4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No.FDA-2012-N-0564]

Agency Information Collection Activities; Proposed Collection; Comment Request; Dietary Supplement Labeling Requirements and Recommendations under the Dietary Supplement and Nonprescription Drug Consumer Protection Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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. This notice solicits comments on the information collection provisions of the Dietary Supplement and Nonprescription Drug Consumer Protection Act (the DSNDCPA) and the 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."

DATES: Submit either electronic or written comments on the collection of information by [**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@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, we are publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite 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.

Dietary Supplement Labeling Requirements and Recommendations under the Dietary Supplement and Nonprescription Drug Consumer Protection Act

OMB Control Number 0910-0642--Extension

In 2006, the Dietary Supplement and Nonprescription Drug Consumer Protection Act (the DSNDCPA) 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), we 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 our interpretation of the labeling requirements for section 403(y) of the FD&C Act and our views on the information that should be included on the label. We believe that the guidance will enable persons to meet the criteria for labeling that are established in section 403(y) of the FD&C Act.

We estimate the burden of this collection of information 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 we exercised enforcement discretion until September 30, 2010, to enable all firms to meet the labeling requirements for dietary supplements. At this time, therefore, we expect that all labels required to include the domestic address or telephone number pursuant to section 403(y) of the FD&C Act have been revised accordingly. Thus our current burden estimate for this information collection applies only to new product labels.

In row 1 of table 1 we estimate the total annual hourly burden necessary to comply with the requirement under section 403(y) of the FD&C Act to be 1,112 hours. Using historical A.C. Nielson Sales Scanner Data, we estimate the number of dietary supplement stock keeping units for which product sales 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 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 our 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, we expect 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 we estimate 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 our knowledge of food and dietary supplement labeling, we estimate it would require less than 0.2 hours (12 minutes) per product label to include such a statement.

Dated: August 17, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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