whether the informtion 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. 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. 06–1159 Filed 2–7–06; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: National Implementation of Head Start National Reporting System on Child Outcomes.

OMB No.: 0970–0249.

Description: The Administration on Children, Youth and Families (ACYF), within the Administration for Children and Families (ACF) of the Department of Health and Human Services (HHS), is requesting comments on plans to implement the Head Start National Reporting System (HSNRS) on Child Outcomes. Child-outcomes information collected by this implementation is expected to enhance Head Start programs' accountability and quality.

HSNRS addresses Presidentially mandated reforms and Congressionally mandated requirements for information on specific child outcomes and provides Head Start program managers and teachers with useful information to support program-improvement strategies.

HSNRS has three major goals. First, HSNRS will provide local Head Start programs with information about the progress of groups of children on a limited number of performance measures. This information is captured by measuring how children are doing at the beginning and at the end of each program year. Second, HSNRS will capture the same set of information across the nation in a consistent manner, allowing for creation of normative comparison groups. Individual programs can use this information to target needs for training and technical assistance. Third, the child-outcomes information captured in HSNRS should serve as one component of the current national progress monitoring effort, which involves on-site, systematic review of programs. The Head Start Bureau can use compiled HSNRS data as part of the process for ensuring the effectiveness of services. These results can highlight the needs of specific groups of children, identify local programs' technical assistance and training needs, and contribute to the accountability of Head Start.

The first three rounds of the HSNRS national implementation (2003–04, 2004–05, and 2005–06 program years) were successful. In each round of the data collection, over 400,000 assessments were completed, making this the largest assessment of preschool children ever conducted. Over 99 percent of Head Start programs and Head Start parents and children cooperated fully with the HSNRS procedures. The HSNRS data show good internal reliability, both in terms of Item Response Theory (IRT) reliability and Cronbach's Coefficient Alpha at the individual child-level, for both English-language and Spanish-language assessments. IRT estimates of the internal reliability of the program-level English-language assessment scores were excellent, with most IRT-reliability coefficients greater than .90.

For each program year, participating local Head Start programs received HSNRS Program Reports at the aggregated program-level for the fall assessment (baseline) and the spring assessment (fall-spring growth). These reports provided local Head Start programs with information about the progress of their children in all assessed domains and demonstrated how these scores compared to all other Head Start children (national-level reference tables) as well as children in similar programs (sub-group reference tables).

HSNRS will continue to collect child-outcomes information from children who are four years old or older and who will enter Kindergarten next year. As in the previous three years, all eligible Head Start children will be assessed twice a year using a standardized direct child-assessment battery. The assessment battery will address a limited set of early literacy, language, and numerary skills.

Twice a year, HSNRS will also collect teachers' reports of social-emotional development of Head Start children using standardized rating scales. These social-emotional rating scales will be field-tested in spring 2006 prior to national implementation in fall 2006. Head Start teachers will rate children in their classrooms on the aspects of cooperative classroom behaviors, preschool learning behaviors, and problem behaviors.

HSNRS will also collect health and safety information on children and programs, including children's height and weight, immunization status, receipt of dental care, and occurrences of injuries requiring medical attention.

Respondents: Head Start children and Head Start staff.

ANNUAL BURDEN ESTIMATES

Respondents and activities	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Fall Implementation				
Head Start Children: Participate in Child Assessments	425,000	1	¼	106,250
Head Start Staff (Assessors): Participate in 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	¼	106,250
Head Start Teachers: Participate in Training on Social-Emotional Development Ratings	38,500	1	1	38,500
Head Start Teachers: Complete Social-Emotional Development Ratings	38,500	11	⅙	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

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