

**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: 202-395-7285, Email: [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV). Attn: Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2013-22996 Filed 9-20-13; 8:45 am]

**BILLING CODE 4184-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title:* State Personal Responsibility Education Program (PREP).

*OMB No.:* 0970-0380.

*Description:* The Patient Protection and Affordable Care Act, 2010, also known as health care reform, amended Title V of the Social Security Act (42 U.S.C. 701 *et seq.*) as amended by sections 2951 and 2952(c), by adding section 513, authorizing the Personal Responsibility Education Program (PREP). The President signed into law the Patient Protection and Affordable Care Act on March 23, 2010, Public Law 111-148, which added the new PREP formula grant program. The purpose of this program is to educate adolescents

on both abstinence and contraception to prevent pregnancy and sexually transmitted infections (STIs); and at least three adulthood preparation subjects. The Personal Responsibility Education grant program funding is available for fiscal years 2010 through 2014. Pursuant to monitoring these state programs, grantees submit a semiannual report on their performance.

A request is being made to solicit comments from the public on paperwork reduction as it relates to ACYF's receipt of the following document from applicants and awardees:

**Performance Progress Report**

*Respondents:* 50 States and 9 Territories, to include, District of Columbia, Puerto Rico, Virgin Islands, Guam, American Samoa, Northern Mariana Islands, the Federated States of Micronesia, the Marshall Islands and Palau

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Performance Progress Reports .....	59	2	16	1,888

*Estimated Total Annual Burden Hours: 1,888.*

**Additional Information**

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 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. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2013-N-0985]

**Complex Issues in Developing Drug and Biological Products for Rare Diseases; Public Workshop; Request for Comments**

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

**ACTION:** Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled "Complex Issues in Developing Drug and Biological Products for Rare Diseases." The purpose of the public workshop is twofold: To discuss complex issues in clinical trials for developing drug and biological products ("drugs") for rare

diseases, including endpoint development and selection, use of surrogate endpoints and the accelerated approval pathway, clinical trial design, conduct and analysis, safety considerations, and dose selection; and to discuss ways to encourage and accelerate the development of new therapies for pediatric rare diseases. FDA is seeking input on these topics from academic, clinical, and treating communities; patients and advocacy groups; industry; and governmental agencies. Input from this public workshop will help develop a strategic plan to encourage and accelerate the development of new therapies for rare diseases.

*Date and Time:* The public workshop will be held on January 6, 2014, from 8 a.m. to 5 p.m. and on January 7, 2014, from 8 a.m. to 4:45 p.m.

*Location:* The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <http://>