United States Food and Drug Administration

RECLASSIFICATION PETITIONS FOR MEDICAL DEVICES

OMB Control No. 0910-0138--Extension

SUPPORTING STATEMENT

Terms of Clearance: n/a

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection helps support implementation of statutory provisions found in sections 513(e) and (f), 514(b), 515(b), and 520(l) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c(e) and (f), 21 U.S.C. 360d(b), 21 U.S.C. 360e((b), and 21 U.S.C. 360j(l)) pertaining to the reclassification of medical devices. Specifically, the FD&C Act establishes three tiers of regulatory control for medical devices, by establishing three classes of medical devices, and requiring that all devices be classified into one of these three classes. The classification of a device depends upon the degree of regulatory control necessary to provide a reasonable assurance of the safety and effectiveness of the device. The three tiers of regulatory control are: 1) Class I - general controls, subject to sections 501 adulteration, 502 misbranding, 510 registration, 516 banned devices, 518 notification and other remedies, 519 records and reports, and 520 general provisions of the FD&C Act; 2) Class II - performance standards; and 3) Class III - premarket approval.

Implementing regulations in 21 CFR part 860, subpart C (parts 860.120 through 860.136) provide that any person may petition for reclassification of a device from any class to any other class and prescribe requisite format and content elements for reclassification petitions submitted to the agency. Each petition must include supporting data to show why reclassification of the device type will provide reasonable assurance of the safety and effectiveness of the device type. The principal data in such a petition will typically be reports of clinical trials. We also provide information on our website at https://www.fda.gov/about-fda/cdrh-transparency/reclassification regarding medical device reclassification, which may serve as a helpful resource to respondents.

We therefore request OMB approval of the information collection provisions found in 21 CFR part 860, subpart C, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

FDA's Center for Devices and Radiological Health (CDRH) is responsible for reviewing petitions for reclassification and determining whether the subject device will be reclassified. In

some instances, FDA also submits such petitions to one of its medical device advisory panels for review and recommendations. FDA's decision regarding the reclassification of a device is based primarily upon the information contained in the petition. Respondents to the information collection are private sector, for-profit businesses.

3. Use of Improved Information Technology and Burden Reduction

FDA's Center for Devices and Radiological Health has not identified reclassification petitions as a type of submission it is currently prepared to accept electronically (21 CFR 860.123). However, reclassification petitions must be submitted as set forth in the applicable regulations, which provide for the submission of an original and two copies (§ 860.123(b)(4)). Each petition must include supporting data to show why reclassification of the device type will provide reasonable assurance of the safety and effectiveness of the device type. The principal data in such a petition will typically be reports of clinical trials. We estimate that 0% of the respondents will use electronic means to fulfill the agency's requirement or request.

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

There is no undue burden imposed on small entities as a result of the information collection.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements.

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 07/09/2024 (89 FR 56390). One comment was received, but it was not related to this information collection.

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 identification and handling of information collected. Data will be kept private to the extent allowed by law:

The Privacy Act of 1974

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted is name and contact information that may be supplied with an application. FDA determined that although PII is collected it 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 retrieve records from the information collected. Through instruction, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

The Freedom of Information Act

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 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, 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

21 CFR Part; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
§ 860.123; supporting data for reclassification petitions	12	1	12	497	5,964

Based on current trends, FDA anticipates that 12 petitions will be submitted each year. The number of responses is based on the average number of submissions received per year. Submission instructions, including addresses, are provided in § 860.123(b).

The time required to prepare and submit a reclassification petition, including the time needed to assemble supporting data, averages 497 hours per petition. This average is based upon estimates by FDA administrative and technical staff who are familiar with the requirements for submission of a reclassification petition, have consulted and advised manufacturers on these requirements, and have reviewed the documentation submitted.

12b. Annualized Cost Burden Estimate

The mean hourly wage for a life, physical and social scientist ($42* per hour), doubled to account for overhead, is $84 per hour which yields an estimated annual cost to respondents of $500,976. The hourly wage rate has been updated based on the Bureau of Labor Statistics, Occupational Employment Statistics, May 2023 National Industry-Specific Occupational Employment Estimates for life, physical and social scientists (SOC Code Number 19-0000, https://www.bls.gov/oes/current/oes_nat.htm#19-0000).

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs (rounded)
Life, physical and social scientist	5,964	$84	$500,976

* Rounded to the nearest dollar amount.

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 allot the equivalent of six full time employees (FTEs) annually to reviewing and processing reclassification petitions. Assuming a fully-loaded cost (salary plus overhead) of $348,721 per one FTE, the estimated annual Federal cost is $2,092,326.

15. Explanation for Program Changes or Adjustments

Our estimated burden for the information collection reflects an increase of 6 responses and a corresponding increase of 2,982 hours. We attribute this adjustment to an increase in the average number of submissions per year we received over the last few years.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

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

FDA will display the expiration date of OMB approval as required.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.