

**Seleda Perryman,**  
*Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title:* State Plan for Foster Care and Adoption Assistance—Title IV–E.  
*OMB No.:* 0980–0141.  
*Description:* A title IV–E plan is required by section 471 part IV–E of the Social Security Act (the Act) for each public child welfare agency requesting Federal funding for foster care, adoption assistance and guardianship assistance

under the Act. The title IV–E plan provides assurances the programs will be administered in conformity with the specific requirements stipulated in title IV–E. The plan must include all applicable State statutory, regulatory, or policy references and citations for each requirement as well as supporting documentation. A title IV–E agency may use the pre-print format prepared by the Children’s Bureau of the Administration for Children and Families or a different format, on the condition that the format used includes all of the title IV–E State plan requirements of the law.

Public Law 110–351, the Fostering Connections to Success and Increasing Adoptions Act of 2008, created a new title IV–E plan option to provide a Guardianship Assistance Program for relatives of children in foster care (section 471(a)(28) of the Act). The Guardianship Assistance program was made effective for States upon

enactment of Public Law 110–351 (October 7, 2008).

Effective October 1, 2009, Public Law 110–351 will allow Tribes, Tribal organizations and Tribal consortia to directly operate title IV–E programs for foster care maintenance payments, adoption assistance and kinship guardianship assistance.

The law also made a number of other changes to title IV–E plan requirements and eligibility criteria. The law’s provisions expanding the scope of the title IV–E program necessitates a revision of the preprint.

*Respondents:* State and Territorial Agencies (State Agencies) administering or supervising the administration of the title IV–E programs and Federally-recognized Tribes, Tribal organizations and Tribal consortia administering title IV–E programs.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Title IV–E Plan .....	33	1	16	528

Estimated Total Annual Burden Hours: 528.

**Additional Information**

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L’Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

**OMB Comment**

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7245, Attn: Desk Officer for the Administration for Children and Families.

Dated: July 23, 2009.  
**Janean Chambers,**  
*Reports Clearance Officer.*  
 [FR Doc. E9-17934 Filed 7-28-09; 8:45 am]  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Proposed Collection; Comment Request; Parental Knowledge, Attitudes, and Behaviors Related to Pediatric Cardiovascular Health**

**SUMMARY:** In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

*Proposed Collection:* Describe the proposed information collection activity as follows. Include: *Title:* Parental Knowledge, Attitudes, and Behaviors Related to Pediatric Cardiovascular Health; *Type of Information Collection Request:* New; *Need and Use of*

*Information Collection:* Coinciding with the release of the Integrated Pediatric Cardiovascular Risk Reduction Guidelines, the National Heart, Lung, and Blood Institute (NHLBI) will conduct a national public awareness campaign to help parents understand that risk for cardiovascular disease (CVD) begins in childhood, and to engage them in encouraging healthy habits in their children to promote heart health and reduce their children’s CVD risk now and as they grow. Currently, little is known about parental knowledge, attitudes, and behaviors related to heart health in children. Serving as a baseline for evaluation of NHLBI’s outreach activities related to the campaign, this study seeks to learn the following: (a) Parents’ awareness of cardiovascular disease risk factors in children and knowledge of what to do for risk reduction, (b) parents’ level of efficacy toward taking action to promote cardiovascular health and reduce risk factors, and (c) parents’ behaviors related to cardiovascular health. The findings will provide valuable information that will enable NHLBI to identify the gaps in knowledge and awareness and target specific information in communications with parents. NHLBI will also be able to determine parents’ efficacy related to the actions needed to promote their

children's heart health, allocating resources for the campaign to provide support to overcome perceived barriers; *Frequency of Response*: One-time survey; *Affected Public*: Individuals or households; and *Type of Respondents*: Parents and caregivers of children ages 0–7. The annual reporting burden is as follows: *Estimated Number of Respondents*: 1,175; *Estimated Number of Responses per Respondent*: 1; *Average Burden Hours per Response*: .167; and *Estimated Total Annual Burden Hours Requested*: 196.23. *There are no Capital Costs, Operating Costs and/or Maintenance Costs to report.*

*Request for Comments*: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**FOR FURTHER INFORMATION CONTACT**: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Amy Pianalto, National Heart, Lung, and Blood Institute, NIH, 31 Center Drive, Building 31A, Room 4A10, Bethesda, MD 20892; or call non-toll-free number 301–594–2093 or e-mail request, including your address, to [pianaltoa@nhlbi.nih.gov](mailto:pianaltoa@nhlbi.nih.gov).

*Comments Due Date*: Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: July 21, 2009.

**Amy Pianalto,**

*Office of Communications and Legislative Activities, NHLBI, National Institutes of Health.*

[FR Doc. E9–18071 Filed 7–28–09; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2009–N–0097]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Request for Samples and Protocols

**AGENCY**: Food and Drug Administration, HHS.

**ACTION**: Notice.

**SUMMARY**: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES**: Fax written comments on the collection of information by August 28, 2009.

**ADDRESSES**: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910–0206. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT**: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

**SUPPLEMENTARY INFORMATION**: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Request for Samples and Protocols—(OMB Control Number 0910–0206)—Extension

Under section 351 of the Public Health Service Act (42 U.S.C. 262), FDA has the responsibility to issue regulations that prescribe standards designed to ensure the safety, purity, and potency of biological products and to ensure that the biologics licenses for such products are only issued when a product meets the prescribed standards. Under § 610.2 (21 CFR 610.2), the Center for Biologics Evaluation and Research (CBER) or the Center for Drug Evaluation and Research may at any time require manufacturers of licensed biological products to submit to FDA

samples of any lot along with the protocols showing the results of applicable tests prior to distributing the lot of the product. In addition to § 610.2, there are other regulations that require the submission of samples and protocols for specific licensed biological products: §§ 660.6 (21 CFR 660.6) (Antibody to Hepatitis B Surface Antigen); 660.36 (21 CFR 660.36) (Reagent Red Blood Cells); and 660.46 (21 CFR 660.46) (Hepatitis B Surface Antigen). Section 660.6(a) provides requirements for the frequency of submission of samples from each lot of Antibody to Hepatitis B Surface Antigen product, and § 660.6(b) provides the requirements for the submission of a protocol containing specific information along with each required sample. For § 660.6 products subject to official release by FDA, one sample from each filling of each lot is required to be submitted along with a protocol consisting of a summary of the history of manufacture of the product, including all results of each test for which test results are requested by CBER. After official release is no longer required, one sample along with a protocol is required to be submitted at 90-day intervals. In addition, samples, which must be accompanied by a protocol, may at any time be required to be submitted to CBER if continued evaluation is deemed necessary.

Section 660.36(a) requires, after each routine establishment inspection by FDA, the submission of samples from a lot of final Reagent Red Blood Cell product along with a protocol containing specific information. Section 660.36(a)(2) requires that a protocol contain information including, but not limited to, manufacturing records, certain test records, and identity test results. Section 660.36(b) requires a copy of the antigenic constitution matrix specifying the antigens present or absent to be submitted to the CBER Director at the time of initial distribution of each lot. Section 660.46(a) contains requirements as to the frequency of submission of samples from each lot of Hepatitis B Surface Antigen product, and § 660.46(b) contains the requirements as to the submission of a protocol containing specific information along with each required sample. For § 660.46 products subject to official release by FDA, one sample from each filling of each lot is required to be submitted along with a protocol consisting of a summary of the history of manufacture of the product, including all results of each test for which test results are requested by CBER. After notification of official release is received, one sample along