drug product had undergone a regulatory review period that the approval of EPIVIR™ represented the first permitted commercial marketing or use 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 EPIVIR™ is 1,582 days. Of this time, 1,448 days occurred during the testing phase of the regulatory review period, while 134 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: July 21, 1991. The applicant claims July 24, 1991, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 21, 1991, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: July 7, 1995. The applicant claims June 29, 1995, as the date the new drug application (NDA's) for EPIVIR™ (NDA's 20–564 and 20–596) were initially submitted. However, FDA records indicate that NDA's 20–564 and 20–596 were submitted on July 7, 1995 (the date the User Fee checks were received by the agency). Both NDA's were originally received by the agency on June 30, 1995, unaccompanied by the appropriate User Fee checks. Review of a NDA does not begin until the correct amount of User Fee money has been received by the agency from the sponsor of the NDA.

3. *The date the application was approved*: November 17, 1995. FDA has verified the applicants's claim that NDA's 20–564 and 20–596 were approved on November 17, 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 836 days of patent term extension..

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 15, 1996, 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 November 12, 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: April 26, 1996.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 96–12092 Filed 5–13–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95E–0408]

Determination of Regulatory Review Period for Purposes of Patent Extension; TRUSOPT®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for TRUSOPT® 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 human drug product.

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 human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. 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 (for example, 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 human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product TRUSOPT® (dorzolamide hydrochloride). TRUSOPT® is indicated in the treatment for elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for TRUSOPT® (U.S. Patent No. 4,797,413) from Merck & Co., 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 January 26, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of TRUSOPT® represented the first permitted commercial marketing or use 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 TRUSOPT® is 2,101 days. Of this time, 1,736 days occurred during the testing phase of the regulatory review period, while 365 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: March 11, 1989. FDA has verified the applicant's claim that the date that the investigational new drug application (IND) became effective was March 11, 1989.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: December 10, 1993. FDA has verified the applicant's claim that the new drug application (NDA) for TRUSOPT® (NDA 20–408) was initially submitted on December 10, 1993.

3. *The date the application was approved*: December 9, 1994. FDA has verified the applicant's claim that NDA 20–408 was approved on December 9, 1994.

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 1,232 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 15, 1996, 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 November 12, 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: April 26, 1996.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 96–12093 Filed 5–13–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[ORD–086–N]

New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: February and March 1996

AGENCY: Health Care Financing Administration (HCFA).

ACTION: Notice.

SUMMARY: This notice lists new proposals for Medicaid demonstration projects submitted to the Department of Health and Human Services during the months of February and March 1996 under the authority of section 1115 of the Social Security Act. This notice also lists proposals that were approved, disapproved, pending, or withdrawn during this time period. (This notice can be accessed on the Internet at HTTP://WWW.HCFA.GOV/ORD/ORDHP1.HTML.)

COMMENTS: We will accept written comments on these proposals. We will, if feasible, acknowledge receipt of all comments, but we will not provide written responses to comments. We will, however, neither approve nor disapprove any new proposal for at least 30 days after the date of this notice to allow time to receive and consider comments. Direct comments as indicated below.

ADDRESSES: Mail correspondence to: Susan Anderson, Office of Research and Demonstrations, Health Care Financing Administration, Mail Stop C3–11–07, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT: Susan Anderson, (410) 786–3996.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 1115 of the Social Security Act (the Act), the Department of Health and Human Services (HHS) may consider and approve research and demonstration proposals with a broad range of policy objectives. These demonstrations can lead to improvements in achieving the purposes of the Act.

In exercising her discretionary authority, the Secretary has developed a number of policies and procedures for reviewing proposals. On September 27, 1994, we published a notice in the Federal Register (59 FR 49249) that specified (1) The principles that we ordinarily will consider when approving or disapproving demonstration projects under the authority in section 1115(a) of the Act; (2) the procedures we expect States to use in involving the public in the development of proposed demonstration projects under section 1115; and (3) the procedures we ordinarily will follow in reviewing demonstration proposals. We are committed to a thorough and expeditious review of State requests to conduct such demonstrations.

As part of our procedures, we publish a notice in the Federal Register with a monthly listing of all new submissions, pending proposals, approvals, disapprovals, and withdrawn proposals. Proposals submitted in response to a grant solicitation or other competitive process are reported as received during the month that such grant or bid is awarded, so as to prevent interference with the awards process.

II. Listing of New, Pending, Approved, and Withdrawn Proposals for the Months of February and March 1996

A. Comprehensive Health Reform Programs

1. New Proposals: The following comprehensive health reform proposal was received during the month of February.

Demonstration Title/State: Medicaid Demonstration Project for Los Angeles County—California.

Description: The State is pursuing a section 1115 demonstration designed to stabilize the Los Angeles County health care system, and to foster a restructuring process that is responsive to the needs of the community in the development of a more cost effective system.

Date Received: February 29, 1996.

State Contact: John Rodriguez, Deputy Director, Medical Care Services, Department of Health Services, 714/744 P Street, P.O. Box 942732, Sacramento, CA 94234–7320, (916) 654–0391.

Federal Project Officer: Gina Clemons, Health Care Financing Administration, Office of Research and Demonstrations, Office of State Health Reform Demonstrations, Mail Stop C3–18–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

No new proposals were received during the month of March.

2. Pending, Approved, and Withdrawn Proposals: We did not approve or disapprove any proposals during February or March nor were any proposals withdrawn during those months. The one new pending proposal added to the month of March is: Medicaid Demonstration Project for Los Angeles County—California. See above II.A.1. for further description. Pending proposals for the month of November 1995 published in the Federal Register on January 23, 1996, 61 FR 1769, remain unchanged with the addition of above for the months of February and March.