Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5(a)(2)).

CONTESTING RECORD PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7).

RECORD SOURCE CATEGORIES:

Summary prescription drug claim information contained in this system is obtained from the Prescription Benefit Package (PBP) Plans and Medicare Advantage (MA–PBP) Plans daily and monthly drug event transaction reports, Medicare Beneficiary Database (09–70–0530), and other payer information to be provided by the TROOP Facilitator.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE PRIVACY ACT:

None.

[FR Doc. E7–2984 Filed 2–21–07; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: National Directory of New Hires.

OMB No.: 0970–0166.

Description: Public Law 104–193, the ''Personal Responsibility and Work Opportunity Reconciliation Act of 1996,'' requires the Office of Child Support Enforcement (OCSE) to operate a National Directory of New Hires (NDNH) to improve the ability of State child support enforcement agencies to locate noncustodial parents and collect child support across State lines. The law requires employers to report newly hired employees to States. States are then required to periodically transmit new hire data received from employers to the NDNH, and to transmit wage and unemployment compensation claims data to the NDNH on a quarterly basis. Federal agencies are required to report new hires and quarterly wage data directly to the NDNH. All data is transmitted to the NDNH electronically.

Respondents: Employers, State Child Support Enforcement Agencies, State Workforce Agencies, Federal Agencies.

Annual Burden Estimates:

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
New Hire: Employers Reporting Manually	5,166,000	3.484	.025	449,959
New Hire: Employers Reporting Electronically	1,134,000	33.272	.00028	10,565
New Hire: States	54	83.333	66.7	300,150
Quarterly Wage & Unemployment Compensation	54	8	.033	14
Multistate Employers' Notification Form	2,808	1	.050	140

Estimated Total Annual Burden Hours: 760,828.

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. E-mail address: *infocollection@acf.hhs.gov*. All requests should be identified by the title of the information collection.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after the 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: 202–395–6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: February 15, 2007.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 07–789 Filed 2–21–07; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Needs Assessment for Promoting Cultural Competence and Diversity in Youth Mentoring Programs Toolkit.

OMB No.: New Collection.

Description: The Department of Health and Human Services' (HHS) Mentoring Children of Prisoners (MCP) program, administered under the Family Youth Services Bureau (FYSB) within the Administration for Children and Families (ACF), was authorized by the Promoting Safe and Stable Families Act of 2001 (SSFA, Pub. L. 107–133). The MCP program is designed to nurture children who have one or both parents incarcerated. The Secretary of HHS is mandated to appropriate funds for the MCP grant program, specifically for evaluation, research, training, and technical assistance. In FY 2004, grantees began submitting progress reports to HHS.

FYSB will conduct an assessment of the mentoring community to identify and assess needs for the purpose of building a toolkit of practical information and tools to assist mentoring programs in promoting cultural competence and diversity of their programs. The toolkit modules address recruiting minority mentors, assessing and matching mentors and mentees, training, educating program staff and participants, and promoting ethnic identity development.

Respondents: Mentoring Children of Prisoners grantees and National Mentoring Partnership (MENTOR) affiliated mentoring organizations.

Annual Burden Estimates:

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Mentoring ToolKit Web-based Needs Assessment Questionannaire	442	1	.75	332
Mentoring ToolKit Web-based focus group	40	1	1	40
Mentoring ToolKit Web-based Feedback questionnaire	100	1	.25	25

Estimated Total Annual Burden Hours: 397

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: 202–395–6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: February 15, 2007.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 07–790 Filed 2–21–07; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0252]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for LEVEMIR 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: Beverly Friedman, Office of Regulatory Policy (HFD–7), 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 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 LEVEMIR (insulin determir (rDNA origin)). LEVEMIR is indicated for once or twice-daily subcutaneous administration in the treatment of adult patients with diabetes mellitus who require basal (long acting) insulin for the control of hyperglycemia. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for LEVEMIR (U.S. Patent No. 5,750,497) from Novo Nordisk A/S, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 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 LEVEMIR 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 LEVEMIR is 2,896 days. Of this time, 1,971 days occurred during the testing phase of the regulatory review period, while 925 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) became effective*: July 14, 1997. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 14, 1997.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: December 5, 2002. FDA has verified the applicant's claim that the new drug application (NDA) for LEVIMIR (NDA 21–536) was initially submitted on December 5, 2002.

3. *The date the application was approved*: June 16, 2005. FDA has verified the applicant's claim that NDA 21–536 was approved on June 16, 2005.

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,