U.S. Food and Drug Administration
Reclassification Petitions for Medical Devices
OMB Control No. 0910-0138

SUPPORTING STATEMENT Part A. Justification

Terms of Clearance: None.

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA or we) regulations and accompanying guidance. Under 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), 360d(b), 360e(b), and 360j(l)) and part 860, subpart C, of the Code of Federal Regulations (21 CFR 860), FDA has the responsibility to collect data and information contained in reclassification petitions. The reclassification provisions of the FD&C Act allow any person to petition for reclassification of a device from any of the three classes, i.e. I, II, and III, to another class. The reclassification content regulation (21 CFR 860.123) requires submission of valid scientific evidence demonstrating that the proposed reclassification will provide a reasonable assurance of safety and effectiveness of the device type for its indications for use.

The reclassification procedures regulation requires the submission of specific data when a manufacturer is petitioning for reclassification. This includes, among other things, specification of the type of device, a statement of the action requested, and a justification for the request to reclassify. The petition also includes both a "supplemental data sheet" (§ 860.123(a)(3)) (Form FDA 3427) and a "classification questionnaire" (§ 860.123(a)(4)) (Form FDA 3429). Each of these forms contains a series of questions concerning the safety and effectiveness of the device type.

In the *Federal Register* of March 25, 2014, (79 FR 16252), FDA issued a proposed rule that would eliminate the need for Forms FDA 3427 and FDA 3429. However, because the proposed rule has not been finalized, we continue to include the forms in the burden estimate for this information collection.

The reclassification provisions of the FD&C Act serve primarily as a vehicle for manufacturers to seek reclassification from a higher to a lower class, thereby reducing the regulatory burden placed on a particular device type. If approved, petitions requesting classification from class III to class II or class I provide an alternative route to market in lieu of premarket approval for class II devices; most reclassification petitions are submitted seeking reclassification of class III devices. If approved, petitions requesting reclassification from class I or II, to a different class, may increase requirements. Neither the Act nor the regulations require that any device type be reclassified.

2. Purpose and Use of the Information Collection

The staff of the 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.

3. Use of Improved Information Technology and Burden Reduction

Pursuant § 860.123, reclassification petitions must be addressed to the appropriate mailing address listed in paragraph (b)(1) and must contain an original and two copies, as indicated in paragraph(b)(4). Section 860.123 does not specifically provide for the use of electronic submissions. However, the forms (Form FDA 3427 and Form FDA 3429) are electronically fillable. Each petition is unique, containing information with supporting data to show why reclassification for 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.

FDA estimates that 95% of the respondents will use electronic means to partially 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

Any individual or organization may submit reclassification petitions; the requirements are the same regardless of the organization's size. There are no user fees for reclassification petitions. FDA aids small businesses in dealing with the regulations by providing guidance and information through CDRH's Division of International and Consumer Education (DICE). DICE provides technical and non-financial assistance to firms through a comprehensive program including seminars, educational conferences, printed and electronic information materials, and via e-mail and a toll-free telephone number. Other CDRH staff members are also available to respond to questions. Alternatively, the FDA may provide assistance through its Regional Small Business Representatives. FDA has provided a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/.

FDA's Center for Devices and Radiological Health (CDRH) has followed the guidelines set by the Small Business Administration (SBD) on what constitutes a small business. For manufacturing, a small business cannot exceed 500 employees. Approximately 95% of U.S. medical device manufacturing establishments are under 500 employees.

6. Consequences of Collecting the Information Less Frequently

Information collection is consistent with statutory requirements of the act and applicable regulations. Respondents will respond to the date collection occasionally when they elect to petition the Agency for reclassification of a medical device. If the information were collected less frequently, manufacturers would not be able to take advantage of the

reclassification alternative provided in the FD&C Act. Petitions for reclassification are submitted only when an organization or individual seeks reclassification; as discussed above, the law does not require FDA to reclassify devices, but does require that FDA review the reclassification petitions received.

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 7, 2018, (83 FR 9743). We received one comment.

   The comment supports continued use of Forms FDA 3427 and FDA 3429. Specifically, the commenter is addressing the issue of discontinuing the forms as referenced above in paragraph 1, wherein FDA issued a proposed rule in 79 FR 16252 to eliminate the need for the Forms. Because FDA is not discontinuing use of the Forms at this time, and this comment relates to the proposed rule (79 FR 16252) and not to the information collection itself, we make no changes to this information collection based on the comment.

   CDRH has continually maintained contact with industry. Informal communications concerning the importance and effect of reclassification are provided primarily through trade organizations, and via CDRH's website.

9. Explanation of Any Payment or Gift to Respondents

   No payment or gift is provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

    The confidentiality of information received by FDA is consistent with and limited to the Freedom of Information Act (FOIA) and the agency's published regulations of "Public Information," under 21 CFR Part 20, which prohibit FDA from releasing to the public any information that cannot be disclosed. Such information is redacted from any information released by FDA under FOIA and FDA regulations.

Analysis of Potential Privacy Risks and Requirements/Assurance of Privacy

In renewing this information collection, staff from FDA's Center for Device and Radiological Health, Office of the Center Director consulted the Center for Device and Radiological Health, Office of Communications and Education, Division of Information Disclosure and the FDA Privacy Officer to identify potential risks to the privacy of individuals whose information may be handled by or on behalf of FDA in association with the information collection, if finalized as proposed. In this case, the subject collection does not involve solicitation or collection of personally identifiable information (PII) by or on behalf of FDA/CDRH. Specifically, FDA/CDRH does not solicit or intend to collect personally identifiable information (PII) and will not maintain

records subject to the Privacy Act or otherwise operate a Privacy Act System of Records in relation to this proposed collection.

11. Justification for Sensitive Questions

The information collection does not include questions that are of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

FDA estimates the burden of this collection as follows:

Table 1.--Estimated Annual Reporting Burden

Activity	FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Supporting data for reclassification petition—21 CFR 860.123		6	1	6	497	2,982
Supplemental Data Sheet	3427	6	1	6	1.5	9
General Device Classification Questionnaire	3429	6	1	6	1.5	9
Total						3,000

Based on current trends, FDA anticipates that 6 petitions will be submitted each year. The time required to prepare and submit a reclassification petition, including the time needed to assemble supporting data and to prepare the forms, averages 500 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 is $40.68 per hour. We have doubled the wage rage to $81.36 to account for benefits and overhead. The hourly wage multiplied by 3,000 total burden hours yields an estimated annual cost to respondents of $244,080. The hourly wage rate has been updated based on May 2017

Bureau of Labor and Statistics data for life, physical, and social scientists (SOC Code Number 19-0000, http://www.bls.gov/oes/current/oes_nat.htm).

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Life, physical and social scientist	3,000	$81.36	$244,080

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 it spends an average of six full time equivalents (FTEs) reviewing and processing reclassification petitions. Based on a cost of $292,383 per position (which is the agency's projected average cost of an FTE including their benefits*), the estimated annual Federal cost is $1,754,298.

*Based on the Department of Health and Human Services, Fiscal Year 2017, Food and Drug Administration, Justification of Estimates for Appropriations Committees--ALL PURPOSE table (pp. 9-11).

15. Explanation for Program Changes or Adjustments

There are no changes in burden hour estimate from the previous information collection. There are no adjustments or program changes.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no tabulated results to publish for this information collection.

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

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

17. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.