Dated: May 6, 2009.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. E9–11150 Filed 5–13–09; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; The Impact of Continuing Medical Education on Physician Practice

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Clinical Center, the National Institutes of Health will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget for review and approval.

Proposed Collection: Title: The impact of Continuing Medical Education on physician practice: *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* This study will assess the value of the Continuing Medical Education conferences held at the NIH. The primary objective of the survey is to determine if conferences have had an impact on whether the physician has changed their practice as a result of the information presented in the conference. *Frequency of response:* On occasion. *Affected Public:* Physicians, dentists, nurses, and other health care providers. The annual reporting burden is as follows:

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Doctoral Level	7,500	2	0.017	255
Other Health Care Provider	2,500	2	0.017	85
Total				340

There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

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 function 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 to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Linda Wisniewski, Nurse Consultant, Office of Clinical Research Training and Medical Education, CC, NIH, Building 10, Room 1N252B, 9000 Rockville Pike, Bethesda, MD 20892 or 301–496–9425 or e-mail your request, including your address to: *wisniewskil@cc.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Laura Lee,

Project Clearance Liaison, Warren Grant Magnuson Clinical Center, National Institutes of Health.

[FR Doc. E9–11308 Filed 5–13–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Title IV–E Programs Quarterly Financial Report.

OMB No.: 0970–0205.

Description: Historically, State agencies have administered programs under title IV–E of the Social Security Act for the Foster Care and Adoption Assistance Programs. The Administration for Children and Families provides Federal funding at the rate of 50 percent for most of the administrative costs of these programs and at other rates for other specific categories of costs as detailed in Federal statute and regulations.

The enactment of Public Law 110–351, the ''Fostering Connections to Success and Increasing Adoptions Act of 2008'' introduced two major changes to the title IV–E programs: (1) The inception of the Guardianship Assistance Program for all grantees, effective October 1, 2008 and, (2) the availability of these programs to Tribes and Tribal Organizations, effective October 1, 2009.

We anticipate that this form will be revised and redesigned to be applicable to both State and Tribal grantees.

This form is submitted quarterly by each State or Tribe to estimate its funding needs for the upcoming fiscal quarter and to report expenditures for the fiscal quarter just ended. The information collected in this report is used by this agency to calculate quarterly Federal grant awards and to enable oversight of the financial management of the programs.

Respondents: State agencies (including the District of Columbia and Puerto Rico) and Tribal agencies (starting in FY 2010) administering the Foster Care, Adoption Assistance and Guardianship Assistance programs under Title IV–E of the Social Security Act.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Title IV–E Programs Quarterly Financial Report	70	4	20	5,600

Estimated Total Annual Burden Hours: 5,600.

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 Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. *E-mail address: grjohnson@acf.hhs.gov.* 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: May 6, 2009.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. E9–11149 Filed 5–13–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2004–E–0266 (formerly 2004E–0446), FDA–2004–E–0270 (formerly 2004E–0391), and FDA–2004–E–0332 (formerly 2004E–0399)]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for SENSIPAR 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 which 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. Submit electronic comments to *http://www.regulations.gov*

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

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 human drug product 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 SENSIPAR (cinacalcet hydrochloride). SENSIPAR is indicated for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease on dialysis and for the treatment of hypercalcemia in patients with parathyroid carcinoma. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for SENSIPAR (U.S. Patent Nos. 6,011,068; 6,211,244; and 6,313,146) from NPS Pharmaceuticals, Inc., and the Patent and Trademark Office requested FDA's assistance in determining the patents' eligibilities for patent term restoration. In a letter dated October 19, 2004, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of SENSIPAR 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 SENSIPAR is 2,089 days. Of this time, 1,906 days occurred during the testing phase of the regulatory review period, while 183 days occurred during the approval phase. These periods of time were derived from the following dates: