the appendix for each application, should be delivered to Robert L. Robins (address above). No supplemental material will be accepted after the closing date. FDA's authority to fund research projects is under section 301 of the PHS Act. FDA's research program is described in the Catalog of Federal Domestic Assistance, No. 93.103. Applications submitted under this program must comply with 45 CFR part 46—Protection of Human Subjects where applicable and requirements of the Office of Protection from Research Risks. The outside of the mailing package and item 2 of the application face page should be labeled ''Response to RFA–FDA–CDER–97–1''.

VIII. Method of Application

A. Submission Instructions

Applications will be accepted during normal working hours, 8 a.m. to 4:30 p.m., Monday through Friday, on or before the March 14, 1997, deadline.

Applications will be considered received on time if sent or mailed on or before the receipt dates as evidenced by a legible U.S. Postal Service dated postmark or a legible date receipt from a commercial carrier, unless they arrive too late for orderly processing. Private metered postmarks shall not be acceptable as proof of timely mailing. Applications not received on time will not be considered for review and will be returned to the applicant.

Note: (Applicants should note that the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on this method, applicants should check with their local post office.)

B. Format for Application

Applications must be submitted on Grant Application Form PHS 398 (Rev. 5/95). All ''General Instructions'' and ''Specific Instructions'' in the application kit should be followed with the exception of the receipt dates and the mailing label address. Do not send applications to the Division of Research Grants, NIH. This information collection is approved under OMB No. 00925–0001. Applications from State and local governments may be submitted on Form PHS 5161 (Rev. 7/92) or PHS 398 (Rev. 5/95). The face page of the application must reflect the request for applications number RFA–FDA–CDER–97–1. This information collection is approved under OMB control number 0937–0189.

C. Legend

Unless disclosure is required by the Freedom of Information Act as amended (5 U.S.C. 552) as determined by the freedom of information officials of the Department of Health and Human Services or by a court, data contained in the portions of an application that have been specifically identified by page number, paragraph, etc., by the applicant as containing confidential commercial information or other information that is exempt from public disclosure will not be used or disclosed except for evaluation purposes.

Dated: January 30, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–2870 Filed 2–4–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96E–0362]

Determination of Regulatory Review Period for Purposes of Patent Extension; DIFFERIN Topical Gel

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for DIFFERIN Topical Gel 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 Topical Gel (adapalene). DIFFERIN Topical Gel 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 Topical Gel (U.S. Patent No. Re. 34,440) 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 Topical Gel 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 DIFFERIN Topical Gel is 2,447 days. Of this time, 1,401 days occurred during the testing phase of the regulatory review period, while 1,046 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 20, 1989. FDA has verified the applicant's claim that the date that the investigational new drug application became effective was on September 20, 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: July 21, 1993. The applicant claims July 15, 1993, as the date the new drug application (NDA) for DIFFERIN Topical Gel (NDA 20–380) was initially submitted. However, FDA records indicate that NDA 20–380 was submitted on July 21, 1993.

3. *The date the application was approved*: May 31, 1996. FDA has verified the applicant's claim that NDA 20–380 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 433 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before April 7, 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 August 4, 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. 97–2871 Filed 2–4–97; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[R–137]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Reinstatement, with change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Internal Revenue Service/Social Security Administration/Health Care Financing Administration Data Match 42 CFR 411.20–411.206; *Form No.:* HCFA–R–137; *Use:* Employers who are identified through a match of IRS, SSA, and Medicare records will be contacted concerning group health plan coverage of identified individuals to ensure compliance with Medicare Secondary Payer provisions found at 42 U.S.C. 1395y(b). *Frequency:* Semi-annually *Affected Public:* Individuals or Households, Business or other for profit, Not for profit institutions, Farms, Federal Government and State, Local or Tribal Government; *Number of Respondents:* 596,241; *Total Annual Responses:* 596,241; *Total Annual Hours Requested:* 2,325,449.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://www.hcfa.gov, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: January 29, 1997.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 97–2764 Filed 2–4–97; 8:45 am]

BILLING CODE 4120–03–P

[HSQ–244–N]

CLIA Program; Clinical Laboratory Improvement Amendments of 1988—Denial of Exemption of Laboratories in the Commonwealth of Puerto Rico

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: The Public Health Service Act provides for the exemption of laboratories from the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) if the State in which they are located has been determined to have requirements equal to or more stringent than those of CLIA. Under our regulations, HCFA's decision to approve or deny a requested exemption from CLIA requirements is published in the Federal Register. This notice announces that a request from the Commonwealth of Puerto Rico for exemption from CLIA requirements has been denied.

EFFECTIVE DATE: The denial of exemption from CLIA was effective on October 28, 1996.

FOR FURTHER INFORMATION CALL:

Lee Feehely, (410) 786–3401.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

Section 353 of the Public Health Service Act, as amended by the Clinical Laboratory Improvement Amendments of 1988 (CLIA), requires any laboratory that performs tests on human specimens to meet the requirements established by the Department of Health and Human Services. Regulations implementing section 353 of the Public Health Service Act are contained in 42 CFR part 493, Laboratory Requirements. Subject to specified exceptions included in subpart D, laboratories must have a current and valid CLIA certificate to test human specimens. Section 353(p) of the Public Health Service Act provides for the exemption of laboratories from CLIA requirements in a State that is