SBC Capital Markets Inc., New York, New York (CMI), a subsidiary of Applicant that engages in a wide range of securities- and derivatives-related activities, including underwriting and dealing in all types of debt and equity securities on a limited basis. *See Swiss Bank Corporation*, 81 Federal Reserve Bulletin 185 (1995) (*Swiss Bank Order*). SGWO and SGWOTC will either be merged with and into CMI at the same time or liquidated promptly thereafter.

Applicant seeks approval to conduct the proposed activities throughout the United States, and plans to conduct the activities on a world-wide basis.

Closely Related to Banking Standard

Section 4(c)(8) of the BHC Act provides that a bank holding company may, with Board approval, engage in any activity ''which the Board after due notice and opportunity for hearing has determined (by order or regulation) to be so closely related to banking or managing or controlling banks as to be a proper incident thereto.''

Applicant states that the Board previously has determined by regulation or order that all of the activities conducted by the United States Subsidiaries or New York Forex, when conducted within the limitations established by the Board in its regulations and in related interpretations and orders, are closely related to banking for purposes of section 4(c)(8) of the BHC Act, and, where applicable, are consistent with section 20 of the Glass-Steagall Act (12 U.S.C. 377). *See* 12 CFR 225.25(b)(4), (b)(15), and (b)(16); *Swiss Bank Order. See also J.P. Morgan & Co. Incorporated*, 75 Federal Reserve Bulletin 192 (1989), *aff'd sub nom. Securities Industries Ass'n v. Board of Governors of the Federal Reserve System*, 900 F.2d 360 (D.C. Cir. 1990), *Order Approving Modifications to the Section 20 Orders*, 75 Federal Reserve Bulletin 751 (1989), *Canadian Imperial Bank of Commerce*, 76 Federal Reserve Bulletin 158 (1990), *Order Approving Modifications to the Section 20 Orders*, 79 Federal Reserve Bulletin 226 (1993), and *Supplement to Order Approving Modifications to Section 20 Orders*, 79 Federal Reserve Bulletin 360 (1993) (Section 20 Orders).

Applicant maintains that these activities will be conducted in conformity with the conditions and limitations established by the Board in prior cases.

Proper Incident to Banking Standard

In order to approve the proposal, the Board must determine that the proposal ''can reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices.'' 12 U.S.C. 1843(c)(8).

Applicant believes that the proposal will produce public benefits that outweigh any potential adverse effects. In particular, Applicant maintains that the proposal will enhance CMI's ability to compete with other financial institutions engaged in the investment banking business at the international level, by providing it with access to the customer base of the United States Subsidiaries and New York Forex, thereby enhancing its ability to compete in customer-oriented businesses such as underwriting and private placements in the United States. Applicant also asserts that the proposal will enable CMI to offer a broader range of products and services to its customers, and will make CMI a more effective competitor in the United States capital and securities markets. In addition, Applicant states that the proposed activities will not result in adverse effects such as an undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices.

In publishing the proposal for comment, the Board does not take a position on issues raised by the proposal. Notice of the proposal is published solely in order to seek the views of interested persons on the issues presented by the notice, and does not represent a determination by the Board that the proposal meets or is likely to meet the standards of the BHC Act or other applicable laws.

Any comments or requests for hearing should be submitted in writing and received by William W. Wiles, Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, not later than August 22, 1995. Any request for a hearing on this notice must, as required by § 262.3(e) of the Board's Rules of Procedure (12 CFR 262.3(e)), be accompanied by a statement of the reasons why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal. This application may be inspected at the offices of the Board of Governors or the Federal Reserve Bank of New York.

Board of Governors of the Federal Reserve System, August 1, 1995.

William W. Wiles,

Secretary of the Board.

[FR Doc. 95–19371 Filed 8–4–95; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95N–0239]

Drug Export; Neupogen® Recombinant Methionyl Granulocyte Colony Stimulating Factor (r-metHuG-CSF) With Sorbitol

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Amgen, Inc., 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.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human biological products under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: Cathy E. Conn, Center for Biologics Evaluation and Research (HFM–610), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–2006.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of human biological products that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act

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.