UNITED STATES FOOD & DRUG ADMINISTRATION

Labeling of Nonprescription Human Drug Products Marketed
Without an Approved Application as Required by the
Dietary Supplement and Nonprescription Drug Consumer Protection Act:
Questions-and-Answers

OMB Control No. 0910-0641

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports implementation of the Dietary Supplement and Nonprescription Drug Consumer Protection Act (DSNDCPA) (Pub. L. 109-462). The Public Law added section 502(x) to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 352(x)), requiring 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 manufacturer, packer, and distributor may receive a report of a serious adverse event associated with its product(s).

Respondents to the information collection are manufacturers, packers, and distributors of nonprescription (over-the-counter (OTC)) human drug products marketed without an approved application. To assist respondents in complying with these labeling requirements of the DSNDCPA, we developed guidance for industry entitled, "*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*." The guidance document covers topics in a question-and-answer format pertaining to:

(1) the meaning of "*domestic address*" for purposes of the labeling requirements of section 502(x) of the FD&C Act;
(2) our recommendation to include 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) our enforcement approach regarding the labeling requirements of section 502(x) of the FD&C Act.

We therefore request extension of OMB approval for the information collection covered in the subject guidance document and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The information collection discussed in the referenced guidance helps to implement section 760 of the FD&C Act. Congress has required that important safety information relating to certain nonprescription human drug products be made available to the FDA by manufacturers, packers,

or distributors so that it can take appropriate action to protect the public health when necessary. To facilitate this goal, section 760 of the FD&C Act (sec.

3. Use of Improved Information Technology and Burden Reduction

As of June 10, 2015, all postmarketing reports required under section 760 of the FD&C Act are required to be submitted electronically. (See the final rule at 79 FR 33072, June 10, 2014.) Reports are submitted via the FDA Adverse Event Reporting System (FAERS) as specified at http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/surveillance/adversedrugeffects/ucm115894.htm.

4. Efforts to Identify Duplication and Use of Similar Information

We have established a number of collections pertaining to safety reports and adverse event reports associated with FDA-regulated products. While the DSNDCPA introduced new reporting, recordkeeping, and labeling requirements for OTC drug products that are marketed without an approved application, this information collection is limited to labeling as discussed in the associated guidance document. Now that the underlying legislation is long established, we will evaluate the collection to see whether consolidation with another ICR is appropriate.

5. Impact on Small Businesses or Other Small Entities

We do not believe the statutory requirements or agency recommendations discussed in the guidance pose undue burden on small entities. At the same time, we provide resources and assistance intended to help small businesses comply with our regulations, available from our website at www.fda.gov.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule discussed in the guidance is consistent with statutory requirements. To best facilitate the submission and receipt of reports of death, serious injury or illness associated as discussed in the associated guidance, certain elements appear on the label.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There is no inconsistency with 5 CFR 1320.5. The specific third-party timeframes are justified by the statutory requirements.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), we published a 60-day notice in the Federal Register of February 11, 2019 (84 FR 3192) requesting public comment of the information collection. No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is provided to respondents of the information collection.

10. Assurance of Confidentiality Provided to Respondents

In consultation with our Privacy Office, we reviewed the information collection to ensure appropriate handling under the Privacy Act. In this case, this information collection does not involve solicitation or collection of personally identifiable information (PII) by or on behalf of FDA. We do not intend to collect personally identifiable information (PII) and will not maintain records subject to the Privacy Act or otherwise operate a Privacy Act System of Records in relation to this specific collection.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature associated with the information.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

We estimate the burden of the collection of information as follows:

Table 1.--Estimated Annual Third-Party Disclosure Burden for New OTC Drug Products

Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Avg. Burden per Disclosure	Total Hours
Include domestic address or phone number and statement of its purpose on OTC drug labeling (21 U.S.C. 502(x))	300	3	900	4	3,600

As reflected in Table 1, we estimate 300 manufacturers will revise approximately 900 labels to add a full domestic address or a domestic telephone number, and should they choose to adopt the guidance's recommendation, to add a statement identifying the purpose of the domestic address or telephone number. We believe that designing the label change would not take longer than 4 hours per label, including the recommended statement. Also, we expect automated printing of the labels would require only a few seconds per label. This estimate accounts for the possibility that every manufacturer will make a label revision, which is unlikely. Because the many nonprescription drug labels currently have a domestic telephone number that satisfies the requirement, we believe some manufacturers will opt not to adopt the guidance's recommendation to add a statement identifying the purpose of the contact address or telephone number, significantly reducing the number of total responses.

12b. Annualized Cost Burden Estimate

Based on previous reviews, we typically estimate $4,000 per label or stock keeping unit (SKU) to make a label revision. If 900 labels are revised, the total cost burden to respondents would be $3.6 million. However, costs may be reduced if made contemporaneously with other scheduled label revisions.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

We estimate no other capital, or maintenance and operating costs associated with the information collection.

14. Annualized Cost to the Federal Government

No cost is estimated for the Federal Government as FDA does not review the labels of nonprescription drugs before marketing.

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

No tabulation or publication plans are associated with the information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.