

*Burden Estimate:* FDA is requesting public comment on the estimated one-time reporting burden from these respondents, as required by 502(x) of the FD&C Act and described in the guidance “Questions and Answers Regarding the Labeling of

Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.” The estimates for one-time reporting are based on FDA’s knowledge of

nonprescription drug product labeling in the United States, whether or not marketed under an approved application.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ONE-TIME REPORTING BURDEN <sup>1</sup>

	Number of respondents	Number of responses per respondent	Total responses	Average burden per response	Total hours
Domestic address or phone number labeling requirement (21 U.S.C. 502(x)) and recommendation to clarify its purpose .....	200	500	100,000	4	400,000

There are no capital costs or maintenance and operating costs associated with this collection of information.

As indicated in Table 1 of this document, we estimate that approximately 200 manufacturers will revise approximately 100,000 labels to add a full domestic address and a domestic telephone number, and should they choose to adopt the draft guidance’s recommendation, to add a statement identifying the purpose of the domestic address or telephone number. FDA believes that designing the label change should not take longer than 4 hours per label. Automated printing of the labels should only require a few seconds per label. This estimate accounts for the possibility that every manufacturer will make label revision, which is unlikely. Because the majority of over-the-counter drug product labels currently have a domestic telephone number that satisfies the requirement, we believe many manufacturers will opt not to adopt the guidance’s recommendation to add a statement identifying the purpose of the address or telephone number, significantly reducing the number of total responses. However, assuming that all labels are revised, we estimate a one-time reporting burden for this information collection of 400,000 hours.

Dated: May 9, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Proposed Collection: Comment Request**

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. 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](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Officer at (301) 443–1984.

*Comments are invited on:* (a) The proposed collection of information for the proper performance of the functions of the Agency; (b) the accuracy of the Agency’s estimate of the burden of the proposed collection 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 on respondents, including through the use of automated collection techniques or other forms of information technology.

**Proposed Project: The Health Education Assistance Loan (HEAL) Program: Forms (OMB No. 0915–0034)—[Revision]**

The Health Education Assistance Loan (HEAL) program provided federally insured loans to assure the availability of funds for loans to eligible students to pay for their education costs. In order to administer and monitor the HEAL program the following forms are utilized: The Lenders Application for Contract of Federal Loan Insurance form (used by lenders to make application to the HEAL insurance program); the Borrower’s Deferment Request form (used by borrowers to request deferments on HEAL loans and used by lenders to determine borrowers’ eligibility for deferment); the Borrower Loan Status update electronic submission (submitted monthly by lenders to the Secretary on the status of each loan); and the Loan Purchase/Consolidation electronic submission (submitted by lenders to the Secretary to report sales, and purchases of HEAL loans).

The annual estimate of burden is as follows:

HRSA form	Number of respondents	Responses per respondent	Total responses	Hours per responses	Total burden hours
Lender’s Application for Contract of Federal Loan Insurance .....	15	1.00	15	.13	1.95
Borrower’s Deferment Request:					
Borrowers .....	28	1.00	28	.17	4.76
Employers .....	23	1.21	28	.08	2.24
Borrower Loan Status Update .....	5	13.00	65	.17	11.05
Loan Purchase/Consolidation .....	2	2.50	5	.07	.35
Total .....	73	.....	.....	.....	20.35

Email comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Reports Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: May 9, 2012.

**Reva Harris,**

*Acting Director, Division of Policy and Information Coordination.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Proposed Collection: Comment Request**

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*Comments are invited on:* (a) The proposed collection of information for the proper performance of the functions of the Agency; (b) the accuracy of the

Agency’s estimate of the burden of the proposed collection 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 on respondents, including through the use of automated collection techniques or other forms of information technology.

**Proposed Project: Maternal, Infant, and Early Childhood Home Visiting Program FY 2012 Competitive Grant Non-Competing Continuation Progress Reports (OMB No. 0915–xxxx)—[New]**

**Activity Code: D89**

On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act (the Act). Section 2951 of the Act amended Title V of the Social Security Act by adding a new section, 511, which authorized the creation of the Maternal, Infant, and Early Childhood Home Visiting Program, ([http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111\\_cong\\_bills&docid=f:h3590enr.txt.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h3590enr.txt.pdf), pages 216–225). The Act responds to the diverse needs of children and families in communities at risk and provides an unprecedented opportunity for collaboration and partnership at the Federal, State, and community levels to improve health and development outcomes for at-risk children through evidence-based home visiting programs.

Under this program, \$125,000,000 was awarded to States on a formula basis in 2010. An additional \$125,000,000 was made available to States on a formula basis in 2011. Additionally, competitive funding was awarded in June 2011 for Development Grants and Expansion Grants. Development Grants were intended to

support the efforts of States and jurisdictions with modest evidence-based home visiting programs to expand the depth and scope of these efforts, with the intent to develop the infrastructure and capacity needed to seek an Expansion Grant in the future. Expansion Grants were intended to support the efforts of States and jurisdictions that had already made significant progress towards a high-quality home visiting program or embedding their home visiting program into a comprehensive, high-quality early childhood system. Thirteen States were awarded Development Grants, and nine States were awarded Expansion Grants. These competitive grants are for 2 years (Development Grants) and 4 years (Expansion Grants), respectively. State grantees of both competitive programs will need to complete non-competing continuation (NCC) progress reports in order to secure the release of FY 2012 and out-year grant funds.

Additional funds are being made available for Development and Expansion Grants in FY 2012. Ten Expansion Grants, totaling \$71.9 million, have been awarded. An additional four to eight Development Grants are anticipated to be awarded, with 2-year project periods. Development Grant recipients will be required to complete one NCC to secure the release of second-year funds. The project period is 4 years for the FY 2011 Expansion grants, and 3 years for the FY 2012 Expansion Grants. Fiscal year 2012 Expansion grant recipients will be required to complete three annual NCCs, and FY 2013 recipients will be required to complete two annual NCCs to secure the release of their out-year funds.

The annual estimate of burden is as follows:

Instrument: A summary of the progress on the following activities	Number of respondents	Responses per respondent	Hours per response	Total burden hours
Implementing home visiting programs .....	25	1	8	200
Fostering the integration of home visiting programs into early childhood systems .....	25	1	8	200
Promoting effective policy to support and strengthen home visiting programs .....	25	1	24	600
Evaluating programs and using the information received to improve the quality of home visiting programs and early childhood systems .....	25	1	8	200
Improving outcomes for families served by the home visiting program .....	25	1	8	200
Providing services to vulnerable or high risk populations .....	25	1	2	50
<b>Total .....</b>	<b>25</b>	<b>.....</b>	<b>.....</b>	<b>1,450</b>