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

0910-0642

SUPPORTING STATEMENT

Terms of Clearance: None.

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 is requesting OMB approval of the information collection provisions in the guidance and the following statutory citation:

21 U.S.C. 343(y) – Reporting

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.

Description of Respondents: The likely respondents 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).

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 dietary supplement. The Agency 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 DSNDCPA 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 the Agency's 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, which would lessen 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 June 14, 2012 (77 FR 35687). No comments were received.

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 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: The likely respondents 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[2]	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Domestic address or phone number labeling requirement (21 U.S.C. 343(y))	1,460	3.8	5,560	0.2 (12 minutes)	1,112
FDA recommendation for label statement explaining purpose of domestic address or phone number	1,460	3.8	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.

[2] Number has been rounded to the nearest tenth.

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. FDA estimates that all labels required to include the domestic address or telephone number pursuant to section 403(y) have been revised by the effective date. Thus, in succeeding years, the Agency estimates that the burden hours associated with the labeling requirements of section 403(y) and the Agency's recommendations on the use of an explanatory statement will apply only to new product labels. Based on the A.C. Nielsen Sales Scanner Data, FDA estimated that the number of dietary supplement SKUs for which sales of the products are greater than zero is 55,600. Assuming that the flow of new products is 10 percent per year, then 5,560 new dietary supplement products will come on the market each year. FDA also estimates that there are about 1,460 dietary supplement manufacturers, re-packagers, re-labelers, and holders of dietary supplements. Assuming the approximately 5,560 new products are split equally among the firms, then each firm would prepare labels for close to four new products per year (5,560 new products/1,460 firms = 3.8 labels per firm. Thus, the estimated total annual disclosures are 5,560 (1,460 firms x 3.8 labels per year = 5,560).

The Agency 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 on their product labels. Based upon its knowledge of food and dietary supplement labeling, FDA estimates that firms would require less than 0.2 hour (12 minutes) per product to comply with the requirement to include the domestic address or telephone number pursuant to section 403(y). The total hour burden of this task is shown in row 1 of Table 1.

FDA estimates that all firms will include an explanatory statement on the label, which lets consumers know the purpose of the domestic address or telephone number on the label of the dietary supplement product. Based upon its knowledge of food and dietary supplement labeling, FDA estimates that firms would require less than 0.2 hour (12 minutes) per product to comply with the Agency's recommendations on the use of an explanatory statement. The total hour burden of this task is shown in row 2 of Table 1.

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 $224,223.68. 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 2012 ($50.41), which makes the annual wage cost for the burden hours approximately $112,111.84 (2,224 hours x $50.41 per hour). To account for overhead, this cost is increased by 100 percent, making the total estimated burden hour cost to the respondent $224,223.68.

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

FDA is requesting to extend approval of the ICR, for which there is a decrease in burden. The burden change is due to an adjustment based on the agency's determination that the number of disclosures per respondent, the total annual number of disclosures, the average burden per disclosure, and the total annual hour burden have decreased. The total number of disclosures per respondent decreased from 76.1644 to 7.6 (a decrease of 68.5644 disclosures). The total annual number of disclosures decreased from 111,200 to 11,120 (a decrease of 100,080 disclosures). The total average burden per disclosure decreased from 8 to 0.4 hour (a decrease of 7.6 hours). The total annual hour burden has

decreased from 444,800 to 2,224 hours (a decrease of 442,576 hours). The decreases were due to the decrease in the number of labels that needed to be redesigned to comply with section 403(y) of the FD&C Act and the guidance.

TABLE 3—Summary of Change in Disclosures and Hour Burden

IC Number	Change in Number of Disclosures per Respondent	Change in Disclosures	Change in Average Burden per Disclosure	Change in Hour Burden
IC#1	-34.2822	-50,040	-3.8	-221,288
IC#2	-34.2822	-50,040	-3.8	-221,288
Total Change	-68.5644	-100,080	-7.6	-442,576

For IC#1, we estimate that the number of disclosures per respondent have decreased from 38.0822 to 3.8 (a decrease of 34.2822 disclosures per respondent). We also estimate that the number of total annual disclosures have decreased from 55,600 to 5,560 (a decrease of 50,040 disclosures), and the average burden per disclosure has decreased from 4 to 0.2 hour (a decrease of 3.8 burden per disclosure). These decreases caused the annual hour burden to decrease from 222,400 to 1,112 (a decrease of 221,288 hours). We are characterizing the decrease as an adjustment because it is based on the decrease in the number of disclosures and the amount burden, as a result of the industry's previous compliance with section 403(y) of the FD&C Act and the guidance.

For IC#2, we estimate that the number of disclosures per respondent have decreased from 38.0822 to 3.8 (a decrease of 34.2822 disclosures per respondent). We also estimate that the number of total annual disclosures have decreased from 55,600 to 5,560 (a decrease of 50,040 disclosures), and the average burden per disclosure has decreased from 4 to 0.2 hour (a decrease of 3.8 burden per disclosure). These decreases caused the annual hour burden to decrease from 222,400 to 1,112 (a decrease of 221,288 hours). We are characterizing the decrease as an adjustment because it is based on the decrease in the number of disclosures and the amount burden, as a result of the industry's previous compliance with section 403(y) of the FD&C Act and the guidance.

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 certification.