United States Food and Drug Administration

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)
APPEALS PROCESSES

OMB Control No. 0910-0738 -- Extension

SUPPORTING STATEMENT

Part A – Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports recommendations found in Food and Drug Administration (FDA) guidance. The guidance document, "*Guidance for Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health Appeals Processes*," (March 2022; available for download from our website at Center for Devices and Radiological Health (CDRH) Appeals Processes | FDA, pertains to the review of decisions or actions by CDRH employees. The guidance document discusses various mechanisms and applicable regulatory authorities, as well as provides format and content instruction, for alternative methods of appealing decisions. At the same time, information collection pertaining to administrative actions to which the Federal government is a party or that occur after an administrative case file has been opened regarding a particular individual or entity, are generally exempt from OMB review and approval under the PRA. Nevertheless, we have characterized burden we attribute to the recommendations discussed in the guidance document as reporting burden and provide an estimate of time and effort that may be incurred by respondents in Question 12 of this supporting statement. While CDRH would already maintain the administrative file forming the basis of a decision on a matter under appeal, the submission of particular information regarding the review request, and the data and information relied on by the requestor in the appeal, will facilitate timely resolution of the decision under review.

We therefore request OMB extension of OMB approval of the information collection found in the document "*Guidance for Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health Appeals Processes*" as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The guidance document is intended to provide respondents with a resource regarding appealing CDRH decisions. For example, the guidance document instructs that respondents may contact the CDRH Ombudsman by e-mail, and it also discusses procedures and associated time schedules should respondents choose to file a petition under 21 CFR 10.75. Other ways in which respondents may appeal CDRH decisions is also discussed. By providing a suggested format outlining the type of information to include in an appeals cover letter, and by encouraging the submission of specific documents germane to the request, we hope to help facilitate resolution. Respondents to the information collection are sponsors, applicants, or manufacturers of medical devices.

3. Use of Improved Information Technology and Burden Reduction

We estimate 99% of respondents will use electronic means to fulfill the information collection.

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

We do not believe the information collection imposes undue burden on small entities.

In addition, to help minimize the impact of regulatory compliance on small businesses, FDA provides personalized assistance through CDRH's Division of Industry and Consumer Education (DICE). DICE's technical and regulatory staff is available to respond to questions, supported by a toll-free dedicated telephone number Monday through Friday from 8 a.m. to 5 p.m., to facilitate this communication. The Division also maintains an email account and a website through which firms may obtain regulatory compliance information. Finally, DICE continues to engage the respondent community through conferences, workshops, and seminars, as well as by developing and disseminating publications and educational materials.

6. Consequences of Collecting the Information Less Frequently

The information collection recommendations discussed in the guidance are consistent with statutory requirements found in section 517A of the Federal Food, Drug, and Cosmetic Act.

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

FDA published a 60-day notice for public comment in the *Federal Register* of July 3, 2025 (90 FR 29563). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974 (5 U.S.C. 552a)

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate handling of information collected. Although this ICR collects personally identifiable information (PII), it is collected in the context of the subject individuals' professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). The PII submitted is the name, work email address, work telephone number, and work address of the

appellant. Although this PII is collected, we have determined that this collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, FDA does not use name or any other personal identifier to routinely retrieve records from the information collected. Through appropriate design, FDA minimized the PII collected to protect the privacy of the individuals.

The Freedom of Information Act (FOIA)

Under FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public (see 21 CFR 20), consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden

Information Collection Recommendations from FDA Guidance	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
CDRH Appeals Process	75	1	75	8	600

12b. Annualized Cost Burden Estimate

We assume that the information collection will be completed by regulatory affairs professionals and executive administrative assistants. We use, $87.86 the U.S. Bureau of Labor Statistics' May 2024 National Occupational Employment and Wage Estimates, Occupational Employment and Wage Statistics mean wage rate for a Lawyer (occupation code 23-1011), to calculate the burden for regulatory affairs professionals. We also use, $37.05, the mean wage rate for Executive Secretaries and Executive Administrative Assistants (occupation code 43-6011), to calculate the burden for executive administrative assistants. We doubled these figures to account for benefits and overhead.

Table 2. – Estimated Annual Cost Burden

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Costs (rounded)
Regulatory Affairs Professional	510	$176	$89,760
Executive Administrative Assistant	90	$74	$6,660
Total			$96,420

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

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

We estimate a 0.5 full time equivalent (FTE) allocation for reviewing appeal requests in accordance with section 517A of the FD&C Act and as discussed in the referenced guidance document. Using an internal cost model, we assume an annual rate of $$362,271.92 for a fully-loaded FTE, including benefits and overhead, we calculate Federal costs to be $181,136 (rounded).

15. Explanation for Program Changes or Adjustments

Our estimated burden for the information collection reflects an overall increase of 320 hours and a corresponding increase of 40 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collection will not be published or tabulated.

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

Consistent with established practice FDA will publish a *Federal Register* notice announcing OMB approval of the information collection associated with this guidance document and will display in that notice both the OMB control number and its current expiration date. In addition, the OMB control number will be displayed on the guidance document cover page and include a link to www.reginfo.gov to identify the current expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.