances that relate to physicians services. Council members are expected to participate in all meetings.

Section 1868(c) of the Act provides for payment of expenses and a per diem allowance for Council members at a rate equal to payment provided members of other advisory committees. In addition to making these payments the Department of Human Services provides management and support services to the Council.

(Section 1868 of the Social Security Act (42 U.S.C. 1395ee); 5 U.S.C. App.2)

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

Dated: December 23, 1997.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 97–33939 Filed 12–29–97; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting of the Advisory Committee to the Director

Pursuant to Public Law 92–463, notice is hereby given of a telephone conference call meeting of the Advisory Committee to the Director, National Cancer Institute, January 12, 1998, at the National Institutes of Health, Building 31, Room 11A10, 9000 Rockville Pike, Bethesda, MD 20892.

The entire meeting will be open to the public from 10:00 a.m. to 11:00 a.m. Attendance by the public is limited to space available. Individuals who plan to attend and need special assistance such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below.

Name of Committee: Advisory Committee to the Director.

Contact Person: Susan J. Waldrop, Executive Secretary, Federal Building, Room 312, Bethesda, MD 20892, (301) 496–1458.

Date of Meeting: January 12, 1998.

Place of Meeting: National Institutes of Health, Building 31, Room 11A10, 9000 Rockville Pike, Bethesda, MD 20892.

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

Agenda: To update the Committee on the progress of the NCI working groups.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(CATALOG OF FEDERAL DOMESTIC ASSISTANCE PROGRAM NUMBERS: 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control.)

Dated: December 22, 1997.

LaVeen Ponds,

Acting Committee Management Officer, NIH.

[FR Doc. 97–33943 Filed 12–29–97; 8:45 am]

BILLING CODE 4410–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Meetings

Pursuant to Public Law 92–463, notice is hereby given of the meetings of the National Center for Research Resources Initial Review Group and the Scientific and Technical Review Board on Biomedical and Behavioral Research Facilities, National Center for Research Resources (NCRR), for February 1998. These meetings will be open to the public as indicated below to discuss program planning; program accomplishments; administrative matters such as previous meeting minutes; the report of the Director, NCRR; review of budget and legislative updates; and special reports or other issues relating to committee business. Attendance by the public will be limited to space available.

These meetings will be closed to the public as indicated below in accordance