U.S. Food and Drug Administration
Center for Devices and Radiological Health Appeals Processes

OMB Control Number 0910-0738

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The guidance document "Guidance for Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health Appeals Processes" describes the processes available to outside stakeholders to request additional review of decisions or actions by the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) employees. FDA is seeking approval for the reporting burden associated with requests for additional review of decisions and actions by CDRH employees as described in the guidance.

Individuals outside of FDA who disagree with a decision or action taken by CDRH and wish to have it reviewed or reconsidered have several processes for resolution from which to choose, including: requests for supervisory review of an action; petitions; and hearings. Of these, by far the most commonly used is a request for supervisory review under 21 CFR 10.75 (a "10.75 appeal"). Section 517A of the FD&C Act, added by section 603 of the FDA Safety and Innovation Act of 2012, includes requirements pertaining to the process and timelines for 10.75 appeals of "significant decisions" regarding premarket notifications (510(k)s), applications for premarket approvals (PMAs), and applications for investigational device exemptions (IDEs).

A request for review under section 10.75 should be based on the information that was already present in the administrative file at the time of the decision that is being reviewed as provided in 21 CFR 10.75(d). Section 517A of the FD&C Act refers to significant decisions regarding the information in the administrative file for premarket notifications (section 510(k)), PMAs (section 515), and IDEs (section 520(g)). Submissions are collected under existing regulations which specify the information manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of medical devices. The information collections associated with these regulations are currently approved by the Office of Management and Budget (OMB) as follows: the collections of information in 21 CFR part 807, subpart E (premarket notification) have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814 (premarket approval) have been approved under OMB control number 0910-0231; and the collections of information in 21 CFR part 812 (investigational device exemption) have been approved under OMB control number 0910-0078.

While CDRH already possesses in the administrative file the information that would form the basis of a decision on a matter under appeal, the submission of particular information regarding the request itself and the data and information relied on by the requestor in the appeal would facilitate timely resolution of the decision under review. The guidance describes the collection of information not expressly specified under existing regulations: the submission of the request for review, minor clarifications as part of the request, and supporting information.

Although submitters may employ whatever format best meets their needs when requesting supervisory review of decisions, the guidance suggests a commonly-used format intended to facilitate the Center's timely processing of requests for review and to ensure that the submitter's request includes sufficient information to permit a substantive review of the issues under appeal. The Center recommends a cover letter which contains: (1) a statement that a review is being requested under 21 CFR 10.75 at a particular supervisory level for the specific submission, (2) a request for either an in-person meeting or a teleconference to provide the submitter an opportunity to make the case directly to the review authority, or a request for expedited review without a meeting or teleconference; (3) if desired, a request for the review authority to convene a meeting of the relevant Advisory Panel, or a request for referral of the review to outside expertise along with a justification for either such request; (4) a clear statement of the issue under appeal dispute and a discussion of why the relief sought by the submitter should be granted; and (5) an explicit statement of the relief or action being requested. The submitter is encouraged to submit a list of references to documents already in the administrative file or may include copies of these documents with the cover letter.

Based on CDRH's experience with appeals, the Agency expects that most persons requesting additional review of decisions will have gathered the materials listed in the previous paragraph when identifying the existence of a dispute with the Agency. Consequently, FDA anticipates the collection of information attributed solely to the guidance will be minimal.

The Medical Devices Dispute Resolution Panel (DRP) is intended to provide a means for independent review of a scientific controversy between a stakeholder and FDA. The DRP fulfills two statutory mandates under the FD&C Act: the requirement of section 515(g)(2)(B) for review of PMA approvals and denials by an advisory committee "which may not be panels under section 513; and the requirement of section 562 for a process for review of scientific controversies by a sponsor, applicant, or manufacturer of a drug or device product for which no other section of the FD&C Act "provides a right of review of the matter in controversy…" CDRH recommends that a request to convene the DRP follow the same guidelines described for requests for supervisory review of decisions.

2. Purpose and Use of the Information Collection

As described under Circumstances Making the Collection of Information Necessary, the guidance document provides information to outside stakeholders about the processes available to request additional review of decisions or actions by CDRH employees. The

guidance also provides the new procedures and timelines for appeals of significant decisions under 21 CFR 10.75, as established by section 603 of FDASIA in July 2012.

By providing a suggested format which outlines what types of information should be in an appeals cover letter and encouraging submitters to reference specific documents in the administrative file which are germane to the appeal request, CDRH expects that a predictable and reliable process for appeals will reduce the burden to outside stakeholders requesting an appeal. The materials that submitters provide to CDRH in a request for supervisory review will also facilitate the Center's processing of requests, help ensure that the submitter's request includes sufficient information to permit a substantive review of the issues under appeal, and help meet statutory time frames for reviews of significant decisions. Respondents are sponsors, applicants, or manufacturers of medical devices.

3. Use of Improved Information Technology and Burden Reduction

Premarket appeals are filed in the same manner as the premarket submission being appealed and have to be e-copy compliant. Other apples are filed electronically (i.e. pdf document attached to email).

FDA estimates that 99% of respondents will use electronic means to fulfill the Agency's requirement or request.

4. Efforts to Identify Duplication and Use of Similar Information

The information collection for this guidance document does not duplicate any other information collection and is not collected by any other agency in the Government. In an appeals request, CDRH does not require the submission of any information already contained in the administrative file, rather, allows the submitter to simply reference documents in the file. Submitters also have the option of providing electronic or hard copies of documents if they prefer.

5. Impact on Small Businesses or Other Small Entities

FDA estimates that 1,450 respondents are considered small businesses.

FDA helps to minimize the impact on small businesses through personalized assistance and guidance provided by the Division of Information and Consumer Education (DICE) within CDRH. DICE's technical and regulatory staff is available to respond to questions. A toll-free dedicated telephone number, available Monday through Friday from 8 a.m. to 5 p.m., was established to facilitate this communication. The Division also maintains an email account and a website which firms may use to obtain regulatory compliance information. DICE participates in and presents conferences, workshops, and seminars for industry and develops and disseminates publications and educational materials. These efforts help assure that the burden on small manufacturers is minimized.

6. Consequences of Collecting the Information Less Frequently

This information is only collected if an outside stakeholder disagrees with a decision or action taken by CDRH and requests an Agency review of the decision under 21 CFR 10.75.

If this information is not collected, CDRH will not be able to determine whether an outside stakeholder's appeal is a request for supervisory review of a significant decision under section 517A of the FD&C Act or whether a scientific controversy under dispute can be accurately assessed.

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 March 8, 2019 (84 FR 8530). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

   The FDA will not provide any payments or gifts to respondents of this information collection.

10. Assurance of Confidentiality Provided to Respondents

    This ICR collects personally identifiable information (PII). The PII submitted in the appeal is the name, work email address, work telephone number, and work address. The guidance document "Guidance for Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health Appeals Processes" describes the processes available to outside stakeholders to request additional review of decisions or actions by CDRH employees. Individuals outside of FDA who disagree with a decision or action taken by CDRH employees and wish to have it reviewed or reconsidered have several processes for resolution from which to choose, including: requests for supervisory review of an action, petitions, and hearings.

    FDA further determined that this collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to routinely retrieve records from the information collected.

    In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected. FDA minimized the PII to be collected to protect the privacy of individuals.

    The confidentiality of the information submitted under this 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 information does not contain questions pertaining to any matter commonly considered private or of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

FDA estimates it will receive 35 requests annually from outside stakeholders requesting additional review of decisions and actions by CDRH employees. The Agency reached this estimate based on data collected by CDRH over recent years. Based on the Agency's experience with past requests, FDA estimates it will take outside stakeholders approximately 8 hours to prepare a request.

Table 1 – Estimated Annual Reporting Burden in Hours

	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
CDRH Appeals Processes Guidance Document	35	1	35	8	280

12b. Annualized Cost Burden Estimate

FDA estimates an average wage rate of $72 per hour for a Regulatory Affairs Professional* and $29.96 per hour for an Executive Administrative Assistant** for preparing and submitting the information requested under the guidance.

* The estimated wage rate for a Regulatory Affairs Professional is based on The Regulatory Affairs Professional Society (RAPS) average total annual compensation of $150,422 for a U.S. regulatory affairs professional (https://www.raps.org/getattachment/Careers/Scope-of-Practice-Survey/2016-Scope-of-Practice-Compensation-Report-for-the-Regulatory-Profession.pdf.aspx?lang=en-US, p. 11, accessed 10/26/18). The hourly wage rate of $72 assumes a 40-hour work week and is rounded to the nearest dollar.

** The estimated wage rate for an Executive Administrative Assistant is based on the May 2017 National Industry-Specific Occupational and Wage Estimates, U.S. Department of Labor, Bureau of Labor Statistics, Occupation code 43-6011, (https://www.bls.gov/oes/current/naics4_339100.htm#43-0000).

Table 2 – Estimated Annual Cost Burden

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs (rounded to the nearest dollar)
Regulatory Affairs Professional	245	$72	$17,640
Executive Administrative Assistant	35	$29.96	$1,049
Total			$18,689

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

FDA estimates that 0.5 full time equivalent (FTE) positions will be needed to appropriately determine whether an appeal request for review of a decision meets the criteria of a "significant decision" under section 517A of FDASIA. This will be done at FDA headquarters in Silver Spring, MD. Based on a cost of $270,305 per position (which is the agency's projected average cost of an FTE in CDRH including their non-pay costs*), the estimated annual Federal cost is $135,153.

*Based on the Food and Drug Administration fully loaded FTE cost model (domestic) for FY 2018, as provided by agency economists.

15. Explanation for Program Changes or Adjustments

The number of appeals that the Center receives fluctuates from year to year but the trend has been pointing down since 2012. Based on our data from the last 3 years we have revised the No. of Respondents and Total Annual Responses from 50 to 35. This adjustment has caused a decrease of 120 hours to the estimated Total Hours.

16. Plans for Tabulation and Publication and Project Time Schedule

The results of this information collection are not to be published.

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

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.