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; ExcimedTM 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 ExcimedTM 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 ExcimedTM UV200LA/SVS APEX Excimer Laser Systems. ExcimedTM 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 ExcimedTM 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 ExcimedTM UV200LA/SVS ÂPEX 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 ExcimedTM 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.