



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2024-N-5944]

#### 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:** Submit written comments (including recommendations) 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 submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review - Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0773. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRAStaff@fda.hhs.gov](mailto: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 Part 1, Subpart O

This information collection supports FDA regulations regarding the sanitary transportation of human and animal food. Section 402(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342(i)), establishes 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. Section 416 (21 U.S.C. 350e) of the FD&C Act, requires 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 of the FD&C Act 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.

Additionally, section 703 of the FD&C Act (21 U.S.C. 373) provides that a shipper, carrier by motor vehicle or rail vehicle, receiver, or other person subject to section 416 of the FD&C Act must, 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 part 1, subpart O (21 CFR 1.900 through 1.934) that establish requirements for the sanitary transportation of human and animal food, as well as prescribe procedures for respondents who wish to request a waiver for any requirement. Under section 1.924 of 21 CFR part 1, subpart O, waivers are requested in the same manner as prescribed in § 10.30 (21 CFR 10.30). Electronic submissions are accepted via [www.regulations.gov](http://www.regulations.gov) as prescribed in § 10.30(b)(1). The collections of information in § 10.30 have been approved under OMB control number 0910-0191. For additional information

regarding Agency implementation of sections 402(i), 416, and 703 of the FD&C Act, visit our website at <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-sanitary-transportation-human-and-animal-food>.

*Description of Respondents:* Respondents to this collection of information are domestic shippers and carriers, and in certain circumstances, foreign shippers of human and animal food. Respondents are from the private sector (for-profit businesses).

In the *Federal Register* of June 27, 2025 (90 FR 27628), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received in support of the information collection.

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

Table 1.--Estimated Annual Recordkeeping Burden<sup>1</sup>

| 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<br>(5 minutes)             | 124,669     |

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

Table 2.--Estimated Annual Reporting Burden<sup>1</sup>

| 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          |

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

Table 3.--Estimated Annual Third-Party Disclosure Burden<sup>1</sup>

| 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<br>(~35 mins.)         | 132         |

<sup>1</sup>There are no capital costs or operating and maintenance 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. However, we note that due to rounding, the number of total burden hours recorded by OMB (124,848 hours) has increased by one hour (now 124,849 hours).

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

