DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Medical Device Classification Procedures: Incorporating FDA Safety and Innovation Act Procedures

Docket No. FDA-2013-N-1529

Final Regulatory Impact Analysis
Final Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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Economics Staff
Office of Planning
Office of Policy, Planning, Legislation, and Analysis
Office of the Commissioner

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the final rule under E.O. 12866, E.O. 13563, E.O. 13771, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). E.O.s 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). E.O. 13771 requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." We believe that this final rule is not a significant regulatory action as defined by E.O. 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. This final rule largely codifies existing FDA practices and clarifies the classification and reclassification procedures currently used. For these reasons, and because panel meetings, which represent the largest source of Agency and industry costs in this analysis, are one-time occurrences, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $150 million, using the most current (2017) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

This final rule amends the regulations governing the process for classification and reclassification of medical devices. It codifies Food and Drug Administration Safety and Innovation Act (FDASIA) amendments to the Federal Food, Drug and Cosmetic Act (the FD&C Act) that are already in effect and updates generally the regulations for device classification and reclassification proceedings to provide clarity.

The costs of this final rule include initial learning costs faced by medical device manufacturers and affiliated regulatory consultants upon publication of the rule, in addition to annual costs incurred by the Agency and industry related to preparation and participation in additional panel meetings. We estimate the rule's present discounted cost, over a ten-year period, to equal $2.0 million at a three percent discount rate and $1.7 million at a seven percent discount rate. Our estimates of the annualized costs are $0.24 million at a three percent discount rate and $0.24 million at a seven percent discount rate.

The principal benefits of this final rule stem from the reduction in regulatory and economic burden that will accompany the elimination of some paperwork filing requirements, in addition to the enhanced consistency and uniformity across reclassification proceedings. These cost savings will accrue to both medical device manufacturers and to the Agency. Further benefits may be derived from the decreased time a petition will need to be reviewed for device reclassification, and the subsequent potential benefits realized by consumers and producers. We estimate these overall cost savings over the next ten years to be $0.05 million at a three percent discount rate and $0.04 million at a seven percent discount rate. Our estimates of the annualized cost savings are $0.006 million at a three percent discount rate and $0.006 million at a seven percent discount rate. The estimated costs and cost savings are summarized for a 10-year period in Table 1 and for an infinite period in Table 2.

Table 1: Summary of Estimated Costs and Cost Savings (in $ Millions 2016 dollars, at 3% and 7% discount rates, over a 10-year period)

	Primary (3%)	Lower Bound (3%)	Upper Bound (3%)	Primary (7%)	Lower Bound (7%)	Upper Bound (7%)
Present Value of Costs	$ 2.022	$ 0.014	$ 23.050	$ 1.668	$ 0.014	$ 18.982
Present Value of Cost Savings	$ 0.047	$ 0.041	$ 0.061	$ 0.039	$ 0.034	$ 0.050
Present Value of Net Costs	$ 1.975	$ (0.027)	$ 22.989	$ 1.629	$ (0.020)	$ 18.932
Annualized Costs	$ 0.237	$ 0.002	$ 2.702	$ 0.237	$ 0.002	$ 2.703
Annualized Cost Savings	$ 0.006	$ 0.005	$ 0.007	$ 0.006	$ 0.005	$ 0.007
Annualized Net Costs	$ 0.231	$ (0.003)	$ 2.695	$ 0.231	$ (0.003)	$ 2.696

Notes: Benefits include reduction in administrative burden and enhanced clarity and uniformity in petition process. Range of estimates captures uncertainty around petitioner response.

Table 2: EO 13771 Summary Table (in $ Millions 2016 dollars, at a 7% discount rate, over an infinite time horizon)

	Primary (7%)	Lower Bound (7%)	Upper Bound (7%)
Present Value of Costs	$ 3.377	$ 0.014	$ 38.593
Present Value of Cost Savings	$ 0.080	$ 0.070	$ 0.102
Present Value of Net Costs	$ 3.297	$ (0.056)	$ 38.491
Annualized Costs	$ 0.236	$ 0.001	$ 2.700
Annualized Cost Savings	$ 0.006	$ 0.005	$ 0.007
Annualized Net Costs	$ 0.230	$ (0.005)	$ 2.693

II. Final Regulatory Impact Analysis

A. Market Failure Requiring Federal Regulatory Action

The FDA is issuing this final rule to amend 21 CFR Part 860, the regulations governing the classification and reclassification of medical devices under the FD&C Act. This final rule implements the provisions mandated by the FDASIA requiring the use of administrative orders instead of issuing regulations to change the classification of devices and to require premarket approval (PMA) applications for preamendments class III devices. The FDA is also amending other provisions of its device classification regulations to provide a procedure for the use of administrative orders in other reclassification proceedings initiated by FDA and to update generally its regulations governing the classification and reclassification of devices.

FDASIA was signed into law on July 9, 2012, and, among many initiatives, sought to further medical device innovation. This final rule integrates the administrative order procedures mandated by

FDASIA with the existing statutory criteria applicable to the classification and reclassification of medical devices and provides for the classification of devices in the lowest regulatory class consistent with the public health. Previously, classifying and reclassifying devices was accomplished by rulemaking (issuing a regulation). Under this final rule, an administrative order process is used to reclassify a device. This process includes publication of a proposed order in the Federal Register, consideration of public comments, and a device classification panel meeting before issuing a final order. This final rule also covers procedures for requiring ("calling for") PMAs of class III preamendments devices.[1] These devices may be marketed without submission of a PMA until the FDA requires such an application. Previously, requiring PMAs involved the full rulemaking process, whereas FDASIA amended the FD&C Act to require an administrative order process.

The regulation is part of the implementation of the FDASIA amendments to the FD&C Act regarding device reclassification and classification procedures and also a general alignment of the use of administrative order procedures across FDA reclassification and classification proceedings. It is not in response to a market failure. Previously, there may have been an institutional failure leading to a lack of clarity regarding reclassification procedures, leading to erroneous reclassification petitions and corresponding costs on the part of the FDA and petitioners.

The procedures as described under this final rule will decrease the administrative burden for both the FDA and potential petitioners. The elimination of duplicative questionnaire forms currently required for petitions and potential exemptions from some premarket notification procedures. The final rule also describes the organization of the panel meetings that are part of the administrative order process.

[1] Preamendment devices are pre-1976 medical devices that have been classified into class III by regulation and devices found substantially equivalent by means of premarket notification procedures to such preamendment devices or to devices within that generic device type.

B. Comments on the Proposed Rule and Our Responses

In the Federal Register of March 25, 2014 (79 FR 16252), FDA issued a proposed rule entitled "Medical Device Classification Procedures" and requested public comment on the proposed rule within 90 days following its publication.

In this section, we describe and respond to the comments we received on our analysis of the impacts presented in those sections. We have numbered each comment 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.

(Comment 1) One comment expressed concern about potential overlap between this rule and the final rule for the Unique Device Identifier (UDI) system in September 2013. Specifically, that if any device were to be classified into a higher risk category, its manufacturer may face an accelerated and unanticipated UDI system compliance timeline, implying that there may be additional costs that have not been considered here or in the UDI system final rule.

(Response 1) Reclassification of devices to a higher class is rare. However, to the extent that a reclassification would affect the UDI compliance dates or UDI labeling requirements applicable to a device, FDA will consider issues of compliance with UDI requirements, as appropriate, on a case-by-case basis.

(Comment 2) Some comments expressed concern about the methods used to evaluate the economic and administrative burdens that this rulemaking imposes on medical device manufacturers, specifically if this rulemaking were to lead to new class or special controls definitions.

(Response 2) This final rule does not finalize any of the proposed definitions these comments address, and only updates and clarifies the regulations surrounding classification and reclassification

proceedings. It does not change the criteria used in the reclassification process and does not affect devices previously approved or cleared to be marketed, so estimating any additional costs related to premarket approvals would be out of scope for this analysis of economic and regulatory impacts. This final rule reflects the FDA's current practices, and in the time since the implementation of FDASIA-mandated changes, the trend of six reclassification petitions per year, on average, has remained the same. The proposed rule and these comments were published in 2014, and the number of average annual reclassification petitions has not changed since.

(Comment 3) One comment provided estimates for the average cost of preparing for and participating in a panel meeting that were greater than those in the primary cost estimates discussed in this final regulatory impact analysis or in earlier PRA analyses.

(Response 3) The premise of these estimates is the proposed revisions of the class definitions that are not included in this final rule. Many comments claimed that these proposed revisions would lead to the reclassification of many existing devices, and the potential up-classification of new and existing devices, prompting additional reclassification petitions and panel meetings. Some of these petitions would occur within the context of PMA applications, which are more costly and burdensome than the conventional reclassification process. Since these proposed definition revisions are not part of this final rule, we consider this panel meeting cost estimate to be more moderate. However, we have considered a much greater estimate for panel meeting preparation and participation in our upper bound cost estimates.

C. Costs and Benefits

1. Baseline

This final rule is part of the implementation of the FDASIA amendments to the FD&C Act which provide for device classification or reclassification through use of administrative orders. The Agency's practice before the enactment of FDASIA is the baseline for this analysis.

Many of the procedural changes in this final rule have been in effect since the effective date of FDASIA, and the remaining procedural changes in this rulemaking are being established to enhance uniformity and clarity among classification and reclassification procedures. Upon its passage in 2012, FDASIA changed the classification and reclassification proceedings under FD&C Act sections 513(e), 515(b), and 515(i). The FDA also adopted a similar process for FDA-initiated reclassification proceedings under FD&C Act sections 513(f)(3) and 520(l). These sections represent different possible classification or reclassification proceedings, depending on the status of the device or the initiator (i.e., by petition or by FDA's own initiative). This initiative to achieve consistency and reduced ambiguity among classification and reclassification procedures reflects the current practices of the Agency since 2012. Medical device manufacturers, petitioners, and the Agency have followed these updated administrative order procedures since the enactment of FDASIA in July 2012. This final rule fully implements and codifies the procedural updates for all classification and reclassification proceedings under the FD&C Act.

To evaluate the potential costs and benefits of this rule, we need to understand the trends of petition submissions and what impacts this final rule may have on the reclassification petition process. There is no centralized database for all varieties of petition requests submitted to the FDA or initiated by the FDA. The FDA Dockets website[2] contains records of all reclassification petitions, and CDRH maintains a publicly accessible historical database of CDRH-related petitions on a separate website.[3] Only a subset of the petitions listed here fall under the scope of this final rule, which amends 21 CFR Part 860, covering the classification and reclassification of medical devices. Further corroboration is provided by the information collection data submitted to the OMB for review as required by the Paperwork Reduction Act. This documentation process also estimates an average annual reclassification petition load of six per year (Ref. 1).

[2] https://www.fda.gov/RegulatoryInformation/Dockets/default.htm

[3] https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhfoiaelectronicreadingroom/ucm150022.htm

2. Costs

We anticipate that medical device firms that may pursue or be subject to this rule's changes in reclassification proceedings will incur costs to learn the requirements of the rule. The FDA estimates, as of September 2017, that approximately 13,000 medical device firms may be affected by this rule. We note that this is an approximate figure and some uncertainty is involved in its derivation. This estimate is obtained from the FDA's establishment registration and owner-operator data; we discuss this and other data sources regarding the number of firms in this industry in the small entity analysis section below.

It is unlikely that each of these firms will review this rule in pursuit of reclassification for their devices. A relatively small number of firms comprise very large proportions of medical device manufacturing and sales[4], and the small and medium-sized companies rely on regulatory consulting firms and trade association groups for assistance with initiatives such as reclassification petitions.[5] The larger firms use in-house staff for the reading and interpretation of these regulations. Small and medium-sized firms may rely on in-house staff, trade associations, or third-party regulatory consulting firms for support in learning of this rule.

We model the one-time learning costs as the time required by medical device manufacturers' regulatory affairs experts to access and review the final rule. We estimate that a regulatory affairs expert would incur a burden of between 15 minutes and 30 minutes to access the rule and would read the provisions at a rate of 200 to 250 words per minute. The preamble and codified regulatory text are approximately 6,000 words and we estimate that it would take between 0.4 to 0.5 hours for a legal affairs expert to read the rule.

[4] For instance, the largest subgroup within the medical devices industry by value of shipments and receipts for services, is Surgical and medical instrument manufacturing (NAICS 339112) according to the 2012 Economic Census. 1,184 companies comprise this subgroup, and the 50 largest companies (4.2% of the total number of companies) represent 76.7% of the subgroup's total receipts (Ref 4).

[5] Furthermore, FDA assists small medical device companies with technical and regulatory assistance through CDRH's Division of International and Consumer Education (DICE). CDRH uses gross receipts/sales criteria for determining small business qualification.

To collect data on third-party regulatory consulting firms and their fees and services, we conducted internet searches and consulted CDRH staff. We identified 22 such entities, and calculated the average hourly rate as $167 per hour (in 2016 dollars) (Ref. 2). This hourly rate is a fully loaded measure that includes overhead and benefits. Applying this rate to the hourly burdens, we obtain a cost of between $108.55 and $167 for a regulatory affairs expert to access and read the final rule (i.e., between 0.25 hours and 0.5 hours to access the rule + between 0.4 hours and 0.5 hours to read the rule * $167 per hour). We use the midpoint of this hourly bill ((108.55 + 167) / 2 = $137.78) as one hourly cost measure.

An alternative measure for in-house staff may be the median hourly wage of a legal regulatory affairs expert as reported in the Bureau of Labor Statistics, Occupational Employment Statistics, (May 2016 National Industry-Specific Occupational Employment Estimates) for a Lawyer ($56.81), which is then doubled to account for overhead (Ref. 3). Applying the fully loaded median hourly cost to the hourly burdens, we obtain a cost of between $73.85 and $113.62 for a regulatory affairs expert to access and read the final rule (i.e., between 0.25 hours and 0.5 hours to access the rule + between 0.4 hours and 0.5 hours to read the rule * $113.62 per hour). We use the midpoint of these costs ((73.85 + 113.62) / 2 = $93.74) as another potential hourly cost measure.

We estimate the overall labor costs using the respective hourly cost measure for each type of firm, $137.78 for 22 regulatory consulting firms and $93.74 for 50 medical device manufacturers (representing the largest firms in this industry). The total access and learning costs for all affected entities equals $7718. We assume that each manufacturer would incur the access and reading costs the first year following publication of this final rule.

This final rule will increase consistency and uniformity among reclassification proceedings. If medical device manufacturers perceive a decrease in the economic and regulatory burden of initiating and submitting reclassification petitions, we might expect an increase in the number of petitions they submit.

Panel meetings are not a mandatory component to all petition types governed by this final rule. The FD&C Act does not require panel meetings in the administrative orders process for 513(f)(3) petitions for reclassification of postamendments devices or 520(l)(2) petitions for transitional devices. In

contrast, FDASIA mandated panel meetings as part of the administrative order process that governs classification and reclassification requests submitted under 513(e), 515(b), and 515(i). However, we cannot rule out the possibility that, in general, better alignment of the various processes governing reclassification proceedings may result in additional panel meetings due to reasons such as additional petitions or the increasing complexity over time of devices. Our baseline of reclassification requests and petitions prior to FDASIA incorporates the recent trends of petition filings and the use of panel meetings on an annual basis, and we therefore include the estimated costs of one additional panel meeting here as a potential cost. We address both Agency and industry costs here.

FDA costs involve preparing and participating in panel meetings. These resources include the time spent setting up meetings, reviewing industry materials, preparing meeting materials, and participating in meetings. To estimate the value of these resources, we multiply the reviewer's economic value of time by the average time spent preparing and participating in panel meetings [= (the average time to prepare and participate) x (reviewer's economic value of time) x (total expected number of additional panel meetings)]. We estimate that the average panel meeting takes approximately 420 hours to prepare. The participants include approximately one lead reviewer, fourteen agency reviewers, one clinician, one statistician, one analyst, one panel coordinator, one Designated Federal Officer, one Conflict of Interest (COI) analyst, one director of field operations, four agency directors (including COI/Ethics and Advisory Committee Oversight and Management Staff), two audio-visual technicians, and a transcriptionist. The average meeting requires 170 hours to set up (i.e., reserve room, preparing room's audio-visuals, print materials, and coordinating logistics). The analyst, statistician, and clinician require approximately 150 hours to review industry materials and to report their results to agency reviewers and directors. Finally, the reviewers and directors invest another 100 hours reviewing industry materials and preparing meeting materials. Together, we estimate that the average panel meeting takes approximately 420 hours to prepare (=170 to set up meetings + 150 hours to review and discuss materials + 100 hours to prepare materials). We estimate that FDA participation times to approximately equal 180 hours. The average meeting lasts one to two working days (8 to 16 hours), and thus the average meeting lasts about twelve hours. Because

most meetings contain approximately fifteen agency scientists (one lead reviewer and fourteen agency scientists) we estimate that average agency participation times equal 180 staff hours (= fifteen participants * twelve hours). Together, these values indicate that the total time spent preparing and participating in meetings is 600 hours (= 420 hours to prepare + 180 hours to participate).

The cost per full-time employee (FTE) for FY 2016, which includes pay, information and management technology, general and administrative overhead, and rent, is $260,286 for an FDA-CDRH employee. Based on 2080 hours worked per year, the hourly cost of staff time equals $125.14 (Ref. 5). With the expectation of one additional panel meeting per year, the available data and consultation with CDRH staff indicate that the Agency's additional annual cost equals approximately $75,084 (= one additional panel meeting per year * 600 hours to prepare and participate * $125.14 per hour).

For every additional panel meeting, industry will face additional costs to prepare and to participate as well. We have no direct data on these costs. However, we assume that manufacturers prepare similar materials, and thus require similar preparation times. Additional preparation time may be necessary due to statistical and clinical questions from the FDA. As a result, we estimate that manufacturers similarly spend 900 hours preparing for panel meetings (600 hours to review and discuss the reclassification and Agency requests + 300 hours to prepare their materials).

We estimate that industry participation times approximately equal 60 hours. The average meeting lasts one to two working days (8 to 16 hours), and thus we expect the average meeting lasts 12 hours. Because most meetings contain approximately five industry representatives, we estimate average industry participation times to roughly equal 60 hours (= five participants * twelve hours). Together, these values indicate that manufacturers spend approximately 960 hours preparing and participating in panel meetings (= 900 hours preparing for meetings + 60 hours participating in meetings). Using the average hourly bill of $167 cited earlier (Ref. 2) for industry representatives, we estimate that the additional annual cost equals approximately $160,320 (= one additional panel meeting per year * 960 hours to prepare and participate * $167 per hour). This number may vary widely, however, depending on whether the panel

preparation is completed by the manufacturer itself or through a third-party consulting firm. It may also vary depending on the complexity and risks of the devices involved.

Adopting this final rule may impose modest costs on manufacturers and the Agency. We estimate the annual cost to manufacturers associated with requiring panel meetings to equal $160,320, while agency costs equal $75,084. Together, we expect the rule's total annual costs from an additional panel meeting to be approximately $235,404.

Given these values for panel meetings, along with our estimates for the initial learning costs, we estimate the rule's present discounted cost, over a ten-year period, to equal $2.0 million at a three percent discount rate and $1.7 million at a seven percent discount rate. Our estimates of the annualized cost are $0.24 million at a three percent discount rate and $0.24 million at a seven percent discount rate.

The discussion above represents our primary cost estimates given the trends and costs observed thus far. In the following section, we also consider lower and upper bound cost estimates for potential scenarios where we observe changes in device reclassification trends or costs. We propose one additional reclassification request and thus one additional panel meeting per year in our primary costs analysis. Should the average number of reclassification petitions remain the same and so necessitate no additional panel meetings, neither the Agency nor industry would experience additional costs beyond the manufacturers' initial learning and adjustment costs illustrated earlier. These costs occur within the first year after publication of this final rule, and are estimated to be $7718 as calculated earlier in this section.

Several factors may contribute to higher potential costs for this final rule. For instance, we may be underestimating the number of additional reclassification petitions submitted by medical device manufacturers (which would lead to additional costly panel meetings), as well as the individual cost components, incurred by both firms and by the FDA, of the panel meetings themselves.

Since the flow of reclassification petitions has been relatively stable between the start of 2005 and the passage and implementation of FDASIA in 2012, we expect the trends in reclassification petitions to remain relatively stable over the following several years. Furthermore, no comments significantly disagreed with this estimate from the PRA.

Our primary cost estimate for one additional panel meeting incorporated costs incurred by both medical device firms and FDA. Consultation with both FDA and industry resources suggest that some instances of panel meeting preparation and participation may include average costs upwards of $750,000, depending on whether the costs are borne by a manufacturer or external consultancies. This is typically for panel meetings that accompany device submissions early in the premarket application process and not necessarily solely for reclassification petitions. However, we can use this figure as an upper bound for these cost estimates to accommodate a range of uncertainty surrounding the precise costs. Depending on the needs of the panel meeting, the FDA may incur logistics and staffing costs greater than those estimated earlier, and so we double this number (from $75,084 to $150,168) as well to establish an upper bound.

In the scenario where we see an additional three reclassification petitions per year, our high cost estimates for one year are approximately $2.7 million (= (three additional panel meetings per year * $750,000 per meeting costs on the part of industry) + (three additional panel meetings per year * $150,168 per meeting costs on the part of the FDA)). We estimate these present discounted costs, over a ten-year period, to equal $23.04 million at a three percent discount rate and $18.98 million at a seven percent discount rate. Our estimates of the annualized cost are approximately $2.70 million at a three percent discount rate and $2.70 million at a seven percent discount rate.

3. Benefits

This final rule will slightly reduce the administrative burden and certain costs that are associated with current reclassification practices, primarily through the elimination of questionnaire forms that must accompany classification and reclassification petitions. The costs of these forms are part of our baseline – they were required by Part 860 prior to the passage of FDASIA and the form requirement was not affected by FDASIA . Evaluating the removal of these forms uses baselines both prior to and following the enactment of FDASIA. Removing these required forms from the petition process is expected to reduce

the preparation and review times associated with reclassification petitions, resulting in modest cost savings for both external petitioners and the Agency.

Reclassifying a medical device type based on new scientific information and risk assessments can have benefits for many stakeholders as well. For instance, if device types are reclassified to reflect new evidence on their safety and effectiveness, then individuals and medical device manufacturers experience gains from having devices classified in the lowest regulatory class consistent with the protection of the public health.

a. Cost Savings

The final rule removes the filing requirements to complete two FDA forms– specifically the FDA Forms 3427 and 3429 from the Part 860 medical device regulations. We expect modest cost savings and easing of economic and regulatory burden due to the reduction in time required in preparing and reviewing these forms. We estimate Agency savings as the approximate total costs to review these questionnaires [= (average time to review a questionnaire) * (hourly cost of review time) * (total number of classification questionnaires)].

According to estimates from the Office of Management and Budget's Information Collection database, the FDA received approximately six reclassification petitions for medical devices per year, between the calendar years 2005 and 2016, and, on average, petitioners dedicate three hours to the completion of set of forms that accompany the reclassification petition (Ref. 1). This trend has remained relatively stable over the full calendar years 2013-2016 following the enactment of FDASIA in 2012. Our baseline incorporates the current trend of petitions, panel meetings, and FDA forms on an annual basis, and we include the estimated costs of one additional reclassification petition, and resulting set of questionnaire forms here as a potential consideration. Therefore, we project that implementing this final rule would result in an annual reduction of seven questionnaires.

Agency reviewers estimate that the average questionnaire requires three hours to access and inspect. Using FDA's cost per FTE to determine the value of review time ($125.14 per hour), we estimate

that eliminating this form requirement will lead to Agency savings of approximately $2628 per year (seven classification questionnaires per year * three hours to review one questionnaire * $125.14 per hour).

Manufacturer or petitioner savings approximately equal the total costs to complete these questionnaires [= (average time to complete one questionnaire) * (manufacturer or petitioner's economic value of time) * (total number of classification questionnaires)]. For the manufacturer or petitioner's value of time, we use the midpoint of the hourly bills of the regulatory staff from consulting firms and large device firms (($165 + $112) / 2 = $138.5) identified previously in the Costs section of this analysis. Using three hours for completing a questionnaire, we estimate that eliminating this form requirement will lead to manufacturer or petitioner savings of approximately $2919 per year (seven classification questionnaires per year * three hours to complete one questionnaire * $139 per hour).

The overall cost savings derived from removing the requirement of submitting FDA forms that currently accompany classification or reclassification petitions are $5547 (2016$). Given this value, we estimate the rule's present discounted value of cost savings, over a 10-year period, to equal $0.047 million at a 3 percent discount rate and $0.039 million at a 7 percent discount rate.

In the following section, we also consider estimates of cost savings for potential scenarios where we observe three additional reclassification petitions (and three additional sets of FDA forms) to form an upper bound cost savings estimate.

In the lower bound scenario, industry and the FDA would act on the current trend of an average of six petitions per year, thus attaining cost savings from the elimination of six sets of FDA forms per year. Using the same hourly wage and time figures from our primary cost savings calculations, we estimate lower bound cost savings from removing the requirement of submitting FDA forms that currently accompany classification or reclassification petitions are $4755 (2016$). Given this value, we estimate the rule's present discounted value of lower bound cost savings, over a 10-year period, to equal $0.041 million at a 3 percent discount rate and $0.033 million at a 7 percent discount rate.

In the higher cost scenario, we consider the addition of three petitions per year. This means industry and the FDA would attain cost savings from the elimination of nine sets of FDA forms per year. Using the same hourly wage and time figures from our primary cost savings calculations, we estimate an upper bound cost savings from removing the requirement of submitting FDA forms that currently accompany classification or reclassification petitions are $4755. Given this value, we estimate the rule's present discounted value of lower bound cost savings, over a 10-year period, to equal $0.061 million at a 3 percent discount rate and $0.050 million at a 7 percent discount rate.

b. Other Benefits

This rule reduces the administrative burden and costs that both the FDA and petitioners encounter during reclassification proceedings due to the removal of required forms. This rule also amends the regulations to be consistent with the FDASIA amendments to the FD&C Act. This uniformity between the regulations and the statutory requirements for reclassification and for calling for PMAs for preamendments devices will enhance the clarity for the order process. Together, these changes result in a less costly pathway for classification and reclassification proceedings and potential efficiency gains for the medical device market at large.

It is possible that the time between evaluating a petition and completing the reclassification proceeding (with its requisite steps of a proposed order, panel meeting, comment solicitation, and a final order) will decrease.

The potential benefits of more frequent reclassifications are large, but difficult to quantify due to the variability in the functionality and effects among regulated medical devices. The purpose of reclassification is to identify the appropriate class for a medical device type and outline any special controls, if necessary, that are consistent with the protection of the public health mission of the FDA. The economic impact of the final rule on FDA actions calling for PMAs for preamendments Class III devices is minimal due to the very few preamendments devices now remaining in Class III. For this

reason, although we discuss these effects into account notionally in this report, they do not appear statistically in our analysis.

III. Supplementary Analyses

A. Distributional Analysis

The primary estimates in this analysis of economic impacts are of the direct compliance costs and direct cost savings for medical device firms and the FDA. They are relatively minor and not expected to significantly affect unit prices paid by consumers, wages paid to employees, or in returns to capital. Similarly, we do not foresee any disproportionate impact on any specific population groups, or any advantaged or disadvantaged groups, due to the minimal impact from this final rule as compared to the baseline conditions.

B. Small Entity Analysis

We examined the economic implications of the proposed rule as required by the Regulatory Flexibility Act. If a rule will have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires us to analyze regulatory options that would lessen the economic effect of the rule on small entities. This final rule would impose a modest administrative burden on small entities, incurred only by those filing reclassification petitions. Panel meetings are one-time occurrences and are not at all frequent in comparison to the number of medical devices and manufacturers overall. We certify that the final rule will not have a significant economic impact on a substantial number of small entities. This analysis, together with other relevant sections of this document, serves as the final regulatory flexibility analysis, as required under the Regulatory Flexibility Act.

Our evaluation above of costs, cost savings, and benefits uses an estimate of approximately 13,000 medical device firms. The 2012 Economic Census listing 5,903 domestic firms over seven unique

medical device NAICS (North American Industry Classification System) codes (2017 Economic Census numbers are not yet available).[6] The FDA maintains a registration database that lists owners or operators of facilities that are involved in the manufacture and distribution of medical devices intended for use in the United States. As of September 2017, this FDA database lists 5,350 domestic manufacturers.

As long as a medical device is intended for use in the United States, the corresponding manufacturing establishment must register with the FDA; this is the case if the parent firms are domestic or foreign, or if their production facilities are domestic or foreign. The owner-operator marketing the device is then subject to this final rule. There is some uncertainty around our estimate of 13,000. Some firms or facilities may not appear in our registration database – our estimate is current as of September 2017, and firms or facilities may enter or exit the market over the course of time. Finally, some registrations may be duplicates, and some facilities are bought and sold between firms.

The Small Business Administration (SBA) considers medical device manufacturers to qualify as small businesses when they employ no more than a threshold number of workers – these thresholds vary by NAICS codes and are outlined in Table 3 (Ref. 7). Using the employment statistics from the 2012 Economic Census, we determine the number of medical device firms that may be considered small entities (Ref. 8).[7] This analysis indicates that approximately 98-99 percent of medical device establishments qualify as small businesses according to the SBA criteria.

Although the percentage of firms that are small entities is large, this final rule is not likely to be significant for the industry at large or for most small businesses due to the infrequency of reclassification proceedings. Our estimate, discussed earlier in the Costs section, of the potential number of one to three additional reclassification petitions and subsequent panel meetings would not represent a significant economic impact on a substantial number of small firms.

[6] We adopt the NAICS codes used by the International Trade Administration in their 2016 Medical Devices Report (Ref. 6): 325413 (In-Vitro Diagnostic Substances Manufacturing), 334510 (Electromedical and Electrotherapeutic Apparatus Manufacturing), 334517 (Irradiation Apparatus Manufacturing), 339112 (Surgical and Medical Instrument Manufacturing), 339113 (Surgical Appliances and Supplies Manufacturing), 339114 (Dental Equipment and Supplies Manufacturing), and 339115 (Ophthalmic Goods Manufacturing).

[7] 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.

Table 4 reports the final rule's estimated impact on small entities. The estimated impact is evaluated by the ratio between the average number of panel meetings per year and number of small entities in each size category (0-19, 20-99, and 100-499 employees). The likelihood of a firm participating in a reclassification effort and a subsequent panel meeting across these size categories ranges from less than 1% to 1.1%. There may be more than one firm manufacturing the device type subject to reclassification, so these probabilities may even be over-estimated. Overall, panel meetings are one-time occurrences and affect relatively few devices within the industry landscape.

Table 3: Small Business Size Standards for Medical Device Firms

2012 NAICS Code	Description of 2012 NAICS Code	Number of domestic establishments	SBA Size Standard - Number of Employees	% Small Firms
325413	In-Vitro Diagnostic Substance Manufacturing	237	1,250	98
334510	Electromedical and Electrotherapeutic Apparatus Manufacturing	791	1,250	99
334517	Irradiation Apparatus Manufacturing	169	1,000	98
339112	Surgical and Medical Instrument Manufacturing	1,337	1,000	99
339113	Surgical Appliances and Supplies Manufacturing	2,079	750	99
339114	Dental Equipment and Supplies Manufacturing	721	750	99
339115	Ophthalmic Goods Manufacturing	569	1,000	99

Table 4: Estimated Impact of the Final Rule on Small Business Entities

Establishments in Size Category			Estimated Likelihood of Panel Meeting
Employees	Count	Percent	
0 - 19	3915	68%	<1%
20 - 99	1219	21%	<1%
100 - 499	631	11%	1.1%
Source: 2012 Economic Census; NAICS 325413, 334510, 334517, 339112, 339113, 339114, 339115.			

C. International effects

We do not expect this final rule to have significant or disproportionate impact on imports or exports. Additionally, any impacts on United States subsidiaries and establishments of foreign entities were considered in our main analysis of costs and benefits. This final rule should not have any effects on foreign firms beyond those on domestic firms.

IV. References

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4. U.S. Census Bureau. 2012. "2012 Economic Census of the United States (EC1231SR2) - Manufacturing: Subject Series: Concentration Ratios: Share of Value of Shipments Accounted for by the 4, 8, 20, and 50 Largest Companies for Industries: 2012." Retrieved July 2017 from https://factfinder.census.gov.
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8. 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.