Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act

OMB Control No. 0910-0642

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

In 2006, the Dietary Supplement and Nonprescription Drug Consumer Protection Act (the DSNDCPA) (Public Law 109-462, 120 Stat. 3469) amended 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. The DSNDCPA also amended the FD&C Act to add section 403(y) (21 U.S.C. 343(y)), which requires the label of a dietary supplement marketed in the United States to include a domestic address or domestic telephone number through which the product's manufacturer, packer, or distributor may receive a report of a serious adverse event associated with the dietary supplement.

In the Federal Register of September 1, 2009 (74 FR 45221), FDA announced the availability of a guidance document entitled, "Guidance for Industry: Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act." The guidance document contains questions and answers related to the labeling requirements in section 403(y) of the FD&C Act and provides guidance to industry on the use of an explanatory statement before the domestic address or telephone number. The guidance document provides the agency's interpretation of the labeling requirements for section 403(y) of the FD&C Act and the agency's views on the information that should be included on the label. The agency believes that the guidance will enable persons to meet the criteria for labeling that are established in section 403(y) of the FD&C Act.

FDA, therefore, is requesting OMB approval of the information collection provisions in the guidance, including the following:

21 U.S.C. 343(y) – Third-Party Disclosure

Labeling of dietary supplements – Section 403(y) of the FD&C Act (21 U.S.C. 343(y)) requires the label of a dietary supplement being marketed in the United States to include a domestic address or domestic phone number through which the responsible person may receive a report of a serious adverse event associated with such dietary supplement.

Recommendation for clear, prominent statement – Although section 403(y) does not require a dietary supplement label to include anything other than a domestic address or phone number for the responsible person, FDA recommends in the guidance document

that the label also bear a clear, prominent statement informing consumers that the domestic address or phone number is for reporting serious adverse events associated with use of the product.

2. Purpose and Use of the Information Collection

Requiring the label of a dietary supplement marketed in the United States to include a domestic address or domestic phone number will facilitate the reporting of serious adverse events associated with the use of the product. When the responsible person chooses to provide a domestic address (rather than a phone number) for adverse event reporting, FDA concludes that the statute requires the product label to bear a full U.S. mailing address that includes the street address or P.O. Box, city, state, and zip code of the responsible person (i.e., the manufacturer, packer, distributor, or retailer identified on the dietary supplement label). FDA finds that Congress's use of the term "domestic address" in section 403(y) is a clear and unambiguous directive that dietary supplement labels include all information necessary to enable a serious adverse event report to reach the responsible person. An address does not serve its intended purpose unless it includes all the information necessary to enable mail to reach its destination.

Similarly, when the responsible person chooses to provide a domestic phone number for adverse event reporting, FDA concludes that the statute requires the phone number on the product label to include the area code. Without the area code, the phone number is incomplete and does not serve its intended purpose of enabling the consumer to contact the responsible person to report a serious adverse event.

The reporting of serious adverse events related to dietary supplements to FDA, as required by the DSNDCPA, is important for public health reasons. Reporting of serious adverse events to FDA will serve as an early warning sign of potential public health issues associated with dietary supplements. Without notification of all serious adverse events associated with dietary supplements, FDA would be unable to investigate and follow-up promptly, which in turn could cause delays in alerting the public when safety problems are found. In addition, the information received will provide a reliable mechanism to track patterns of adulteration in dietary supplements that would support efforts by FDA to target limited inspection resources to protect the public health.

3. Use of Improved Information Technology and Burden Reduction

Dietary supplement firms may use any information technology available to them to reduce the burden of including a domestic address or domestic phone number on the label of their products. FDA estimates that zero percent (0%) of the domestic addresses or telephone numbers and explanatory statements will be disclosed electronically in the next three years.

4. Efforts to Identify Duplication and Use of Similar Information

The use of the term "domestic address" in section 403(y) of the FD&C Act contrasts with Congress's use of a different term, "place of business," in section 403(e) of the FD&C Act (21 U.S.C. 343(e)). Section 403(e) provides that foods, including dietary supplements, are misbranded unless the product label bears the name and place of business of the manufacturer, packer, or distributor of the food. FDA's regulations interpret "place of business" to require only the firm's city, state, and zip code to appear on the product label, as long as the firm's street address is listed in a current telephone directory or other city directory (21 C.F.R. 101.5(d)). The use of the term "domestic address" in section 403(y) demonstrates Congress's intent to require the responsible person's full address, including the street address or P.O. Box, to appear on dietary supplement labels when the responsible person has opted to receive serious adverse event reports by mail. If Congress had considered the less complete address already required under the "place of business" labeling requirements to be adequate for serious adverse event reporting, there would have been no need to impose a new, more specific requirement in section 403(y) for the responsible person's "domestic address" to appear on dietary supplement labels.

5. Impact on Small Businesses or Other Small Entities

FDA estimates that eighty percent (80%) of respondents are small businesses. The labeling requirements are mandated by the DSNDCPA and there is no statutory exception for small businesses. The same labels are required from large and small firms. There is no special burden placed on small businesses by these information collection provisions. However, FDA aids small businesses in dealing with the requirements of the FD&C Act through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. FDA has provided a Small Business Guide on its website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. The DSNDCPA requires dietary supplement labels to include a domestic address or domestic phone number through which reports of serious adverse events can be received. FDA believes that the inclusion of a domestic address or domestic phone number on the label of the dietary supplement will promote prompt and accurate reporting of a serious adverse event by product consumers to the responsible person, consistent with the Congressional intent of the DSNDCPA and important for public health reasons. Delayed reporting by the public to the responsible person, due to an incomplete address or phone number on the label, would in turn delay the responsible person's reporting of an event to FDA, thereby diminishing the effectiveness of adverse event reporting as an early warning sign of possible safety problems with dietary supplements. Without prompt notification of all serious adverse events associated with dietary supplements, FDA would be unable to investigate and follow-up promptly, which in turn could cause delays in alerting the public when safety problems are found.

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

There are no special circumstances associated with this collection of information.

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

In accordance with 5 CFR 1320.8(d), a 60-day notice for public comment was published in the Federal Register on August 24, 2015 (80 FR 51278). One comment was posted to the docket subsequent to the publication of the agency's 30-day notice. While the comment did not respond to any of the four information collection topics solicited, FDA acknowleges this feedback.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

Section 761(f)(2) of the FD&C Act (21 U.S.C. 379aa-1(f)(2)) provides that a serious adverse event report submitted to FDA, including any new medical information submitted, shall be considered a record about an individual under section 552a of title 5, United States Code (commonly referred to as the "Privacy Act of 1974") and a medical or similar file the disclosure of which would constitute a violation of section 552 of such title 5 (commonly referred to as the "Freedom of Information Act"), and shall not be publicly disclosed unless all personally identifiable information is redacted.

11. Justification for Sensitive Questions

This information collection does not involve questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

Description of Respondents: Respondents to the information collection include businesses engaged in the manufacture, packing, or distribution of dietary supplements marketed in the United States. Respondents are from the private sector (for-profit businesses).

12a. Annualized Hour Burden Estimate

FDA estimates the burden for this information collection as follows:

Table 1. -- Estimated Annual Third-Party Disclosure Burden[1]					
Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Domestic address or phone number labeling requirement (21 U.S.C. 343(y))	1,700	3.27	5,560	0.2 (12 minutes)	1,112
FDA recommendation for label statement explaining purpose of domestic address or phone number	1,700	3.27	5,560	0.2 (12 minutes)	1,112
Total					2,224

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

The labeling requirements of section 403(y) of the FD&C Act became effective on December 22, 2007, although FDA exercised enforcement discretion until September 30, 2010 to enable all firms to meet the labeling requirements for dietary supplements. At this time, therefore, FDA expects that all labels required to include the domestic address or telephone number pursuant to section 403(y) have been revised accordingly. Thus, FDA's current burden estimate for this information collection applies only to new product labels. In row 1 of Table 1, FDA estimates the total annual hourly burden necessary to comply with the requirement under section 403(y) to be 1,112 hours. Using historical A.C. Nielsen Sales Scanner Data, FDA estimates that the number of dietary supplement stock keeping units for which sales of the products are greater than zero to be 55,600. Assuming that the flow of new products is 10 percent per year, then each year approximately 5,560 new dietary supplement products are projected to enter the market. Estimating that there are about 1,700 dietary supplement manufacturers, re-packagers, re-labelers, and holders of dietary supplements subject to the information collection requirement (using the figure 1,460 as provided in FDA's final rule of June 25, 2007 (72 FR 34752), on the "Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements," and factoring for a 2 percent annual growth rate), we calculate an annual disclosure burden of 3.27 disclosures (labels) per firm. Last, FDA expects that firms prepare the required labeling for their products in a manner that takes into account at one time all information required to be disclosed and therefore believe that less than 0.2 hours (12 minutes) per product label would be expended to fulfill this requirement.

In row 2 of Table 1, FDA estimates the total burden associated with the recommendation to include an explanatory statement on dietary supplement product labels letting consumers know the purpose of the domestic address or telephone number to be 1,112 hours. Based upon FDA's knowledge of food and dietary supplement labeling, it estimates it would require less than 0.2 hours (12 minutes) per product label to include such a statement.

The total reporting hour burden is 2,224 hours, which equals the burden for the required domestic address or telephone number (1,112) plus the burden for the explanatory statement before the domestic address or telephone number (1,112).

12b. Annualized Cost Burden Estimate

FDA estimates the annualized burden hour cost to respondents for this collection of information to be approximately $228,760.64. FDA estimates that a respondent's employees responsible for implementing the label change required by section 403(y) of the FD&C Act and recommended by this guidance would make an average wage equivalent to that of a Federal government employee at the GS-14/Step-1 rate for the Washington-Baltimore locality pay area for the year 2015 ($51.43), which makes the annual wage cost for the burden hours approximately $114,380.32 (2,224 hours x $51.43per hour). To account for overhead, this cost is increased by 100 percent, making the total estimated burden hour cost to the respondent $228,760.64.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no capital, start-up, operating, or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

Label revisions in response to the guidance are not submitted to FDA for review. Therefore, the only costs to FDA as a result of section 403(y) of the FD&C Act and this guidance would be the costs associated with overseeing compliance with the new labeling. FDA expects these costs to be very small.

15. Explanation for Program Changes or Adjustments

The burden for this collection remains unchanged.

16. Plans for Tabulation and Publication and Project Time Schedule

We are not publishing any information received as a result of this information collection.

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

We are not seeking approval to not display the expiration date for OMB approval of the information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification0642 S