participation in the electronic submission process. The opportunity to provide the information in electronic format could reduce the Agency's previous estimates for the time to prepare each submission. However, as a conservative approach for the purpose of this analysis, FDA is assuming that the availability of new Form FDA 3666 and the opportunity to submit the information in electronic format will have no effect on the average time to prepare a submission. While FDA does not charge for the use of the ESG, FDA requires respondents to obtain a public key infrastructure certificate in order to set up the account. This can be obtained in-house or outsourced by purchasing a public key certificate that is valid for 1 year to 3 years. The certificate typically costs from $20 to $30.

Dated: May 9, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012–11689 Filed 5–14–12; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2012–N–0454]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on 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

**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 extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This guidance solicits comments on ''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.''

**DATES:** Submit either electronic or written comments on the collection of information by July 16, 2012.

**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:** Juanmanuel Vilela,Office of Information Management, Food and Drug Administration,1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *juanmanuel.vilela@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 extension 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.

### Guidance for Industry on 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—(OMB Control Number 0910–0640)—Extension

On December 22, 2006, the President signed into law the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Pub. L. 109–462, 120 Stat. 3469). This law amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) with respect to serious adverse event reporting for dietary supplements and nonprescription drugs marketed without an approved application.

Section 502(x) of the FD&C Act (21 U.S.C. 352(x)), which was added by Public Law 109–462, requires the label of a nonprescription drug product marketed without an approved application in the United States to include a domestic address or domestic telephone number through which a responsible person may receive a report of a serious adverse event associated with the product. The guidance document contains questions and answers relating to this labeling requirement and provides guidance to industry on the following topics: (1) The meaning of ''domestic address'' for purposes of the labeling requirements of section 502(x) of the FD&C Act; (2) FDA's recommendation for the use of an introductory statement before the domestic address or phone number that is required to appear on the product label under section 502(x) of the FD&C Act; and (3) FDA's intent regarding enforcing the labeling requirements of section 502(x) of the FD&C Act. Separate guidance, issued by the Center for Food Safety and Applied Nutrition on reporting for dietary supplements, is announced elsewhere in the **Federal Register**.

*Title:* Guidance for Industry on 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.

*Description of Respondents:* Respondents to this collection of information are manufacturers, packers, and distributors whose name (pursuant to section 502(b)(1) of the FD&C Act) appears on the label of a nonprescription drug product marketed in the United States without an approved application.

*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 [1]

| | 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* 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 |