Dated: March 29, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–07369 Filed 3–31–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2012–N–0471, FDA–2012–N–0294]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.* 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.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB Control number	Date approval expires
Prescription Drug User Fee Cover Sheet; Form FDA 3397	0910–0297	3/31/2019
Food Additives; Food Contact Substances Notification System	0910–0495	3/31/2019

Dated: March 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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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 ICR should be received no later than May 31, 2016.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N–39, 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: Maternal, Infant, and Early Childhood Home Visiting Program Funding Opportunity Announcement for Formula Grant Awards OMB No. 0906–xxxx—New.

Abstract: The Maternal, Infant, and Early Childhood Home Visiting (Federal Home Visiting) Program, administered by the Health Resources and Services Administration (HRSA) in close 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. Formula grant awards support Federal Home Visiting Program grantees in meeting statutory and programmatic objectives for implementing high quality home visiting programs and coordinating with comprehensive statewide early childhood systems. All fifty states, the District of Columbia, five territories, and nonprofit organizations that would provide services in jurisdictions that have not directly applied for or been approved for a grant are eligible to receive formula grant awards. There are currently 56 entities with formula grant awards.

Need and Proposed Use of the Information: This information collection is requested for eligible entities to submit applications in response to annual formula Funding Opportunity Announcements (FOA) beginning in Fiscal Year (FY) 2017.

On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act (ACA). Section 2951 of the ACA amended Title V of the Social Security Act by adding a new section, 511, which authorized the creation of the Federal Home Visiting Program. A portion of funding under this program is awarded to participating states and eligible jurisdictions using a funding formula. Formula funding is the main funding mechanism used by HRSA to provide support to eligible entities for the provision of voluntary high-quality home visiting services to families living in at-risk communities.

The information collected will be used to provide guidance to eligible entities on how to prepare and submit applications in response to annual

FOAs beginning in FY 2017. The application will provide project plans and budgets for upcoming years. This information will permit federal staff to assess whether the proposed activities align with statutory and programmatic requirements and objectives and will result in the implementation of a high-quality project. Applications in response to annual FOAs are submitted via Grants.gov.

Failure to collect this information would result in the inability of HRSA to collect information necessary for the determination of the responsiveness and quality of applications and would subject the government to undue risk in awarding formula funds under the Federal Home Visiting Program.

Applicants will be required to submit several types of information in addition to the SF–424 Forms which are included under a separate Information Collection Request. These types of information include: (1) Project Abstract, (2) Project Narrative, (3) Budget Justification, (4) Program-Specific Forms and Tables, and (5) Attachments.

Likely Respondents: Eligible entities under the Social Security Act, Title V, Section 511(c) (42 U.S.C., Section 711(c)), as added by Section 2951 of the ACA (Pub. L. 111–148).

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
Federal Home Visiting Program Formula Funding Opportunity Announcement	56	1	56	80	4,480
Total	56	1	56	80	4,480

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.

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2016–07319 Filed 3–31–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Heritable Disorders in Newborns and Children; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, codified at 5 U.S.C. App.), notice is hereby given of the following meeting:

Name: Advisory Committee on Heritable Disorders in Newborns and Children.

Dates and Times: May 9, 2016, 9:00 a.m. to 5:00 p.m. (Meeting time is tentative.) May 10, 2016, 9:00 a.m. to 3:00 p.m. (Meeting time is tentative.)

Place: Webcast and In-Person, Fishers Lane Conference Center, Terrace Level, 5635 Fishers Lane, Rockville, MD 20852.

Status: The meeting will be open to the public with attendance limited to space availability. Participants also have the option of viewing the meeting via webcast. Whether attending in-person or via webcast, all participants must register for the meeting. The registration link will be made available at *http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/.* The registration deadline is Friday, April 29, 2016, 11:59 p.m. Eastern Time.

Purpose: The Advisory Committee on Heritable Disorders in Newborns and Children (Committee), as authorized by Public Health Service Act, title XI, section 1111 (42 U.S.C. 300b–10), as amended by the Newborn Screening Saves Lives Reauthorization Act of 2014 (Pub. L. 113–240), was established to advise the Secretary of the Department of Health and Human Services about the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. In addition, the Committee's recommendations regarding additional conditions/heritable disorders for screening that have been adopted by the Secretary are included in the Recommended Uniform Screening Panel (RUSP) and constitute part of the comprehensive guidelines supported by the Health Resources and Services Administration. Pursuant to section 2713 of the Public Health Service Act, codified at 42 U.S.C. 300gg–13, non-grandfathered health plans and group and individual health insurance issuers are required to cover evidence-informed care and screenings included in the HRSA-supported comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years (in the individual market, policy years) beginning on or after the date that is 1 year from the Secretary's adoption of the condition for screening.

Agenda: The Committee will hear presentations and discussions on topics including newborn screening long-term follow-up, the Newborn Sequencing in Genomic Medicine and Public Health projects, screening for lysosomal storage disorders, and prenatal education regarding newborn screening bloodspots. The Committee will also review draft reports from the Pilot Study and Cost Analysis workgroups and hear updates from the Committee's subcommittees on Laboratory Standards and Procedures, Follow-up and Treatment, and Education and Training Tentatively, the Committee is expected to review and/or vote on whether or not the nominated condition Guanidinoacetate Methyltransferase