Seleda Perryman,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. E9–12023 Filed 5–21–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0299]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Agency Information Collection Request. 60-Day Public Comment Request.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed information collection request for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden. To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov*, or call the Reports Clearance Office on (202) 690–6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above e-mail address within 60-days.

Proposed Project: Adolescent Family Life Care and Prevention End of Year Report Templates (Revision) OMB No. 0990–0299, Office of Adolescent Pregnancy Programs (OAPP).

Abstract: OAPP is proposing to revise the current OMB approved Adolescent Family Life Care and Prevention End of Year Report Templates. The current OMB approval is applicable through May 31, 2009. All AFL grantees are required by their Notice of Grant Awards to submit an end of year report once per year. The current End of Year Report templates provide a degree of standardization across the AFL grantees, allowing for more complete data collection by OAPP for program assessment.

OAPP is also proposing to consolidate 0990–0300–AFL Prevention Project End of Year Report Template ICR and 0990–0299–AFL Care and Prevention End of Year Report Templates ICR. After the approval by OMB on 0990–0299 ICR, OAPP will eliminate 0990–0300. This action will reduce the redundancy across ICRs and lessen the number of burden hours reported by including both templates under one ICR (0990–0299).

The original title will be changed to Adolescent Family Life End of the Year Report Template.

ESTIMATED ANNUALIZED BURDEN TABLE

Forms (if necessary)	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
End of Year Report Templates (program and evaluation for prevention and care grants)	65	1	65	4,225

Seleda Perryman,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. E9–12014 Filed 5–21–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institute for Occupational Safety and Health; Decision To Evaluate a Petition To Designate a Class of Employees for the University of Rochester in Rochester, NY, To Be Included in the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice as required by 42 CFR 83.12(e) of a decision to evaluate a petition to designate a class of employees for the University of Rochester in Rochester, New York, to be included in the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000. The initial proposed definition for the class being evaluated, subject to revision as warranted by the evaluation, is as follows:

Facility: University of Rochester.

Location: Rochester, New York.

Job Titles and/or Job Duties: Laboratory Technicians who worked in the University of Rochester Atomic Energy Project laboratory building.

Period of Employment: September 1, 1943 through June 19, 1945.

FOR FURTHER INFORMATION CONTACT: Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 513–533–6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to *OCAS@CDC.GOV.*

Christine M. Branche,

Acting Director, National Institute for Occupational Safety and Health.

[FR Doc. E9–12007 Filed 5–21–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10185 and CMS–10141]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the

Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Part D Reporting Requirements and Supporting Regulations under 42 CFR 423.505; *Form Number:* CMS–10185 (OMB#: 0938–0992); *Use:* Title I, Part 423, § 423.514 describes CMS' regulatory authority to establish requirements for Part D sponsors. It is noted that each Part D plan sponsor must have an effective procedure to develop, compile, evaluate, and report to CMS, its enrollees, and the general public, at the times and in the manner that CMS requires, statistics in the following areas: (1) The cost of its operations; (2) The availability of utilization of its services; (3) The availability, accessibility; and acceptability of its services; (4) Information demonstrating that the Part D plan sponsor has a fiscally sound operation; and (5) other matters that CMS may require. Subsection 423.505 of the Medicare Prescription Drug Modernization and Modernization Act establishes as a contract provision that Part D Sponsors must comply with the reporting requirements for submitting drug claims and related information to CMS. Data collected via Medicare Part D Reporting Requirements will be an integral resource for oversight, monitoring, compliance and auditing activities necessary to ensure quality provision of the Medicare Prescription Drug Benefit to beneficiaries. Please see the supporting documentation, ''Revisions to 2nd Draft of CY 2010 Part D Reporting Requirements'' document to view a list of current changes. *Frequency:* Reporting—yearly, quarterly and semi-annually; *Affected Public:* Business or other for-profit; *Number of Respondents:* 4,526; *Total Annual Responses:* 380,184; *Total Annual Hours:* 157,450. (For policy questions regarding this collection contact Alice Lee-Martin at 410–786–4578. For all other issues call 410–786–1103.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Prescription Drug Benefit Plan Program: *Use:* Part D plans use the information discussed to comply with the eligibility and associated Part D participating requirements. CMS will use this information to approve contract applications, monitor compliance with contract requirements, make proper payment to plans, and to ensure that correct information is disclosed to enrollees, both potential and current enrollees. *Form Number:* CMS–10141 (OMB#: 0938–0964); *Frequency:* Reporting—quarterly, semi-annually and yearly; *Affected Public:* Business or other for-profits and Individuals or households; *Number of Respondents:* 19,937,772; *Total Annual Responses:* 38,152,764; *Total Annual Hours:* 34,730,676. (For policy questions regarding this collection contact Eugenia Mattison-Gibson at 410–786–2564. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *June 22, 2009:* OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–6974, E-mail: *OIRA_submission@omb.eop.gov*.

Dated: May 15, 2009.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E9–11939 Filed 5–21–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–E–0307]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for INTELENCE 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.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

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