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

procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before August 21, 1995, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: July 5, 1995.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 95–17832 Filed 7–19–95; 8:45 am]

BILLING CODE 4160–01–F

Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HF (Food and Drug Administration) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, and 56 FR 29484, June 27, 1991, as amended most recently in pertinent part at 53 FR 8978, March 18, 1988) is amended to reflect the following reorganization in the Food and Drug Administration (FDA).

The Office of Training and Communications, Center for Drug Evaluation and Research (CDER) is being established to place stronger emphasis on professional training, and inter- and intra-Center communications. All training and communications functions have been centralized into the new Office.

Under section HF–B, Organization:

1. Delete the subparagraph Office of Management (HFN12), under the Office of the Center Director (HFN1), in its entirety and insert a new subparagraph reading as follows:

Office of Management (HFN12). Monitors the development and operation of planning systems for Center activities and resource allocations and advises the Center Director on Center administrative policies and guidelines and information systems and services.

Directs and counsels Center managers through program evaluation and technological forecasting.

Plans and directs Center operations for financial and personnel management, and office services.

Directs Center organization, management, and information systems.

Manages studies designed to improve processes and resource allocations in the Center.

Advises the Center on contract and grant proposals.

Provides coordination for receipt and distribution of initial drug applications and other related documents.

2. Insert the following new subparagraph, the Office of Training and Communications (HFN13), under the subparagraph titled Office of the Center Director (HFN1).

Office of Training and Communications (HFN13). Prepares, develops, and coordinates Center and Agency responses to drug-related requests under the Freedom of Information Act, Privacy Act, and other statutes.

Provides leadership and direction for all Center internal and external communications.

Plans, coordinates, and evaluates policies, procedures, and programs for the orientation and training of Center staff.

Provides scientific and technical resources and other library services to CDER staff in support of Center and Agencywide needs.

3. Prior Delegations of Authority. Pending further delegations, directives, or orders by the Commissioner of Food and Drugs, all delegations of authority to positions of the affected organizations in effect prior to this date shall continue in effect in them or their successors.

Dated: July 10, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 95–17783 Filed 7–19–95; 8:45 am]

BILLING CODE 4160–01–M

National Institutes of Health

National Institute of Environmental Health Sciences: Opportunity for a Cooperative Research and Development Agreement (CRADA) for Development of Antibodies to the Cancer Metastasis Suppressor Gene KAI1

AGENCY: National Institute of Environmental Health Sciences, National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) seeks an agreement with a company(s) which can pursue commercial development of antibodies to the KAI1, a cancer metastasis suppressor gene (U.S. Patent Application Serial No. 08/430,225). The National Institute of Environmental Health Sciences has also determined that antibodies to this gene can be used in diagnosis of malignant cancers of the prostate and other tissues. A CRADA for the co-development of diagnostic antibodies will be granted to the awardee(s).

ADDRESSES: Proposals and questions about this opportunity may be addressed to Dr. J. Carl Barrett, NIEHS, Mail Drop C2–15, PO Box 12233, Research Triangle Park, NC 27709. Telephone (919) 541–2992; Fax (919) 541–7784; E-mail BARRETT@NIEHS.NIH.GOV.

DATE: Capability statements must be received by NIH on or before September 18, 1995.

SUPPLEMENTARY INFORMATION: The National Institute of Environmental Health Sciences has shown that the KAI1 gene can suppress metastasis of prostate cancer and is downregulated in human malignant prostate cancers. Therefore, it may be of use in distinguishing prostate cancers that will progress and be lethal from nonfatal cancers. The role of this gene in other cancers is currently under investigation. This protein is a transmembrane protein. Antibodies to the extracellular domain of the protein should detect its expression in tissue sections and tumor biopsies and be used in cancer diagnosis and prognosis.

The CRADA is for the development of antibodies to this protein and the development of cancer diagnostic tests.