4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0013]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Sanitary Transportation of Human and Animal Food

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 0910-0773. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, 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.

Sanitary Transportation of Human and Animal Food--21 CFR 1.900

OMB Control Number 0910-0773--Extension

This information collection supports FDA regulations regarding the sanitary transportation of human and animal food. The regulations are intended to focus on preventing food safety problems throughout the food chain and were issued under the Sanitary Food Transportation Act of 2005 (2005 SFTA), and the FDA Food Safety Modernization Act, enacted in 2011. The 2005 SFTA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act), in part, by creating section 416 (21 U.S.C. 350e), which directs us to issue regulations to require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use prescribed sanitary transportation practices to ensure that food is not transported under conditions that may render the food adulterated. Section 416 also directs that we prescribe appropriate human and animal food transportation practice requirements relating to: (1) sanitation; (2) packaging, isolation, and other protective measures; (3) limitations on the use of vehicles; (4) information to be disclosed to carriers and to manufacturers; and (5) recordkeeping.

In addition, the 2005 SFTA created section 402(i) of the FD&C Act (21 U.S.C. 342(i)), which provides that food that is transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food under conditions that are not in compliance with the regulations issued under section 416 is adulterated and section 301(hh) of the FD&C Act (21 U.S.C. 331(hh)), which prohibits the failure by a

shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food to comply with the regulations issued under section 416.

The 2005 SFTA also amended section 703 of the FD&C Act (21 U.S.C. 373) by providing that a shipper, carrier by motor vehicle or rail vehicle, receiver, or other person subject to section 416 shall, on request of an officer or employee designated by FDA, permit the officer or employee, at reasonable times, to have access to and to copy all records that are required to be kept under the regulations issued under section 416.

Accordingly, we issued regulations in 21 CFR 1.900 that establish requirements for the sanitary transportation of human and animal food. The regulations include certain recordkeeping requirements, procedures and information collection for respondents who wish to request a waiver for any requirement, as well as third-party disclosures regarding sanitary specifications.

In the *Federal Register* of February 20, 2019 (84 FR 5087), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of the information collection as follows:

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

21 CFR Section; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
1.912; Record retention	1,502,032	1	1,502,032	0.083 (5 minutes)	124,669

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

We estimate an annual recordkeeping burden of 124,669 hours, consistent with the estimate found in the Final Regulatory Impact Analysis for the 2016 final rule and used to establish the information collection. This assumes 1,502,032 workers will spend an average of 5 minutes on activities related to the record retention requirements under 21 CFR 1.912. We expect these activities will likely include documenting procedures and training, as well as

sanitary transportation operations and specification requirements.

Table 2.--Estimated Annual Reporting Burden[1]

21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
1.914; Waiver petitions	2	1	2	24	48

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

We estimate one waiver petition from each of two firms will be submitted and respondents will spend 24 hours to prepare and submit the petition to FDA.

Table 3.--Estimated Annual Third-Party Disclosure Burden[1]

21 CFR Section; Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
1.908; Disclosure of sanitary specifications; operating temperature conditions	226	1	226	0.5833 (~35 mins.)	132

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

Finally, we estimate an annual third-party disclosure burden of 132 hours, consistent with the currently approved burden estimate for this collection of information. We assume each of 226 firms will spend an average of 35 minutes, annually, disclosing written records as required under 21 CFR 1.908.

Cumulatively, we have reduced our burden estimate for the information collection. We made this adjustment to reflect the removal of one-time burden associated with implementation of the new regulatory requirements. Because these provisions have since become effective, the one-time estimates previously included have been removed.

Dated: May 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-11532 Filed: 6/3/2019 8:45 am; Publication Date: 6/4/2019]