published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: July 5, 1995.

Alan M. Rulis,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–17789 Filed 7–19–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0209]

Drug Export; CellCept (Mycophenolate Mofetil) 500 Milligram (mg) Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Syntex Laboratories has filed an application requesting conditional approval for the export of the human drug CellCept (mycophenolate mofetil) 500 mg tablets to the European Union (EU) member countries (Austria, Belgium, Denmark, Germany, Finland, France, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom) through Switzerland for packaging and labeling.

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 drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: James E. Hamilton, Center for Drug Evaluation and Research (HFD–310), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–594–3150.

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 drugs 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 Syntex Laboratories, 3401 Hillview Ave., P.O. Box 10850, Palo Alto, CA 94303, has filed an application requesting conditional approval for the export of the human drug CellCept (mycophenolate mofetil) 500 mg tablets to the EU member countries (Austria, Belgium, Denmark, Germany, Finland, France, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom) through Switzerland for packaging and labeling. CellCept (mycophenolate mofetil) is indicated for the prophylaxis of organ rejection and for the treatment of refractory organ rejection in patients receiving allogenic renal transplants. The application was received and filed in the Center for Drug Evaluation and Research on May 22, 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 July 31, 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 Drug Evaluation and Research (21 CFR 5.44).

Dated: July 10, 1995.

Betty L. Jones,

Deputy Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 95–17786 Filed 7–19–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95M–0180]

Chiron Vision Corp.; Premarket Approval of Adatomed Silicone Oil OP5000

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Chiron Vision Corp., Irvine, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Adatomed Silicone Oil OP5000. After reviewing the recommendation of the Opthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of November 4, 1994, of the approval of the application.

DATES: Petitions for administrative review by August 21, 1995.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Debra Y. Lewis, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2018.

SUPPLEMENTARY INFORMATION: On March 5, 1992, Chiron Vision Corp., Irvine, CA 92718–1903, submitted to CDRH an application for premarket approval of Adatomed Silicone Oil OP5000. The device is an intraocular fluid and is indicated for use as a prolonged retinal tamponade in selected cases of complicated retinal detachments.

On October 28, 1993, the Ophthalmic Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application.

On November 4, 1994, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and