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 helps support implementation of the Sanitary Food Transportation Act of 2005 (2005 SFTA) and the FDA Food Safety Modernization Act of 2011 (FSMA). The 2005 SFTA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act), in part, by creating section 416 of the FD&C Act (21 U.S.C. 350e). Section 416(b) of the FD&C Act 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.

Specifically, the statute requires the establishment of sanitary practices for the transport of food along with recordkeeping requirements that document the: (1) sanitation; (2) packaging, isolation, and other protective measures; (3) limitations on the use of vehicles; and (4) disclosures to carriers and to manufacturers required by the regulations. Section 416(c) also provides that the regulations are to include a list of nonfood products that may, if shipped in a bulk vehicle, render adulterated food that is subsequently transported in the same vehicle and a list of nonfood products that may, if shipped in a motor vehicle or rail vehicle (other than a tank vehicle or bulk vehicle), render adulterated food that is simultaneously or subsequently transported in the same vehicle. Section 111(a) of FSMA, directed us to issue these sanitary transportation regulations.

In addition, the 2005 SFTA created section 402(i) in 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) in the FD&C Act (21 U.S.C. 331(hh)) to prohibit 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 adding section 703(b), which 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. FDA's authority for SFTA also derives from sections 402(a)(1), (a)(3), (a)(4), and 701(a) of the FD&C Act (21 U.S.C. 371(a)).

Accordingly, we promulgated regulations at § 21 CFR part 1 subpart O (1.900-1.934), pertaining to the sanitary transportation of human and animal food. As discussed above, the regulations prescribe recordkeeping to document safety practices, procedures for the submission of waivers, and required disclosures to other operators engaged in the transport of food. 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 and foreign shippers and carriers of human and animal food (except fully packaged shelf-stable foods, live food animals and raw agricultural commodities (RACs) when RACs are transported by farms) except 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 will 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 USDA. To prevent duplication of effort, its 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

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 by providing 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 $25,500,000 in annual receipts, consistent with the size-based standard established by the U.S. Small Business Administration for truck transportation firms.

6. Consequences of Collecting the Information Less Frequently

Disclosure and recordkeeping occur on a regular basis while reporting occurs only occasionally. We believe this collection schedule imposes the minimum burden on respondents in fulfilling the requirements of the regulations.

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 20, 2019 (84 FR 5087). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No gift or payment is provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

This regulation does not specify confidentiality. However, records that may be reviewed during FDA inspections are subject to FDA regulations on the release of information in 21 CFR Part 20. Confidential commercial information is protected from disclosure under FOIA in accordance with section 552(a) and (b) (5 U.S.C. 552(a) and (b)) and by part 20. To the extent that § 20.64 applies, we will honor the confidentiality of any data in investigation records compiled for law enforcement purposes.

Privacy Act of 1974

This ICR does not request any personally identifiable information and does not include a form that requires a Privacy Act Statement.

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 Costs

12a. Annualized Hour Burden Estimate

The information collection includes recordkeeping, reporting, and third-party disclosure requirements as reflected in the tables below:

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

21 CFR section; activity	No. of recordkeepers	No. of records per recordkeeper	Total annual records	Avg. burden per recordkeeping	Total hours
1.912; Record retention	1,502,032	1	1,502,032	0.083 (5 mins.)	124,669

[1] There are no operations and maintenance costs associated with annual recordkeeping burden.

We estimate an annual recordkeeping burden of 124,669 hours. 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	Avg. burden per response	Total hours
1.914; Waiver petitions	2	1	2	24 hrs.	48

[1] There are no operations and maintenance costs associated with annual reporting burden.

We estimate one waiver petition from each of two firms will be submitted and each respondent 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	Number of disclosures per respondent	Total annual disclosures	Avg. burden per disclosure	Total hours
1.908; Sanitary specifications; operating temperature conditions	226	1	226	0.5833 (35 mins.)	131

[1] There are no operations and maintenance costs associated with annual third-party disclosure burden.

We estimate an annual third-party disclosure burden of 132 hours. We assume each of 226 firms will spend an average of 35 minutes, annually, disclosing written records as required under 21 CFR 1.908.

Total annual burden for this collection is estimated at 124,489 hours (124,669 recordkeeping hours, 48 reporting hours, and 132 third-party disclosure hours.)

12b. Annualized Cost Burden Estimate

We estimate that the burden of this information collection results in a total of 124,489 hours annually. The salary that a company will pay an employee to respond to the information collection is considered a cost burden. We estimate that three types of respondent employees will be responsible for information collection: cargo and freight agents; first-line supervisors of transportation and material-moving machine and vehicle operators; and, managerial or professional employees such as plant managers, food safety specialists, and in-house legal counsel. We base our estimate of the wage rates on the Bureau of Labor Statistics, Occupational Employment Statistics, May 2017, National Industry-Specific Occupational Employment and Wage Estimates1.

Table 4–Cost Burden Estimate Annual Costs			
Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Cargo and Freight Agent (97.5% total hours)	121,728	$30.51	$3,713,921.28
First-Line Supervisors of Transportation and Material-Moving Machine and Vehicle Operators (2.4% total hours)	2,996	$39.98	$119,780.08
Managerial or Professional Employees (0.1% total hours)	124	$94.40	$11,705.60
Total	124,848		$3,845,406.96

Therefore, total costs for this collection of information is $3,845,406.96.

[1] https://www.bls.gov/oes/2017/may/oessrci.htm.

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

The information collection reflects agency adjustments. Since last OMB review we have removed one-time burdens we previously attributed to implementation of the new regulations and realization of compliance dates. Because these milestones have been met, we have removed initial burden we ascribed to associated with activities. This results in an overall decrease to the information collection by 1,778,351 responses (from 3,280,611 to 1,502,260), by 250,416 burden hours (from 375,265 to 124,849), and by $83,708 in cost adjustments.

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.