4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0429]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by 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 0910-0641. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRAStaff@fda.hhs.gov.

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.

Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act

OMB Control Number 0910-0641--Extension

Section 502(x) of the Federal, Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 352(x)), added by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Pub. L. 109-462), requires the label of a nonprescription drug product marketed without an approved application in the United States to include a domestic address or domestic telephone number through which a manufacturer, packer, and distributor may receive a report of a serious adverse event associated with the product. The guidance document entitled "Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Questions and Answers" explains how FDA interprets this requirement. The guidance discusses the meaning of "domestic address" for purposes of the labeling requirements of section 502(x) of the FD&C Act, 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 502(x) of the FD&C Act, and FDA's intent regarding enforcing the labeling requirements of section 502(x) of the FD&C Act.

In the *Federal Register* of February 11, 2019 (84 FR 3192), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

Description of Respondents: Respondents to this collection of information are manufacturers, packers, and distributors whose name (under section 502(b)(1) of the FD&C Act) appears on the label of a nonprescription drug product marketed in the United States without an approved application.

As indicated in table 1 of this document, we estimate that 300 manufacturers will revise approximately 900 labels to add a full domestic address or a domestic telephone number, and should they choose to adopt the guidance's recommendation, to add a statement identifying the purpose of the domestic address or telephone number. We believe that designing the label change should not take longer than 4 hours per label. Automated printing of the labels should only require a few seconds per label.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Third-Party Disclosure Burden for New OTC Drug Products[1]

Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Including a domestic address or phone number and a statement of its purpose on OTC drug labeling (section 502(x) of the FD&C Act)	300	3	900	4	3,600

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: May 23, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-11295 Filed: 5/29/2019 8:45 am; Publication Date: 5/30/2019]