United States Food and Drug Administration
Current Good Manufacturing Practice, Hazard Analysis,
and Risk-Based Preventive Controls For Human Food

OMB Control No. 0910-0751

SUPPORTING STATEMENT **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

On January 4, 2011, the Food Safety Modernization Act (FSMA) (Public Law 111–353) was signed into law. The legislation enables the Food and Drug Administration (FDA, us or we) to better protect the public health by helping to ensure the safety and security of the food supply. FSMA amends the Federal Food, Drug, and Cosmetic Act to establish a modernized, prevention-based food safety system. Specifically, section 103 of FSMA amends the Federal Food, Drug, and Cosmetic Act (FD&C Act, the act) to create new section 418. Section 418(a) requires the owner, operator, or agent in charge of a facility to evaluate hazards that could affect food manufactured, processed, packed, or held by the facility; identify and implement preventive controls; monitor the performance of those controls; and maintain records demonstrating compliance. Sections 418(b)-(i) contain more specific requirements applicable to facilities, including corrective actions (§ 418(e)), verification (§ 418(f)), a written plan and documentation (§ 418(h)), and reanalysis of hazards (§ 418(i)). Finally, section 103(e) of FSMA creates a new section 301(uu) in the FD&C Act (21 U.S.C. 331(uu)) to prohibit "[t]he operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418 [of the FD&C Act]." FDA has promulgated regulations to implement the provisions of FSMA, which are codified at 21 CFR part 117.

Accordingly, we are requesting OMB approval of the information collection provisions found in 21 CFR part 117 and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

Respondents to the information collection are owners, operators, or agents-in-charge of food facilities required to register under section 415 of the FD&C Act. There are approximately 83,819 such facilities. Information collected will assist FDA in determining facility compliance with current good manufacturing practice requirements and in ensuring that food safety systems include hazard analysis and risk-based preventive controls. Records will be examined during food facility inspections and in the event of an outbreak or other food safety incident involving the food manufactured at the facility. Certain "qualified" facilities are subject to modified requirements. Qualified facilities must report their status as such a facility and are thus subject to the reporting requirements identified in the regulations.

3. Use of Improved Information Technology and Burden Reduction

Reporting requirements solicit what we believe is the minimal information necessary. At this time the information may be submitted to FDA either electronically or by mail, however we encourage electronic submissions. We have developed Form FDA 3942a (approved under OMB Control No. 0910-0854) to facilitate the reporting process. We expect the recordkeeping requirements will utilize an electronic format determined to be most appropriate by respondents. Under the regulations, records must be available upon FDA request during inspection or to review a food safety incident.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. Facilities may already maintain much of the information now required. As FDA has been Congressionally mandated to implement FSMA provisions, we believe that duplication of the information collection from another source is unlikely. Similar requirements apply to animal foods for which the associated information collection is covered under OMB Control No. 0910-0789.

5. Impact on Small Businesses or Other Small Entities

FDA has made an effort to minimize any impact the regulations have on small businesses. We provided for extended and staggered compliance dates for respondents qualifying as small businesses and believe this will benefit smaller businesses and lower compliance costs. Additionally, we have developed small entity compliance guides to assist facilities in meeting the regulatory requirements.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements. If corrective actions are necessary, further monitoring will be conducted. Data can be collected hourly, daily, weekly, or yearly as determined by the hazards encountered in a particular manufacturing process. FDA believes that the information collection schedules represent the least amount of burden necessary to ensure the effectiveness of the regulations and ensure food safety.

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

There are no special circumstances for 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 June 1, 2018 (83 FR 25466). One comment was received stating that our estimate of burden associated with creating a food safety plan was too low and suggested a much higher figure. We are appreciative of this comment. However, because the annual burden is

based on an industry average and included nearly 50,000 estimated respondent; and because we continue to evaluate this relatively new collection, we have retained our estimate. At the same time, we continue to invite comment so that we might better refine our estimates for all elements of the collection.

9. Explanation of Any Payment or Gift to Respondents

There are no payments or gifts to respondents associated with this collection of information.

10. Assurance of Confidentiality Provided to Respondents

There is no assurance of confidentiality associated with this collection of information.

11. Justification for Sensitive Questions

This collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

*12a. Annualized Hour Burden Estimate*

We estimate the burden of the information collection below.

*Reporting*

Table 1 – Estimated Annual Reporting Burden[1]

| 21 CFR Section | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
|---|---|---|---|---|---|
| 117.201(e); qualified facility | 37,134 | 0.5 | 18,567 | 0.5 | 9,284 |

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

Qualified facilities must report their status as such a facility every 2 years; status will likely be reported electronically through a web portal maintained by FDA. We estimate that approximately 37,134 qualified facilities will spend 0.5 hours every 2 years reporting to FDA their status as a qualified facility, for a total annual burden of 9,284 hours (37,134 facilities x 0.5 responses annually x 0.5 hours per response).

*Recordkeeping*

Table 2 – Estimated Annual Recordkeeping Burden[1]

| 21 CFR Part 1; Subpart 117 | No. of Recordkeepers | No. of Records Per Recordkeeper | Total Annual Records | Avg. Burden per Recordkeeping | Total Hours |
|---|---|---|---|---|---|
| 117.126(c) and 117.170(d); food safety plan and reanalysis | 46,685 | 1 | 46,685 | 110 | 5,135,350 |
| 117.136; assurance records | 16,285 | 1 | 16,285 | 0.25 | 4,071 |
| 117.145(c); monitoring records | 8,143 | 730 | 5,944,390 | 0.05 | 297,220 |
| 117.150(d); corrective actions and corrections records | 16,285 | 2 | 32,570 | 1 | 32,570 |
| 117.155(b); verification records | 8,143 | 244 | 1,986,892 | 0.05 | 99,345 |
| 117.160; validation records | 3,677 | 6 | 22,062 | 0.25 | 5,515 |
| 117.475(c)(7)-(c)(9); supplier records | 16,285 | 10 | 162,850 | 4 | 651,400 |
| 117.180(d); training records for preventive controls qualified individual | 46,685 | 1 | 46,685 | 0.25 | 11,671 |
| TOTAL | | | | | 6,237,142 |

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

We estimate approximately 46,685 facilities will need to create a food safety plan, which is a compilation of many written food safety procedures. We further estimate that creation of the food safety plan will require 110 hours, averaged among facilities. Multiplying these figures (46,685 facilities x 110 hours) provides our estimate of 5,135,350 hours.

We estimate the burden associated with assurance records to be approximately 4,071 hours, allotting 15 minutes per record averaged over an estimated 16,285 establishments.

We believe the burden associated with keeping monitoring records is 297,220 hours. This figure was reached by estimating that approximately 8,143 facilities will need to keep additional records of the monitoring that they do of different activities within their food facilities. We then estimate that this will result in an average of 730 records per recordkeeper; and that it will take 3 minutes (0.05 hours) per record for the activity.

We estimate the recordkeeping burden associated with corrective action records is 32,570 hours. This estimate was reached by calculating that 2 times per year 16,285 facilities will have corrective actions to document and that this activity will take one hour per record.

We estimate that recordkeeping burden associated with verification records is 99,345 hours. This figure was calculated by estimating that 8,143 will need to keep the requisite verification records; averaging 244 records per recordkeeper; and then for 3 allotting minutes (0.05 hours) per record.

We estimate the recordkeeping burden associated with validation records to be 5,515 hours. This figure was calculated by estimating that 3,677 facilities will keep records of six validation activities for an average of 22,062 records per recordkeeper, and then factoring 15 minutes (0.25 hours) per record.

We estimate the recordkeeping burden associated with supplier records to be 651,400 hours. This figure was calculated by estimating that approximately 16,285 establishments will maintain an average of 10 applicable records and that the total time for this activity will be about 4 hours per record.

We estimate the recordkeeping burden associated with training for the preventive controls qualified individual to be 11,671. This figure is based on approximately 46,685 establishments needing to document the training of their preventive controls qualified individuals, and by allotting 15 minutes (0.25 hours) for the activity.

Finally, under § 117.206(a)(5) facilities are required to keep records documenting (1) the monitoring of temperature controls for refrigerated packaged food, (2) the corrective actions taken when there is a problem with the control of temperature for refrigerated packaged food, and (3) the verification activities relating to the temperature control of refrigerated packaged food; however, we believe that the keeping of such records is already common industry practice and therefore we have not estimated a burden for this activity.

*Third-Party Disclosure*

Table 3 – Estimated Annual Third-Party Disclosure Burden

| 21 CFR Section | No. of Respondents | No. of Disclosures per Respondent | Total Annual Disclosures | Avg. Burden per Disclosure | Total Hours |
|---|---|---|---|---|---|
| 117.201(e); disclosure of food manufacturing facility address | 37,134 | 1 | 37,134 | 0.25 | 9,284 |

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

Under § 117.201(e) qualified facilities must include the address of the facility where the food is manufactured in their label. We estimate the hour burden of this disclosure is 15 minutes per disclosure. This requirement will cause the 37,134 qualified facilities to spend 0.25 hours adding their address to their new labels for a total hour burden of about 9,284 hours (37,134 facilities x 0.25 hours per response).

*12b. Annualized Cost Burden Estimate*

We measure costs based on the best available information from government, industry, and academic sources.

| Annualized Cost Burden Estimate | | | |
|---|---|---|---|
| **Type of Respondent** | **Total Burden Hours** | **Hourly Wage Rate** | **Total Respondent Costs** |
| Qualified Individual | 5,135,350 | $56.00 | $287,579,600 |
| Industrial Production Manager | 1,101,792 | $47.78 | $52,643,622 |
| Food Manufacturing Production Worker | 18,568 | $19.91 | $369,689 |
| Total | | | $340,592,911 |

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

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

14. Annualized Cost to the Federal Government

These activities will be covered by existing resource allocations. Therefore, we are estimating zero cost to the Federal government.

15. Explanation for Program Changes or Adjustments

Our estimated burden for the information collection remains unchanged. Compliance dates continue to be realized.

16. Plans for Tabulation and Publication and Project Time Schedule

Information will not be published for statistical use.

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

We are not seeking approval not to display the expiration date of OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.