

**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<br>respondents | Number of<br>responses per<br>respondent | Average<br>burden hours<br>per response | Total burden<br>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]

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## 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