



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0429 (formerly Docket No. 2007D-0496)]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Questions and Answers Regarding the 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 (the PRA).

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 oir_submission@omb.eop.gov. All comments should be identified with the title. Also include the FDA 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, PRStaff@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.

Guidance for Industry on Questions and Answers Regarding the 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 FD&C Act (21 U.S.C. 352(x)), which was 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 contains questions and answers relating to this labeling requirement and provides guidance to industry on the following topics: (1) The meaning of "domestic address" for purposes of the labeling requirements of section 502(x) of the FD&C 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 502(x) of the FD&C Act; and (3) FDA's intent regarding enforcing the labeling requirements of section 502(x) of the FD&C Act.

Description of Respondents: Respondents to this collection of information are manufacturers, packers, and distributors whose name (issued in 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.

In the Federal Register of July 17, 2015 (80 FR 42502), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment. However, these comments did not address the information collection.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Third-Party Disclosure Burden¹

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 (21 U.S.C. 502(x))	300	3	900	4	3,600

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

Dated: February 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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