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