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

0910-NEW

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

On December 22, 2006, the President signed into law the Dietary Supplement and Nonprescription Drug Consumer Protection Act (DSNDCPA) (Public Law 109-462, 120 Stat. 3469). This law amends the Federal Food, Drug, and Cosmetic Act (the Act) with respect to serious adverse event reporting for dietary supplements and nonprescription drugs marketed without an approved application. The law also amended the 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.

On January 2, 2008, FDA announced the availability of a draft guidance document entitled "Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act" (73 FR 197). On December 11, 2008, FDA announced the availability of a revised version of the same draft guidance document (73 FR 75438). The guidance document contains questions and answers relating to the labeling requirements in section 403(y) of the Act and provides guidance to industry on the following topics: (1) The meaning of "domestic address" for purposes of the labeling requirements of section 403(y) of the 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 403(y) of the Act; and (3) FDA's intent regarding enforcing the labeling requirements of section 403(y) of the 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 the 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 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 the 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 dietary supplement.

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 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

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 Act through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency.

6. Consequences of Collecting the Information Less Frequently

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, due to an incomplete address or phone number on the label, by the public to the responsible person 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 information collection.

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

As required by section 3506(c)(2)(B) of the Paperwork Reduction Act of 1995 (PRA), FDA provided an opportunity for public comment on the proposed information collection in a notice that published in the Federal Register on January 2, 2008 (73 FR 197).

Several comments suggested that FDA underestimated the number of dietary supplement labels that would have to be revised. Two comments noted that in the past FDA had estimated the number of distinct dietary supplement labels at 29,514, and another

comment noted that in the past FDA had estimated the number of distinct dietary supplement labels at 75,000. Several other comments suggested that the number of dietary supplements sold in the United States was between 50,000 and 60,000 products based on information from the Office of Dietary Supplements at the National Institutes of Health (NIH). All the aforementioned comments suggested that the costs associated with re-labeling the dietary supplements represented a significant burden to the industry.

Based on these comments, FDA has revised its estimate of the number of labels that would have to be redesigned to include the complete domestic address or domestic phone number of the responsible person for each dietary supplement stockkeeping unit (SKU). FDA used A.C. Nielsen Sales Scanner Data from 2004 to improve its estimate of the number of dietary supplement SKUs. The 2004 A.C. Nielsen scanner data are more recent and more complete than the data FDA used to derive the estimate used in the 60-day notice. FDA also adjusted the Nielsen scanner data estimate to account for methods of sale not covered by the Nielsen scanner data, such as non-participating retailers and internet sales. Based on the adjusted Nielson scanner data, FDA estimates that the number of dietary supplement SKUs for which sales of the products are greater than zero is 55,600. This number of SKUs is similar to the number of dietary supplement products that was suggested by several comments and the number estimated by the Office of Dietary Supplements at NIH.

FDA did not receive any comments regarding the number of firms that would be responsible for re-labeling the dietary supplement products. Therefore we retain our estimate that there are about 1,460 dietary supplement firms that must comply with the labeling requirements of section 403(y) of the Act. Assuming the 55,600 SKUs are split equally among the firms, then each firm would be responsible for updating about 38 SKUs. FDA also did not receive any comments regarding how many of the dietary supplement SKUs would have to undergo a label change to include the complete domestic address or domestic phone number of the responsible person as required by the DSNDCPA. Thus, as in the 60-day notice, FDA is assuming conservatively that all labels will need to be redesigned.

Several comments noted that the overall process of changing a label requires a significant amount of time to implement; however, FDA did not receive any estimates of the actual time it would take to assess the current layout of each label and redesign it. FDA also did not receive any estimates of how many firms would choose to include an explanatory statement on the reason for the domestic address or telephone number appearing on the label of the dietary supplement product, though several comments speculated that all or nearly all firms would be likely to include an explanatory statement. Because we did not receive any comments on the burden associated with each of these tasks, we retain our original estimates: we assume conservatively that all firms will include an explanatory statement on the label, and we estimate that the redesign of each label to include the domestic address or telephone number and the explanatory statement will take a total of 8 hours (4 hours for each change).

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for any payment or gift 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 contain questions of a sensitive nature (e.g., those regarding sexual behavior and attitudes, religious beliefs, etc).

12. Estimates of Annualized Burden Hours and Costs

FDA estimates the burden for this information collection as follows:

Hour Burden Estimate

Table 1. -- Estimated One-Time Reporting Burden1

	No. of Respondents	Annual Frequency per Response	Total annual Responses	Hours Per Response	Total Hours
Domestic address or phone number labeling requirement (21 U.S.C. 343(y))	1,460	38.0822	55,600	4	222,400
FDA recommendation for label statement explaining purpose of domestic address or phone number	1,460	38.0822	55,600	4	222,400
Total Burden Hours					444,800

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

Reporting Burden

Based on the information provided by the A.C. Nielson scanner data, FDA is able to estimate that the number of dietary supplement SKUs for which sales of the products are greater than zero is 55,600. FDA also estimates that there are about 1,460 dietary supplement manufacturers, re-packagers, re-labelers, and holders of dietary supplements. Assuming the 55,600 SKUs are split equally among the firms, then each firm would be responsible for updating about 38 SKUs. Thus the hour burden estimate to re-label all dietary supplement SKUs with a domestic address or telephone number is 222,400 hours as 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, and that the redesign of each label to include such information will take a total of 4 hours. The total hour burden of this task is shown in row 2 of Table 1.

Estimated Annualized Cost for the Burden Hours

FDA estimates the annualized burden hour cost to respondents for this collection of information to be approximately $43,786,112. FDA estimates that a respondent's employees responsible for implementing the label change required by section 403(y) of the 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 2009 ($49.22), which makes the annual wage cost for the burden hours approximately $21,893,056 (444,800 hours x $49.22 per hour). To account for overhead, this cost is increased by 100 percent, making the total estimated burden hour cost to the respondent $43,786,112.

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

There are no capital costs or operating and 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 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

This is a new collection. The increase in reporting reflect our estimate of the number of dietary supplements that would need to be re-labeled to include a domestic address or telephone number of a responsible person; this burden is a one time burden.

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

No exceptions to the certification statement were identified.