Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: February 21, 2003.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 03–4603 Filed 2–26–03; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Agency Recordkeeping/Reporting Requirements Under Emergency Review by the Office of Management and Budget (OMB)

Title: Design and field testing of Head Start National Reporting System on Child Outcomes.

OMB No.: New Request.

Description: The Administration on Children, Youth and Families (ACYF), Administration for Children and Families (ACF) of the Department of Health and Human Services (DHHS) is requesting comments on plans to conduct the Design and Field Testing of the Head Start National Reporting System on Child Outcomes. This study is being conducted under contract with Westat and Xtria (#282–98–0015) to collect child outcomes information that will be used for program improvement in Head Start.

The purpose of this field test is to create the framework and procedures for a national outcomes report of children's ability and progress on the Presidentially and congressionally-mandated standards of learning. This effort will involve a subsample of 36 Head Start programs. In these programs, we will collect direct assessment data on approximately 1,440 sample children as well as their demographic information, the backgrounds of their respective classroom teachers, and the characteristics of their respective programs. This data will be used to develop and evaluate a system to report this outcome information.

After designing the framework and procedures for the National Reporting System, Westat/Xtria will then evaluate how well such a system would work, based on analysis of direct assessment data from a national sample of programs, classes, and children. Westat will then recommend any modifications to the design for the full national implementation year of the National Reporting System (NRS), based on the results of the field test. This could include recommendations on the training procedures of field staff or modifications of the assessment battery.

In the implementation of the NRS, staff training in collecting and submitting data will be critical. In order to ensure high quality data for the NRS, two different approaches to staff training will be evaluated in two study conditions:

Standard Training

The NRS will use a ''training the trainers'' training program. This effort will involve a subsample of 26 programs drawn from around the country. Selected staff from each program will travel to Rockville, Maryland to be trained in the procedures to teach other Head Start staff members how to administer the assessment battery and how to use the computer reporting system (Condition Two). Once trained, these ''trained trainers'' will return to their respective Head Start programs and train their local teachers how to administer the assessment battery and how to use the computer reporting system.

Extended Training

This training condition will involve a subsample of 10 Head Start programs drawn from around the country. These programs will receive the standard 3-day training workshop plus one extra day of extended training on how to conduct training sessions for their local Head Start staff (Condition One).

The field test will also evaluate any differences between the types of assessors administering the assessment. Head Start classroom teachers, the first type of assessor, will be responsible for administering the assessment to children from their own classroom. The second type of assessor is any other Head Start staff, or ''non-classroom teachers,'' including program coordinators, education coordinators, education specialists, or even teachers from other classrooms (*e.g.,* teacher from classroom A assesses children from classroom B). The purpose of examining these types of assessors is to determine if there are any differences in the administration of the assessment and/or the scores collected by these different types of assessors. Any possible bias or unreliability in the assessment scores collected by the different types of assessors, and the ease of administration and fidelity to standard administration procedures will be evaluated.

Respondents: Head Start Children and Head Start Staff.

Annual Burden Estimates: Estimated Annual Response Burden to Respondents for the Design and field testing of Head Start National Reporting System on Child Outcomes.

ESTIMATED RESPONSE BURDEN FOR RESPONDENTS IN THE HEAD START NATIONAL REPORTING SYSTEM FIELD TEST—SPRING 2003

Activities	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Head Start Children: Complete Direct Assessments	1440	1	1/3	480
Head Start Staff: Administer Direct Assessment	144	10	1/3	480
Head Start Staff: Enter Child Demographic Information	1440	1	1/12	120
Head Start Staff: Enter Teacher Background Information	144	1	1/30	4.8
Head Start Children: Parallel Child Assessments administered by Field Staff	480	1	1/3	160
Program Directors Technology Survey	400	1	1/4	100
Condition One Head Start Staff: Training as Trainers for the Direct Child Assessments	10	1	28	280
Condition Two head Start Staff: Training as Trainers for the Direct Child Assessments	26	1	20	520
Head Start Staff: Training Local Staff for the Direct Child Assessments	36	1	8	288
Head Start Staff: Receiving Training for the Direct Child Assessments	144	1	8	1152
Totals for Spring 2003				3,584.8

Additional Information: ACF is requesting that OMB grant a 180 day approval for this information collection under procedures for emergency processing by March 15, 2003. A copy of this information collection, with applicable supporting documentation, may be obtained by calling the Administration for Children and Families, Reports Clearance Officer, Robert Sargis at (202) 690–7275. In addition, a request may be made by sending an e-mail request to: *rsargis@acf.dhhs.gov.*

Comments and questions about the information collection described above should be directed to the following address by March 15, 2003: Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ACF, Office of Management and Budget, Paper Reduction Project, 725 17th Street, NW., Washington, DC 20503.

Dated: February 21, 2003.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 03–4585 Filed 3–26–03; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01E–0367]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Starlix 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 Dockets Management Branch (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 Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3460.

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 Starlix (nateglinide). Starlix is indicated as monotherapy to lower blood glucose in patients with Type 2 diabetes (non-insulin dependent diabetes mellitus, NIDDM) whose hyperglycemia cannot be adequately controlled by diet and physical exercise and who have not been chronically treated with other anti-diabetic agents. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Starlix (U.S. Patent No. 34,878) from Novartis, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 2, 2001, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Starlix 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 Starlix is 2,147 days. Of this time, 1,775 days occurred during the testing phase of the regulatory review period, while 372 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective*: March 9, 1995. The applicant claims February 7, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND became effective on March 9, 1995, which is 30 days after FDA's receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: December 17, 1999. FDA has verified the applicant's claim that the new drug application (NDA) for Starlix (NDA 21–204) was initially submitted on December 17, 1999.

3. *The date the application was approved*: December 22, 2000. FDA has verified the applicant's claim that NDA 21–204 was approved on December 22, 2000.

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 1,259 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management (*see* **ADDRESSES**) written comments and ask for a redetermination by April 28, 2003. 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 26, 2003. 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 Dockets Management Branch. Three copies of any information are to be submitted, except that individuals may submit a single copy. Copies 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