Director, Office of the Assistant Secretary for Planning and Evaluation, DHHS, Room 440–D, Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201, telephone (202) 690–7100, or Marjorie S. Greenberg, Acting Executive Secretary, NCVHS, NCHS, CDC, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone (301) 436–7050. Information also is available on the NCVHS home page of the HHS website: http://aspe.os.dhhs.gov/ncvhs.

Dated: March 26, 1997.

James Scanlon,

Director, Division of Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 97–8597 Filed 4–3–97; 8:45 am]

BILLING CODE 4151–04–M

Centers for Disease Control and Prevention

[30 DAY–3–97]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Office on (404) 639–7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

1. Congenital Syphilis Case Investigation and Report Form (CDC 73.126 REV 09–91)–(0920–0128). This request is for a 3-year extension of clearance. Reducing congenital syphilis (CS) is a national objective in the DHHS Report entitled *Healthy People 2000: Midcourse Review and 1995 Revisions.* Objective 19.4 of this document states the goal: ''reduce congenital syphilis to an incidence of no more than 40 cases per 100,000 live births'' by the year 2000. In order to meet this national objective, an effective surveillance system for CS must be continued in order to monitor current levels of disease and progress towards the year 2000 objective. This data will also be used to develop intervention strategies and to evaluate ongoing control efforts. The total annual burden hours are 500.

Respondents	Number of respondents	Number of responses/respondent (in hrs.)	Average burden/response (in hrs.)
State and local health department ..	2000	1	0.25

Dated: March 28, 1997.

Wilma G. Johnson,

Acting Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–8618 Filed 4–3–97; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

[Docket No. 96E–0503]

Determination of Regulatory Review Period for Purposes of Patent Extension; XALATAN™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for XALATAN™ 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, 12420 Parklawn Dr., rm. 1–23, 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 XALATAN™ (latanoprost). XALATAN™ is indicated for the reduction of elevated intraocular pressure in patents with open-angle glaucoma and ocular hypertension who are intolerant of other intraocular pressure lowering medications or insufficiently responsive (failed to achieve target IOP determined after multiple measurements over time) to another intraocular pressure lowering medication. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for XALATAN™ (U.S. Patent No. 4,599,353) from the Trustees of Columbia University in the City of New York, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 18, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of XALATAN™ 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 XALATAN™ is 1,875 days. Of this time, 1,519 days occurred during the testing phase of the regulatory review period, while 356 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*: April 20, 1991. The applicant claims April 18, 1991, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 20, 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*: June 16, 1995. The applicant claims June 14, 1995, as the date the new drug application (NDA) for XALATAN™ (NDA 20–597) was initially submitted. However, FDA records indicate that NDA 20–597 was submitted on June 16, 1995.

3. *The date the application was approved*: June 5, 1996. FDA has verified the applicant's claim that NDA 20–597 was approved on June 5, 1996.

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 1,116 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 3, 1997, 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 October 1, 1997, 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: March 27, 1997.

Allen B. Duncan,

Acting Associate Commissioner for Health Affairs.

[FR Doc. 97–8619 Filed 4–3–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96E–0509]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for PHOTOFRIN® 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, 12420 Parklawn Dr., rm. 1–23, 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 PHOTOFRIN® (porfimer sodium). PHOTOFRIN® is indicated for palliation of patients with completely obstructing esophageal cancer, or of patients with partially obstructing esophageal cancer who, in the opinion of their physician, cannot be satisfactorily treated with neodymium:yttrium:aluminum:garnet (Nd:YAG) laser therapy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for PHOTOFRIN® (U.S. Patent No. 5,145,863) from Health Research, 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 February 18, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of PHOTOFRIN® 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 PHOTOFRIN® is 4,065 days. Of this time, 3,441 days occurred during the testing phase of the regulatory review period, while 624 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*: November 11, 1984. The applicant claims October 15, 1984, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 11, 1984, which was 30 days after FDA receipt of the IND on October 12, 1984.

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*: April 13, 1994. The applicant claims April 12, 1994, as the