Reclassification Petitions for Medical Devices

0910-0138
RIN # 0910-8H75

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is requesting extension of approval from the Office of Management and Budget (OMB) for the information collection requirements regarding reclassification petitions under 21 CFR 860.123.

This regulation requires device manufacturers to provide, in a petition for device reclassification, specification of the type of device, a statement of the action requested, and a justification for the request to reclassify.

The authority for 21 CFR part 860, Medical Device Classification Procedures, is from 21 U.S.C. 360c, 360d, 360e, 360i, 360j, 371, 374.

The 1976 amendments to the Food, Drug, and Cosmetic Act (the FD&C Act) provide 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. The amendments also provide for changing device classification.

The Safe Medical Devices Act of 1990 and the 1992 amendments amended the definition of a Class II device. Under the 1990 amendments, Class II (now identified as special controls) devices are those devices for which there is insufficient information to show that the general controls alone will provide reasonable assurance of the safety and effectiveness of the device type, but for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards.

In addition to the mandated classification of all device types offered legally for sale prior to the enactment of the amendments, post-amendments devices that are not substantially equivalent to a pre-amendments device are automatically placed in Class III by section

513(f) of the FD&C Act. Preamendments device types that were classified into class III are reviewed through the premarket notification (510(k)) process. FDA will call for Premarket Approval applications (PMAs) under section 515(b) of the FD&C Act for the preamendments Class III device types, unless they are reclassified. Preamendments device types that were regulated as new drugs by FDA (known as transitional devices), prior to the enactment of the amendments, were automatically placed into Class III and required PMA, by section 520(l) of the FD&C Act. FDA may propose to reclassify a transitional device if it believes we have sufficient information to provide reasonable assurance of the safety and effectiveness of the device type with general or general and special controls. A manufacturer may also petition the Agency to reclassify a transitional device type. The reclassification procedures regulation requires a manufacturer to submit specific data when petitioning for reclassification.

The FD&C Act provides for any person to petition for reclassification of a device from any class to any other class. However, these provisions 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, the reclassification petition provides an alternative route to market, i.e., 510(k), in lieu of PMA for Class II devices; most reclassification petitions are submitted seeking reclassification of Class III device types that currently require PMA, to avoid the need for PMA. Neither the Act nor the regulations require that any device type be reclassified.

Medical Device Classification Procedures Final Rule:

FDA issued a final rule, "Medical Device Classification Procedures" (12/17/2018, 83 FR 64443), to amend its regulations governing classification and reclassification of medical devices to conform to the applicable provisions of the FD&C Act as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA). FDA is also made additional changes unrelated to the FDASIA requirements to update its regulations governing classification and reclassification of medical devices. FDA took this action to codify the procedures and criteria that apply to classification and reclassification of medical devices and to provide for classification of devices in the lowest regulatory class consistent with the public health and the statutory scheme for device regulation.

Among other things, the rule eliminates the requirement for petitioners to complete Form FDA 3429 (Classification Questionnaire) and Form FDA 3427 (Supplemental Data Sheet). Therefore, we are requesting revision of the estimated information collection burden to reflect the elimination of the two forms.

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.

Respondents are private sector, for-profit businesses.

3. Use of Improved Information Technology and Burden Reduction

A final rule was published in the Federal Register of March 20, 1997 (62 FR 13430) that would, under certain circumstances, permit the Agency to accept electronic submissions. The intended effect of the rule is to permit the use of electronic technologies in a manner that is consistent with FDA's overall mission. Published in the same issue of the Federal Register (62 FR 13467), is a notice of the establishment of a public docket to provide information on submissions the Agency is prepared to accept electronically. FDA's Center for Devices and Radiological Health has not identified reclassification petitions as a type of submission it is prepared to accept electronically. Reclassification petitions must be addressed to the appropriate mailing address listed in § 860.123(b)(1) and must contain an original and two copies (§ 860.123(b)(4)). Section 860.123 does not specifically provide for the use of electronic submissions. 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 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

The Food and Drug Administration is the only Federal agency responsible for premarket review of medical devices; as such, there is no duplication of effort.

Similar information to what is needed for reclassification of devices may exist in the PMA applications for some devices. If the PMA applicant is willing to make information from their PMA public, this information may also be used for purposes of reclassification. If, however, the applicant of the PMA is not willing to make their information public, FDA is precluded from using the data to assist reclassifying devices by sections 520(c) and (h) of the FD&C Act. However, the Agency can rely on all publicly available information, such as literature, to assist in reclassification decisions.

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.

The Small Business Administration (SBA) considers medical device manufacturers to qualify as small businesses when they employ no more than a certain number of workers – these thresholds vary by NAICS codes (U.S. Small Business Administration , Table of Small Business Size Standards. (February 2016). https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf). Using the

employment statistics from the 2012 Economic Census, we determine the number of medical device firms that may be considered small entities (U.S. Census Bureau. 2012. "2012 Economic Census of the United States (EC1231SA1) - Manufacturing: Subject Series: Location of Manufacturing Plants: Employment Size for Subsectors and Industries by U.S., State, County and Place." Retrieved July 2017 from https://factfinder.census.gov).[1] This analysis indicates that approximately 98-99 percent of medical device establishments qualify as small businesses according to the SBA criteria.

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.

6. Consequences of Collecting the Information Less Frequently

Respondents will respond to the data 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 proposed rule, "Medical Device Classification Procedures," in the FEDERAL REGISTER of 03/25/2014 (79 FR 16252).

Two of the comments we received for the proposed rule were related to the information collection. The comments in the final rule are numbered to help distinguish between different comments. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value, importance, or the order in which it was received. The comments from the final rule and our response is set out below:

> (Comment 5) We received a significant amount of comments on the proposed definitions in proposed § 860.3. Several comments opposed finalizing the proposed definitions in proposed § 860.3 stating that the proposed definitions conflict with the statutory definitions of class I,

[1] The 2012 Economic Census measures establishment employment size in bands of 500-999, 1,000-2,499, and 2,500 employees or more. For the firms in NAICS categories that have SBA size standards of 750 or 1,250, we use a proportionate number of firms to determine the numerator. Regardless, any alternative calculation does not affect the rounded percentage result.

II, and III and that the proposed definitions will result in uncertainty and the inappropriate classification of many products, as well as impose additional costs and paperwork burdens on industry that should be analyzed in this rulemaking.

Specifically, several comments opposed the proposed changes to the class III definition because of the perception that the changes, if finalized, would make the definition overly broad and result in more devices being classified into class III, while other comments viewed the more detailed criteria of the proposed class III definition as possibly limiting FDA's ability to rely on other standards for assessing risk. Several comments contended that the proposed change of the wording of the definitions of class I and class II, by substituting the wording "intended for a use" in place of "for a use", would introduce a subjective intent criterion for devices that otherwise might be classified or reclassified into class I and would require or result in the up-classification of some devices. While not specifically opposing the stand-alone definition of general controls as proposed, several comments raised an overall concern about changing the definitions of class I and class II in this rulemaking, on the grounds that the proposed change is not required to implement section 608 of FDASIA. In addition, a number of commenters indicated that the terms "general controls" and "special controls" are well understood and there are few, if any, public health issues relating to its use in the Part 860 regulations, and that changing the definitions will likely create uncertainty without benefit and disturb decades of reliance on the current class I, II, and III definitions.

On the other hand, some commenters indicated that the proposed definition for class II was too broad and that it would capture devices that they thought should be regulated as class III.

Some commenters also opposed the proposed amendments to the definition of "generic type of device." One commenter opposed allowing more than one generic type of device in a classification regulation stating that the term "generic type of device" is synonymous with the scope of each classification regulation. Another commenter opposed using product codes as part of the definition stating that they serve a limited and internal purpose and are unnecessary in this rulemaking to implement section 608 of FDASIA.

Several comments also requested FDA clarify how reclassification determinations under the revised Part 860 regulations would apply to previously approved or cleared devices, including the economic and paperwork burdens of the reclassifications imposed by the definitions changed in this rulemaking and in the future reclassifications authorized under this final rule.

(Response 5) This rule does not finalize any of the proposed definitions in proposed § 860.3; we are only finalizing the proposed removal of three definitions (21 CFR 860.3(a), (f), and (g)). Given the volume and diversity of opposing comments, we do not believe that finalizing the revised definitions that we initially proposed would add clarity or transparency to stakeholders' understanding of the Part 860 regulations as amended in this final rule.

The principal purpose of this final rule is to implement section 608 of FDASIA mandating administrative order procedures for FDA actions changing the classification of medical devices and requiring PMAs. Our intent in proposing the definitions, and to update and to clarify the Part 860 regulations in the proposed rule was to reflect our current regulatory practices and not to make substantive changes, except as needed to conform the current Part 860 regulations to the FDASIA-mandated changes. Nonetheless, as stated above, we do not believe that it is necessary to finalize the proposed definitions and thus, the proposed definitions in § 860.3 will not be finalized. In this rulemaking, we are proceeding to finalize

the clarifications to Part 860 to reflect our current regulatory practices and conform to the FDASIA mandated changes.

This final rule does not constitute a reclassification action by FDA with respect to any particular medical device. As previously stated, the proposed definitions in the proposed rule were not intended to change the classification of any cleared or approved devices. Moreover, we are not finalizing any of these proposed definitions. This rulemaking deals only with the procedures for changing device classifications. These procedures, and specifically the changes effected to the Part 860 regulations by this final rule, are not determinative of the outcome of future reclassification proceedings. Therefore, this final rule does not include analysis of the economic or paperwork burden of the changes in this final rule.

The final rule removes the requirement to provide two forms, FDA Form 3429 (General Device Classification Questionnaire) and FDA Form 3427 (Supplemental Data Sheet), as part of the form and content of a reclassification petition, because the Agency no longer finds the forms useful (amended §§ 860.84, and 860.123 of this final rule, removing current §§ 860.84(c)(3) and (4), and 860.123(a)(3) and (4)).

(Comment 15) Several comments disagreed with the Agency's proposal to remove FDA Forms 3427 and 3429 as filing requirements for petitions seeking the classification of preamendments devices (proposed § 860.84) and for petitions for the reclassification of postamendments devices (proposed §860.123). They argued that the forms provide a valuable framework for classification panels and are informative materials for panelists and that not providing the information contained in the forms will decrease panel efficiency, prejudice the petitioner, and bias the Part 860 classification and reclassification processes. The comments acknowledged that the forms are inadequate; but these commenters recommended that the forms should be improved, rather than eliminated.

(Response 15) We disagree. As stated in our proposed rule, we believe that a more efficient use of FDA and petitioner resources would be to focus on the detailed, rather than summarized, information that the petitioner, FDA, panelists, and the public provide in the proceeding concerning available valid scientific evidence concerning the device and the appropriate regulatory controls to provide reasonable assurance of the safety and effectiveness of the device. On January 30, 2017, the President directed FDA and other agencies of the U.S. Government, in accordance with the APA and other applicable law, to identify existing regulations to be repealed and, when issuing new regulations, to eliminate existing regulatory costs so that the incremental cost of new regulations, when offset by the eliminated costs, would be zero or minimized (E.O. 13771, 82 FR 9339). The economic and regulatory burden associated with FDA Forms 3427 and 3429 as filing requirements in the case of petitions seeking the reclassification of devices, and the cost savings from removing these requirements are estimated in the PRA section of the proposed rule and in Sections VII (Economic Analysis of Impacts) and IX (PRA) of this final rule. Accordingly, this rule finalizes the provisions removing FDA Forms 3427 and 3429 from the Part 860 regulations, as proposed without change (amended §§ 860.84 and 860.123 of this final rule, removing current 860.84(c)(3) and (4), and 860.123(a)(3) and (4)).

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 given to respondents.

10. Assurance of Confidentiality Provided to Respondents

No assurance of confidentiality is provided. Information provided to, or obtained by, FDA is subject to release under the Freedom of Information Act (5 U.S.C. 552) and the implementing regulations contained in 21 CFR Parts 20 and 21. Reclassification petitions are placed on public display, and FDA does not withhold any information. FDA advises petitioners not to include confidential information in their petitions.

11. Justification for Sensitive Questions

The information 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

12 a. 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

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, 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 ($35.06 per hour), doubled to account for overhead, is $70.12 per hour which yields an estimated annual cost to respondents of $141,510. The hourly wage rate has been updated based on the Bureau of Labor Statistics, Occupational Employment Statistics, May 2016 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	2,982	$70.12	$209,098

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

Using the FDA Fully Loaded FTE Cost Model (Domestic) for FY 2016, we estimate that the total annual cost including pay, information and management technology, general and administrative overhead, and rent for a CDRH employee is $260,286. Based on 2080 hours worked per year, the hourly cost of staff time equals $125.14.*

FDA estimates that it spends an average of six full time equivalents (FTEs) reviewing and processing reclassification petitions. Based on a cost of $260,286 per FTE, the estimated annual Federal cost is $1,561,716.

* FDA Fully Loaded FTE Cost Model (Domestic) for FY 2016. Technical Memorandum, 2017.

15. Explanation for Program Changes or Adjustments

The final rule, "Medical Device Classification Procedures," amends the regulations governing the classification and reclassification process for medical devices. Among other things, it eliminates the requirement for petitioners to complete Form FDA 3429 (Classification Questionnaire) and Form FDA 3427 (Supplemental Data Sheet). Therefore, we have removed the information collection burden estimates for forms FDA 3427 and FDA 3429 (section 12a). This caused an hour burden reduction of 18 hours. We also updated the annualized cost burden estimate (section 12b) to reflect the revised estimated burden hours and updated the wage data.

16. Plans for Tabulation and Publication and Project Time Schedule

The results of reclassification of medical device actions will not be published for statistical use. Under § 860.125, when the Commissioner chooses to refer a reclassification petition to a classification panel for its recommendation under § 860.134(b), or the Commissioner is required to consult with a panel concerning a reclassification petition submitted under § 860.130(d) or received in a proceeding under § 860.133(b), or the Commissioner chooses to consult with a panel with regard to the

reclassification of a device initiated by the Commissioner under § 860.134(c) or § 860.136, the Commissioner will distribute a copy of the petition, or its relevant portions, if applicable, to each panel member and will consult with the panel. Under § 860.130(d)(1), the Commissioner shall consult with a classification panel and may secure a recommendation with respect to reclassification of a device from a classification panel. The panel will consider reclassification in accordance with the consultation procedures of § 860.125. A recommendation submitted to the Commissioner by the panel will be published in the *Federal Register* when the Commissioner publishes an administrative order under §860.130. Under § 860.130(d)(1), the Commissioner may change the classification of a device by administrative order published in the *Federal Register* following publication of a proposed reclassification order in the *Federal Register*, a meeting of a device classification panel described in section 513(b) of the Federal Food, Drug, and Cosmetic Act, and consideration of comments to a public docket. Under § 860.130(e), within 180 days after the filing of a petition for reclassification under this section, the Commissioner will either deny the petition by order published in the *Federal Register* or give notice of the intent to initiate a change in the classification of the device.

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

    FDA is not seeking approval to not display the expiration date of OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

    There are no exceptions to the certification.