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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0074]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; State Enforcement Notifications

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 0910-0275. 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.

State Enforcement Notifications

OMB Control Number 0910-0275--Extension

This information collection supports Agency regulations. Specifically, section 310(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 337(b)) authorizes a State to enforce certain sections of the FD&C Act in its own name and within its own jurisdiction. However, before doing so, a State must provide notice to FDA according to § 100.2 (21 CFR 100.2). The information required in a letter of notification under § 100.2(d) enables us to identify the food against which a State intends to take action and to advise that State whether Federal enforcement action against the food has been taken or is in process. With certain narrow exceptions, Federal enforcement action precludes State action under the FD&C Act.

In the *Federal Register* of February 7, 2018 (83 FR 5438), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment in support of the information collection.

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

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Part	No. of Respondents	No. of Responses per Respondents	Total Annual Responses	Average Burden per Response	Total Hours
21 CFR Section 100.2(d)	1	1	1	10	10

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

The estimated burden for this information collection has not changed since the last OMB approval. The estimated reporting burden for § 100.2(d) is minimal because enforcement notifications are seldom used by States. During the last 3 years, we have not received any new

enforcement notifications; therefore, we estimate that one or fewer notifications will be submitted annually. Although we have not received any new enforcement notifications in the last 3 years, we believe these information collection provisions should be extended to provide for the potential future need of a State government to submit enforcement notifications informing us when it intends to take enforcement action under the FD&C Act against a particular food located in the State.

Dated: June 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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