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