FDA Recall Regulations
OMB Control Number 0910-0249
SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 701 of the Federal Food, Drug, and Cosmetic Act, and 21 CFR Part 7, Subpart C, set forth the recall regulations (guidelines) and provide guidance to manufacturers on recall responsibilities. The guidelines apply to all regulated products (i.e., food, including animal feed; drugs, including animal drugs; medical devices, including in vitro diagnostic products; cosmetics; biological products intended for human use; and tobacco).

The Food and Drug Administration (FDA) is requesting approval from the Office of Management and Budget for the information collection requirements contained in:

21 CFR 7.46 - Firm Initiated Recall – Reporting

Requests firms that voluntarily remove or correct foods and drugs (animal or human), cosmetics, medical devices, biologics, and tobacco to immediately notify the appropriate FDA district office of such actions. The firm is to provide complete details of the recall reason, risk evaluation, quantity produced, distribution information, firms' recall strategy and a contact official.

21 CFR 7.49 - Recall Communications – Third Party Disclosure

Requests firms to notify their direct accounts of the recall and to provide recipients with a ready means of reporting to the recalling firm.

21 CFR 7.53 - Recall Status Reports - Reporting

Requests that recalling firms provide periodic status reports so the FDA can assess the progress of the recall.

21 CFR 7.55(b) - Termination of a Recall - Reporting

Provides an opportunity for a firm to request in writing that FDA terminate the recall.

21 CFR 7.59 – General Industry Guidance – Reporting

Prepare and maintain a current written contingency plan for use in initiating and effecting a recall in accordance with 7.40 through 7.49, 7.53, and 7.55.

21 CFR 7.59 – General Industry Guidance – Recordkeeping

Maintain product distribution records as are necessary to facilitate location of products that are being recalled.

2. Purpose and Use of the Information Collection

The agency recognizes that situations may arise involving health risks presented by unsafe products. The recall provisions of 21 CFR Part 7, Subpart C provide the information necessary for FDA to monitor recalls and assess the adequacy of a firm's efforts in a recall. It also permits FDA to evaluate whether a recall has been completed in a manner which assures that unreasonable risk of substantial harm to the public health has been eliminated and that violative products have been corrected or removed from the market.

3. Use of Improved Information Technology and Burden Reduction

FDA is continuously seeking ways to reduce the reporting burden through advances in information technology. Firms have the option, and are encouraged, to provide required information for recalls via email to the Recall Coordinators at FDA. It is estimated that approximately 95% of recall submissions will be provided electronically via email.

4. Efforts to Identify Duplication and Use of Similar Information

The recall regulation imposes a burden that is not duplicative in its entirety of any comparable requirement imposed by government or industry, to FDA's knowledge. Some similar information is available to FDA, for example in the mandatory reporting requirement in 21 CFR Part 806 for reports of corrections and removals of medical devices and Section 417 of the Act for reportable food registry. However, the recall regulation requests additional information from recalling firms such as status reports and requests for recall terminations.

5. Impact on Small Businesses or Other Small Entities

The requirements will not fall disproportionately on small business. It is not possible to provide an exemption for small business or to reduce the requirements for small business without seriously compromising the public health. However, FDA does assist small business through the Office of Small Manufacturers Assistance.

6. Consequences of Collecting the Information Less Frequently

Most of the information collected for recalls is a one time collection, with the exception of recall status reports. 21 CFR 7.53 states that the recalling firm is requested to submit periodic recall status reports so that the agency may assess the progress of the recall. The frequency of such reports will be determined by the relative urgency of the recall and will be specified by FDA in each recall case; generally the reporting interval will be between two and four weeks.

The impact of not collecting the information or requesting the reports and notification in those instances where FDA has determined that recall should be conducted could seriously compromise the public health.

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), on November 17, 2017, (82 FR 54359) FDA published in the Federal Register a 60-day notice soliciting public comment. FDA received one comment that did not suggest any changes to the information collection burden estimates.

9. Explanation of Any Payment or Gift to Respondents

   No payment or gift was provided.

10. Assurance of Confidentiality Provided to Respondents

    No sensitive information is sought under this information collection. Some confidential commercial information may be reported to FDA but FDA's public information regulations (21 CFR Part 20) will govern the release of data.

11. Justification for Sensitive Questions

    Questions of a sensitive nature are not applicable to this information collection.

12. Estimates of Annualized Burden Hours and Costs

    12 a. Annualized Hour Burden Estimate

    A search of the FDA database was performed to determine the number of recalls that took place during fiscal years 2014 to 2016. The resulting number of total recalls and terminations (8,560) from this database search were then averaged over the three years, and the resulting per year average of recalls and terminations (2,853) are used in estimating the current annual reporting and third party disclosure burden in this document.

    The following is a summary of the estimated annual burden hours for recalling firms (manufacturers, processors, and distributors) to comply with the reporting requirements of FDA's recall regulations recognizing that there may be a vast difference in the information collection and reporting time involved in different recalls of FDA's regulated products

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

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

21 CFR Section	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Firm initiated recall (§ 7.46) and recall communications (§ 7.49)	2,853	1	2,853	25	71,325
Recall status reports (§ 7.53)	2,853	13	37,089	10	370,890
Termination of a recall (§ 7.55(b))	2,853	1	2,853	10	28,530
General industry guidance (§ 7.59)	2,853	1	2,853	15	42,795
Total					513,540

Table 2--Estimated Annual Third-Party Disclosure Burden[1]

21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Recall communications (§ 7.49)	2,853	518	1,477,854	2.88 minutes	70,937

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

FDA estimates the recordkeeping found at 21 CFR 7.59 to be zero as this recordkeeping is usual and customary to these respondents.

12b. Annualized Cost Burden Estimate

FDA regulates many different types of products including, but not limited to, medical products, food and feed, cosmetics, and tobacco products. Further, FDA notes that not all recall events reported to the Agency are similar in nature and may entail different information and volume of information on a case-by-case basis. Therefore, the FDA has no information which would allow it to make any meaningful estimate of the cost to FDA regulated industry to conduct recalls.

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

There is one program support FTE for each operational FTE for a total of 102 FTEs (51 operational FTEs + 51 program support FTEs = 102 total FTEs). Every year FDA calculates the full-loaded cost of a FTE. This cost includes salary, benefits, travel, training, IT support, overhead, rent and supplies. In FY 2018 the fully-loaded FTE cost was $267,783 per FTE, resulting in a total anticipated annualized cost to FDA of $27,313,886 to fund the 102 FTEs in this program.

15. Explanation for Program Changes or Adjustments

The adjustment in burden is due to the decreased number of respondents from 3,801 to 2,853 (-948). When applied to each IC the decrease in the number of respondents affects the annual number of responses, decreasing it by 224,958. In addition, FDA discovered that 21 CFR 7.59 (general industry guidance) contained information collection that was not previously approved and, therefore, added it to this ICR for extension of OMB approval. With the addition of this IC 42,795 hours were added to the total estimated number of burden hours requested. Despite this addition, the decrease in the number of respondents reduced the total estimated hourly burden by 137,409 hours. (104,229 Program Change Due to Agency Discretion + 1,896 Change Due to Adjustment in Agency Estimate = 137,409.)

16. Plans for Tabulation and Publication and Project Time Schedule

The reporting requirements contained in this proposal will not be published, tabulated or manipulated

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

We are not seeking approval to exempt display of the OMB approval date on any documents that are associated with this information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.