UNITED STATES FOOD & DRUG ADMINISTRATION

Sanitary Transportation of Human and Animal Food

OMB Control No. 0910-0773

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports FDA regulations regarding the sanitary transportation of human and animal food. Section 402(i) of the 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. 360e) of the Federal Food, Drug, and Cosmetic Act (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 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) by provides 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 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. For additional information regarding Agency implementation of the 2005 SFTA, visit our website at https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/sanitation-transportation-guidance-documents-regulatory-information.

We therefore request extension of OMB approval for the information collection provisions covered in the applicable regulations and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The regulations and supporting information collection are intended to ensure that transportation practices do not create food safety risks. Practices that create such risk include failure to properly refrigerate food, inadequate cleaning of vehicles between loads, and failure to properly protect

food during transportation. This builds on current safe food transport practices and is focused on ensuring that persons engaged in the transportation of food that is at the greatest risk for contamination during transportation follow appropriate sanitary transportation practices.

Description of Respondents: Respondents to the information collection are domestic shippers and carriers, and in certain circumstances, foreign shippers of human and animal food. There are exceptions including for food that is completely enclosed and does not require temperature controls for safety, live food animals (except molluscan shellfish) and raw agricultural commodities (RACs) when RACs are transported by a farm), those engaged in food transportation operations that have less than $500,000 in total annual sales. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

The information collection requirements solicit what we believe is the minimal information necessary to ensure safety of transported food. We believe that 100% of respondents use electronic means to fulfill the information collection requirements. Additionally, firms seeking a waiver under 21 CFR 10.30 may submit them electronically.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. The term "*food*" is defined consistent with section 201(f) of the FD&C Act, which includes raw materials and ingredients. This definition also includes animal food and food subject to the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act administered by the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture. To prevent duplication of effort, FDA's compliance policy is to inform FSIS when an apparent violation is encountered involving a meat or poultry product that has left a USDA inspected establishment. FSIS carries out in-commerce surveillance activities to verify that entities whose business activities involve FSIS-regulated products prepare, store, transport, sell, offer for sale or transportation, import, and export such products in compliance with FSIS statutory and regulatory requirements. FSIS has issued guidance for the safe transportation and distribution of meat, poultry and egg products; however, it does not have requirements that directly address transportation operations for these foods. This collection of information complements FSIS's efforts to promote the application of sanitary food transportation practices for FSIS-regulated meat, poultry, and egg products. We intend to continue to work together with FSIS to facilitate this shared objective while carrying out our respective regulatory programs.

5. Impact on Small Businesses or Other Small Entities

There is no undue burden on small entities. We estimate that, among firms analyzed, ninety-eight percent (98%) of shippers/receivers and ninety-five percent (95%) of carriers are small businesses. We have attempted to assist small businesses by exempting very small firms with less than $500,000 in total annual sales and provided staggered compliance dates for other small businesses. The term "*small business*" means a business employing fewer than 500 persons, except that for carriers by motor vehicle that are not also shippers and/or receivers. The term also refers to a

business having less than $27,500,000 in annual receipts, consistent with the size-based standard established by the U.S. Small Business Administration for truck transportation firms.

We also assist small businesses in complying with regulatory requirements through Regional Small Business Representatives and through scientific and administrative staffs within the agency. Assistance is also available for small businesses via the agency's website at https://www.fda.gov/industry/small-business-assistance.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), we published a 60-day notice for public comment in the *Federal Register* of February 24, 2022 (87 FR 10369). One comment was received, however it did not address any of the information collection topics solicited.

9. Explanation of Any Payment or Gift to Respondents

No gift or payment is provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although the ICR collects personally identifiable information (PII), it is collected in the context of the subject individuals' professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). The PII submitted via petitions for a waiver request is name, address, email address, and telephone number. FDA determined that although PII is collected, the collection is not subject to the Privacy Act of 1974, and the particular notice and other requirements of the Privacy Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

This information collection does not involve questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

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.

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.

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.

12b. Annualized Cost Burden Estimate

To determine cost burden we make the following assumptions: we estimate that three types of respondent employees are responsible for information collection: cargo and freight agents (BLS Category 43-5011, mean hourly wage $21.19, fully loaded hourly wage $31.79); first-line supervisors of transportation and material-moving machine and vehicle operators (BLS Category 53-1040, mean hourly wage $29.60, fully loaded hourly wage $44.40); and managerial or professional employees such as plant managers, food safety specialists, and in-house legal counsel (BLS Category 11-1021, mean hourly wage $54.02, fully loaded hourly wage $81.03). We base our estimate of the wage rates on the Bureau of Labor Statistics, Occupational Employment Statistics, May 2021, National Industry-Specific Occupational Employment and Wage Estimates[1] and multiply the hourly wage by 1.5 (i.e., 150%) for a fully loaded wage rate which covers overhead. Therefore, the total costs for this collection of information is estimated to be $4,012,835.03.

Table 4.--Estimated Annual Cost Burden

[1] https://www.bls.gov/oes/2021/may/oessrci.htm. The wage table is searchable by occupation title using the "Text search table" field.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Cargo and Freight Agent (97.5% total hours)	121,729	$31.79	$3,869,764.91
First-Line Supervisors of Transportation and Material-Moving Machine and Vehicle Operators (2.4% total hours)	2,996	$44.40	$133,022.40
Managerial or Professional Employees (0.1% total hours)	124	$81.03	$10,047.72
Total	124,849		$4,012,835.03

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

Our review of retained records will generally occur as part of FDA's routine or for-cause inspection activities. Because these activities are covered by existing resource allocations, we are estimating zero cost to the Federal government.

15. Explanation for Program Changes or Adjustments

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 have removed the denotation of costs as this is included at Question 12b. of the supporting statement.

16. Plans for Tabulation and Publication and Project Time Schedule

Information is not to be published for statistical use.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Approval for not displaying the expiration date of OMB approval is not being sought.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.