ANNUAL BURDEN ESTIMATES—Continued

Respondents and activities	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Head Start Staff: Enter Information on Computer-Based Reporting System (CBRS)	1,800	1	3	5,400
Spring Implementation				
Head Start Children: Participate in Child Assessments	425,000	1	1/4	106,250
Head Start Staff (Assessors): Participate in Refresher Training on Child Assessments	25,000	1	4	100,000
Head Start Staff (Local HSNRS Trainers): Participate in Training on Child Assessments	1,800	1	4	7,200
Head Start Staff (Assessors): Administer Child Assessments	25,000	17	1/4	106,250
Head Start Teachers: Participate in Refresher Training on Social-Emotional Development Ratings	38,500	1	1/2	19,250
Head Start Teachers: Complete Social-Emotional Development Ratings	38,500	11	1/6	70,583
Head Start Teachers: Complete Child Health Questions	38,500	11	1/12	35,292
Head Start Staff: Complete Health and Safety of Program Questions	1,800	1	1/12	150
Head Start Staff: Enter Information on CBRS	1,800	1	3/2	2,700
Total Annual Burden Estimates	.....	.....	.....	917,300

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 this 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. E-mail: *infocollection@acf.hhs.gov.*

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: February 2, 2006.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 06–1160 Filed 2–7–06; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004E–0307]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ALIMTA 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. 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, 240–453–6681.

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 ALIMTA (pemetrexed). ALIMTA in combination with cisplatin is indicated for the treatment of patients with malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery. ALIMTA as a single agent is indicated

for the treatment of patients with locally advanced metastatic non-small cell lung cancer after prior chemotherapy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ALIMTA (U.S. Patent No. 5,344,932) from Eli Lilly and Co., 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 ALIMTA 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 ALIMTA is 4,166 days. Of this time, 4,038 days occurred during the testing phase of the regulatory review period, while 128 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*: September 10, 1992. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on September 10, 1992.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: September 30, 2003. The applicant claims September 29, 2003, as the date the new drug application (NDA) for ALIMTA (NDA 21–462) was initially submitted. However, FDA records indicate that NDA 21–462 was submitted on September 30, 2003.

3. *The date the application was approved*: February 4, 2004. FDA has verified the applicant's claim that NDA 21–462 was approved on February 4, 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 1,784 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 April 10, 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 August 7, 2006. 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: January 5, 2006.

Jane A. Axelrad,

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

[FR Doc. E6–1642 Filed 2–7–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; NIH Intramural Research, Training Program Application

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 Office of the Director, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: NIH Intramural Research Training Program Applications.

Type of Information Collection Request: Revision/OMB No. 0925–0299; February 28, 2006.

Need and Use of Information Collection: The proposed information collection activity is for the purpose of collecting data related to the availability of Training Fellowships in the NIH Intramural Research Program. This information must be submitted in order to receive due consideration for a fellowship and will be used to determine the eligibility and quality of potential awardees.

Frequency of Response: On occasion.

Affected Public: Individuals seeking Intramural Training Opportunities and references for these individuals.

Type of Respondents: Postdoctoral, predoctoral, post-baccalaureate, technical, clinical, and student IRTA applicants. There are no capital costs, operating costs, and/or maintenance costs to report.

Type of respondent	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Postdoctoral	1,000	3.00	1.00	3,000
Predoctoral	175	1.00	1.00	175
Postbaccalaureate	2,090	1.00	1.00	2,090
Technical	175	1.00	1.00	175
Clinical	300	1.00	1.00	300
Student	7,000	1.00	1.00	7,000
References for all categories	31,395	1.00	0.33	10,360
Total	42,135	1.0474665	0.5482378	23,100

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 agency, including whether the information will have practical utility;