ERTACZO 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 Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6699.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 Director 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 ERTACZO (sertaconazole nitrate). ERTACZO is indicated for the topical treatment of athlete's foot (interdigital tinea pedis) caused by certain fungus (*Trichophyton rubrum*, *T. mentagrophytes*, and *Epidermophyton floccosum*). ERTACZO is for people 12 years of age and older who have a normal immune system. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ERTACZO (U.S. Patent No. 5,135,943) from Ferrer Internacional, S.A., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated August 31, 2004, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ERTACZO represented the first permitted commercial marketing or use of the product. 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 ERTACZO is 2,718 days. Of this time, 1,914 days occurred during the testing phase of the regulatory review period, while 804 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective:* July 3, 1996. The applicant claims June 11, 1996, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 3, 1996, 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 of the act:* September 28, 2001. FDA has verified the applicant's claim that the new drug application (NDA) for ERTACZO (NDA 21–385) was initially submitted on September 28, 2001.

3. *The date the application was approved:* December 10, 2003. FDA has verified the applicant's claim that NDA 21–385 was approved on December 10, 2003.

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 1,776 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written comments and ask for a redetermination by July 11, 2005. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 8, 2005. 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 Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 29, 2005.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 05–9462 Filed 5–11–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Evaluation of National Cancer Institute's Central Institutional Review Board To Improve Cancer Clinical Trials System

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health 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 July 19, 2004 on page 43003 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: Title: Evaluation of National Cancer Institute's Central Institutional Review Board to Improve Cancer Clinical Trials System. *Type of*

Information Collection Request: NEW. *Need and Use of Information Collection:* This study will evaluate the effectiveness of the Central Institutional Review Board (CIRB), a pilot project designed to streamline the protocol activation process by conducting human subject protection reviews that can be utilized by local Institutional Review Boards (IRB) for facilitated approval of multi-institutional, NCI-sponsored Phase 3 clinical trials. This evaluation includes two surveys that will be made available online to minimize respondent burden. The CIRB survey will assess acceptance level and satisfaction of local IRB chairs, coordinators, and principal investigators with the CIRB. The Cooperative Group Staff Survey will assess the opinions and experiences of the operations and regulations staff of the nine Clinical Trials Cooperative Groups about CIRB operations, office processes, and procedures. The findings will provide valuable information concerning whether the CIRB is meeting its intended goals and will provide recommendations for change and further study. *Frequency of Response:* Once. *Affected Public:* Registered members of the CIRB and Clinical Trials Cooperative Group Staff. *Type of Respondents:* IRB chairs, IRB coordinators, principal investigators, and the operations and regulations staff of Clinical Trials Cooperative Groups. The annualized cost to respondents is estimated at $5,500. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report. *Estimated Number of Respondents:* 279. *Estimated Number of Responses per Respondent:* 1. *Average Burden per Response:* 0.50 hours. *Estimated Total Annual Burden Hours Requested:* 139.50. The total burden estimate per respondent is shown below.

TABLE 1.—TOTAL BURDEN ESTIMATE PER RESPONDENT

Type of respondent	Estimated number of respondents	Estimated number of responses per respondent	Average burden per response	Estimated total annual burden hour request
IRB Chairs, IRB Coordinators, principal investigators	225	1	0.50	112.50
Clinical Trials Cooperative Group operations and regulations staff	54	1	0.50	27
Total				139.50

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are able to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Bryce B. Reeve, PhD, Outcomes Research Branch, ARP, DCCPS, National Cancer Institute, 6130 Executive Blvd. MSC 7344, Bethesda, MD 20892–7344. Phone: (301) 594–6574, e-mail: *reeveb@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of this publication.

Dated: May 1, 2005.

Rachelle Ragland-Greene,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 05–9510 Filed 5–11–05; 8:45 am]

BILLING CODE 4101–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Data Collection; Comment Request, Survey of Colorectal Cancer Screening Policies, Programs, and Systems in U.S. Health Plans

Summary: In compliance with the provisions of Section 3507(1)(D) of the Paperwork Reduction Act of 1995, for opportunity for public comments on proposed data collection projects, the National Institutes of Health (NIH), National Cancer Institute (NCI) 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 October 29, 2004 (Volume 69, No. 209, pages 63159–63160) 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 number.

Proposed Collection: Title: Survey of Colorectal Cancer Screening Policies, Programs, and Systems in U.S. Health Plans. *Type of Information Collection Request:* New. *Need and Use of Information collection:* This study will obtain information on policies, programs, and practices for colorectal cancer screening among health plans in the U.S. The purpose of the study is to assess (1) Health plan policies, programs, and practices for colorectal cancer screening; (2) health plan activities in response to the National Committee on Quality Assurance's new Health Employer Data Information Set measure for colorectal cancer screening; and (3) characteristics of health plans and plan policies and activities that may be associated with higher rates of colorectal cancer screening. A questionnaire will be administered by mail or Internet using a national sample of health plans. Study participants will be health plan medical directors or administrators, and they will select their