

2. *The date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e):* February 20, 1992. The applicant claims November 19, 1991, as the date the premarket approval application (PMA) for Excimed™ UV200LA/SVS APEX Excimer Laser Systems was initially submitted. However, FDA records indicate that PMA P910067 submitted on November 19, 1991, was incomplete. FDA refused this application and notified the applicant of this fact by letter dated February 7, 1992. The completed PMA was then submitted on February 20, 1992, which is considered to be the PMA initially submitted date.

3. *The date the application was approved:* March 10, 1995. FDA has verified the applicant's claim that PMA P910067 was approved on March 10, 1995.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 609 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 6, 1995, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before February 15, 1996, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 28, 1995.

Stuart L. Nightingale,
Associate Commissioner for Health Affairs.
[FR Doc. 95-19425 Filed 8-4-95; 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 (HHS), is publishing the following summaries of proposed collections for public comment.

1. *Type of Information Collection Request:* Reinstatement, with change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Alternative Quality Assessment Survey; *Form No.:* HCFA-667; *Use:* This survey is used in lieu of an onsite survey for those Clinical Laboratory Improvement Amendments of 1988 (CLIA) laboratories with good performance determined by their last onsite survey, and is designed to screen laboratories and alert HCFA to where an onsite inspection is vital. The survey has been revised to reflect CLIA's streamlined inspection process, to reduce burden and improve the CLIA system by rewarding good performance. *Frequency:* Annually; *Affected Public:* Business or other for profit, not for profit, Federal Government, State, local, or tribal government; *Number of Respondents:* 4,000; *Total Annual Hours:* 6,000.

2. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Data Collection and Analysis for Generating Procedure Specific Cost Estimates; *Form No.:* HCFA R-181; *Use:* The Survey of Practice Costs is a survey of provider practices whose services are covered by the Medicare Fee Schedule (MFS). The data collected from this survey will enable HCFA to meet its congressional mandate to develop resource-based practice expense relative value unit estimates for the MFS by 1998; *Frequency:* Annually; *Affected Public:* Individuals or households, business or other for profit; *Number of Respondents:* 3,500; *Total Annual Hours:* 10,500.

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: John Burke, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: July 31, 1995.

Kathleen B. Larson,
Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 95-19391 Filed 8-4-95; 8:45 am]

BILLING CODE 4120-03-P

National Institutes of Health

National Center for Research Resources; Notice of Meeting of the Board of Scientific Counselors, NCRR

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Board of Scientific Counselors, National Center for Research Resources, August 30, 1995, in Building 45, Room A, National Institutes of Health, Bethesda, Maryland.

This meeting will be open to the public from 8:00 a.m. to 12 noon for the review of the Intramural Research Program. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in sec. 552b(c)(6), Title 5, U.S.C. and sec. 10(d) of Pub. L. 92-463, the meeting will be closed to the public on August 30 from 1:00 p.m. to adjournment for the review, discussion and evaluation of individual programs and projects conducted by the National Institutes of Health, including consideration of personnel qualifications and performance, the competence of individual investigators, and similar items, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. Sonja Shorts, Assistant to the Executive Secretary, NCRR, Building 12, Room 12A, National Institutes of Health, Bethesda, Maryland, 20894-2425, Area Code 301, 496-6023, will provide a summary of the meeting and a roster of the Board members and substantive program information upon request. Individuals who plan to attend the open session and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Shorts in advance of the meeting.

Dated: August 2, 1995.

Susan K. Feldman,
Committee Management Officer, NIH.
[FR Doc. 95-19406 Filed 8-4-95; 8:45 am]

BILLING CODE 4140-01-M

National Institute of Allergy and Infectious Diseases; Notice of Meetings: National Advisory Allergy and Infectious Diseases Council; Acquired Immunodeficiency Syndrome Subcommittee; Allergy and Immunology Subcommittee; Microbiology and Infectious Diseases Subcommittee

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the National Advisory Allergy and Infectious Diseases Council, National Institute of Allergy and Infectious Diseases, and its subcommittees on September 11-12, 1995. Meetings of the Council, NAAIDC Allergy and Immunology Subcommittee and the NAAIDC Microbiology and Infectious Diseases Subcommittee will be held at the National Institutes of Health, Building 31C, Bethesda, Maryland. The meeting of the NAAIDC Acquired Immunodeficiency Syndrome Subcommittee will be held at the Bethesda Holiday Inn, 8120 Wisconsin Avenue, Bethesda, Maryland.

The meeting of the full Council will be open to the public on September 11 in Conference Room 10 from approximately 1 p.m. until 4 p.m. for opening remarks of the Institute Director, discussion of procedural matters, Council business, and a report from the Institute Director which will include a discussion of budgetary matters. The primary program will include an update on AIDS vaccine research, an overview of clinical research core curriculum, a review of the Office of AIDS Research, and the annual report of the Division of Intramural Research.

On September 12 the meetings of the NAAIDC Allergy and Immunology Subcommittee and NAAIDC Microbiology and Infectious Diseases Subcommittee will be open to the public from 8:30 a.m. until adjournment. The subcommittee will meet in conference rooms 9 and 10 respectively. The meeting of the NAAIDC Acquired Immunodeficiency Syndrome Subcommittee will be open to the public from 8 a.m. until adjournment on September 12. The subcommittee will meet at the Bethesda Holiday Inn, 8120 Wisconsin Avenue, Bethesda, Maryland.

In accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and sec. 10(d) of Pub. L. 92-463, the meeting of the NAAIDC Acquired Immunodeficiency Syndrome Subcommittee, NAAIDC Allergy and Immunology Subcommittee and the NAAIDC Microbiology and Infectious Diseases Subcommittee will be closed to

the public for approximately four hours for review, evaluation, and discussion of individual grant applications. It is anticipated that this will occur from 8:30 a.m. until approximately 1 p.m. on September 11, in conference rooms 7, 9 and 10 respectively. The meeting of the full Council will be closed from 4 p.m. until recess on September 11 for review, discussion, and evaluation of individual grant applications. These applications and the discussions would reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. Claudia Goad, Committee Management Officer, National Institute of Allergy and Infectious Diseases, Solar Building, Room 3C26, National Institutes of Health, Bethesda, Maryland 20892, 301-496-7601, will provide a summary of the meeting and a roster of committee members upon request. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Goad in advance of the meeting.

Dr. John J. McGowan, Director, Division of Extramural Activities, NIAID, NIH, Solar Building, Room 3C20, 6003 Executive Boulevard, Rockville, Maryland 20892, telephone 301-496-7291, will provide substantive program information.

(Catalog of Federal Domestic Assistance Program Nos. 93.855 Immunology, Allergic and Immunologic Diseases Research, 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health)

Dated: August 2, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95-19410 Filed 8-4-95; 8:45 am]

BILLING CODE 4140-01-M

National Institute of Allergy and Infectious Diseases; Notice of Meeting: AIDS Research Advisory Committee, NIAID

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the AIDS Research Advisory Committee, National Institute of Allergy and Infectious Diseases, on September 12, 1995, in the Versailles Ballroom of the Holiday Inn, 8120 Wisconsin Avenue, Bethesda, Maryland.

The entire meeting will be open to the public from 8 a.m. until adjournment. The AIDS Research Advisory Committee (ARAC) advises and makes

recommendations to the Director, National Institute of Allergy and Infectious Diseases, on all aspects of research on HIV and AIDS related to the mission of the Division of AIDS (DAIDS).

The Committee will provide advice on scientific priorities, policy, and program balance at the Division level. The Committee will review the progress and productivity of ongoing efforts, and identify critical gaps/obstacles to progress, and provide concept clearance for proposed research initiatives. Attendance by the public will be limited to space available.

Ms. Anne P. Claysmith, Executive Secretary, AIDS Research Advisory Committee, DAIDS, NIAID, NIH, Solar Building, Room 2B06, telephone 301-402-0755, will provide a summary of the meeting and a roster of committee members upon request. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Claysmith in advance of the meeting.

(Catalog of Federal Domestic Assistance Program Nos. 93.855, Immunology, Allergic and Immunologic Diseases Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health)

Dated: August 2, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95-19407 Filed 8-4-95; 8:45 am]

BILLING CODE 4140-01-M

National Institute of Diabetes and Digestive and Kidney Diseases; Meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council and its Subcommittees

Pursuant to Pub. L. 92-463, notice is hereby given of a meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council and its subcommittees, National Institute of Diabetes and Digestive and Kidney Diseases, on September 20-21, 1995. The meeting of the full Council will be open to the public September 20, from 8 a.m. to noon and again on September 21, from 10 a.m. to noon in Conference Room 10, Building 31C, National Institutes of Health, Bethesda, Maryland, to discuss administrative issues relating to Council business and special reports. The following subcommittee meetings will be open to the public September 20 from 1 p.m. to 2 p.m.: Diabetes, Endocrine and Metabolic Diseases Subcommittee meeting will be held in Conference Room 10, Building 31C; Digestive