10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 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 USPTO 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 has approved for marketing the human drug product ONIVYDE (irinotecan sucrose octasulfate). ONIVYDE in combination with fluorouracil and leucovorin, is indicated for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy. Subsequent to this approval, the USPTO received patent term restoration applications for ONIVYDE (U.S. Patent Nos. 8,147,867 and 8,329,213) from Merrimack Pharmaceuticals, Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated August 12, 2016, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of ONIVYDE represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for ONIVYDE is 2,536 days. Of this time, 2,354 days occurred during the testing phase of the regulatory review period, while 182 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 (FD&C Act) (21 U.S.C. 355(i)) became effective:* November 13, 2008. FDA has verified the applicant's claim that November 13, 2008, is the date the investigational new drug application became effective.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* April 24, 2015. FDA has verified the applicant's claim that the new drug application (NDA) for ONIVYDE (NDA 207793) was initially submitted on April 24, 2015.

3. *The date the application was approved:* October 22, 2015. FDA has verified the applicant's claim that NDA 207793 was approved on October 22, 2015.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 613 days or 1,215 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (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.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: February 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–02590 Filed 2–8–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request, Information Collection Request Title: The Maternal, Infant, and Early Childhood Home Visiting Program Performance Measurement Information System, OMB Number: 0906–0017—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than April 10, 2018.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, 14N39, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: The Maternal, Infant, and Early Childhood Home Visiting Program Performance Measurement Information System, OMB Control Number: 0906–0017—Revision.

Abstract: This clearance request is for continued approval of the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program Performance Measurement Information System. The MIECHV Program, administered by HRSA in partnership with the Administration for Children and Families, supports voluntary, evidence-based home visiting services during pregnancy women and to parents with young children up to kindergarten entry. States, certain non-profit organizations, and Tribal entities are eligible to receive funding from the MIECHV Program and have the flexibility to tailor the program to serve the specific needs of their communities. HRSA is revising the data collection forms for the MIECHV Program by making the following changes:

- Form 1: Update all tables to include specific guidance to account for and report missing data.
- Form 1, Tables 1 and 2: Update table titles to reflect ''participants served by MIECHV.''
- Form 1, Table 5: Update to reflect correct age categories of ''<1 year''; ''1–2 years''; ''3–4 years''; and ''5–6 years.''
- Form 1, Table 8: Revise the category of ''Never Married'' to read ''Never Married (excluding not married but living together with partner).''
- Form 1, Table 10: Delete.
- Form 1, Table 18: Delete.
- Form 1, Table 22: Revise to only include children greater than or equal to 12 months of age. Title will be updated to ''Index Children (≥12 months of age) by Usual Source of Dental Care.''
- Form 1, Notes: Revise to include Table-specific notes.
- Form 1, Definition of Key Terms: Update definitions for Tables 1, 3, 5, 12, 13, 15, 17, 20, 21, and 22.
- Form 2: Update all measures to include specific guidance to account for and report missing data.
- Form 2, Measure 3: Update denominator to reflect correct inclusion criteria.
- Form 2, Measure 4: Update measure to benchmark receipt of well-child visits to specific ages.
- Form 2, Measure 9: Update numerator to clarify that investigated cases of maltreatment must have occurred within the reporting period.
- Form 2, Measure 10: Update denominator to clarify the appropriate unit of analysis is the index child.
- Form 2, Measure 14: Update measure to reflect current terminology and the timing within which screenings should be reported.
- Form 2, Measure 15: Update measure and numerator to include primary caregivers enrolled in middle school.
- Form 2, Measure 16: Update numerator to reflect correct inclusion criteria.
- Form 2, Measure 17: Update denominator to reflect correct inclusion criteria.
- Form 2, Measure 19: Update denominator to reflect correct inclusion criteria.
- Form 2, Definitions of Key Terms: Update definitions for measures 1–19.

HRSA is also requesting an extension of this information collection request through November 30, 2021.

Need and Proposed Use of the Information: HRSA uses performance information to demonstrate program accountability with legislative and program requirements and continuously monitor and provide oversight to MIECHV Program awardees. The information is also used to provide quality improvement guidance and technical assistance to awardees and help inform the development of early childhood systems at the national, state, and local level. HRSA is seeking to revise demographic, service utilization, and select clinical indicators for participants enrolled in home visiting services. In addition, HRSA will collect a set of standardized performance and outcome indicators that correspond with the statutorily identified benchmark areas. In the future, HRSA anticipates that MIECHV funding decisions may be allocated, in part, based on this data. This notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, information can be collected in a timely manner.

Likely Respondents: MIECHV Program awardees.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Form 1: Demographic, Service Utilization, and Select Clinical Indicators	56	1	56	560	31,360
Form 2: Performance Indicators and Systems Outcome Measures	56	1	56	200	11,200
Total	56		56		42,560

HRSA specifically requests comments on (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.

Amy McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018–02594 Filed 2–8–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Designation of a Class of Employees for Addition to the Special Exposure Cohort

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

ACTION: Notice.

SUMMARY: HHS gives notice of a decision to designate a class of employees from the Ames Laboratory in Ames, Iowa, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, NIOSH, 1090 Tusculum Avenue, MS C–46, Cincinnati, OH 45226–1938, Telephone 1–877–222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV*.

SUPPLEMENTARY INFORMATION:

Authority: 42 U.S.C. 7384q(b). 42 U.S.C. 7384*l*(14)(C).

On February 1, 2018, as provided for under 42 U.S.C. 7384*l*(14)(C), the Secretary of HHS designated the following class of employees as an addition to the SEC:

All employees of the Department of Energy, its predecessor agencies, and their contractors or subcontractors who worked in any area of the Ames Laboratory in Ames, Iowa, during the period from January 1, 1971, through December 31, 1989, for a number of work days aggregating at least 250 work days, occurring either solely under this employment or in combination with work days within the parameters established for one or more other classes of employees included in the Special Exposure Cohort.

This designation will become effective on March 3, 2018, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any provision by Congress regarding the decision by HHS to add the class to the SEC.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2018–02675 Filed 2–8–18; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: National Survey of Organ Donation Attitudes and Practices, OMB No. 0915–0290—Reinstatement With Change

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for reinstatement with change of a previously approved information collection, assigned OMB control number 0915–0290, which expired on March 31, 2015. Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate below or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than April 10, 2018.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, 14N39, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

Information Collection Request Title: National Survey of Organ Donation Attitudes and Practices, OMB No. 0915–0290—Reinstatement With Change

Abstract: HRSA is requesting approval from OMB for a reinstatement with change of a previously approved collection of information (OMB control number 0915–0290). The National Survey of Organ Donation Attitudes and Practices (NSODAP) is conducted approximately every 6–7 years and serves a critical role in providing HRSA and the donation community with data regarding why Americans choose to donate organs, current barriers to donation, and potential new approaches to increasing donations. Survey data and derived analytic insights inform HRSA's public outreach and educational initiatives. HRSA is improving the quality and relevance of the data collected by making the following changes:

(1) HRSA is increasing the ability to produce more precise results by targeting 10,000 completed surveys (increased from 3,250 in 2012). This increase will allow for a more accurate and robust analysis of the attitudes and donation practices of important subgroups such as Americans over the age of 50 and various minority populations. While the precision of the results from the survey will increase, respondent burden will be reduced and survey completion costs will be lower resulting in a cost neutral change.

(2) HRSA is streamlining the data collection process to minimize respondent burden. Of the 10,000 targeted completed surveys, 8,000 will be completed online by a nationally representative web panel composed of Americans over the age of 18 who have already agreed to participate in a survey. Web panels target a representative section of a population used by other approved surveys. HRSA will complete the remaining 2,000 surveys by telephone. In 2012, all 3,250 surveys were conducted by telephone and respondents were contacted using random-digit dialing, a process that yielded a low response rate. Contacting respondents by telephone will remain a part of the survey protocol to compare current data to the 2012 data. However, for this survey, identification of a sample of adults over the age of 18 for a telephone survey will be from a national list of home addresses. Prior to contact, those selected for the telephone survey will receive a mailed pre-notification letter with information about the survey. This mailing will improve survey cooperation and reduce the number of people contacted for the survey. Additionally, it is more time and cost effective to take the survey online than taking the survey by phone