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 CAMPTOSAR® (irinotecan hydrochloride). CAMPTOSAR® is indicated for the treatment of patients with metastatic carcinoma of the colon or rectum whose disease has recurred or progressed following 5–FU based therapy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for CAMPTOSAR® (U.S. Patent No. 4,604,463) from Kabushiki Kaisha Yakult Honsha, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 24, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of CAMPTOSAR® 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 CAMPTOSAR® is 2,111 days. Of this time, 1,941 days occurred during the testing phase of the regulatory review period, while 170 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*: September 5, 1990. FDA has verified the applicant's claim that the date that the investigational new drug application became effective was on September 5, 1990.

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 28, 1995. FDA has verified the applicant's claim that the new drug application (NDA) for CAMPTOSAR® (NDA 20–571) was initially submitted on December 28, 1995.

3. *The date the application was approved*: June 14, 1996. FDA has verified the applicant's claim that NDA 20–571 was approved on June 14, 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 1,139 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before March 31, 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 July 28, 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: January 17, 1997.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 97–2067 Filed 1–27–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96E–0361]

Determination of Regulatory Review Period for Purposes of Patent Extension; DIFFERIN Solution

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for DIFFERIN Solution 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 DIFFERIN Solution (adapalene). DIFFERIN Solution is indicated for the topical treatment of acne vulgaris. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for DIFFERIN Solution (U.S. Patent No. 5,015,758) from Centre International de Recherches Dermatologiques (CIRD), and the Patent and Trademark Office requested FDA's

assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 24, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of DIFFERIN Solution 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 had determinated that the applicable regulatory review period for DIFFERIN Solution is 2,814 days. Of this time, 1,651 days occurred during the testing phase of the regulatory review period, while 1,163 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*: September 18, 1988. FDA has verified the applicant's claim that the date that the investigational new drug application became effective was on September 18, 1988.

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*: March 26, 1993. The applicant claims March 19, 1993, as the date the new drug application (NDA) for DIFFERIN Solution (NDA 20–338) was initially submitted. However, FDA records indicate that NDA 20–338 was submitted on March 26, 1993.

3. *The date the application was approved:* May 31, 1996. FDA has verified the applicant's claim that NDA 20–338 was approved on May 31, 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 257 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before March 31, 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 July 28, 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: January 17, 1997.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 97–2068 Filed 1–27–97; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

Submission for OMB Review; Comment Request; NCI Cancer Information Service Community Services Database Survey and Verification

SUMMARY: Under the provisions of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the Federal Register on May 3, 1996, page 19943 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

PROPOSED COLLECTION: Describe the proposed information collection activity as follows. Include:

Title: NCI Cancer Information Service Community Services Database Survey and Verification.

Type of Information Collection Request: New.

Form Number: Not applicable.

Need and Use of Information Collection: The CIS provides the general public, cancer patients, families, health professionals, and others with the latest information on cancer. Essential to fulfilling its role as a referral source for cancer patients and their families is the identification, acquisition, and dissemination of information about hospitals, breasts and cervical cancer screening clinics, and cancer pain management programs. This effort involves sending a survey tool or a verification instrument annually to approximately 17,135 respondents.

Frequency of Response: Annual.

Affected Public: Not-for-profit institutions; Business or other for-profit; Federal Government; State, Local or Tribal Government.

Type of Respondent: Administrators of hospitals, pain centers, screening facilities.

The annual reporting burden is as follows:

Estimated Number of Respondents: 17,135 respondents.

Estimated Number of Responses per Respondent: One (1) per year).

Average Burden Hours Per Response: .167 hours.

Estimated Total Annual Burden Hours Requested: 2,862 hours.

The annualized cost to respondents is estimated at: $34,338.54. There are no Capital Costs to report. There are no Operating of Maintenance Costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Year 1:				
Administrators of hospitals, pain centers, screening facilities	18,027	1	0.167	3,011
Year 2:				
New Organizations and verification	16,605	1	0.167	2,773
Year 3:				
New Organizations and verification	16,774	1	0.167	2,801