

# UNITED STATES FOOD & DRUG ADMINISTRATION

## FDA Recall Regulations

OMB Control Number 0910-0249 – *Extension*

### SUPPORTING STATEMENT – **Part A: Justification**

#### 1. Circumstances Making the Collection of Information Necessary

This information collection helps support implementation of section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371) pertaining to product recalls, and regulations in part 7 (21 CFR part 7), subpart C promulgated to clarify and explain associated practices and procedures by the U.S. Food and Drug Administration (FDA, the agency). Sections 7.49, 7.50, and 7.59 (21 CFR 7.49, 7.50, and 7.59) apply specifically to product recalls, which may be undertaken voluntarily and at any time by manufacturers and distributors, or at the request of the agency. Recalls are terminated when all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy. The regulations also provide for corrective actions to be taken regarding violative products and establish specific requirements that enable us to monitor and assess the adequacy of a firm’s efforts in this regard. The provisions include reporting to FDA on the initiation and termination of a recall, as well as submitting recall status reports and making required communication disclosures. Specific guidance regarding recalls is set forth in § 7.59, although product-specific guidance documents may also be developed to assist respondents to the information collection. Agency guidance documents are issued in accordance with our good guidance regulations in 21 CFR 10.115, which provide for public comment at any time.

Consistent with § 7.50, all recalls monitored by FDA are included in an “Enforcement Report” once they are classified and may be listed prior to classification when FDA determines the firm’s removal or correction of a marketed product(s) meets the definition of a recall. Recall data in the Enforcement Report can be accessed through the weekly report publication, the quick and advanced search functionalities, and an Application Programming Interface (API). Instructions for navigating the report, accessing and using the API, and definitions of the report contents are found at <https://www.fda.gov/safety/enforcement-reports/enforcement-report-information-and-definitions>.

We therefore request extension of OMB approval for the information collection found in our regulations in 21 CFR part 7 (*Recalls (Including Product Corrections)—Guidance on Policy, Procedures, and Industry Responsibilities*) and associated guidance, as discussed in this supporting statement.

#### 2. Purpose and Use of the Information Collection

Regulations in 21 CFR 7.40 explain that product recall is “*an effective method of removing or correcting consumer products that are in violation of laws administered by the Food and Drug*

*Administration. Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective.”* The purpose of the information collection is to achieve these objectives. The regulations also permit 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 majority of agency business is conducted electronically reflecting industry trends in this regard; we estimate 95% of respondents will fulfill the information collection through electronic means.

### 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

The information collection poses no undue burden on small entities, nor do requirements fall disproportionately on small business. At the same time, we provide information resources to both respondents and consumers regarding FDA product recalls from our website at: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/recall-resources>. We also provide small business assistance resources on our website and through consumer-staff employees throughout the agency.

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

The information collection schedule is consistent with statutory and regulatory requirements. 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 the Federal Register of January 8, 2021 (86 FR 1508), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received. .

## 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

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

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

Activity; 21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Firm initiated recall; § 7.46	2,779	1	2,779	25	69,475
Termination of recall; § 7.55	2,095	1	2,095	10	20,950
Recall status reports; § 7.53	2,779	13	36,127	10	361,270
Total			41,001		451,695

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

A review of agency data shows that 8,337 recalls were conducted during fiscal years 2017 through 2019, for an average of 2,779 recalls annually. We assume an average of 25 hours is needed to submit the requisite notification to FDA, for a total annual burden of 69,475 hours. Similarly, during the same period, 6,287 recalls were terminated, for an average of 2,095 recall terminations annually, and we assume an average of 10 hours is needed for the corresponding information collection activity. To determine burden associated with recall status reports we divided the average number of annual submissions (36,127) by the average number of annual respondents (2,779) and assume 10 hours is necessary for the corresponding information collection, resulting in 361,270 hours annually.

Table 2.--Estimated Annual Third-Party Disclosure Burden<sup>1</sup>

Activity; 21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Recall communications; § 7.49	2,779	445	1,236,655	0.05 (3 minutes)	61,832.75

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

To determine burden associated with recall communication disclosures described in § 7.49, we calculated an average of 445 disclosures per recall and attribute 3 minutes for each disclosure, resulting in 61,832.75 burden hours annually. We provide no estimate for recordkeeping in 21 CFR 7.59, regarding these activities to be 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 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

We have adjusted our estimate to reflect an overall decrease in the average number of annual responses by 245,846 and a decrease in the average number of annual burden hours by 70,949.25 since our last review of the information collection. The adjustment reflects a decrease in FDA-product recalls over the most recent calendar years.

### 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.