microbiological laboratory technologist would work an average of 76.5 hours annually (153 infants × 0.5 hours per infant = 76.5 hours) to prepare and analyze fecal samples taken from infants in the controlled study. All estimates are shown in table 2. Therefore, a total of 156 additional annual burden hours (3 + 38.25 + 38.25 + 76.5 = 156) are estimated to account for the information collection burden resulting from the need to conduct a controlled study in order to gather data to substantiate a new structure/function claim, or a structure/function claim that lacks sufficient prior evidence, for a total of 166 total annual hours (156 + 10 = 166) for the upkeep and generation of information used to substantiate structure/function claims. Including the one-time burden of 160 hours annualized over 3 years (160/3 = 53.3), the total annual record keeping burden is 219.3 hours (166 + 53.3 = 219.3). There are no estimated capital costs or operating and maintenance costs associated with this information collection.

TABLE 1—ESTIMATED ONE-TIME HOURLY RECORDKEEPING BURDEN

Recordkeeping activity	Number of respondents	First year frequency of recordkeeping	Total records	Hours per record	Total hours
First Year Hourly Burden					
Assembling Records Related to Substantiation of Existing Structure/Function Claims	10	1	10	16	160
Total First Year Only Recordkeeping Burden					*160

TABLE 2—RECORDKEEPING BURDEN

Recordkeeping activity	Number of respondents	Annual frequency of recordkeeping	Total records	Hours per record	Total hours
Recurring Hourly Burden					
*Annualized Recordkeeping Burden from Table 1	10	1	5.3	1	53.3
Maintaining Records Related to Substantiation of Structure/Function Claims.	10	1	10	1	10
Controlled Study—Principal Investigator	1	1	1	3	3
Controlled Study—Sample Collector	1	153	153	0.25 (15 minutes)	38.25
Controlled Study—Nurse/Heath Care Professional.	1	153	153	0.25 (15 minutes)	38.25
Controlled Study—Lab Tech	1	153	153	0.5 (30 minutes)	76.5
Total Recordkeeping Burden					219.3

Before the proposed information collection provisions contained in this draft guidance become effective, we will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the proposed information collection provisions. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

IV. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.*

1. Moro, G., F. Mosca, V. Miniello, *et al.,* ''Effects of a New Mixture of Prebiotics on Faecal Flora and Stools in Term Infants.'' *Acta Paediatrica,* 2003. Supplement September 1991(441): pp. 77–79.
2. Boehm, G., M. Lidestri, P. Casetta,, *et al.,* ''Supplementation of a Bovine Milk Formula with an Oligosaccharide Mixture Increases Counts of Faecal Bifidobacteria in Preterm Infants.'' *Archives of Disease in Childhood Fetal and Neonatal Edition,* 2002. 86(3): pp. F178–181.
3. Pickering, L.K., D.M. Granoff, J.R. Erickson, *et al.,* ''Modulation of the Immune System by Human Milk and Infant Formula Containing Nucleotides.'' *Pediatrics,* 1998. 101(2): pp. 242–249.

Dated: August 29, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–21725 Filed 9–8–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Maternal, Infant, and Early Childhood Home Visiting Program Cost Reporting Pilot Study

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

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from

the public during the review and approval period.

DATES: Comments on this ICR should be received no later than October 11, 2016.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Maternal, Infant, and Early Childhood Home Visiting Program Cost Reporting Pilot Study

OMB No. 0906–xxxx—NEW

Abstract: The Maternal, Infant, and Early Childhood Home Visiting Program (Federal Home Visiting Program), administered by HRSA in partnership with the Administration for Children and Families, supports voluntary, evidence-based home visiting services during pregnancy and to parents with young children up to kindergarten entry. States, Tribal entities, and certain nonprofit organizations are eligible to receive funding from the Federal Home Visiting Program and have the flexibility to tailor the program to serve the specific needs of their communities. Funding recipients may subaward grant funds to organizations, otherwise known as Local Implementing Agencies (LIAs), in order to provide services to eligible families in at-risk communities.

Need and Proposed Use of the Information: This information collection is requested to conduct a pilot study to test the reliability of a standardized cost reporting tool for the provision of evidence-based home visiting services. The information collected will be used to: Test the reliability and feasibility of implementing a proposed set of standardized cost metrics and organizational characteristics across various contexts; estimate preliminary total costs for implementing evidence-based home visiting services, including ranges, and; further refine cost metrics and the cost reporting tool based on feedback received through the pilot study. Proposed standard cost metrics have been developed based on a review of the existing literature for measures of home visiting costs, as well as from ongoing discussions with developers of evidence-based home visiting models.

HRSA received comments from one respondent during the public comment period which estimated the hourly burden per response to be 16 hours. The estimated burden has been revised to reflect this feedback. Further, the commenter expressed an interest in using the tool to analyze the cost-benefit and overall value of home visiting programs. While the cost reporting tool may be useful in collecting information that will lead to additional cost-benefit analyses, those analyses are outside the scope of the current project. A full response to the comments can be accessed in Part A of the Supporting Statement.

Likely Respondents: Organizations, including LIAs providing evidence-based home visiting services through the Federal Home Visiting Program.

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
Cost Elements Table	90	1	90	15.5	1,395
Organizational Characteristics Table	90	1	90	0.5	45
Total	[1] 90		90		1,440

[1] The same 90 individuals complete the Cost Elements Table and the Organizational Characteristics Table.

Jason E. Bennett,

Director, Division of the Executive Secretariat.

[FR Doc. 2016–21734 Filed 9–8–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Small Rural Hospital Transitions Project

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

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than October 11, 2016.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance