and administration high priority demonstrations. The application will be used to gather information about the characteristics of the applicant's organization, benefits, and services they propose to offer, success in operating the model, and evidence that the model is likely to be successful in the Medicare program. The standard application will be used for all waiver demonstrations and will reduce the burden on applicants, provide for consistent and timely information collections across demonstration, and provide a user-friendly format for respondents.

Frequency: On Occasion.

Affected Public: Business or other for-profit and Not-for-profit institutions.

Number of Respondents: 75.

Total Annual Responses: 75.

Total Annual Hours: 1600.

5. *Type of Information Collection Request:* Extension of a currently approved collection.

Title of Information Collection: Conditions of Coverage of Suppliers of End Stage Renal Disease (ESRD).

Form No.: CMS–R–52 (OMB# 0938–0386).

Use: This package is needed to encourage proper distribution and effective utilization of ESRD treatment sources while maintaining and improving the efficient delivery of care by physicians and dialysis facilities.

Frequency: Annually.

Affected Public: Business or other for-profit and Federal Government.

Number of Respondents: 4,297.

Total Annual Responses: 4,297.

Total Annual Hours: 148,785.

6. *Type of Information Collection Request:* Revision of a currently approved collection.

Title of Information Collection: Information Collection Requirements in the Hospice Conditions Coverage. The following regulations are affected: 42 CFR 418.22; 418.24; 418.28; 418.56(b), (e)(1), (e)(3); 418.58; 418.70(e); 418.83; 418.96(b); and 418.100(b).

Form No.: CMS–R–30 (OMB# 0938–0302).

Use: Establishes standards for hospices that wish to participate in the Medicare program. The regulations establish standards for eligibility, reimbursement standards and procedure, and delineate conditions that hospices must meet to be approved for participation in Medicare.

Frequency: On occasion.

Affected Public: Business or other for-profit.

Number of Respondents: 2,316.

Total Annual Responses: 2,316.

Total Annual Hours: 5,981,427.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://cms.hhs.gov/regulations/pra/default.asp,* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, 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 OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: April 10, 2003.

Dawn Willinghan,

Acting Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances.

[FR Doc. 03–9548 Filed 4–17–03; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Tribal Temporary Assistance for Needy Families Quarterly Financial Report.

OMB No.: New Request.

Description: The form provides specific data regarding expenditures and provides a mechanism for Tribes to request grant awards and certify the availability of State matching funds. Failure to collect this data would seriously compromise ACF's ability to monitor expenditures. This information is also used to estimate outlays and may be used to prepare ACF budget submissions to Congress. The following citations should be noted in regards to this collection: 45 CFR 286.255.

Respondents: Tribal TANF Agencies.

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–196TT	20	4	2	160

Estimated Total Annual Burden Hours: 160.

In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: April 15, 2003.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 03–9639 Filed 4–17–03; 8:45 am]

BILLING CODE 4104–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03E–0031]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for VFEND 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 Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3460.

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 VFEND (voriconaxole). VFEND is indicated for use in the treatment of the following fungal infections: Invasive *aspergillosis* and serious fungal infections caused by *scedosporium apiospermum* and *fusarium spp.*, including *fusarium solani*, in patients intolerant of or refractory to other therapies. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for VFEND (U.S. Patent No. 5,567,817) from Pfizer, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 4, 2003, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of VFEND 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 VFEND is 2,452 days. Of this time, 1,898 days occurred during the testing phase of the regulatory review period, while 554 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:* September 8, 1995. The applicant claims September 27, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 8, 1995, 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:* November 17, 2000. FDA has verified the applicant's claim that the new drug application (NDA) for VFEND (NDA 21–266) was initially submitted on November 17, 2000.

3. *The date the application was approved:* May 24, 2002. FDA has verified the applicant's claim that NDA 21–266 was approved on May 24, 2002.

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 945 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Dockets Management Branch (see **ADDRESSES**) written comments and ask for a redetermination by June 17, 2003. 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 October 15, 2003. 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. Three copies of any mailed information 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 31, 2003.

Jane A. Axelrad,

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

[FR Doc. 03–9577 Filed 4–17–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00E–1248]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for TIKOSYN and is publishing this notice of that determination as required by law. FDA has made the determination