second edition SE FAQ guidance. Based on the comments received on the September 2011 draft guidance and the March 2015 final guidance, we are now issuing the second edition FAQ final guidance.

The second edition FAQ guidance describes FDA's current thinking on whether and when a change to a tobacco product's label, product quantity in the package, additives, or specifications renders that product a ''new tobacco product'' subject to premarket review. It explains that a manufacturer may submit streamlined SE reports for certain modifications to labels and changes to product quantity. The guidance also explains FDA's plans and processes for review of the streamlined SE reports. Finally, this guidance responds to several questions that have been raised about the SE process more generally.

The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved information collections. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in sections 905(j) and 910 of the FD&C Act (21 U.S.C. 387e(j) and 387j, respectively), as amended by the Tobacco Control Act (Pub. L. 111–31), have been approved under OMB control number 0910–0673; the collections of information in 21 CFR part 25 have been approved under OMB control number 0910–0322.

III. Comments

A. General Information About Submitting Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document.

B. Public Availability of Comments

Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.* As a matter of Agency practice, FDA generally does not post comments submitted by individuals in their individual capacity on *http://www.regulations.gov.* This is determined by information indicating that the submission is written by an individual, for example, the comment is identified with the category ''Individual Consumer'' under the field titled ''Category (Required),'' on the ''Your Information'' page on *http://www.regulations.gov.* For this document, however, FDA will not be following this general practice. Instead, FDA will post on *http://www.regulations.gov* comments to this docket that have been submitted by individuals in their individual capacity. If you wish to submit any information under a claim of confidentiality, please refer to 21 CFR 10.20.

C. Information Identifying the Person Submitting the Comment

Please note that your name, contact information, and other information identifying you will be posted on *http://www.regulations.gov* if you include that information in the body of your comments. For electronic comments submitted to *http://www.regulations.gov,* FDA will post the body of your comment on *http://www.regulations.gov* along with your state/province and country (if provided), the name of your representative (if any), and the category identifying you (*e.g.,* individual, consumer, academic, industry). For written submissions submitted to the Division of Dockets Management, FDA will post the body of your comments on *http://www.regulations.gov,* but you can put your name and/or contact information on a separate cover sheet and not in the body of your comments.

IV. Electronic Access

Persons with access to the Internet may obtain an electronic version of the guidance at either *http://www.regulations.gov* or *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm.*

Dated: August 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–22494 Filed 9–4–15; 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

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (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 Information Collection Request must be received no later than November 9, 2015.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10C–03, Parklawn Building, 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 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 No. 0906–xxxx—New

Abstract: The Maternal, Infant, and Early Childhood Home Visiting Program (MIECHV), administered by HRSA in partnership with the Administration for Children and Families (ACF), supports voluntary, evidence-based home visiting services during pregnancy and to parents with young children up to kindergarten entry. States 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.

Need and Proposed Use of the Information: HRSA will use the proposed information to demonstrate program accountability and continuously monitor and provide oversight to Home Visiting Program grantees. The information will also be used to provide quality improvement guidance and technical assistance to grantees and help inform the development of early childhood systems at the national, state, and local level. HRSA is seeking to collect 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.

Demographic, Service Utilization, and Clinical Indicators Data

These data will describe the population served by the MIECHV Program, including the unduplicated count of the number of participants and participant groups by primary insurance coverage. These data will provide other socio-demographic characteristics of program participants and their utilization of services, such as program retention. Additionally, these data will describe several select clinical indicators of program participants, such as the percent of eligible participants who deliver their child preterm. This information will be collected from participants once, at enrollment in home visiting services and aggregated and reported to HRSA by state/territory grantees once annually.

Performance and Outcome Benchmark Data

These data constitute a discrete set of standardized performance and outcome indicators that correspond with the statutorily identified benchmark areas. These data will provide aggregate totals, percentages, and rates for performance and outcome indicators that are salient to the MIECHV Program, home visiting services more generally, and the at-risk populations served. These data will be collected from participants based on the appropriate measurement period defined for each measure and aggregated and reported to HRSA by state/territory grantees once annually.

This information will be used to demonstrate accountability with legislative and programmatic requirements. It will also be used to monitor and provide continued oversight for grantee performance and to target technical assistance resources to grantees. In the future, it is anticipated the MIECHV funding decisions may be allocated based on grantee performance, including on benchmark performance areas.

Likely Respondents: Home Visiting Program grantees.

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 Information Collection Request 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 Clinical Indicators Data	56	1	56	650	36,400
Performance and Outcome Benchmark Data	56	1	56	200	11,200
Total	56		56		47,600

HHS 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.

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–22545 Filed 9–4–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

[OMB NO. 0917–0028]

Request for Public Comment: 30-Day Proposed Information Collection: Addendum to Declaration for Federal Employment, Child Care and Indian Child Care Worker Positions

AGENCY: Indian Health Service, HHS.

ACTION: Notice and request for comments. Request for extension of approval.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, Public Law (Pub. L.) 104–13 [44 United States Code (U.S.C.) section 3507(a)(1)(D)], the Indian Health Service (IHS) is submitting to the Office of Management and Budget (OMB) a request for an extension of a previously approved collection of information titled, ''Addendum to Declaration for Federal Employment, Child Care and Indian Child Care Worker Positions,'' Office of Management and Budget (OMB) Control Number 0917–0028, which expires November 30, 2015.

This previously approved information collection project was last published in the **Federal Register** (80 FR 43100) on July 21, 2015, and allowed 60 days for public comment, as required by 44 U.S.C. 3506(c)(2)(A). The IHS received no comments regarding this collection. The purpose of this notice is to solicit public comments on specific aspects of the proposed information collection, which are to be submitted directly to OMB for a 30 day period.