

EXHIBIT 1. ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Data collection	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Total .....	15	n/a	n/a	68

\* Individuals that cannot attend the focus groups will be interviewed one-on-one. Clinical staff includes IC leaders, QI team members and unit staff. Managers include the chief nursing officer and chief medical officer.

EXHIBIT 2. ESTIMATED ANNUALIZED COST BURDEN

Data collection	Number of respondents	Total burden hours	Average hourly wage rate	Total cost burden
Pre-intervention focus groups with clinical staff *	3	27	\$36.73 *	\$992
Pre-intervention focus groups with managers *	3	3	\$138.38 **	\$415
Clinical staff survey .....	3	8	\$36.73 *	\$294
Post-intervention focus groups with clinical staff *	3	27	\$36.73 *	\$992
Post-intervention focus groups with managers *	3	3	\$138.38 **	\$415
Total .....	15	68	na	\$3,108

\* Based upon the mean hourly wage for Registered Nurses in Nassau and Suffolk County, NY as reported by the Bureau of Labor Statistics in May 2008.

\*\* Based on report of a private survey of HR departments conducted in November 2009 in New York, NY published by <http://www.salary.com>; 3 chief nursing officers at \$101.14/hr and 3 chief medical officers at \$175.61/hour.

**Estimated Annual Costs to the Federal Government**

Exhibit 3 shows the annualized and total cost to the federal government for

this two year research project. Project development covers steps taken to revise the research plan and begin

implementation. The total cost is estimated to be \$500,001.

EXHIBIT 3. ANNUALIZED AND TOTAL COST TO THE FEDERAL GOVERNMENT

Cost component	Annualized cost	Total cost
Project Management .....	\$125,526	\$251,052
Project Development .....	\$54,622	\$109,244
Data Collection Activities .....	\$41,864	\$83,728
Travel .....	\$4,000	\$8,000
Overhead .....	\$23,754	\$47,507
Total .....	\$250,001	\$500,001

**Request for Comments**

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of

automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All will become a matter of public record.

Dated: May 21, 2010.

**Carolyn M. Clancy,**  
Director.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Agency Recordkeeping/Reporting Requirements Under Emergency Review by the Office of Management and Budget**

*Title:* State Personal Responsibility Education Program.

*OMB No.:* New Collection.

*Description:* An emergency request is being made to solicit comments from the public on paperwork reduction as it relates to ACYF's receipt of the following documents from applicants and awardees:

- Application for Formula Grant
- Performance Progress Reports
- Year 1 Implementation Plan
- Performance Measure Reporting

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
Application to include program narrative .....	59	1	40	2360
Performance Progress Reports .....	59	2	10	1180
Year 1 Implementation Plan .....	59	1	30	1770
Performance Measure Reporting .....	59	1	10	590

*Estimated Total Annual Burden Hours: 5900.*

*Additional Information:*

The Year 1 Implementation Plan is only required to be completed and submitted in the first year of the project period. This is a one time submission and will not occur annually.

The potential awardees could include organizations and other entities awarded in year 3 of the project period in States that did not apply for funding in the first 2 years of the project period.

A copy of this information collection, with applicable supporting documentation, may be obtained by calling the Administration for Children and Families, Reports Clearance Officer, Robert Sargis at (202) 690-7275. Interested persons are invited to submit comments regarding this request. Comments must be received within thirty days from the publication date of this Notice.

Comments about the information collection described above should be directed to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ACF, Office of Management and Budget, Paperwork Reduction Project, 725 17th Street NW., Washington, DC 20503; FAX: (202) 395-7285; e-mail: [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov).

Dated: May 25, 2010.

**Robert Sargis,**  
*Reports Clearance Officer.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-N-0248]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Format and Content Requirements for Over-the-Counter Drug Product Labeling**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the standardized format and content requirements for the labeling of over-the-counter (OTC) drug products.

**DATES:** Submit either electronic or written comments on the collection of information by August 2, 2010.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-

796-3792,  
[Elizabeth.berbakos@fda.hhs.gov](mailto:Elizabeth.berbakos@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Format and Content Requirements for OTC Drug Product Labeling (OMB Control Number 0910 0340)—Reinstatement**

In the **Federal Register** of March 17, 1999 (64 FR 13254), we amended our