ESTIMATED ANNUALIZED BURDEN HOURS

Burden category	Number of respondents per year	Number of responses per respondent	Average burden per response (hours)
1. Screening interview only	13,333	1	10/60
2. Screener, family, and sample person interviews only	300	1	1.10
3. Screener, family, and sample person interviews and MEC examination (including pilot studies)	5,180	1	5.9
4. Second dietary recall interview	4,300	1	30/60
5. Telephone Interview (FCBS)	3,000	1	20/60
6. Follow-up, special studies, and tests of procedures	4,000	1	5.9

Dated: September 19, 2006.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 06–8164 Filed 9–22–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: DHHS/ACF/ASPE/DOL Enhanced Services for the Hard-to-Employ Demonstration and Evaluation: Rhode Island 15-Month Survey Amendment.

OMB No. 0970–0276.

Description: The Enhanced Services for the Hard-to-Employe Demonstration and Evaluation Project (HtE) seeks to learn what works in this area to date and is explicitly designed to build on past research by rigorously testing a wide variety of approaches to promote employment and improve family functioning and child well-being. The HtE project is designed to help Temporary Assistance for Needy Families (TANF) recipients, former TANF recipients, or low-income parents who are hard-to-employ. The project is sponsored by the Office of Planning, Research and Evaluation (OPRE) of the Administration for Children and Families (ACF), the Office of the Assistant Secretary for Planning and Evaluation (ASPE) in the U.S. Department of Health and Human Services (HHS), and the U.S. Department of Labor (DOL).

The evaluation involves an experimental, random assignment design in four sites, testing a diverse set of strategies to promote employment for low-income parents who face serious obstacles to employment. The four include: (1) Intensive care management to facilitate the use of evidence-based treatment for major depression among parents receiving Medicaid in Rhode Island; (2) job readiness training, worksite placements, job coaching, job development and other training opportunities for recent parolees in New York City; (3) pre-employment services and transitional employment for long-term TANF participants in Philadelphia; and (4) home- and center-based care, enhanced with self-sufficiency services, for low-income families who have young children or are expecting in Kansas and Missouri.

Materials for follow-up surveys for each of these sites were previously submitted to OMB and were approved. The purpose of this submission is to add physiological measures to the follow-up effort to the Rhode Island study.

Respondents: The respondents to this component of the Rhode Island follow-up survey will be low-income parents and their children from the Rhode Island site currently participating in the HtE Project. As described in the prior OMB submission, these parents are Medicaid recipients between the ages of 18 and 45 receiving Medicaid through the managed care provider United Behavioral Health (UBH) in Rhode Island who meet study criteria with regard to their risk for depression. Children are the biological, adopted, and step-children of these parents, between the ages of 1 and 18 years of age.

The annual burden estimates are detailed below, and the substantive content of each component will be detailed in the supporting statement attached to the forthcoming 30-day notice.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
RI 15-month, parent physiological component	400	8	5 minutes or .08 hrs	266.66
RI 15-month young child physiological component	160	8	5 minutes or .08 hrs	106.66
RI 15-month youth physiological component	242	8	5 minutes or .08 hrs	161.33

Estimated Total Annual Burden Hours: 534.65.

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: *infocollection@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: September 19, 2006.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 06–8110 Filed 9–22–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0031]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for CLOLAR 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.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

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 CLOLAR (clofarabine). CLOLAR is indicated for the treatment of pediatric patients 1 to 21 years old with relapsed or refractory acute lymphoblastic leukemia after at least two prior regimens. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for CLOLAR (U.S. Patent No. 5,661,136) from Southern Research Institute, 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 24, 2006, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of CLOLAR 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 CLOLAR is 2,200 days. Of this time, 1,926 days occurred during the testing phase of the regulatory review period, while 274 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 (the act) (21 U.S.C. 355(i)) became effective*: December 22, 1998. The applicant claims February 10, 1999, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 22, 1998, the date FDA removed the clinical hold on the application.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: March 30, 2004. The applicant claims September 26, 2003, as the date the new drug application (NDA) for CLOLAR (NDA 21–673) was initially submitted. However, FDA records indicate that NDA 21–673 was submitted in its entirety on March 30, 2004.

3. *The date the application was approved*: December 28, 2004. FDA has verified the applicant's claim that NDA 21–673 was approved on December 28, 2004.

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 1,303 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 November 24, 2006. 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 March 26, 2007. 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: September 1, 2006.

Jane A. Axelrad,

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

[FR Doc. 06–8115 Filed 9–22–06; 8:45 am]

BILLING CODE 4160–01–S