PHASE VI ESTIMATE OF RESPONDENT BURDEN—Continued

[Note: Total burden is annualized over a 5-year period]

Instrument	Respondent	Number of respondents	Total average number of responses per respondent	Hours per response	Total burden hours	5-Year average annual burden hours
Total Summary	13,274	.....	271,439	.....	28,156	

[1] An average of 23 stakeholders in up to 26 grant communities will complete the System of Care Assessment interview. These stakeholders will include site administrative staff, providers, agency representatives, family representatives, and youth.
[2] Number of respondents across 26 grantees (5223), in addition to 318 children/families from the comparison sample. Average based on a 5 percent attrition rate at each data collection point.
[3] Number of responses per respondent is five over the course of the study (once every 6 months for 24 months, with one baseline/intake response, and 4 follow-up responses).
[4] Approximate number of caregivers with children over age 5, based on Phase IV data submitted as of 12/08. Also includes 318 children/families from the comparison sample.
[5] Approximate number of caregivers with children 3 and older, based on Phase IV data submitted as of 12/08. Also includes 318 children/families from the comparison sample.
[6] Approximate number of caregivers with either: (1) Children served at the roughly 7 early childhood-focused communities, for whom the instrument is required; or (2) children aged 0 to 12 at other communities, where the instrument is optional (we estimate that ⅓ of caregivers will be administered the instrument when it is optional). Estimates are based on Phase IV data submitted as of 12/08.
[7] Approximate number of caregivers with either: (1) Children served at the roughly 7 early childhood-focused communities, for whom the instrument is required; or (2) children aged 0 to 5 at other communities, where the instrument is optional (we estimate that ⅓ of caregivers will be administered the instrument when it is optional). Estimates are based on Phase IV data submitted as of 12/08.
[8] Based on Phase IV finding that approximately 63 percent of the children in the evaluation were 11 years old or older. Also includes 318 children/families from the comparison sample.
[9] With the exception of the MSSC–R, respondents only complete Service Experience Study measures at follow-up points. See Footnote #3 for the explanation about the average number of responses per respondent.
[10] Approximate number of children/families in each sector, for the Sector and Comparison Study. This includes cases within the communities, as well as within the comparison sample.
[11] For each community, 1 respondent will be a caregiver and 3 respondents will be administrators/providers.
[12] Assumes that each community will use flexible funds expenditures on average for approximately one quarter of the children/youth enrolled.
[13] Assumes that three expenditures, on average, will be spent on each child/youth receiving flexible fund benefits.
[14] Assumes that each child/youth in system of care communities and in the comparison sample will have 100 service episodes, on average.
[15] Total Annual Burden (hours) is the product of Number of Distinct Respondents × Average Annual Number of Responses per Respondent × Average 5-Year Burden per Response (hours).

Written comments and recommendations concerning the proposed information collection should be sent by September 10, 2009 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202–395–5806.

Dated: August 5, 2009.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. E9–19228 Filed 8–10–09; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: ACF Uniform Project Description.

OMB No.: 0970–0139.

Description: The Administration for Children and Families (ACF) has more than 50 discretionary grant programs. The proposed information collection form would be a uniform discretionary application form eligible for use by grant applicants to submit project information in response to ACF program announcements. ACF would use this information, along with other OMB-approved information collections, to evaluate and rank applicants and protect the integrity of the grantee selection process. All ACF discretionary grant programs would be eligible but not required to use this application form. The application consists of general information and instructions; the Standard Form 424 series that requests basic information, budget information and assurances; the Project Description requesting the applicant to describe how these objectives will be achieved; along with assurances and certifications. Guidance for the content of information requested in the Project Description is found in OMB Circular A–102 and 45 CFR Part 74.

Respondents: Applicants for ACF Discretionary Grant Programs.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
UPD	6,752	1	40	270,080

Estimated Total Annual Burden Hours: 270,080

Additional Information: Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the

information collection. *E-mail address: infocollection@acf.hhs.gov*.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, *Fax:* 202–395–7245, *Attn:* Desk Officer for the Administration for Children and Families.

Dated: August 6, 2009.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E9–19170 Filed 8–10–09; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–E–0053]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

ADDRESSES: Submit written or electronic 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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological 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 biological product and continues until FDA grants permission to market the biological 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 biological 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 biologic product NPLATE (romiplostim). NPLATE is indicated for the treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for NPLATE (U.S. Patent No. 6,835,809) from Amgen 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 26, 2009, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of NPLATE 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 NPLATE is 2,319 days. Of this time, 2,014 days occurred during the testing phase of the regulatory review period, while 305 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: April 19, 2002. The applicant claims April 23, 2002, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 19, 2002, the date of the FDA correspondence removing the clinical hold on the application.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262)*: October 23, 2007. FDA has verified the applicant's claim that the biologics license application (BLA) for NPLATE (BLA 125268/0) was initially submitted on October 23, 2007.

3. *The date the application was approved*: August 22, 2008. FDA has verified the applicant's claim that BLA 125268/0 was approved on August 22, 2008.

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 818 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 or electronic comments and ask for a redetermination by October 13, 2009. 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 February 8, 2010. 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