4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0642. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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) (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.

In the Federal Register of June 14, 2012 (77 FR 35687), FDA published a 60-day notice requesting public comment on the proposed collection of information. The Agency received no comments in response to the notice.

FDA estimates 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[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	1,112
FDA recommendation for label statement explaining purpose of domestic address or phone number	1,460	3.8	5,560	0.2	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) of the FD&C Act 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) of the FD&C Act 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 stock keeping units 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 is approximately 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 hours per product to comply with the requirement to include the domestic address or telephone number pursuant to section 403(y) of the FD&C Act. 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 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 (1,112 hours) plus the burden for the explanatory statement before the domestic address or telephone number (1,112 hours). This estimate is 3,336 hours lower than the 5,560 hours reported in the 60-day notice published June 14, 2012, due to an Agency reassessment that 0.2 hours per disclosure more accurately reflects the burden. This reassessment is based on the Agency's expectation that firms, estimated to design four new labels per year, are familiar with the requirement to include the domestic address or telephone number in their product labels. It is also based on FDA's recommendations on the use of an explanatory statement and our expectation that the disclosed information (domestic address or telephone number and explanatory statement) would not change from product label to product label. Thus, FDA estimates that firms would not need a full hour per label, but rather, approximately 24 minutes per label to include this information.

Dated: August 16, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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