FDA Recall Regulations

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 (OMB) 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 – 3rd 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.

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 the 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

The 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 the Food and Drug Administration in each recall case; generally the reporting interval will be between 2 and 4 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), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of 8/4/2014 (79 FR 45197). No comments were received.

FDA regulates a wide variety of industry and product types. In November 2003, FDA issued guidance for industry on product recalls which included recommendations for the types of records and information industry should submit to the Agency for their recall actions. Since the issuance of the guidance, recall procedures have not altered and although the number and types of recall actions have been increasing and may be contributing to the volume and frequency of reporting, the types of recall information recommended for submission has not changed. Therefore, FDA believes that outside consultation with industry on the information collection request was not necessary.

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 guideline. 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 2011 - 2013. The resulting number of total recalls 11,403 from this database search were then averaged over the three years, and the resulting per year average of recalls (11,403 divided by 3 years equals 3,801 is used in estimating the current annual reporting burden for this report).

Additionally, a search of the FDA database was performed to determine the number of consignees during the fiscal years 2011-2013. The resulting number of total respondents (disclosures) (1,691,445) was then averaged over the three years, (total number of annual respondents (disclosures) divided by the number of respondents (3801). The resulting number of disclosures per respondent is (445) which is referenced on Table 2 and is used in estimating the current annual 3rd party disclosure burden for this report.

The following is a summary of the estimated annual burden hours for recalling firms (manufacturers, processors, and distributors) to comply with the voluntary 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

21 CFR Part	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Firm Initiated recall - 21 CFR 7.46	3,801	1	3,801	25	95,025
Recall Status Reports - 21 CFR 7.53	3,801	13	49, 413	10	494,130
Termination of a Recall - 21 CFR 7.55(b)	3,801	1	3,801	10	38,010
Total					627,165

Table 2.--Estimated Annual Third-Party Disclosure Burden

21 CFR Part	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Recall Communications - 21 CFR 7.49	3801	445	1,691,445	Approx. 0.056 hrs	94,721

The annual reporting burdens are explained as follows:

I. Total Annual Reporting

A. *Firm Initiated Recall*

Request firms voluntarily remove or correct foods and drugs (human or animal), 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. Under these portions of the collection of information, the agency estimates it will receive 3801 responses annually based on the average number of recalls over the last three fiscal years.

B. *Recall Status Reports*

Request that recalling firms provide periodic status reports so the FDA can ascertain the progress of the recall. This request only applies to firms with active recalls, and is estimated to be reported every 2-4 weeks. This collection of information will generate approximately 494,130 responses annually, based on the average number of recalls over the last three fiscal years (3,801), multiplied by the conservative frequency of reporting per year (13).

C. *Termination of a Recall*

Provide the firms an opportunity to request in writing that FDA end the recall. The agency estimates it will receive 3,801 responses annually based on the average number of recalls over the past three fiscal years.

II. 3rd Party Disclosure

A. Recall Communications

Request firms to notify their consignees of the recall and to provide recipients with a ready means of reporting to the recalling firm. Under this portion of the collection of information, the agency estimates firms will provide 1,691,445 notifications annually based on the number of respondents/consignees 3,801 multiplied by the number of disclosures per respondent 445 equal 1,691,445. The total number of hours 94,721 (based on 1,691,445 multiplied by .056 hours).

III. Hours Per Response Estimates

FDA regulates many different types of products including, but not limited to, medical products, food and feed, cosmetics, and tobacco products. From FY2011 – FY2013, FDA classified approximately 11,403 recalls of FDA-regulated 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, FDA could not calculate or determine an estimate for the average burden per response for a particular or specific product type or area and has based its estimates for all industries that it regulates. Variables in the type of products, the quantity and level of distribution and the various circumstances of recall notifications could cause the hours per response to vary significantly. The best guesstimate of average burden hours per response from previous information collection request reports are utilized again for the current estimates on burden hours per response.

IV. Hours Per 3rd Party Disclosure Estimates

FDA regulates many different types of products including, but not limited to, medical products, food and feed, cosmetics, and tobacco products. FDA notes that not all 3rd Party Disclosure provided by firms to their consignees are similar in nature and may entail different methods and mediums of communication. FDA estimates the burden for 3rd Party Disclosure per recall event to be an average of 25 hours. This burden estimate factored out to the average number of consignees per recall (445) results in a burden per disclosure estimate of approximate hrs (25 hours per recall/445 disclosures/recall = 0.056hr).

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

A search of the FDA database was performed to determine the average number of recalls, and hours spent on recalls during fiscal years 2011 – 2013. The data showed that FDA classified an average of 3,801 industry actions per year as recalls. Each of the 3,801 situations underwent a review process to determine if it met the recall definition, whether a hazard to health existed, to what level the recall should extend, what classification was appropriate, and the level of FDA recall audit checks necessary to assure consumer protection. The 3,801 recalls, resulted in an average of 95,025 total hours spent conducting recall checks, and coordinating recall efforts per 21 CFR 7.46 and 7.49.

There are 2 program FTEs for each operational FTE for a total of 102 program FTEs (2:1 ratio of Program FTEs to Operational FTEs x 51 Operational FTEs = 102 Program FTEs). The GS-14 projected annual salary + benefits (averaged over next three years FY ’14 – FY’16) is $116,500 per FTE, resulting in a total anticipated annualized cost to FDA of $11,883,000 (102 Program FTEs x $116,500 annual salary + benefits = 11,883,000).

15. Explanation for Program Changes or Adjustments

There were several adjustments necessary for this information collection period. The first adjustment was FDA re-estimated the burden by conducting a search of the FDA database.

There was an increase in 21 CFR 7.46, Firm Initiated Recalls and 21 CFR 7.49, Recall Communications by 700 (number of respondents) and an increase of 36,030 hours. The total estimated annual reporting burden has increased by 349,102 (from 278,063 to 627,165) total hours (see Table 1). This search was performed in order to update the data set used to estimate the number of respondents per year for FDA Recalls. Due to the variability in frequency that voluntary recalls occur from industry, FDA has taken the three year average of the number of recalls which took place during fiscal years 2011 – 2013 and applied that result to estimate the annual number of respondents.

The second adjustment necessary for this information collection renewal is the average number of termination requests received per year was adjusted to be equal to the number of recalls per year. The third adjustment is the Recall Strategy (21 CFR 7.42) is no longer included in the table since there is no reporting recommendation or requirement in this regulation. The reporting recommendation for Recall Strategy is contained in 21 CFR 7.46. Hence, the average burden for responses previously reported under 7.42 has now been added to the average burden for response for 7.46.

The fourth adjustment is the reference Section C.II.IV - Hours per 3rd Party Disclosure Estimates -FDA estimates the burden for 3rd Party Disclosure per recall event to be an average of 25 hours. This burden estimate factored out to the average number of consignees per recall (445) results in a burden per disclosure estimate of approx. hrs (25 hrs per recall/445 disclosures/recall = 0.056hr) versus previous reporting .0282485 hours per average burden per disclosure.

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.