previously authorized for marketing in the United States first requires the submission of an IND to FDA. FDA regulations in §§ 312.22 and 312.23 (21 CFR 312.22 and 312.23) contain the general principles underlying the IND submission and the general requirements for an IND's content and format. This guidance clarifies these requirements related to the initial entry of an unapproved drug, including well-characterized, therapeutic, biotechnology-derived products.

Because of the manufacturing and toxicologic differences between well-characterized, therapeutic, biotechnology-derived products and other biologic products, the guidance only applies to drugs that are not also biologics and to well-characterized, therapeutic, biotechnology-derived biologic products. For products not covered by the guidance the center responsible for the product should be contacted for guidance.

The requirements in §§ 312.22 and 312.23 permit a great deal of flexibility in the amount and depth of data to be submitted in an IND, depending in large part on the phase of the investigation and the specific human testing proposed. In some cases, the extent of that flexibility and the limited data needed has not been appreciated. FDA believes that clarification of these requirements will decrease the submission of unnecessary data and help expedite the entry of new drugs into clinical testing by increasing transparency and reducing ambiguity and inconsistencies. These clarifications will reduce the amount of information ordinarily submitted in an IND, yet continue to provide the agency with the data it needs to assess the safety of the proposed Phase 1 study.

The most significant clarifications contained in the guidance are FDA's willingness to accept an integrated summary report of toxicology findings as initial support for human studies based upon unaudited, draft, toxicological reports of completed animal studies, as well as specific manufacturing data that FDA will accept as appropriate for a Phase 1 study. This guidance applies equally to both commercial and individual investigator sponsors of IND's.

As part of the President's Reinventing Government Initiative, FDA has been reviewing its regulatory processes to determine which requirements could be reduced or eliminated without lowering health and safety standards. These clarifications of the IND requirements have been identified during this review and should significantly reduce the burden on industry regarding data submitted in Phase 1 IND's without sacrificing the quality of FDA's review of the IND.

In addition to this guidance, FDA is preparing an advance notice of proposed rulemaking (ANPR) that will describe proposed revisions to the IND regulations that FDA is contemplating to facilitate further the entry of drugs into clinical studies so that safe and effective drugs can be made available in the United States more quickly. The ANPR is expected to be published in the first quarter of 1996 and will address the possibility of: (1) A specific single dose IND with limited data requirements and (2) reducing or eliminating the IND submission requirements for individual investigators who would like to use products already in Phase 2 of commercial development.

Although this guidance does not create or confer any rights for or on any person and does not operate to bind FDA or the industry, it does represent the agency's current thinking on data requirement issues related to the initial entry of an unapproved drug into human studies in the United States.

Although the guidance is being implemented immediately because it merely clarifies existing regulations and is expected to reduce the data submission burden on the industry, FDA is soliciting comments on the guidance that will be taken into account in making further revisions or clarifications to the IND process. FDA is particularly interested in comments on how the guidance could be extended to cover biological products other than well-characterized, therapeutic, biotechnology-derived products or whether a separate guidance should be developed for those products.

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

Dated: January 8, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–943 Filed 1–23–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

Public Information Collection Requirements Submitted for Public Comment and Recommendations

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 summaries of proposed collections for public comment. Interested persons are invited to send comments regarding the 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.

1. Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration; *Form No.:* HCFA–2728; *Use:* This form captures the necessary medical information required to determine Medicare eligibility of an end stage renal disease claimant. It also captures the specific medical data required for research and policy decisions on this population as required by law. *Frequency:* Annually; *Affected Public:* Individuals or households, business or other for-profit, not-for-profit institutions; *Number of Respondents:* 60,000; *Total Annual Hours Requested:* 25,200.

To request copies of the proposed paperwork collections referenced above, call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Planning and Analysis Staff, Attention: Louis Blank, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: January 16, 1996

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources.

[FR Doc. 96–910 Filed 1–23–96; 8:45 am]

BILLING CODE 4120–03–P

National Institutes of Health

National Cancer Institute; Notice of Meeting

Notice is hereby given of the meeting of the National Cancer Institute Board of Scientific Advisors Cancer Centers Program Working Group, January 24–25, 1996 at the Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, Maryland.

This meeting will be open to the public on January 24, from 8:00 am to 1:30 pm for overview and discussion of the Institute's Cancer Centers Extramural Program.

The meeting will be closed to the public on January 24, from 1:30 pm to approximately 7:00 pm and on January 25 and 8:30 am to adjournment for discussion of confidential issues relating to the review, discussion and evaluation of individual programs and programs and projects conducted by the Cancer Centers Extramural Program. These discussions will reveal confidential trade secrets or commercial property such as patentable material, and personal information including consideration of personnel qualifications and performance, the competence of individual investigators and similar matters, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Information pertaining to the meeting may be obtained from Dr. Paulette Gray, Executive Secretary, National Cancer Institute Board of Scientific Advisors, National Cancer Institute, 6130 Executive Blvd., EPN, Rm. 600, Bethesda, MD 20892, (301–496–4218). Individuals who plan to attend and need special assistance such as sign language interpretation or other reasonable accommodations should contact Dr. Paulette Gray in advance of the meeting.

Dated: January 18, 1996.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 96–1129 Filed 1–23–96; 8:45 am]

BILLING CODE 4140–01–M

National Eye Institute et al.; Amended Notice of Meetings

Due to the partial shutdown of the Federal Government, notice is hereby given of changes and/or postponements in the following meetings, as previously advertised in the Federal Register.

1. National Eye Institute

National Advisory Eye Council (NAEC) was to have convened at 8:30 a.m., January 25, 1996, Executive Plaza North, Conference Room G, 6130 Executive Boulevard, Bethesda, MD, as published in the Federal Register on December 20, 1995, (60 FR 244 65661). The meeting has been changed to March 7, Executive Plaze North, Conference Room H. As previously advertised, the meeting will be open from 8:30 a.m. to approximately 11:30 a.m., and will be closed from 11:30 a.m. to adjournment.

2. National Institute on Aging

National Advisory Council on Aging was to have convened on February 1 and February 2, 1996, National Institutes of Health, Building 31, Conference Room 6, Bethesda, MD, as published in the Federal Register on December 7, 1995. (60 FR 235 62871). The meeting has been changed to a one-day teleconference on February 1, same location. The meeting will be open from 1 p.m. to 2 p.m., and will be closed from 2 p.m. to adjournment.

3. National Institute of Allergy and Infectious Diseases

National Advisory Allergy and Infectious Diseases Council (NAAIDC) and its Subcommittees, were to have convened at 8 a.m., January 29, 1996, as published in the Federal Register December 7, 1995, (60 FR 235 62871).

—The closed sessions of the subcommittee meetings, scheduled for January 29, 8 a.m. to 1 p.m. are canceled.

—The open session of the NAAIDC Microbiology and Infectious Diseases Subcommittee was to have convened on January 30 at 8:30 a.m., but has been changed to January 29, 10 a.m. to 1 p.m., National Institutes of Health, Building 31, Conference Room 6.

As previously advertised in the Federal Register, the meeting of the full Council will be open to the public on January 29, Conference Room 6, from 1 p.m. to 3:30 p.m., and will be closed from 3:30 p.m. to recess. The NAAIDC Allergy and Immunology Subcommittee will be open to the public on January 30, Conference Room 8, 8:30 a.m. to adjournment. The NAAIDC Acquired Immunodeficiency Syndrome Subcommittee will be open to the public on January 30, 8 a.m. to recess, and on January 31, 8 a.m. to adjournment, Executive Board Conference Room, Natcher Building.

Dated: January 19, 1996.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 96–1131 Filed 1–23–96; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Mental Health; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the National Advisory Mental Health Council of the National Institute of Mental Health for January 1996.

The meeting will be open to the public, as indicated, for discussion of NIMH policy issues and will include current administrative, legislative, and program developments. Attendance by the public will be limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the contact person named below in advance of the meeting.

In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 4, U.S.C. and section 10(d) of Public Law 92–463, a portion of the Council will be closed to the public as indicated below for the review, discussion and evaluation of individual grant applications. These applications, evaluations, and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. Joanna L. Kieffer, Committee Management Officer, National Institute of Mental Health, Parklawn Building, Room 9–105, 5600 Fishers Lane, Rockville, MD 20857, Area Code 301, 443–4333, will provide a summary of the meeting and a roster of committee members.

Other information pertaining to the meetings may be obtained from the contact person indicated.

Name of Committee: National Advisory Mental Health Council.

Date: January 29, 1996.

Place: Conference Rooms G and H, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Open: January 29, 9 a.m. to 12 p.m.

Closed: January 29, 1 p.m. to adjournment.

Contact Person: Carolyn Strete, Ph.D., Executive Secretary, Parklawn Building,