regarding: (1) Pediatric research conducted under sections 351, 409I, and 499 of the Public Health Service Act and sections 501, 502, 505, 505A, and 505B, 510K, 515, and 520m of the Federal Food, Drug, and Cosmetic Act; (2) identification of research priorities related to pediatric therapeutics (including drugs and biological products) and medical devices for pediatric populations and the need for additional diagnostics and treatments of specific pediatric diseases or conditions, (3) the ethics, design, and analysis of clinical trials related to pediatric therapeutics (including drugs and biological products) and medical devices, (4) pediatric labeling disputes as specified in Public Law 107–109 and Public Law 110–85, (5) pediatric labeling changes as specified in Public Law 107–109 and Public Law 110–85, (6) adverse event reports for drugs studied under Public Law 107–109 and 110–85 and labeled, (7) any safety issues that may occur as specified Public Law 107–109 and Public Law 110–85, (8) any other pediatric issue or pediatric labeling dispute involving FDA-regulated products, (9) pediatric ethical issues including research involving children as subjects as specified in 21 CFR 50.54; and (10) any other matter involving pediatrics for which FDA has regulatory responsibility.

The Committee also advises and makes recommendations to the Secretary directly or to the Secretary through the Commissioner on research involving children as subjects that is conducted or supported by the Department of Health and Human Services as specified in 45 CFR 46.407.

II. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

III. Application Procedure

Individuals may self nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest should be sent to the FDA contact person (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from the pediatric pharmaceutical research and biotechnology manufacturing industry.

Authority: This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: August 7, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–19639 Filed 8–9–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Proposed Information Collection Activity: Comment Request

The Health Resources and Services Administration (HRSA) periodically publishes abstracts of information collection submitted for review to the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of clearance requests submitted to OMB for review, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office at (301) 443–1984.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Maternal, Infant, and Early Childhood Home Visiting Program Information System: Data Collection Forms (OMB No. 0915–xxxx)—[New]

On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148), legislation designed to make quality, affordable, health care available to all Americans, reduce costs, improve health care quality, enhance disease prevention, and strengthen the health care workforce. Through a provision authorizing the creation of the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program, the Act responds to the diverse needs of children and families in communities at risk and provides an unprecedented opportunity for collaboration and partnership at the Federal, State, Tribal, and community levels to improve health and development outcomes for at-risk children through evidence-based home visiting programs. The MIECHV Program is designed: (1) To strengthen and improve the programs and activities carried out under Title V; (2) to improve coordination of services for at-risk communities; and (3) to identify and provide comprehensive services to improve outcomes for families who reside in at-risk communities. Formula-based and competitive grants have been awarded to States, other eligible jurisdictions, and, under a legislative provision setting aside dedicated funds for a Tribal MIECHV program, to eligible Indian Tribes and consortia of Tribes, Tribal Organizations, and Urban Indian Organizations. Competitive grants to non-profit organizations to provide home visiting in certain States are anticipated.

The Social Security Act, Title V, Section 511 (42 U.S.C. 711), as amended by the Patient Protection and Affordable Care Act of 2010, requires that MIECHV grantees collect both socio-demographic data and data to measure improvements for eligible families in six specified areas (referred to as ''benchmark areas'') that encompass the major goals for the program. The Supplemental Information Request for the Submission of the Updated State Plan for a State Home Visiting Program (SIR), published on February 8, 2011, further listed a variety of constructs under each benchmark area for which grantees were to select and submit relevant performance measures. Per Section 511(d)(1)(B)(i) of the legislation, no later than 30 days after the end of the third year of the program, grantees are required to

demonstrate improvement in at least four of the six benchmark areas. The SIR and subsequent MIECHV guidance documents for both competitive and formula grants also require that grantees report annually on the constructs under each benchmark area, as well as on demographic, service utilization, budgetary and other administrative data related to program implementation.

The proposed data collection and reporting forms were initially developed by an internal MIECHV workgroup in consultation with evidence-based home visiting model developers and selected grantees and further refined based on comments received during the previous 60-day public comment period. The data collected with the proposed forms will be used to track grantees' progress in demonstrating improvement under each benchmark area and provide an overall picture of the population being served. The proposed data collection forms are as follows:

Home Visiting Form 1—Demographic and Service Utilization Data for Enrollees and Children

This form will be utilized by all MIECHV program grantees (including Tribal program grantees) and will collect data to determine the unduplicated number of participants and of participant groups by primary insurance coverage. This form will also request data on the demographic characteristics of program participants as well as service utilization data.

Home Visiting Form 2—Grantee Performance Measures

States, the District of Columbia, and territories participating in the MIECHV program have already selected relevant performance indicators for the legislatively identified benchmark areas. This form provides a template for these jurisdictions and non-profit grantees implementing home visiting programs to report aggregate data on their already selected and approved performance measures.

While there will be variation in the data collection and reporting burden to grantees based on the number of families served and data system capabilities, the annual estimate of burden is as follows:

Reporting document	Annual number of respondents	Number of responses per respondent	Total responses	Average burden hours per response	Total burden hours
HV Form 1: Demographic and Service Utilization Data for Enrollees and Children	[1] 81	1	81	731	59,211
HV Form 2: Grantee Performance Measures	[2] 56	1	56	313	17,528
Total	81		81		76,739

[1] In addition to 56 jurisdictions and non-profit organizations, it is estimated that up to 25 Tribal MIECHV program grantees will utilize Form 1 to report on demographic and service utilization data for all participant families.
[2] Does not include Tribal program grantees.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806. Please direct all correspondence to the ''attention of the desk officer for HRSA.''

Dated: August 6, 2012.

Wendy Ponton,

Director, Office of Management.

[FR Doc. 2012–19665 Filed 8–9–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

Health Resources and Services Administration (HRSA) periodically publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office at (301) 443–1984.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Maternal, Infant and Early Childhood Home Visiting Program FY 2012 Non-Competing Continuation Progress Report (OMB No. 0915-xxxx)—[New] Activity Code: X02

On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act (ACA). Section 2951 of the Act amended Title V of the Social Security Act by adding a new section, 511, which authorized the creation of the Maternal, Infant, and Early Childhood Home Visiting Program, (*http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h3590enr.txt.pdf,* pages 216–225). The Act responds to the diverse needs of children and families in communities at risk and provides an unprecedented opportunity for collaboration and partnership at the federal, state, and community levels to improve health and development outcomes for at-risk children through evidence-based home visiting programs.

Under this program, $125 million was made available to states on a formula basis in both fiscal years (FY) FY 2010 and 2011. This funding was awarded to support states in implementing their Updated State Plans. Additionally, competitive funding was awarded in June 2011 for Development Grants and Expansion Grants. Development Grants are intended to support states and jurisdictions with modest evidence-based home visiting programs to expand the depth and scope of these efforts, with the intent to develop the infrastructure and capacity needed to seek an Expansion Grant in the future. Expansion Grants are intended to support states and jurisdictions that had already made significant progress towards a high-quality home visiting program or embedding their home visiting program into a comprehensive, high-quality early childhood system. Thirteen states were awarded Development Grants, and nine states were awarded Expansion Grants. These competitive grants are for 2 years (Development Grants) and 4 years (Expansion Grants), respectively. Grantees will be completing FY 2011 Progress Reports on activities conducted since September 30, 2011, along with an update on the activities to be conducted