requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Amgen, Inc., 1840 Dehavilland Dr., Thousand Oaks, CA 91320–1789, has filed an application requesting approval for the export of the human biological product Neupogen® Recombinant Methionyl Granulocyte Colony Stimulating Factor (r-metHuG-CSF) with sorbitol in vials, pre-filled syringes, and purified bulk, to Australia, Austria, Belgium, Canada, Denmark, Finland, France, Federal Republic of Germany, Iceland, Ireland, Italy, Japan, Luxembourg, The Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom. Neupogen® is indicated for the reduction in the duration of neutropenia and its clinical sequelae in patients undergoing myeloblative therapy followed by autologous or allogeneic bone marrow transplantation and the reduction in the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for non-myeloid malignancy. Neupogen® is used in patients, children or adults, with severe chronic neutropenia (severe congenital neutropenia, cyclic neutropenia, and idiopathic neutropenia) induces a sustained increase in absolute neutrophil counts in peripheral blood and a reduction of infection and related events. The application was received and filed in the Center for Biologics Evaluation and Research on June 15, 1995, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by August 17, 1995, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Biologics Evaluation and Research (21 CFR 5.44).

Dated: July 24, 1995.

James C. Simmons,

Acting Director, Office of Compliance, Center for Biologics Evaluation and Research.

[FR Doc. 95–19426 Filed 8–4–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95E–0147]

Determination of Regulatory Review Period for Purposes of Patent Extension; Excimed™ UV200LA/SVS APEX Excimer Laser Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Excimed™ UV200LA/SVS APEX Excimer Laser Systems and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device Excimed™ UV200LA/SVS APEX Excimer Laser Systems. Excimed™ UV200LA/SVS APEX Excimer Laser Systems are indicated for phototherapeutic keratectomy (PTK) procedures which treat superficial pathology located in the anterior 100 microns of the cornea. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Excimed™ UV 200LA/SVS APEX Excimer Laser Systems (U.S. Patent No. 4,941,093) from Summit Technology, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated June 21, 1995, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of Excimed™ UV200LA/SVS APEX Excimer Laser Systems represented the first commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Excimed™ UV200LA/SVS APEX Excimer Laser Systems is 2,271 days. Of this time, 1,156 days occurred during the testing phase of the regulatory review period, while 1,115 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a clinical investigation involving this device was begun*: December 22, 1988. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act for human tests to begin became effective on December 22, 1988.

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