CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)
APPEALS PROCESSES

OMB Control No. 0910-0738

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, us or we) guidance. The guidance document, "*Guidance for Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health Appeals Processes*," (March 2022), 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 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*," and discussed in this supporting statement. Because we revised the guidance document in March 2022 to update contact information, we have characterized our submission as a revision.

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 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 Information 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

In accordance with 5 CFR 1320.8(d), we published a 60-day notice for public comment in the Federal Register of February 18, 2022 (87 FR 9365). 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

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate handling of information collected. This ICR collects personally identifiable information (PII), and 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.

The confidentiality of the information submitted as recommended in the guidance is governed by 21 CFR Part 20 and appropriate FDA regulations (807.95 for premarket notification; 814.9 for PMAs; and part 812 for IDEs). Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory disclosure of government records (5 U.S.C. 552(b)(1-9). One such provision, 5 U.S.C. 552(b)(4) exempts "*trade secret and commercial or financial information that is privileged or confidential*" from the requirement of public disclosure. Additionally, Section 520(c) of the FD&C Act prohibits FDA from disclosing any information exempted from public disclosure under 5 U.S.C. 552(b)(4).

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 Processes (March 2022)	35	1	35	8	280

12b. Annualized Cost Burden Estimate

We assume that the information collection will be completed by regulatory affairs professionals and executive administrative assistants. We use, $71.17, the U.S. Bureau of Labor Statistics' May 2021 National Occupational Employment and Wage Estimates, https://www.bls.gov/oes/current/oes_nat.htm, mean wage rate for a Lawyer (occupation code 23-1011), to calculate the burden for regulatory affairs professionals. We also use, $32.15, 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	245	$142.34	$34,873
Executive Administrative Assistant	35	$64.30	$2,251
Total			$37,124

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. Assuming and annual wage of $297,561 for a full FTE to include benefits, we calculate Federal costs to be $148,781 (rounded).

15. Explanation for Program Changes or Adjustments

Upon review of this information collection, we have made no adjustments to the currently approved burden estimate.

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

FDA will display the OMB control number as required by 5 CFR 1320.5 (and 5 CFR 1320.8(b)(1)); however, because documents are more frequently being accessed electronically, we have implemented technological changes enabling us to display the expiration date by linking to approval information found at www.reginfo.gov. We now include the OMB control number and expiration date on the guidance landing page, allowing those who download the document an easily identifiable option to view this information. This also allows the agency to more easily update the expiration date upon renewal and/or revision of OMB approval. We are taking this approach to improve compatibility with our current our website platform (Drupal).

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.