FDA Recall Regulations

0910-0249
SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 701 of the Federal Food, Drug, and Cosmetic Act (Attachment A), and 21 CFR Part 7, Subpart C (Attachment B), 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; and biological products intended for human use).

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 7.42 - Recall Strategy - Reporting
Requests firms to develop a recall strategy including provisions for public warnings and effectiveness checks.

21 CFR 7.46 - Firm Initiated Recall - Reporting
Requests firms that voluntarily remove or correct foods and drugs (animal or human), cosmetics, medical devices, biologicals, 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
Requires 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 access 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.

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.

   FDA also utilizes the Recall Enterprise System (RES) which is an electronic data system used by FDA recall personnel to submit, update, classify, and terminate recalls. The RES increases efficiency in processing recall information by:

   - Allowing field coordinators to input recall information via an on-line, Intranet system;
   - Combining five separate documents for a recall event into a single system, allowing users to build a record of the entire recall by entering information as it becomes available thus reducing preparation time and providing consistency throughout the agency;
   - Reducing duplication of efforts between the Field Offices, OE, the centers, and Offices of Public Affairs;
   - Increasing communication of recall information between the field, headquarters, and the appropriate center(s) offices;
   - Providing a central, searchable database to more efficiently track information and generate and disseminate reports of recall activities
   - Using a uniform Health Hazard Evaluation (HHE) form or a form equivalent to the HHE form to promote consistency in evaluating potential health hazards and/or risks agency-wide while supporting wider use of electronic precedent health hazard assessment files to expedite recall classifications; and,
   - Providing the public with "real-time" information about the FDA recall process
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4. Efforts to Identify Duplication and Use of Similar Information

   The recall regulation imposes a burden that is not duplicative of any comparable requirement imposed by government or industry, to FDA's knowledge. Similar information is not available to FDA.

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 requiring 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

8a. Publication in the FEDERAL REGISTER
In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of 06/29/2011 (76 FR 38184). One comment was received which was PRA related.

Please see the one comment responded to below, FDA separated the comment to address each point.

(Comment) One comment noted that FDA Average Burden Per Response (ABPR) are low. The commenter estimates are double the estimates provided by FDA.

(Response) FDA regulates many different types of products including, but not limited to, medical products, food and feed, cosmetics, and tobacco products. From FY2008 – FY2010, FDA classified approximately 9,303 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.

(Comment) One comment questioned the validity of the methodology and assumption used by FDA citing that data ranges are not given. The comment encouraged FDA to provide data ranges for industry to assess better the accuracy of the Agency's estimates.

(Response) As stated in the prior response, FDA regulates many different types of products including, but not limited to, medical products, food and feed, cosmetics, and tobacco products. From FY2008 – FY2010, FDA classified approximately 9,303 recalls of FDA-regulated products. Further, FDA notes that not all recall events reported to the Agency are similar in nature where complexity and size of the recall can dictate the amount of recall information and data to be submitted. Therefore, FDA could not provide ranges of the burden for data collection for industry and based its estimates across the entire scope of recalls of FDA-regulated products.

(Comment) One comment suggests that the Agency develop an electronic tool for recall reporting or "eRecall" tool, and ask that industry be able to provide input to any developer of user requirements for such a tool before implementations.

(Response) FDA will consider the suggestion of an electronic recall tool for reporting. However, because of the many types of industries that FDA regulates, such a tool may not be able to accommodate the variety of information specific to many of these industries,

(Comment) One comment suggests that recall requirements should apply only to finished goods that are consumable and that FDA's entire recall program, not just information collection, be reviewed to determine if the program serves the purpose originally intended to protect consumers.

(Response) FDA disagrees with the comment. FDA believes that violative products in the marketplace should be recalled from consignees and customers who received them even if they are not finished goods that are consumables. For example, a recall of a violative product which is used for further manufacture and that poses a health risk would also serve as notification to consignees and customers to remove the recalled product from further use or distribution, including providing instructions for additional recall of products that may have been manufactured using the recalled products.

8b. Outside Consultation

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, and terminations that took place during fiscal years 2008 - 2010. The resulting number of total recalls (9303) and terminations (2858) from this database search were then averaged over the three years, and the resulting per year average of recalls (3101) and terminations (953) are 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 2008-2010. The resulting number of total consignees (8,230,533) was then averaged over the three years, and then further averaged over the average number of recalls per year (3101). The resulting per firm average number of consignees (885) is used in estimating the current annual 3rd party disclosure burden for this report. FDA estimates the total annual industry burden to collect and provide the above information to be 443,820 burden hours.

As part of its monitoring activities, FDA utilizes status reports for assessing firms' recall efforts and 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. The majority change for the frequency per response is due to the increased number of Class I and Class II recalls from FY05-FY07 to FY08-FY10. For example, from FY05-FY07, FDA classified 559 Class I and 5401 Class II recall actions by industry. Comparatively, FDA classified 1304 Class I and 6405 Class II recall actions from FY08-FY10. Class I recalls are those where there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death. Class II recalls are those where use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. Because of the significant health risks Class I and Class II recalls pose to the public, FDA monitors these actions closely to ensure that they are progressing satisfactorily. Status reports provide for current information to FDA regarding the status of industry recalls and serves as an important tool for the agency in its oversight activities.

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
Recall Strategy 21 CFR 7.42	3,101	1	3,101	20	62,020
Firm Initiated recall 21 CFR 7.46	3,101	1	3,101	5	15,505
Recall Status reports and Follow-up 21 CFR 7.53	2,148	13	27,924	10	279,240
Termination of a Recall 21 CFR 7.55(b)	953	1	953	10	9,530

Total					366,295

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	3,101	885	2,744,385	Approx 0.0282485 hrs	77,525
Total					77,525

The annual reporting burdens are explained as follows:

I. Total Annual Reporting

A. *Recall Strategy*

Request firms develop a recall strategy including provision for public warnings and effectiveness checks. Under this portion of the collection of information, the agency estimates it will receive 3,101 responses annually based on the average number of recalls over the last three fiscal years.

B. *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 3,101 responses annually based on the average number of recalls over the last three fiscal years.

C. *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 27,924 responses annually, based on the average number of recalls over the last three fiscal years (3101), less the average number of terminations over the last three fiscal years (953), multiplied by the conservative frequency of reporting per year (13).

E. *Termination of a Recall*

Provide the firms an opportunity to request in writing that FDA end the recall. The agency estimates it will receive 953 responses annually based on the average number of terminations 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 2,744,385 notifications annually based on the average number of consignees per recall per year over the last three fiscal years.

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 FY2008 – FY2010, FDA classified approximately 9,303 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 25 hours. This burden estimate factored out to the average number of consignees per recall (885) results in a burden per disclosure estimate of approx 0.0282485 hrs (25 hrs per recall/885 disclosures per recall = 0.0282485hr).

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. Variables in the type of products, the quantity and level

of distribution and the various circumstances of recall notifications could cause a recall to vary in cost from less that $1,000.00 to more than $1,000,000.00

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 2008 – 2010. The data showed that FDA classified an average of 3,101 industry actions per year as recalls. Each of the 3,101 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. These averages have been used to calculate the anticipated annualized costs for FDA to review, classify, audit, and monitor recall actions over the next three fiscal years. The resulting anticipated annualized cost is $11,883,000/year for the next three fiscal years.

FDA's anticipated costs have increased from $8,119,200 in previous years to $11,849,791/year over the next three fiscal years due to an increase in the number of audit checks accomplished by investigators, increase in recall coordination hours, and increase in program support resulting from the increased average number of recalls; and also due to an estimated increase in salary and benefit costs.
The 3,101 recalls, resulted in an average of 58,995 hours spent conducting recall audit checks, and coordinating recall efforts. The projected investigator conversion factor (CF) is 1,160 resulting in a total of 50 operational FTEs (58,995 Avg. Total Hours/CF of 1,160 = 50.86 or 51 Operational FTEs). 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 projected annual salary + benefits (averaged over next three years FY '11 – FY'14) 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
FDA re-estimated the burden by conducting a search of the FDA database. The burden has increased by 227,220 hours and the annual responses have increased by 19,917. 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 and terminations which took place during fiscal years 2008 – 2010, and applied that result to estimate the annual number of respondents.

Two adjustments were necessary for this information collection renewal. First, Recall Communications (21 CFR 7.49) is no longer considered a part of Firm Initiated Recall (21 CFR 7.46) reporting to FDA. Rather, it is now identified as 3rd Party Disclosure. However, the establishment of Recall Communications as 3rd Party Disclosure did not in itself result in

any change in total burden for this renewal. The burden for Recall Communications simply shifted from being a component of Firm Initiated Recall reporting burden to its own 3rd Party Disclosure burden.

Second, an adjustment to correct the annual frequency per response of Recall Status Reports and Follow-up (21 CFR 7.53) from four to thirteen was necessary. It is stated in 21 CFR 7.53 that periodic status reports are estimated to be reported every 2-4 weeks. The majority change for the frequency per response is due to the increased number of Class I and Class II recalls from FY05-FY07 to FY08-FY10. Taking the conservative factor of four weeks, the result is an annual frequency of reporting of thirteen.

The resulting per year average of recalls (3101) and terminations (953), in addition to the increase in annual frequency per response for status reports have led to an increase in burden for this submission from 216,600 hours annually to 443,820 hours annually and annual responses from 15,162 to 35,079

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.