specific outcomes to be achieved; performance targets which the project is committed to achieving; critical milestones, which must be achieved if results are to be gained; and organizational support; the level of support including the priority this project has for the agency.

Objectives and Need for Assistance 25 Points

Factors: The applicant documents that the project addresses vital needs related to the purposes stated and discussed under this announcement.

Results or Benefits Expected 20 Points

Factor: The extent to which the applicant adequately describes how the project will assure long-term program and management improvements that will aid in removal from the ''at risk category.''

Organizational Profiles 20 Points

Factors: The applicant fully describes, for example in a resume, the experience and skills of the proposed resources of technical assistance showing specific qualifications including how the CSBG eligible entities will be monitored for a specified period of time following the corrective action to assure long-term program and management improvements that will aid the organization from being in the ''at-risk category'' again.

Budget and Budget Justification 5 Points

Factors: (a) The extent to which the resources requested are reasonable and adequate to accomplish the project. (0–3 points)

(b) The extent to which total costs are reasonable and consistent with anticipated results. (0–2 points)

2. Review and Selection Process

No grant award will be made under this announcement on the basis of an incomplete application.

Since ACF will be using non-Federal reviewers in the process, applicants have the option of omitting from the application copies (not the original) specific salary rates or amounts for individuals specified in the application budget and Social Security Numbers, if otherwise required for individuals. The copies may include summary salary information.

Approved But Unfunded Applications

In cases where more applications are approved for funding than ACF can fund with the money available, the Grants Officer shall fund applications in their order of approval until funds run out. In this case, ACF has the option of carrying over the approved applications up to a year for funding consideration in a later competition of the same program. These applications need not be reviewed and scored again if the program's evaluation criteria have not changed. However, they must then be placed in rank order along with other applications in later competition.

VI. Award Administration Information

1. Award Notices

The successful applicants will be notified through the issuance of a Financial Assistance Award document which sets forth the amount of funds granted, the terms and conditions of the grant, the effective date of the grant, the budget period for which initial support will be given, the non-Federal share to be provided, and the total project period for which support is contemplated. The Financial Assistance Award will be signed by the Grants Officer and transmitted via postal mail.

Organizations whose applications will not be funded will be notified in writing.

2. Administrative and National Policy Requirements

Grantees are subject to the requirements in 45 CFR Part 74 (non-governmental) or 45 CFR Part 92 (governmental) and 45 CFR Part 1050.

3. Reporting Requirements

Grantees will be required to submit program progress and financial reports (SF–269) throughout the project period. Program progress and financial reports are due 30 days after the reporting period. In addition, final programmatic and financial reports are due 90 days after the close of the project period.

Program Progress Reports: Semi-Annually.

Financial Reports: Semi-Annually.

VII. Agency Contacts

Program Office Contact

Dr. Margaret Washnitzer, Department of Health and Human Services (HHS), Administration for Children and Families (ACF), Office of Community Services Operations Center, 1515 Wilson Blvd., Suite 100, Arlington, VA 22209. Phone: 800–281–9519. E-mail: *OCSGRANTS@acf.hhs.gov*.

Grants Management Office Contact

Barbara Ziegler-Johnson, Department of Health and Human Services (HHS), Administration for Children and Families (ACF), Office of Community Services Operations Center, 1515 Wilson Blvd., Suite 100, Arlington, VA 22209. Phone: 800–281–9519. E-mail: *OCSGRANTS@acf.hhs.gov*.

VIII. Other Information

The FY 2006 President's budget does not include or propose funding for the community Services Block Grant Training and Technical Assistance Program. Future funding is based on the availability of Federal funds.

Direct Federal grants, subaward funds, or contracts under the Administration for Children and Families programs shall not be used to support inherently religious activities such as religious instruction, worship, or proselytization. Therefore, organizations must take steps to separate, in time or location, their inherently religious activities from the services funded under this program. Regulations pertaining to the Charitable Choice Provisions Applicable to Programs Authorized under the Community Services Block Grant Act can be found at either 45 CFR Part 1050 or the HHS Web site at *http://www.os.dhhs.gov/fbci/waisgate21.pdf*.

Notice: Beginning with FY 2006, the Administration for Children and Families (ACF) will no longer publish grant announcements in the **Federal Register**. Beginning October 1, 2005 applicants will be able to find a synopsis of all ACF grant opportunities and apply electronically for opportunities via: *http://www.Grants.gov*. Applicants will also be able to find the complete text of all ACF grant announcements on the ACF Web site located at: *http://www.acf.hhs.gov/grants/index.html*.

Applicants will not be sent acknowledgements of received applications.

Dated: May 5, 2005.

Josephine B. Robinson,

Director, Office of Community Services.

[FR Doc. 05–9427 Filed 5–11–05; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004E–0316]

Determination of Regulatory Review Period for Purposes of Patent Extension; ERTACZO

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for

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*