

UNITED STATES FOOD & DRUG ADMINISTRATION

Foreign Supplier Verification Programs for  
Importers of Food for Humans and Animals

OMB Control No. 0910-0752

**SUPPORTING STATEMENT Part A: Justification:**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) regulations and associated guidance. Section 301 of the Food and Drug Administration Food Safety Modernization Act (FSMA) (Public Law 111-353) added section 805 to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384a) requiring persons who import food into the United States to perform risk-based foreign supplier verification activities for the purpose of verifying:

- (1) that food is produced in compliance with section 418 (concerning hazard analysis and risk-based preventive controls) or 419 (concerning standards for the safe production and harvesting of certain fruits and vegetables that are raw agricultural commodities (RACs)) of the FD&C Act (21 U.S.C. 350g and 350h), as appropriate;
- (2) the food is not adulterated under section 402 of the FD&C Act (21 U.S.C. 342); and
- (3) the food is not misbranded under section 403(w) of the FD&C Act (21 U.S.C. 343(w)) (concerning food allergen labeling).

Regulations in 21 CFR part 1; subpart L (*Foreign Supplier Verification Programs for Food Importers*) set forth requirements intended to implement risk-based preventive controls (PC) that provide the same level of public health protection as those required under sections 418 and 419 of the FD&C Act, and in compliance with sections 402 and 403(w) of the FD&C Act. The regulations also establish requirements FDA deems necessary and appropriate to verify that food imported into the United States is as safe as food produced and sold within the United States.

Accordingly, we are seeking to extend OMB approval for the information collection provisions found in 21 CFR part 1; subpart L (1.500-1.514) regarding FDA's FSVPs for food importers, and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The information collection requires that respondents establish and maintain records on FSVP activities, including the hazard controls set forth in the regulations. We believe adherence to the hazard control requirements will help ensure that importers safeguard food imported into the United States. The regulations also establish requirements pertaining to reporting to

Customs and Border Protection (CBP) (for subsequent transfer to FDA). Specifically, persons who wish to import food for research or evaluation purposes must submit a declaration that the food will be used for that purpose. Submission of these declarations enables us to effectively monitor whether the requirements for the FSVP exemption for food for research or evaluation are being met.

### 3. Use of Improved Information Technology and Burden Reduction

Although the recordkeeping requirements for FSVPs do not require the use of electronic recordkeeping, we encourage this approach. We expect that most of the importers will maintain their records in electronic format. Likewise, the reporting requirements to CBP specify that the information must be provided electronically. This is necessary to ensure the efficient collection of information by CBP and the subsequent transfer of the information to FDA for FSVP monitoring and enforcement purposes. Therefore, we estimate that 100% of respondents will use electronic means to satisfy the information collection provisions.

### 4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

### 5. Impact on Small Businesses or Other Small Entities

Most respondents are small businesses. To assist respondents with the FSVP requirements we have developed a small entity compliance guide available at: <https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM593089.pdf>.

We also provide a Small Business Guide on our website at: <http://www.fda.gov/ForIndustry/SmallBusinessAssistance/default.htm> along with draft guidance regarding FSVP implementation.

### 6. Consequences of Collecting the Information Less Frequently

The information collection includes recordkeeping undertaken at the discretion of respondents. Information may be reported or retained on a daily, weekly, monthly, or yearly basis depending on which types of documents are being transmitted and which regulations are applicable. Some information from respondents will be needed every time a food is imported into the United States while other information may not be needed every time. For example, a DUNS number will be provided to CBP with every entry line; shipments could occur regularly (e.g., on a weekly basis) between the same importer and foreign supplier, or they could happen once a year, or sporadically. As another example, audit results of a supplying facility could be transmitted to the importer once annually for a relationship between a specific supplier supplying the same product to the same importer over the course of the year. We believe that the reporting and record collection schedules provided for in the regulations are minimal and collecting the information less frequently would undermine our public protection mandate.

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

The reporting requirements concerning (1) declarations of food for research or evaluation (in §1.501(c)) and (2) identification of the importer when a food is offered for importation into the United States (in § 1.509(c)) must be made when filing entry for the food with CBP. Consequently, this reporting must occur as frequently as the food is offered for importation, which could be as often as multiple times in a single day. There are no other special circumstances relating to the information collection request.

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

In the Federal Register of October 22, 2018 (83 FR 53271) we published a 60 day notice in soliciting public comment on the proposed collection of information. No comments were received.

#### 9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for payment or gifts to respondents.

#### 10. Assurance of Confidentiality Provided to Respondents

The information collection does not specify confidentiality. However, records that may be reviewed during FDA inspections of food importers 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.

#### 11. Justification for Sensitive Questions

This information collection does not contain questions of a sensitive nature.

#### 12. Estimates of Annualized Burden Hours and Costs

##### *12a. Annualized Hour Burden Estimate*

Description of Respondents: Generally, respondents include all persons who import food into the United States. We estimate that there are approximately 56,800 respondents who meet the definition of importer as set forth in the regulations.

Table 1.—Estimated Annual Reporting Burden<sup>1</sup>

| 21 CFR Section                                                     | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Avg. Burden Per Response | Total Hours |
|--------------------------------------------------------------------|--------------------|---------------------------------|------------------------|--------------------------|-------------|
| Exemption for Food for research<br>1.501(c)                        | 36,360             | 40                              | 1,454,400              | 0.083<br>(5 mins.)       | 120,715     |
| DUNS number for filing with CBP<br>1.509(c), 1.511(c), 1.512(b)(2) | 56,800             | 157                             | 8,917,600              | 0.02<br>(1.2 mins.)      | 178,352     |
| Total                                                              |                    |                                 |                        |                          | 299,067     |

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

Table 2.—Estimated Annual Recordkeeping Burden

| IC Activity; 21 CFR Section                                                                                                 | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Avg. Burden per Recordkeeping | Total Hours |
|-----------------------------------------------------------------------------------------------------------------------------|----------------------|---------------------------------|----------------------|-------------------------------|-------------|
| Controls for LACF; 1.502(b)                                                                                                 | 2,443                | 4                               | 9,772                | 1                             | 9,772       |
| FSVP RECORDKEEPING <i>including hazard determination, written procedures, reevaluation; audits; and corrective actions:</i> |                      |                                 |                      |                               |             |
| Determine and document hazards; 1.504(a)                                                                                    | 11,701               | 1                               | 11,701               | 3.5                           | 40,954      |
| Review hazard analysis; 1.504(d)                                                                                            | 11,701               | 7                               | 81,907               | 0.33                          | 27,029      |
| Evaluation of food and foreign supplier; 1.505(a)(2), 1.511(c)(1)                                                           | 11,701               | 1                               | 11,701               | 4                             | 46,804      |
| Approval of suppliers; 1.505(b), 1.512(c)(1)(iii)                                                                           | 8,191                | 1                               | 8,191                | 12                            | 98,292      |
| Reevaluation of food and foreign supplier; 1.505(c), 1.512(c)(1)(ii)(A)                                                     | 11,701               | 365                             | 4,270,865            | 0.25                          | 1,067,716   |
| Confirm or change requirements of foreign supplier verification activity; 1.505(c), 1.512(c)(1)(ii)(A)                      | 2,340                | 1                               | 2,340                | 2                             | 4,680       |
| Review of other entities assessments; 1.505(d), 1.512(c)(1)(iii)                                                            | 3,510                | 1                               | 3,510                | 1.2                           | 4,212       |
| Written procedures for use of approved foreign suppliers; 1.506(a)(1), 1.511(c)(2), 1.512(c)(3)(i)                          | 11,701               | 1                               | 11,701               | 8                             | 93,608      |
| Review of written procedures; 1.506(a)(2), 1.511(c)(2)(ii), 1.512(c)(3)(ii)                                                 | 11,701               | 1                               | 11,701               | 1                             | 11,701      |

| IC Activity; 21 CFR Section                                                                                       | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Avg. Burden per Recordkeeping | Total Hours |
|-------------------------------------------------------------------------------------------------------------------|----------------------|---------------------------------|----------------------|-------------------------------|-------------|
| Written procedures for conducting verification activities; 1.506(b), 1.511(c)(3)                                  | 11,701               | 1                               | 11,701               | 2                             | 23,402      |
| Determination and documentation of appropriate supplier verification activities; 1.506(d)(1)-(2) 1.511(c)(5)(i)   | 11,701               | 4                               | 46,804               | 3.25                          | 152,113     |
| Review of appropriate supplier verification activities determined by another entity; 1.506(d)(3) 1.511(c)(5)(iii) | 11,701               | 2                               | 23,402               | 0.33                          | 7,723       |
| Conduct/review audits; 1.506(e)(1)(i), 1.511(c)(6)(i)(A)                                                          | 11,701               | 2                               | 23,402               | 3                             | 70,206      |
| Conduct periodic sampling/testing; 1.506(e)(1)(ii), 1.511(c)(6)(i)(B)                                             | 11,701               | 2                               | 23,402               | 1                             | 23,402      |
| Review records; 1.506(e)(1)(iii), 1.511(c)(6)(i)(C)                                                               | 11,701               | 2                               | 23,402               | 1.6                           | 37,443      |
| Document your review of supplier verification activity records; 1.506(e)(3), 1.511(c)(6)(iii)                     | 11,701               | 6                               | 70,206               | 0.25                          | 17,552      |
| 1.507(a)(1)                                                                                                       | 11,701               | 3.17                            | 37,082               | 1.25                          | 46,353      |
| Written assurances; 1.507(a)(2), 1.507(a)(3), and 1.507(a)(4)                                                     | 11,701               | 8.72                            | 102,038              | 0.50                          | 51,019      |
| Disclosures that accompany assurances; 1.507(a)(2), 1.507(a)(3), and 1.507(a)(4)                                  | 102,038              | 1                               | 102,038              | 0.50                          | 51,019      |
| Document assurances from customers; 1.507(c)                                                                      | 36,522               | 2.8                             | 102,262              | 0.25                          | 25,566      |
| Document corrective actions; 1.508(a) and 1.512(b)(4)                                                             | 2,340                | 1                               | 2,340                | 2                             | 4,680       |
| Investigate and determine FSVP adequacy; 1.508(b), 1.511(c)(1)                                                    | 2,340                | 1                               | 2,340                | 5                             | 11,700      |
| SUBTOTAL for FSVP RECORDKEEPING ITEMIZED ABOVE:                                                                   |                      |                                 | 4,984,036            |                               | 1,917,174   |
| Written assurances for food produced under dietary supplement CGMPs; 1.511(b)                                     | 11,701               | 2.88                            | 33,664               | 2.25                          | 75,744      |
| Document very small                                                                                               | 50,450               | 1                               | 50,450               | 1                             | 50,450      |

| IC Activity; 21 CFR Section                                                                       | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Avg. Burden per Recordkeeping | Total Hours |
|---------------------------------------------------------------------------------------------------|----------------------|---------------------------------|----------------------|-------------------------------|-------------|
| importer/certain small foreign supplier status; 1.512(b)(1)                                       |                      |                                 |                      |                               |             |
| Written assurances associated with very small importer/certain small foreign supplier 1.512(b)(3) | 50,450               | 2.8                             | 141,084              | 2.25                          | 317,439     |
| TOTAL                                                                                             |                      |                                 |                      |                               | 2,370,579   |

### 12b. Annualized Cost Burden Estimate

We estimate that records will be kept by the employee performing the corresponding activity. In most cases, this employee will be, or will be similar to, a production manager in the food manufacturing industry. The mean wage for Standard Occupations Classification (SOC) 11-3051 Production Managers in North American Industry Classification System (NAICS) code 311000 Food Manufacturing in 2010 was \$40.96. (Bureau of Labor Statistics, Occupational Employment Statistics, May 2010, National Industry-Specific Occupational Employment and Wage Estimates for NAICS 31100 - Food Manufacturing, [http://bls.gov/oes/current/naics3\\_311000.htm](http://bls.gov/oes/current/naics3_311000.htm). ) We increased this wage by 50 percent to \$61.44 to account for overhead. The overall estimated cost incurred by the respondents, therefore is \$164,023,050 (2,669,646 burden hours x \$61.44/hr).

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

| Table 3- Estimated Annual Operating and Maintenance Costs                     |                                 |
|-------------------------------------------------------------------------------|---------------------------------|
| 21 CFR Part 1                                                                 | Operating and Maintenance Costs |
| Conduct/Review audits; 1.506(g)(1)(i), 1.506(h), 1.511(c)(5)(i)               | \$3,085,000                     |
| Conduct periodic sampling/testing; 1.506(g)(1)(ii), 1.506(h), 1.511(c)(5)(ii) | \$158,240,430                   |
| Investigate adulteration or misbranding; 1.507(b), 1.511(c)(1)                | \$6,661,250                     |
| Total Annual Costs                                                            | \$167,986,680                   |

### 14. Annualized Cost to the Federal Government

We estimate a “*per-inspection*” cost for the review of records of \$269.25 per review (\$53.85/hour x 5 hours). We assume an average of 500 inspections per year. Thus, our estimated annual cost to the Federal Government for reviewing records during inspections would be \$134,625 (\$269.25 x 500 inspections).

15. Explanation for Program Changes or Adjustments

The estimated burden for the information collection remains unchanged. However, we have removed costs previously attributed to reviewing and implementing newly established requirements, which we believe to have been realized by respondents.

16. Plans for Tabulation and Publication and Project Time Schedule

We are considering using the information that importers would provide to CBP in accordance with proposed § 1.509(c) to help us meet the requirement, stated in section 805(g) of the FD&C Act, to “*publish and maintain on [our] Internet Web site . . . a current list that includes the name and location of, and other important information deemed necessary by [FDA] about, importers participating under this section [i.e., section 805].*” The meaning of the phrase “*importers participating under this section*” is ambiguous. Among other things, it could mean the list must include all importers subject to section 805 or only those subject to section 805 and in compliance with that provision. If so, FDA needs a way to know the identity of these importers. One way to gather this information would be to obtain from CBP the importer information provided in accordance with proposed § 1.509(c).

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

Display of the OMB expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.