paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Airbus Defence and Space Technical Document DT–86–3001, CN–235 Airworthiness Limitations List, Issue R, dated March 20, 2018.

(ii) [Reserved]

(3) For service information identified in this AD, contact Airbus Defense and Space, Services/Engineering Support, Avenida de Aragón 404, 28022 Madrid, Spain; telephone: +34 91 585 55 84; fax: +34 91 585 31 27; email: *MTA.TechnicalService@airbus.com.*

(4) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Des Moines, Washington, on November 29, 2018.

James Cashdollar,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–26621 Filed 12–14–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. FDA–2017–C–2902]

Listing of Color Additives Subject to Certification; D&C Yellow No. 8; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA or we) is confirming the effective date of October 26, 2018, for the final rule that appeared in the **Federal Register** of September 25, 2018, and that amended the color additive regulations to provide for the expanded safe use of D&C Yellow No. 8 as a color additive in contact lens solution.

DATES: The effective date of final rule published in the **Federal Register** of September 25, 2018 (83 FR 48373) is confirmed: October 26, 2018.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Molly A. Harry, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1075.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 25, 2018 (83 FR 48373), we amended the color additive regulations to add § 74.3708, ''D&C Yellow No. 8,'' (21 CFR 74.3708) to provide for the expanded safe use of D&C Yellow No. 8 as a color additive in contact lens solution.

We gave interested persons until October 25, 2018, to file objections or requests for a hearing. We explained that, to file an objection, among other things, persons must specify with particularity the provision(s) to which they object. We also explained that if a person who properly submits an objection wants a hearing, he or she must specifically request a hearing and that failure to do so will constitute a waiver of the right to a hearing (83 FR 48373 at 48375).

We received seven comments regarding our decision to amend the color additive regulations to provide for the expanded safe use of D&C Yellow No. 8 as a color additive in contact lens solution. None of the comments, however, specified with particularity the provision(s) of the regulation to which they objected nor specifically requested a hearing. Therefore, we find that the effective date of the final rule that published in the **Federal Register** of September 25, 2018, should be confirmed.

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of Food and Drugs, we are giving notice that no objections or requests for a hearing were filed in response to the September 25, 2018, final rule. Accordingly, the amendments issued in the final rule became effective October 26, 2018.

Dated: December 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–27234 Filed 12–14–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 860

[Docket No. FDA-2013–N–1529]

RIN 0910–AH75

Medical Device Classification Procedures: Incorporating Food and Drug Administration Safety and Innovation Act Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to amend its regulations governing classification and reclassification of medical devices to conform to the applicable provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA). FDA is also making additional changes unrelated to the FDASIA requirements, to update its regulations governing the classification and reclassification of medical devices. FDA is taking this action to codify the procedures and criteria that apply to the 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.

DATES: This rule is effective March 18, 2019.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: *For information concerning the final rule as it relates to devices regulated by the Center for Devices and Radiological Health (CDRH):* Ana Loloei, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 66, Rm. 5452, Silver Spring, MD 20993–0002.

For information concerning the final rule as it relates to devices regulated by the Center for Biologics Evaluation and Research (CBER): Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire

Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Final Rule

FDA is issuing this final rule to amend part 860 of title 21 of the Code of Federal Regulations (CFR) (part 860), to conform the applicable provisions governing the classification and reclassification of medical devices to the FD&C Act as amended by FDASIA (Pub. L. 112–144). FDASIA, which became effective on July 9, 2012, established new processes for requiring premarket approval (PMA) applications for preamendments devices and for the reclassification of devices by administrative order, instead of by rulemaking. In this final rule, FDA also is amending the provisions of its regulations governing reclassifications initiated by FDA to incorporate the process for issuing administrative orders and to update generally the part 860 regulations governing the classification and reclassification of devices to conform them to the FDASIA changes and current FDA practices. This final rule provides for the classification of devices in the lowest regulatory class consistent with the public health and the statutory scheme for device regulation. We are changing the title of this rulemaking from ''Medical Device Classification Procedures'' to ''Medical Device Classification Procedures: Incorporating Food and Drug Administration Safety and Innovation Act Procedures'' to reflect the limited purpose of this final rule.

B. Summary of the Major Provisions of the Final Rule

FDASIA amended the FD&C Act provisions for reclassification of devices and for requiring PMA applications for preamendments class III devices to change from a rulemaking proceeding to an administrative order process. Under the FD&C Act as amended by FDASIA, prior to publication of a final order reclassifying a device or requiring a PMA application for a preamendments class III device, FDA must publish a proposed order in the **Federal Register**, consider any comments submitted on the proposed order, and hold a device classification panel meeting (see sections 513(e) and 515(b) of the FD&C Act (21 U.S.C. 360c(e) and 360e(b))). To reflect these procedural changes, FDA is issuing this final rule to amend our regulations (amended §§ 860.130, 860.132 and 860.133 of this final rule).

This final rule also clarifies the process where reclassification of a postamendments device or a transitional device is initiated by FDA, rather than in response to a petition (see sections 513(f)(3) and 520(*l*) of the FD&C Act (21 U.S.C. 360c(f)(3) and 360j(*l*))). Specifically, this rule details the procedures for these reclassification actions, which consist of a proposed reclassification order, optional panel consultation, and a final reclassification order published in the **Federal Register** following consideration of comments and any panel recommendations or comments (amended §§ 860.134(c) and 860.136(c) of this final rule). This final rule also removes the requirement for a hearing under part 16 (21 CFR part 16) for reclassifying transitional devices, because we believe the process in this final rule providing for a proposed order, panel consultation as appropriate, consideration of comments, and final order provides sufficient opportunity for participation and review of reclassification of transitional devices.

This final rule also removes two definitions specifically pertaining to FDA forms that the Agency is eliminating under this rule, as we no longer find the forms useful. This rule does not finalize any of the other proposed changes to the current part 860 definitions.

C. Legal Authority

Section 608 of FDASIA amended the procedures for reclassification of devices and for requiring PMA applications for preamendments class III devices (sections 513(e) and 515(b) of the FD&C Act, respectively). FDASIA amended both provisions to remove the prior requirement for a rulemaking proceeding and to replace it with an administrative order process, instead of rulemaking under section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553). Section 701(a) of the FD&C Act (21 U.S.C. 371(a)) permits the issuance of regulations for the efficient enforcement of the FD&C Act.

D. Costs and Benefits

This final rule amends the regulations governing the process for classification and reclassification of medical devices. It codifies FDASIA amendments to 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 10-year period, to equal $2 million at a 3 percent discount rate and $1.7 million at a 7 percent discount rate. Our estimates of the annualized costs are $0.24 million at a 3 percent discount rate and $0.24 million at a 7 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 the overall cost savings over the next 10 years to be $0.05 million at a 3 percent discount rate and $0.04 million at a 7 percent discount rate. Our estimates of the annualized cost savings are $0.006 million at a 3 percent discount rate and $0.006 million at a 7 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. Additional qualitative analysis of this final rule's benefits is included in the Final Regulatory Impact Analysis.

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	$2.002	$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—E.O. 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. Table of Terms, Abbreviations, and Commonly Used Acronyms in This Document

TABLE 3—LIST OF TERMS, ABBREVIATIONS, AND COMMONLY USED ACRONYMS

Term, abbreviation, or acronym	What it means
1976 Amendments	Medical Device Amendments of 1976 (Pub. L. 94–295).
510(k)	Premarket notification.
Agency	Food and Drug Administration.
APA	Administrative Procedure Act, 5 U.S.C. 550 *et seq.*
CFR	Code of Federal Regulations.
De Novo request	Pertaining to the classification process under section 513(f)(2) of the FD&C Act (21 U.S.C. 360c(f)(2)).
E.O	Executive Order.
FACA	Federal Advisory Committee Act, 5 U.S.C. App.
FD&C Act	Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*
FDA	Food and Drug Administration.
FDASIA	Food and Drug Administration Safety and Innovation Act.
FDASIA amendments	Section 608 of FDASIA.
PMA	Premarket approval.
Preamendments device	Medical device that was in commercial distribution before the May 28, 1976 enactment of the 1976 Amendments.
Part 860	21 CFR part 860.
Postamendments device	Medical device that was not in commercial distribution before the May 28, 1976, enactment of the 1976 Amendments.
PRA	Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3520.
Transitional device	Medical device that was regulated as a new drug before the May 28, 1976, enactment of the 1976 Amendments.
UDI	Unique Device Identifier.
U.S.C.	United States Code.
We or us	Food and Drug Administration.

III. Background

A. Need for the Regulation/History of This Rulemaking

The Medical Device Amendments of 1976 (Pub. L. 94–295) (the ''1976 Amendments'') amended the FD&C Act and established a comprehensive system for the regulation of medical devices intended for human use. The FD&C Act establishes the following three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness: class I (general controls), class II (special controls), and class III (premarket approval) (section 513(a)(1) of the FD&C Act).

To change a device classification, FDA can initiate a reclassification or an interested person can petition FDA to reclassify a device based on new information (section 513(e) of the FD&C Act). Prior to FDASIA, FDA was required to use a rulemaking proceeding to reclassify devices based on new information, in accordance with the rulemaking provisions of the APA (see 5 U.S.C. 553). FDASIA amended the FD&C Act to remove the rulemaking requirement and instead to authorize reclassification through an administrative order process (section 608 of FDASIA, amending section 513(e) of the FD&C Act). The FD&C Act, as amended by FDASIA, requires that FDA, prior to publishing a final order, must publish a proposed order in the **Federal Register** and consider any comments submitted on the proposed order. FDASIA also amended the FD&C Act to require that FDA must hold a device classification panel meeting on the proposed reclassification (section 513(e) of the FD&C Act). This final rule implements these statutory changes (section 513(e) of the FD&C Act; amended § 860.130 of this final rule).

FDASIA also amended the provisions of the FD&C Act authorizing FDA to require submission of a PMA application for a preamendments class III device (referred to as a ''call for PMAs''). Preamendments devices are devices that were in commercial distribution before the enactment of the 1976 Amendments. Under the FD&C Act, preamendments devices classified into class III may be marketed upon clearance of a 510(k) submission, and submission of a PMA is not required until FDA has issued a final order requiring premarket approval (section 515(b) of the FD&C Act). As amended by FDASIA, the FD&C Act requires that FDA, in its call for PMAs, publish a proposed order in the **Federal Register**, hold a classification panel meeting, and consider comments on the proposed order (section 515(b) of the FD&C Act, as amended by FDASIA).

Under the FD&C Act, FDA's call for PMAs must, among other things, contain an opportunity for interested persons to request a change in the classification of the device based on new information (section 515(b)(2) of the FD&C Act). After consideration of comments on the proposed order and findings, FDA must either: (1) Finalize the call for PMAs by issuing an administrative order requiring approval of a PMA and publishing in the **Federal Register** findings with respect to: (i) The degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved PMA or a declared completed product development protocol and (ii) the benefit to the public from the use of the device; or (2) publish a notice in the **Federal Register** terminating the proceeding and initiate a reclassification proceeding based on new information (section 515(b)(3) of the FD&C Act, as amended by FDASIA; see section 513(e) of the FD&C Act).

FDASIA amended the FD&C Act to require the use of administrative orders, rather than rulemaking, when FDA calls for PMAs for a preamendments device remaining in class III (section 515(b) of the FD&C Act, as amended by FDASIA), and this final rule implements these statutory changes (new § 860.133 of this final rule).

FDA refers to a device that was not in commercial distribution before the 1976 Amendments as a postamendments device. Postamendments devices are classified automatically into class III by statute, without any rulemaking process (section 513(f)(1) of the FD&C Act). A postamendments device remains in class III and is subject to the PMA requirements unless and until: (1) FDA reclassifies the device into class I or II; (2) FDA issues an order classifying the device into class I or II via the De Novo classification process (see section 513(f)(2) of the FD&C Act); or (3) FDA issues an order finding the device to be substantially equivalent to a predicate device that does not require the filing of a PMA (see section 513(i) of the FD&C Act).

FDA may initiate, or the manufacturer or importer of a device may petition for, the reclassification of a postamendments device classified into class III by operation of law (section 513(f)(3) of the FD&C Act). This final rule clarifies the process where reclassification of a postamendments device remaining in class III is initiated by FDA rather than by a petitioner. This FDA-initiated reclassification process, as detailed in this final rule, consists of a proposed reclassification order, optional panel consultation, and a final reclassification order published in the **Federal Register** following consideration of comments and any panel recommendations or comments (new § 860.134(c) of this final rule). The reclassification order may, as appropriate, establish special controls to provide reasonable assurance of the safety and effectiveness of the device (new § 860.134(d) of this final rule).

Under the 1976 Amendments, Congress classified all those devices previously regulated as new drugs into class III (generally referred to as transitional devices). Under the FD&C Act, FDA may initiate, or the manufacturer or importer of a device may petition for, the reclassification of a transitional device remaining in class III (section 520(*l*)(2) of the FD&C Act). This final rule details the process for reclassification of transitional devices initiated by FDA (new § 860.136(c) of this final rule). This process consists of a proposed reclassification order, optional panel consultation, and a final reclassification order published in the **Federal Register** following consideration of comments and any panel recommendations or comments. This final rule also removes the requirement for a part 16 hearing for transitional devices because we believe the process providing for a proposed order, panel consultation as appropriate, consideration of comments, and final order provide sufficient opportunity for participation and review of reclassification of transitional devices.

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.

One of the comments requested that the comment period be extended for an additional 90 days due to the complexity and importance of the issues raised in the proposed rule. In the **Federal Register** of June 12, 2014 (79 FR 33711), FDA reopened the comment period for an additional 90 days.

By direct final rule published on December 24, 2014 (79 FR 77387) and on August 21, 2017 (82 FR 39534), FDA made technical amendments to its existing part 860 regulations to update the mailing address for reclassification petitions currently found at § 860.123(b)(1); neither the proposed rule nor this final rule changes the updated and amended mailing address.

FDA believes this rule will assist the Agency with efficient enforcement of the FD&C Act because it provides

increased clarity, uniformity, and predictability for stakeholders, particularly regulated entities, regarding the procedural framework for reclassifying medical devices and calling for PMAs.

B. Summary of Comments in Response to the Proposed Rule

The comments on the proposed rule break down into two groups: Generally favorable and supportive comments on the proposals to implement the FDASIA-mandated administrative order procedures to change a device classification or when FDA calls for PMAs; but unfavorable comments on the proposed amendment of the definitions in part 860. Many of the commenters expressed concern that the proposed updates and clarifications to the definitions would result in more devices being classified into burdensome, higher-class device categories, particularly into class III. Other commenters opposed these changes because they were perceived as making the class definitions, particularly for class III, too specific and therefore narrower, which might result in unwarranted reclassification of high-risk devices into lower classes. Regardless of the comment's perspective on the effect of the definitions, the comments questioned our legal authority to make the changes. Other comments expressed uncertainty about our intent in proposing to change the definitions currently in part 860 and recommended that we confirm in the final rule that the purpose of this rulemaking is only to codify existing FDA practices and not to make substantive changes, except as required by the FDASIA amendments.

IV. Legal Authority

Among the provisions that provide authority for this final rule are sections 201(h), 501(f), 510(k), 513(d), (e), (f), and (i), 515(b) and (f), 520(*l*), and 701(a) of the FD&C Act (21 U.S.C. 321(h), 351(f), 360(k), 360c(d), (e), (f), and (i), 360e(b) and (f), 360j(*l*), and 371(a)).

As amended by section 608 of FDASIA, sections 513(e) and 515(b) of the FD&C Act mandate that the reclassification of medical devices and the call for PMAs must be done by administrative order, instead of by rulemaking. This final rule finalizes the conforming edits to applicable regulations in part 860 to be consistent with the administrative order procedures mandated by section 608 of FDASIA. Section 701(a) of the FD&C Act permits the issuance of regulations for the efficient enforcement of the FD&C Act.

V. Comments on the Proposed Rule and FDA Response

A. Introduction

We received 15 sets of comments on the proposed rule, mostly from manufacturers of medical devices and their trade representatives and associations. Comments were also received from medical and health care professionals, patient advocacy groups, and consumers.

We describe and respond to the comments in sections B through F of this section. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same set of comments and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

B. Description of General Comments and FDA Response

Some comments made general remarks supporting or opposing the proposed rule without focusing on a particular proposed provision. In the following paragraphs, we discuss and respond to such general comments.

(Comment 1) Several comments opposed finalizing the proposed rule, and recommended that the Agency should either withdraw the proposed rule and re-propose a rule with only the provisions required to implement section 608 of FDASIA, or issue a revised proposed rule to implement only the FDASIA-mandated changes to the part 860 regulations pertaining to reclassifications and start a separate rulemaking to update and clarify the other provisions of part 860. One of the comments recommended, alternatively, that the Agency should implement the FDASIA-required changes to the part 860 regulations governing device reclassification procedures and should make explicitly clear that, except to finalize edits to part 860 to conform to changes that FDASIA made to the FD&C Act, the changes in this rule are meant to update and clarify the part 860 regulations to reflect FDA's existing practices and should not be interpreted as substantive changes.

(Response 1) As recommended in the last comment, FDA confirms that it is finalizing the proposed rule for the purpose of implementing FDASIA and updating and clarifying the part 860 regulations, without the intent otherwise to make substantive changes. Further, because this final rule does not finalize any of the proposed definitions in the proposed rule, as further discussed in our response to Comment 5, this rule is only finalizing the FDASIA-required changes and a few other edits, as proposed, to update and clarify part 860.

(Comment 2) Two comments requested that FDA hold a public workshop to solicit stakeholder dialogue on changes that would be helpful or needed concerning the part 860 regulations.

(Response 2) The principal purpose of this final rule is to implement the provisions of FDASIA mandating administrative order procedures for FDA actions reclassifying medical devices and calling for PMAs and to update and clarify the existing part 860 regulations, as needed, to, among other things, conform them to the FDASIA-mandated changes and current FDA terminology.

We believe that the issues underlying this rulemaking are adequately developed in the proposed rule and that the comments received and FDA responses in this final rule robustly discuss these issues. As discussed in our response to Comment 5, this final rule does not finalize any of the proposed definitions in the proposed rule (see proposed § 860.3). As such, we do not believe that a public workshop is needed to seek further input prior to finalizing this rulemaking. Apart from this rulemaking, we continue to welcome stakeholder communication about how FDA might improve the part 860 regulations.

(Comment 3) A commenter requested that FDA clarify the interplay between its regulations and the use of administrative orders in the device classification and reclassification process under this final rule, to establish procedures for updating the relevant CFR sections when FDA classifies a device by administrative order, and to clarify whether there will be a central site for viewing orders and supporting documentation.

(Response 3) The FDASIA amendments and this final rule do not change the types of classification actions that the Agency is able to take under the FD&C Act and part 860 nor the way that notices of these actions are published when FDA classifies a device. As explained in Section III.A, Need for the Regulation/History of This Rulemaking, FDASIA revises the procedures that the Agency must use to reach its decision to reclassify or to call for PMAs, *i.e.,* to an administrative

order process instead of rulemaking (see sections 513(e) and 515(b) of the FD&C Act, as amended by section 608 of FDASIA). For other types of reclassifications, the Agency has been issuing administrative orders published in the **Federal Register** (see sections 513(f)(3) and 520(*l*)(2) of the FD&C Act). Our use of administrative orders is governed by the relevant provisions of the FD&C Act and ultimately by the provisions finalized in this rule.

The Agency will announce its reclassification orders by publication of the proposed and final orders in the **Federal Register**. This publication process for reclassification actions is the same as used before the enactment of FDASIA when reclassifications were accomplished by rulemaking, *i.e.,* by notice of such action published in the **Federal Register**.

The FDASIA amendments also require FDA to post annually the number and type of devices reclassified in the previous calendar year (section 608(c) of FDASIA). Since the enactment of FDASIA, the Agency has been listing its reclassification orders, initiated by the Agency or in response to a petition, on two websites, found respectively at *https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm240318.htm* and at *https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm378724.htm.* We intend to update these websites periodically and maintain them to assure transparency and public availability of this information.

(Comment 4) Commenters expressly supported our goal to ensure classification of devices in the lowest regulatory class consistent with the protection of public health and the statutory scheme for the device.

(Response 4) As reiterated in the Summary of this final rule, the Agency reaffirms that this is a goal of our device classification system and one of the purposes of this rulemaking.

C. Comments and FDA Response on the Proposed Definitions

The proposed rule suggested revising the current part 860 definitions of ''class I'', ''class II'', and ''class III'', in part by pulling out language now found in the definitions of ''class I'' and ''class II'' into stand-alone definitions of the terms ''general controls'' and ''special controls.'' We also proposed to update and clarify our part 860 regulations by revising the current definitions of the terms ''generic type of device,'' ''implants,'' and ''supporting or sustaining human life'' and by defining the new term ''special controls guideline.'' Because the intent of the proposed modifications to the part 860 definitions was to provide clarity and not to implicitly change the classification/reclassification process, and because none of these definitional changes is needed to conform the part 860 regulations to the administrative order procedures required by FDASIA, we are not finalizing the proposed definitions in this final rule.

We grouped comments related to the proposed definitions together under the same number below and are responding to them collectively.

(Comment 5) We received a significant number of comments on the proposed definitions of the proposed rule (see proposed § 860.3). Several comments opposed finalizing these proposed definitions stating that they conflicted with the statutory definitions of class I, II, and III, and if finalized, would result in uncertainty and the inappropriate classification of many products, as well as additional costs and paperwork burdens that should be analyzed in this rulemaking.

Specifically, many of these comments opposed the proposed changes to the part 860 definition of ''class III'' 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 that there are few, if any, public health issues relating to their 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, other commenters indicated that the proposed definition of ''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 FDA purpose and are unnecessary in this rulemaking to implement section 608 of FDASIA.

Several comments also requested that 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 proposed definitions changed in this rulemaking and in future reclassifications authorized under this final rule.

(Response 5) This rule does not finalize any of the proposed definitions in proposed § 860.3. We do not believe, given the volume and diversity of opposing comments, that finalizing these definitions would add clarity or transparency to stakeholders' understanding of the part 860 regulations. However, as described in section V.E, we are finalizing the proposed removal of two definitions (§ 860.3(f) and (g)) associated with two forms. FDA did not receive any specific comments about the removal of these definitions.

The principal purpose of this final rule is to implement section 608 of FDASIA, which mandated administrative order procedures for FDA's actions for reclassifying medical devices and calling for PMAs. Our intent in proposing the revised definitions, and in updating and clarifying 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. In this rulemaking, we are proceeding to finalize our other proposed updates and clarifications to part 860 to reflect our current regulatory practices and to

conform to the FDASIA-mandated changes.

This rulemaking primarily amends the procedures for reclassifying devices and calling for PMAs. These procedural changes do not affect the classifications of previously cleared or approved devices. Further, as previously stated, we are not finalizing the proposed definitions; nor were the proposed definitions intended to reclassify any cleared or approved devices. Thus, further clarification of the status of previously cleared or approved devices, including an analysis of the economic or paperwork burden of such potential changes, is not necessary.

D. Comments and FDA Response on FDASIA Implementation

1. Administrative Order Procedures in Part 860 Proceedings

This final rule implements the FDASIA amendments that change the following procedures to an administrative order process: (1) The process by which FDA calls for PMAs for preamendments devices and (2) the regulatory procedures for reclassifying medical devices based on new information in response to a petition, as well as for those begun at FDA's initiative (amended §§ 860.84, 860.130, and 860.132 and new § 860.133 of this final rule, implementing sections 513(e) and 515(b) of the FD&C Act, as amended by section 608 of FDASIA). The administrative order process both for requiring PMA applications and for reclassification based on new information includes issuance of a final order in the **Federal Register** following publication of a proposed order in the **Federal Register**, a meeting of a device classification panel, and consideration of comments—notwithstanding 5 U.S.C. 553, which requires Agencies, including FDA, to follow the APA's procedures when engaging in rulemaking. We received no adverse comments concerning our proposed changes to amend the part 860 regulations for this purpose.

This final rule also clarifies the process for when FDA initiates reclassification of devices under certain provisions of the FD&C Act that were not amended by FDASIA. The proposed rule suggested clarifying the procedures for FDA to take reclassification actions on its own initiative under these provisions, by clarifying the current administrative order process for reclassifying postamendments devices that have been automatically classified into class III (see section 513(f)(3) of the FD&C Act; amended § 860.134(c) and (d) of this final rule) and for reclassifying transitional devices, regulated as new drugs before 1976, that previously have been classified into class III (see section 520(*l*) of the FD&C Act; amended § 860.136(c) and (d) of this final rule).

This final rule clarifies, specifically, that FDA can reclassify any device from class III to either of the other two classes (amended §§ 860.84(d)(6), 860.134(c), and 860.136(b)(4) and (c) of this final rule). This final rule also clarifies that reclassifications may be from *any* class to any other class, *i.e.,* reclassification into a higher class (''up-classification'') or into a lower class (''down-classification'') (amended § 860.130(c)(1) through (3) of this final rule).

(Comment 6) For postamendments devices eligible for the De Novo classification process under section 513(f)(2) of the FD&C Act, one commenter requested FDA to clarify how the De Novo process fits into the classification/reclassification process under part 860.

(Response 6) This final rule does not affect the De Novo classification process. Any person who receives a not substantially equivalent determination in response to a 510(k) submission for a device that has not been previously classified under the FD&C Act may request FDA to classify the device (section 513(f)(2)(A)(i) of the FD&C Act). A person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to classify the device without first submitting a 510(k) (section 513(f)(2)(A)(ii) of the FD&C Act). In either case, the classification criteria are the same (see section 513(a)(1) of the FD&C Act).

When FDA classifies a device type as class I or II via the De Novo classification process, other manufacturers do not necessarily have to submit a De Novo request or PMA application in order to legally market a device of the same type. Instead, manufacturers can use the less burdensome pathway of 510(k) notification, when applicable, to legally market their device, because the device that was the subject of the original De Novo request can serve as a predicate device for a substantial equivalence determination. A device classified via the De Novo classification process may subsequently be reclassified under other provisions of the FD&C Act (see section 513(e) and (f)(3) of the FD&C Act).

In the **Federal Register** of December 7, 2018 (83 FR 63127), FDA published a proposed rule to establish requirements for the De Novo classification process. The proposed rule, if finalized, implements the De Novo classification process under the FD&C Act and establishes procedures and criteria for the submission and withdrawal of a request for De Novo classification. The proposed requirements also establish procedures and criteria for FDA accepting, reviewing, granting, and declining a De Novo request.

(Comment 7) Some comments questioned whether there is legal authority or rationale in a reclassification order under part 860 to down-classify an implant device or life-supporting or life-sustaining device into class I or class II.

(Response 7) The FD&C Act directs FDA to classify and reclassify devices into one of three regulatory control categories based on the criteria set forth in the FD&C Act: Class I (general controls), class II (special controls), and class III (premarket approval), depending upon the degree of regulation necessary to provide reasonable assurance of their safety and effectiveness (section 513(a)(1) of the FD&C Act). There is no requirement in the statute that FDA classify all implant devices or life-supporting or life-sustaining devices (*i.e.,* purported or represented for use in supporting or sustaining human life or use which is of substantial importance in preventing impairment of human health) into class III; nor is there a prohibition on classifying these devices into class I or class II.

Class I devices are subject to a comprehensive set of regulatory authorities called general controls, which include provisions that relate to establishment registration and listing, premarket notification, prohibitions against adulteration and misbranding, records and reports, and good manufacturing practices (see section 513(a)(1)(A) of the FD&C Act). General controls apply to all classes of medical devices and provide FDA with the means of regulating products to assure their safety and effectiveness.

Class II devices are devices for which general controls, by themselves, are insufficient to provide reasonable assurance of the safety and effectiveness of the product, and for which there is sufficient information to establish special controls necessary to provide such assurance (see section 513(a)(1)(B) of the FD&C Act). For implant devices or life-supporting or life-sustaining devices to be classified or reclassified into class II, FDA additionally must describe the special controls that, in addition to general controls, are necessary to provide a reasonable assurance of safety and effectiveness of the device and how such controls

provide such assurance (section 513(a)(1)(B) of the FD&C Act).

Class III devices are devices for which general controls, by themselves, are insufficient and for which there is insufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device, and are purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury (see section 513(a)(1)(C) of the FD&C Act). Whether a device is life-supporting or life-sustaining is only one factor in determining whether the device should be classified as class III and is not determinative of a device's classification. FDA must also consider whether general controls by themselves are sufficient and whether there is sufficient information to establish special controls before classifying a device as class III.

(Comment 8) One comment requested FDA define the term ''unclassified'' or ''not classified'' devices and explain the classification and 510(k) process for devices that fall into these categories.

(Response 8) FDA guidance provides explanations of the terms requested. ''Unclassified devices'' are preamendments devices for which a classification regulation has not been promulgated (Ref. 1). Until the unclassified device type is formally classified and a regulation established, marketing of new devices within this type will require submission of a 510(k). On the other hand, ''not classified devices'' are postamendments devices for which the Agency has not yet reviewed a marketing application or for which the Agency has not made a final decision on such a marketing application (Ref. 1). As we are not finalizing any of the proposed definitions in proposed § 860.3 and there already are established definitions for ''unclassified'' and ''not classified'' devices, it is not necessary, at this time, to add those definitions to part 860 in this rulemaking. Further, aside from conforming the regulatory procedures for certain reclassifications and calling for PMAs for class III preamendments devices to the FD&C Act as amended by FDASIA, this final rule does not affect FDA's traditional treatment of unclassified and not classified devices. Nor does this rule change the 510(k) process applicable to such devices. Future decisions that affect unclassified and not classified devices will be taken, as appropriate, on a case-by-case basis consistent with the relevant authority.

2. Classification Panels

For reclassification proceedings based on new information and for proceedings calling for PMAs for a class III preamendments device, FDA must convene a classification panel and obtain panel recommendations on classification (sections 513(e) and 515(b) of the FD&C Act, as amended by FDASIA; amended §§ 860.130(d)(1) and 860.133(b) of this final rule). On the other hand, for FDA-initiated reclassification proceedings for postamendments devices and transitional devices, which also involve administrative orders, FDA can, as in the past prior to the passage of FDASIA, choose whether to consult with a panel (sections 513(f)(3) and 520(*l*) of the FD&C Act; amended §§ 860.134(b) and (c)(2), 860.136(c)(2), and 860.125(a) of this final rule).

The final rule includes minor changes to the current classification panel provisions of the part 860 regulations to update their terminology (see amended §§ 860.84(d)(2) and 860.10(a) of this final rule, finalizing proposed §§ 860.84(d)(2) and 860.93(a), respectively). The final rule also clarifies that, in the case of a recommended reclassification into class II, the panel must provide FDA its recommendation whether the device should be exempted from the premarket notification requirement under section 510(k) of the FD&C Act (amended §§ 860.15(a) and 860.84(d)(4) of this final rule). The final rule also updates the docket information of the part 860 regulations that indicates where panel recommendations are available for public viewing, by including the FDA website address (amended §§ 860.84(e) and 860.134(b)(4) of this final rule). We received no comments on any of the changes referred to in this paragraph, and we are finalizing these changes as proposed.

(Comment 9) One comment questioned why all reclassification petitions and proposed orders (including FDA-initiated orders) would not be referred to a classification panel and argued that section 608 of FDASIA and logic dictate that all proposed reclassifications, regardless of who initiates the process, should be reviewed by a classification panel.

(Response 9) FDA may refer a matter to a panel either because it is legally required to do so or because it chooses to do so at its own discretion. The FD&C Act, as amended by FDASIA, dictates specific circumstances in which FDA must hold a panel meeting prior to making a classification or reclassification decision, regardless of who initiates the process. For instance, the process for reclassifications based on new information requires that FDA issuance of an administrative order reclassifying a device be preceded by a proposed order, a meeting of a device classification panel, and consideration of comments to a public docket (section 513(e) of the FD&C Act, as amended by FDASIA). On the other hand, the FD&C Act permits FDA to determine whether to hold a panel meeting when FDA initiates the reclassification of a postamendments or a transitional device (sections 513(f)(3) and 520(*l*) of the FD&C Act). In addition, when reclassifying a postamendments device in response to a petition, FDA ''may for good cause shown'' decide to consult with a panel (section 513(f)(3)(B) of the FD&C Act). FDASIA did not amend these authorities; and thus, a panel is not required for proceedings conducted under these authorities (amended §§ 860.134 and 860.136 of this final rule).

When acting at its own discretion, FDA generally considers taking a matter before a panel if, among other things, the matter is of significant public interest or there is additional or special expertise provided by the panel that could assist FDA in its decision making. Regardless of whether a panel meeting is held, the opportunity to submit comments to a public docket on the Agency's recommendation is an integral part of any such action. FDA also considers whether the process followed by FDA reflects the least burdensome approach to classification and reclassification of devices (section 513(a)(3)(D)(ii) of the FD&C Act).

(Comment 10) Several comments objected to FDA's interpretation of section 608 of FDASIA in the proposed rule that would allow panel meetings to be held prior to the issuance of the order proposing to reclassify a device. These commenters believed that our interpretation ignores the structure and language of FDASIA, undermines the panel protections Congress included in FDASIA to ensure that panels scrutinize the scientific and regulatory soundness of the proposed reclassification, and is inconsistent with our panel process in past part 860 proceedings.

(Response 10) The FD&C Act, as amended by FDASIA, does not prescribe when the panel meeting and proposed order must occur in relation to each other. Therefore, the Agency may hold a panel meeting either before or after the issuance of a proposed reclassification order. This approach is consistent with the FDA practice before FDASIA, which allowed FDA, at its discretion, to secure a panel recommendation prior to the

promulgation of a reclassification rule. Prior to FDASIA, when a panel meeting was discretionary, FDA often held a panel meeting before proposing reclassification of the device. Generally, for future reclassifications when a meeting of a device classification panel has not yet occurred, FDA intends to issue a proposed reclassification order before holding the panel meeting if the panel is required.

(Comment 11) Some comments objected to FDA communications with individual panel members by telephone or by mail and alleged that such communications amount to Agency ex parte communications and do not support transparency, stakeholder involvement, or the opportunity to present supporting or opposing information. One comment requested that consultation by mail should either be removed or used only if a panel meeting is infeasible and the circumstances require prompt decisions to protect the public health.

(Response 11) The Agency agrees that every effort should be made to consult with an entire classification panel when possible, and that an adequate record of such consultation is essential. However, there will be circumstances in which statutory time constraints, the necessity to protect the public health, the request by the petitioner for a timely response, or the unavailability of panel members will require the Commissioner to consult by telephone with at least a majority of current voting panel members. Regardless of the method of consultation with panel members, the Agency conducts panel meetings in accordance with part 14 (21 CFR part 14), which includes record keeping and public participation.

The reference to panel ''consultation by mail'' in the current part 860 regulations is removed (§ 860.125(a)(2), removed by this final rule). The Agency intends to continue its past practice, however, of using postal mail, other delivery services, and electronic email to deliver documents to panel members for the purpose of distributing them at FDA's option in advance of and following panel consultations, at attended meetings, or in telephone- or video-conference sessions.

(Comment 12) One comment requested that FDA operate panels under the rules of the Federal Advisory Committee Act (FACA), Public Law 92–464 (1972), as amended, in order to ensure transparency and stakeholder input, specifically, that panel members should be required to disclose financial and nonfinancial conflicts of interests and that FDA should address any conflicts in a prompt and consistent manner.

(Response 12) The Agency conducts panel meetings in accordance with the FACA and part 14 to provide for transparency through a public meeting where stakeholders can be part of the Agency's decision-making process. Meetings are open to all members of the public and include an open public hearing (OPH) portion where the public can participate. **Federal Register** notices are used by the Agency to announce meetings and to provide information on how the public can request to present in the OPH. The pertinent Agency guidance document provides further information on public participation in the OPH (Ref. 2). Meeting announcements and meeting materials are available on the Agency's website. As outlined in the FD&C Act, classification panels are exempt from FACA section 14 pertaining to the duration of the panel (sections 513(e)(1), 513(f)(3)(B), 515(b), and 520(*l*)(2) of the FD&C Act; see also section 513(b)(1) of the FD&C Act).

Panelists are also subject to the financial disclosure provisions of the Ethics in Government Act of 1978, Public Law 95–521, as amended, and its implementing regulations (5 U.S.C. App. 101 *et seq.;* 5 CFR part 2634, subpart I). These requirements apply to ''special government employees'' and regular government employees throughout the Federal Government, including panelists of FDA's classification panels (§§ 14.1(a)(2)(vi) and 14.31). Panelists have to disclose financial interests on Form FDA 3410 (Confidential Financial Disclosure Report for Special Government Employees) that FDA reviews. If a current disqualifying financial interest exists for which a waiver may be granted, such waiver is disclosed on FDA's website prior to the date of the advisory committee meeting to which the waiver applies providing the type, nature, and magnitude of the financial interest (21 U.S.C. 379d-1(c), see 18 U.S.C. 208(b)). Questions 2 and 3 of Form FDA 3410 address past interests as well as anything that may give an appearance of a conflict of interest (5 CFR 2635.502). Financial disclosures provided by special government employees or regular government employees ''shall be confidential and shall not be disclosed to the public'' (5 U.S.C. App. 107).

3. Unique Device Identifier (UDI) Related Issues

The UDI final rule establishing FDA's unique device identification system provided for implementation of UDI requirements over a 7-year period beginning in 2014 according to a schedule of compliance dates based primarily on device classification (78 FR 58785, September 24, 2013). Among other things, FDA's regulations require a device to bear a UDI on its label and packages unless an exception or FDA-approved alternative applies (21 CFR 801.20). A finished device manufactured and labeled prior to the applicable compliance date for the device is excepted from the requirement to bear a UDI for a period of 3 years after that compliance date (21 CFR 801.30(a)(1)).

(Comment 13) A comment requested the Agency to allow supply chain stakeholders at least 3 years to comply with the UDI labeling requirements following the reclassification of any medical device under the part 860 regulations as amended by this final rule, in order to assure consistency with the UDI final rule, which grants a 3-year grace period, for stakeholders to exhaust existing inventories of finished devices labeled prior to the applicable UDI compliance date.

(Response 13) To the extent that a reclassification would affect the UDI compliance dates or UDI labeling requirements (21 CFR part 801, subpart B) applicable to a device, FDA will consider whether additional time to come into compliance with those UDI requirements is appropriate on a case-by-case basis.

(Comment 14) The same commenter requested FDA to review its existing and proposed rules for medical device tracking and reporting, as well as the requirements of the proposed rule, for inconsistencies and discrepancies with the UDI compliance schedule and its 3-year grace period. Specifically, the commenter stated that FDA should assess and include in this final rule measures to relieve the logistical challenges facing distributors and end users who are required to make labeling, tracking, and reporting changes resulting from reclassifications under the part 860 regulations and affecting products distributed commercially prior to, but resold after, the device reclassification.

(Response 14) This rulemaking, as described previously, finalizes changes to part 860 to conform to FDASIA amendments to the FD&C Act for the processes for reclassification and calling for PMAs and does not affect the UDI requirements. Further, any impact of device reclassifications on device compliance with requirements for device labeling (part 801), including the UDI labeling requirements (part 801, subpart B), for device tracking

requirements (21 CFR part 821), and for device reporting requirements (21 CFR part 803), will be addressed on a case-by-case basis.

E. Comments and FDA Response on Removal of Petition Requirements: Classification Questionnaire and Supplemental Data Sheet

The final rule removes the requirement to provide two forms, Form FDA 3429 (General Device Classification Questionnaire) and Form FDA 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 §§ 860.3, 860.84, and 860.123 of this final rule, removing current §§ 860.3(f) and (g), 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 Forms FDA 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 about the device and the appropriate regulatory controls to provide reasonable assurance of the safety and effectiveness of the device. Additionally, on January 30, 2017, the President directed FDA and other Agencies of the U.S. Government to identify existing regulations to be repealed and, in accordance with the APA and other applicable law 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 (Executive Order (E.O.) 13771, 82 FR 9339). The economic and regulatory burden associated with Forms FDA 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 Paperwork Reduction Act (PRA) section of the proposed rule and in section VII, Economic Analysis of Impacts, and section X, PRA, of this final rule. This rule finalizes the provisions removing Forms FDA 3427 and 3429 from the part 860 regulations, as proposed without change (amended §§ 860.3, 860.84 and 860.123 of this final rule, removing current §§ 860.3(f) and (g), 860.84(c)(3) and (4) and 860.123(a)(3) and (4)).

F. Comments on Other Proposed Conforming Changes and Technical Amendments to the Part 860 Regulations

1. Clarifying Amendments to § 860.120(b)

The part 860 regulations explain certain common criteria for reclassifying medical devices under the various authorities of the FD&C Act (§ 860.120(b), containing the general requirements for reclassifications under sections 513(e) and(f), 514(b) (21 U.S.C. 360d(b)), 515(b), and 520(*l*) of the FD&C Act. The final rule removes the term ''substantial equivalence'' in the current version of this part 860 regulation, in order to clarify that reclassifying one device within a generic type of device reclassifies all devices within a generic type of device (amended § 860.120(b) of this final rule).

(Comment 16) Two comments questioned why, under proposed § 860.120(b), the impact of a reclassification decision applies to all devices within the same generic type. Commenters recommended that reclassification should instead be limited to those devices that are substantially equivalent to the reclassified device under question as provided in the current § 860.120(b), because there may be some differences between devices within the same generic type of device that warrant different treatment by a reclassification decision. One commenter suggested that the final rule should provide that the scope of a reclassification decision will be determined based on the reason for the reclassification and the nature of the products affected by the reclassification decision.

(Response 16) Through this rulemaking FDA is clarifying the impact of a reclassification decision under the FD&C Act and is not otherwise changing the scope of reclassifications made in accordance with this provision (see amended § 860.120(b) of this final rule).

The FD&C Act defines the term ''substantial equivalence'' to mean, with respect to a device compared to a predicate device, that FDA has found that the new device has the same intended use as the predicate, has the same technological characteristics as the predicate or different technological characteristics that do not raise different questions of safety and effectiveness from the predicate, and has been demonstrated to be as safe and effective as a legally marketed device (section 513(i) of the FD&C Act). In contrast, the current part 860 regulations define the term ''generic type of device,'' specifically for classification purposes, as a grouping of devices that do not differ significantly in purpose, design, materials, energy sources, function, or any other feature related to safety and effectiveness, and for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness (current § 860.3(i), not amended by this final rule). The term ''generic type of device'' is a more accurate term than ''substantial equivalence'' to describe the impact, scope, and analysis for a reclassification decision and as such we are finalizing the use of ''generic type of device'' as proposed. Accordingly, this rule also finalizes, as proposed, the removal of the reference elsewhere in the part 860 regulations that limited the scope of reclassification to ''substantially equivalent devices'' within the generic type of the reclassified device (amended § 860.120(b) of this final rule).

2. Other Proposed Conforming Amendments

We did not receive comments concerning any of the other proposed conforming amendments or any of the technical amendments described in the following paragraphs of this section. This rule finalizes all of these conforming and technical changes.

The final rule substitutes the terms ''preamendments devices'' and ''postamendments devices,'' in place of ''old devices'' and ''new devices,'' in the part 860 regulations to reflect modern FDA practice (amended §§ 860.84 and 860.134 of this final rule).

To assure uniform reclassification procedures for transitional devices under part 860, the final rule revises the pertinent part 860 regulation to cover the process for reclassification initiated by FDA and to apply to reclassification initiated by manufacturer or importer (amended § 860.136(a) and (b) of this final rule). The final rule also removes the requirement for a part 16 hearing when FDA is reclassifying transitional devices because we believe the

reclassification process under part 860 (*i.e.,* proposed order, panel consultation as appropriate, consideration of comments, and final order) provides sufficient opportunity for participation and review of reclassifications of transitional devices (amended § 860.136 of this final rule).

The final rule revises some of the citations in the part 860 regulations to clarify to which subsection in the FD&C Act these citations refer (amended §§ 860.84(a), 860.123(b)(2), 860.134 (in the section's title), and 860.134(b) of this final rule). Finally, the final rule also makes minor wording changes to certain part 860 regulations to clarify the meaning of these provisions, which are not intended to make any substantive changes (amended §§ 860.7(b), (c)(2), (d)(2), and (g)(1), 860.10(a), 860.120(c), 860.125(a)(2), 860.130(g), and 860.132 of this final rule).

VI. Effective Date

This final rule will become effective 90 days after the date of its publication in the **Federal Register**. During those 90 days, manufacturers will continue to be under an obligation to comply with all applicable provisions of the FD&C Act and applicable regulations.

VII. Economic Analysis of Impacts

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.

This final rule amends the regulations governing the process for classification, reclassification, and calling for PMAs for medical devices. It codifies existing provisions that are already in effect, and updates generally the regulations for device reclassification proceedings.

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 10-year period, to equal $2 million at a 3 percent discount rate and $1.7 million at a 7 percent discount rate. Our estimates of the annualized costs are $0.24 million at a 3 percent discount rate and $0.24 million at a 7 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 the overall cost savings over the next 10 years to be $0.05 million at a 3 percent discount rate and $0.04 million at a 7 percent discount rate. Our estimates of the annualized cost savings are $0.006 million at a 3 percent discount rate and $0.006 million at a 7 percent discount rate.

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Docket No. FDA–2013–N–1529) and is included in the Final Regulatory Impact Analysis available at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm* (Ref. 3).

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) and (k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in E.O. 13175. We have determined that the rule does not contain policies that have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the E.O. and, consequently, a tribal summary impact statement is not required.

X. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Reclassification Petitions for Medical Devices.

Description: This rule eliminates the requirement for petitioners to complete Form FDA 3429 (Classification Questionnaire) and Form FDA 3427 (Supplemental Data Sheet). The estimated information collection burdens for the forms are currently approved under OMB control number 0910–0138.

Description of Respondents: The reporting requirements referenced in this document are imposed on any person petitioning for reclassification of a preamendments device and any manufacturer or importer of the device petitioning for reclassification of a postamendments or transitional device.

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Supporting data for reclassification petition—§ 860.123	6	1	6	497	2,982

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Section 860.123 is being amended to eliminate the requirement for petitioners to complete Form FDA 3429 (Classification Questionnaire) and Form FDA 3427 (Supplemental Data Sheet). This revision reduces the estimated burden by 18 hours. 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.

Based on current trends, FDA anticipates that six 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 form, 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.

We received two comments on the proposed rule that are related to the information collection. Please see Comments 5 and 15 for a description of the comments and our response.

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the PRA.

Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

This final rule refers to previously approved collections of information found in FDA regulations and guidance. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 801, subpart B, regarding unique device identifier, have been approved under OMB control number 0910–0720; the collections of information in 21 CFR part 803, regarding medical device reporting, have been approved under OMB control number 0910–0437; the collections of information in 21 CFR part 807, subparts A through D, regarding establishment registration and listing, have been approved under OMB control number 0910–0625; the collections of information in 21 CFR part 807, subpart E, regarding premarket notification, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket notification, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 821, regarding medical device tracking, have been approved under OMB control number 0910–0442; and the collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844.

XI. Federalism

We have analyzed this final rule in accordance with the principles set forth in E.O. 13132. We have determined that the final rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the final rule does not contain policies that have federalism implications as defined in the E.O. and, consequently, a federalism summary impact statement is not required.

XII. References

The following references are on display at Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m. Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. ''Medical Device Classification Product Codes; Guidance for Industry and FDA Staff'' (April 2013), available at *https://www.fda.gov/MedicalDevices/ucm285317.htm.*
2. ''The Open Public Hearings at FDA Advisory Committee Meetings; Guidance for the Public, FDA Advisory Committee Members, and FDA Staff'' (May 2013), available at *https://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm236144.pdf.*
3. ''Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, and Final Unfunded Mandates Reform Act Analysis for Medical Device Classification Procedures,'' available at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

List of Subjects in 21 CFR Part 860

Administrative practice and procedure, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 860 is amended as follows:

PART 860—MEDICAL DEVICE CLASSIFICATION PROCEDURES

■ 1. The authority citation for part 860 continues to read as follows:

Authority: 21 U.S.C. 360c, 360d, 360e, 360i, 360j, 371, 374.

§ 860.3 [Amended]

■ 2. Amend § 860.3 by removing and reserving paragraphs (f) and (g).

■ 3. Amend § 860.7 by revising paragraph (b) introductory text, the last sentence in paragraph (c)(2), paragraph (d)(2), and the last sentence in paragraph (g)(1) to read as follows:

§ 860.7 Determination of safety and effectiveness.

* * * * *

(b) In determining the safety and effectiveness of a device for purposes of classification, establishment of special controls for class II devices, and premarket approval of class III devices, the Commissioner and the classification panels will consider the following, among other relevant factors:

* * * * *

(c) * * *

(2) * * * Such information may be considered, however, in identifying a device with questionable safety or effectiveness.

(d) * * *

(2) Among the types of evidence that may be required, when appropriate, to determine that there is reasonable assurance that a device is safe are investigations using laboratory animals, investigations involving human subjects, nonclinical investigations, and analytical studies for in vitro diagnostic devices.

* * * * *

(g)(1) * * * The failure of a manufacturer or importer of a device to present to the Food and Drug Administration adequate, valid scientific evidence showing that there is reasonable assurance of the safety and effectiveness of the device, if regulated by general controls alone, or by general controls and special controls, may support a determination that the device be classified into class III.

* * * * *

■ 4. Add § 860.10 to read as follows:

§ 860.10 Implants and life-supporting or life-sustaining devices.

(a) A classification panel will recommend classification into class III of any implant or life-supporting or life-sustaining device unless the panel determines that such classification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. If the panel recommends classification or reclassification of such a device into a class other than class III, it shall set forth in its recommendation the reasons for so doing and an identification of the risks to health, if any, presented by the device. In the case of such a device being recommended for classification or reclassification into class II, the panel shall describe the special controls that, in addition to general controls, the panel believes are necessary to provide reasonable assurance of safety and effectiveness of the device and how such controls provide such assurance.

(b) The Commissioner will classify an implant or life-supporting or life-sustaining device into class III unless the Commissioner determines that such classification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. If the Commissioner proposes to classify or reclassify such a device into a class other than class III, the regulation or order effecting such classification or reclassification will be accompanied by a full statement of the reasons for so doing. A statement of the reasons for not classifying or retaining the device in class III may be in the form of concurrence with the reasons for the recommendation of the classification panel, together with supporting documentation and data satisfying the requirements of § 860.7 and an identification of the risks to health, if any, presented by the device. In the case of such a device being classified or reclassified into class II, the Commissioner shall describe the special controls that, in addition to general controls, the panel believes are necessary to provide reasonable assurance of safety and effectiveness of the device and how such controls provide such assurance.

■ 5. Add § 860.15 to read as follows:

§ 860.15 Exemptions from sections 510, 519, and 520(f) of the Federal Food, Drug, and Cosmetic Act.

(a) A panel recommendation to the Commissioner that a device be classified or reclassified into class I will include a recommendation as to whether the device should be exempted from some or all of the requirements of one or more of the following sections of the Federal Food, Drug, and Cosmetic Act: Section 510 (registration, product listing, and premarket notification), section 519 (records and reports) and section 520(f) (good manufacturing practice requirements of the quality system regulation), and, in the case of a recommendation for classification into class II, whether the device should be exempted from the premarket notification requirement under section 510.

(b) A regulation or an order classifying or reclassifying a device into class I will specify which requirements, if any, of sections 510, 519, and 520(f) of the Federal Food, Drug, and Cosmetic Act the device is to be exempted from or, in the case of a regulation or an order classifying or reclassifying a device into class II, whether the device is to be exempted from the premarket notification requirement under section 510, together with the reasons for such exemption.

(c) The Commissioner will grant exemptions under this section only if the Commissioner determines that the requirements from which the device is exempted are not necessary to provide reasonable assurance of the safety and effectiveness of the device.

■ 6. Amend § 860.84 by:

■ a. Revising the section heading and paragraph (a);

■ b. Removing the semicolon at the end of paragraph (c)(2) and adding ''; and'' in its place;

■ c. Removing paragraphs (c)(3) and (4);

■ d. Redesignating paragraph (c)(5) as paragraph (c)(3); and

■ e. Revising paragraphs (d)(2), (d)(4) through (6), (e), and (g)(2) and (3).

The revisions read as follows:

§ 860.84 Classification procedures for ''preamendments devices.''

(a) This subpart sets forth the procedures for the original classification of a generic type of device that was in commercial distribution before May 28, 1976. Such a device will be classified by regulation into either class I (general controls), class II (special controls) or class III (premarket approval), depending upon the level of regulatory control required to provide reasonable assurance of the safety and effectiveness of the device (§ 860.3(c)). This subpart does not apply to a device that is classified into class III by statute under section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act because the Food and Drug Administration has determined that the device is not ''substantially equivalent'' to any device subject to this subpart or under section 520(*l*)(1) of the Federal Food, Drug, and Cosmetic Act because the device was regarded previously as a new drug. In classifying a *preamendments* device to which this section applies, the Food and Drug Administration will follow the procedures described in paragraphs (b) through (g) of this section.

* * * * *

(d) * * *

(2) A summary of the data upon which the recommendation is based;

* * * * *

(4) In the case of a recommendation for classification into class I, a recommendation as to whether the device should be exempted from the requirements of one or more of the following sections of the Federal Food, Drug, and Cosmetic Act: Section 510 (registration, product listing, and premarket notification), section 519 (records and reports), and section 520(f) (good manufacturing practice requirements of the quality system regulation) and, in the case of a recommendation for classification into class II, whether the device should be exempted from the premarket notification requirement under section 510, in accordance with § 860.15;

(5) In the case of a recommendation for classification into class II or class III, to the extent practicable, a recommendation for the assignment to the device of a priority for the application of a performance standard or a premarket approval requirement, and in the case of classification into class II, a recommendation on the establishment of special controls and whether the device should be exempted from premarket notification in accordance with § 860.15; and

(6) In the case of a recommendation for classification of an implant or a life-supporting or life-sustaining device into class I or class II, a statement of why premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device and an identification of the risks to health, if any, presented by the device, in accordance with § 860.10.

(e) A panel recommendation is regarded as preliminary until the Commissioner has reviewed it, discussed it with the panel if appropriate, and published a proposed regulation classifying the device. Preliminary panel recommendations are filed at Dockets Management Staff upon receipt and are available to the public at *https://www.regulations.gov.*

* * * * *

(g) * * *

(2) If classifying the device into class II, establish the special controls for the device and prescribe whether the premarket notification requirement will apply to the device; and

(3) If classifying an implant, or a life-supporting or life-sustaining device, comply with § 860.10(b).

■ 7. Add § 860.90 to read as follows:

§ 860.90 Consultation with panels.

(a) When the Commissioner is required to consult with a panel concerning a classification under § 860.84, the Commissioner will consult with the panel in one of the following ways:

(1) Consultation by telephone with at least a majority of current voting panel members and, when possible, nonvoting panel members in a telephone or video conference call; or

(2) Discussion at a panel meeting.

(b) The method of consultation chosen by the Commissioner will depend upon the importance and complexity of the subject matter involved and the time available for action. When time and circumstances permit, the Commissioner will consult with a panel through discussion at a panel meeting.

§ 860.93 [Removed]

■ 8. Remove § 860.93.

§ 860.95 [Removed]

■ 9. Remove § 860.95.

■ 10. Amend § 860.120 by revising paragraphs (b) and (c) to read as follows:

§ 860.120 General.

* * * * *

(b) The criteria for determining the proper class for a device are set forth in § 860.3(c). The reclassification of any device within a generic type of device causes the reclassification of all devices within that generic type. Accordingly, a petition for the reclassification of a specific device will be considered a petition for reclassification of all devices within the same generic type.

(c) Any interested person may submit a petition for reclassification under section 513(e), 514(b), or 515(b) of the Federal Food, Drug, and Cosmetic Act. A manufacturer or importer may submit a petition for reclassification under section 513(f) or 520(*l*) of the Federal Food, Drug, and Cosmetic Act. The Commissioner may initiate the reclassification of a device under the following sections of the Federal Food, Drug, and Cosmetic Act:

(1) Section 513(e) (for a classified device other than a device classified into class III under section 513(f)(1) or 520(*l*)(1) of the Federal Food, Drug, and Cosmetic Act);

(2) Section 513(f)(3) (for a device classified into class III under section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act); or

(3) Section 520(*l*)(2) (for a device classified into class III under section 520(*l*)(1) of the Federal Food, Drug, and Cosmetic Act).

■ 11. Amend § 860.123 by:

■ a. Removing paragraphs (a)(3) and (4);

■ b. Redesignating paragraphs (a)(5) through (10) as paragraphs (a)(3) through (8), respectively;

■ c. Removing the period at the end of newly redesignated paragraph (a)(7) and adding ''; and'' in its place; and

■ d. Revising paragraph (b)(2).

The revision reads as follows:

§ 860.123 Reclassification petition: Content and form.

* * * * *

(b) * * *

(2) Marked clearly with the section of the Federal Food, Drug, and Cosmetic Act under which the petition is being submitted, *i.e.,* ''513(e),'' ''513(f)(3),'' ''514(b),'' ''515(b),'' or ''520(*l*) Petition'';

* * * * *

■ 12. Amend § 860.125 by:

■ a. Revising paragraphs (a) introductory text and (a)(1);

■ b. Removing paragraph (a)(2) and redesignating paragraph (a)(3) as paragraph (a)(2);

■ c. Redesignating paragraph (c) as paragraph (d);

■ d. Revising newly redesignated paragraph (d); and

■ e. Adding a new paragraph (c).

The revisions and addition read as follows:

§ 860.125 Consultation with panels.

(a) 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 in one of the following ways:

(1) Consultation by telephone with at least a majority of current voting panel members and, when possible, nonvoting panel members in a telephone or video conference call; or

* * * * *

(c) The Commissioner will consult with a classification panel prior to changing the classification of a device in a proceeding under section 513(e) of the Federal Food, Drug, and Cosmetic Act and § 860.130 upon the Commissioner's own initiative or upon petition of an interested person, and in the latter case, the Commissioner will distribute a copy of the petition, or its relevant portions, to each panel member.

(d) When a petition is submitted under § 860.134 for a postamendments, not substantially equivalent, device, if the Commissioner chooses to consult with the panel, the Commissioner will obtain a recommendation that includes the information described in § 860.84(d). In consulting with a panel about a petition submitted under § 860.130(d), § 860.136(a), or received in a proceeding under § 860.133(b), the Commissioner may or may not obtain a formal recommendation.

■ 13. Amend § 860.130 by revising the section heading and paragraphs (c) through (g) to read as follows:

§ 860.130 General procedures under section 513(e) of the Federal Food, Drug, and Cosmetic Act.

* * * * *

(c) By administrative order published under this section, the Commissioner may change the classification from:

(1) Class I or class II to class III if the Commissioner determines that the device meets the criteria set forth in § 860.3(c)(3) for a class III device; or

(2) Class III or class I to class II if the Commissioner determines that the device meets the criteria set forth in § 860.3(c)(2) for a class II device; or

(3) Class III or class II to class I if the Commissioner determines that the device meets the criteria set forth in § 860.3(c)(1) for a class I device.

(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 this section.

(2) 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.

(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.

(f) If a device is reclassified under this section, the administrative order effecting the reclassification may revoke any special control or premarket approval requirement that previously applied to the device but that is no longer applicable because of the change in classification.

(g) An administrative order under this section changing the classification of a device to class II may provide that such reclassification will not take effect until the effective date of a performance standard for the device established under section 514 of the Federal Food, Drug, and Cosmetic Act or other special controls established under the order. An order under this section changing the classification of a device to class II may also establish the special controls necessary to provide reasonable assurance of the safety and effectiveness of the device.

■ 14. Amend § 860.132 by:

■ a. Revising the section heading and paragraph (a);

■ b. Redesignating paragraph (b) as paragraph (d);

■ c. Revising newly redesignated paragraphs (d) introductory text and (d)(1) and (3); and

■ d. Adding new paragraphs (b) and (c).

The revisions and additions read as follows:

§ 860.132 Procedures when the Commissioner initiates a performance standard or premarket approval proceeding under section 514(b) or 515(b) of the Federal Food, Drug, and Cosmetic Act.

(a) Sections 514(b) and 515(b) of the Federal Food, Drug, and Cosmetic Act require the Commissioner to provide, by notice in the **Federal Register**, an opportunity for interested parties to petition to change the classification of a device based upon new information relevant to its classification when the Commissioner initiates a proceeding to develop a performance standard for the device if in class II or to issue an order requiring premarket approval for the device if in class III.

(b) If the Commissioner agrees that the new information submitted in response to a proposed order to require premarket approval of a device issued under section 515(b) of the Federal Food, Drug, and Cosmetic Act warrants a change in classification, the Commissioner shall follow the administrative order procedures under section 513(e) of the Federal Food, Drug, and Cosmetic Act and § 860.130 to effect such a change.

(c) If the Commissioner does not agree that the new information submitted in response to a proposed order to require premarket approval of a device issued under section 515(b) of the Federal Food, Drug, and Cosmetic Act warrants a change in classification, the Commissioner will deny the petition.

(d) The procedures under section 514(b) of the Federal Food, Drug, and Cosmetic Act are as follows:

(1) Within 30 days after publication of the Commissioner's notice referred to in paragraph (a) of this section, an interested person files a petition for reclassification in accordance with § 860.123.

* * * * *

(3) Within 60 days after publication of the notice referred to in paragraph (a) of this section, the Commissioner either denies the petition or gives notice of the intent to initiate a change in classification in accordance with § 860.130.

■ 15. Add § 860.133 to read as follows:

§ 860.133 Procedures when the Commissioner initiates a proceeding to require premarket approval under section 515(b) of the Federal Food, Drug, and Cosmetic Act.

(a) Section 515(b) of the Federal Food, Drug, and Cosmetic Act applies to proceedings to require premarket approval for a class III preamendments device.

(b) The Commissioner may require premarket approval for a class III preamendments device by administrative order published in the **Federal Register** following publication of a proposed 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 from all affected stakeholders, including patients, payors, and providers. The panel will consider reclassification petitions received in the proceeding in accordance with section 513(e) of the Federal Food, Drug, and Cosmetic and the applicable consultation procedures in § 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 this section.

■ 16. Amend § 860.134 by:

■ a. Revising the section heading and paragraph (a)(3);

■ b. Removing the undesignated paragraph following paragraph (a)(3);

■ c. Adding paragraph (a)(4);

■ d. Revising paragraphs (b) introductory text and (b)(4) and (6); and

■ e. Adding paragraphs (c) and (d).

The revisions and additions read as follows:

§ 860.134 Procedures for reclassification of ''postamendments devices'' under section 513(f)(3) of the Federal Food, Drug, and Cosmetic Act.

(a) * * *

(3) The Commissioner has classified the device into class I or class II in response to a petition for reclassification under this section; or

(4) The device is classified under a request for De Novo classification under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act.

(b) The procedures for effecting reclassification under section 513(f)(3) of the Federal Food, Drug, and Cosmetic Act when initiated by a manufacturer or importer are as follows:

* * * * *

(4) Within 90 days after the date the petition is referred to the panel, following the review procedures set forth in § 860.84(c) for the original classification of a ''preamendments

device'', the panel submits to the Commissioner its recommendation containing the information set forth in § 860.84(d). A panel recommendation is regarded as preliminary until the Commissioner has reviewed it, discussed it with the panel, if appropriate, and developed a proposed reclassification order. Preliminary panel recommendations are filed at Dockets Management Staff upon receipt and are available to the public and posted at *https://www.regulations.gov.*

* * * * *

(6) Within 90 days after the panel's recommendation is received (and no more than 210 days after the date the petition was filed), the Commissioner denies or approves the petition by order in the form of a letter to the petitioner. If the Commissioner approves the petition, the order will classify the device into class I or class II in accordance with the criteria set forth in § 860.3(c) and subject to the applicable requirements of § 860.10, relating to the classification of implants and life-supporting or life-sustaining devices, and § 860.15, relating to exemptions from certain requirements of the Federal Food, Drug, and Cosmetic Act.

* * * * *

(c) By administrative order published under section 513(f)(3) of the Federal Food, Drug, and Cosmetic Act, the Commissioner may, on the Commissioner's own initiative, change the classification from class III under section 513(f)(1) either to class II, if the Commissioner determines that special controls in addition to general controls are necessary and sufficient to provide reasonable assurance of the safety and effectiveness of the device and there is sufficient information to establish special controls to provide such assurance, or to class I if the Commissioner determines that general controls alone would provide reasonable assurance of the safety and effectiveness of the device. The procedures for the reclassification proceeding under this paragraph (c) are as follows:

(1) The Commissioner publishes a proposed reclassification order in the **Federal Register** seeking comment on the proposed reclassification.

(2) The Commissioner may consult with the appropriate classification panel with respect to the reclassification of the device. The panel will consider reclassification in accordance with the consultation procedures of § 860.125.

(3) Following consideration of comments to a public docket and any panel recommendations or comments, the Commissioner may change the classification of a device by final administrative order published in the **Federal Register**.

(d) An administrative order under this section changing the classification of a device from class III to class II may establish the special controls necessary to provide reasonable assurance of the safety and effectiveness of the device.

■ 17. Amend § 860.136 by:

■ a. Revising the section heading, paragraph (a), and paragraph (b) introductory text;

■ b. Removing paragraph (b)(3);

■ c. Redesignating paragraphs (b)(4) through (6) as paragraphs (b)(3) through (5), respectively;

■ d. Revising newly redesignated paragraph (b)(4); and

■ e. Adding paragraphs (c) and (d).

The revisions and additions read as follows:

§ 860.136 Procedures for transitional products under section 520(l) of the Federal Food, Drug, and Cosmetic Act.

(a) Section 520(*l*)(2) of the Federal Food, Drug, and Cosmetic Act applies to reclassification proceedings initiated by the Commissioner or in response to a request by a manufacturer or importer for reclassification of a device currently in class III by operation of section 520(*l*)(1). This section applies only to devices that the Food and Drug Administration regarded as ''new drugs'' before May 28, 1976.

(b) The procedures for effecting reclassification under section 520(*l*) of the Federal Food, Drug, and Cosmetic Act when initiated by a manufacturer or importer are as follows:

* * * * *

(4) Within 180 days after the petition is filed (where the Commissioner has determined it to be adequate for review), the Commissioner, by order in the form of a letter to the petitioner, either denies the petition or classifies the device into class I or class II in accordance with the criteria set forth in § 860.3(c).

* * * * *

(c) By administrative order, the Commissioner may, on the Commissioner's own initiative, change the classification from class III under section 520(*l*) of the Federal Food, Drug, and Cosmetic Act either to class II, if the Commissioner determines that special controls in addition to general controls are necessary and sufficient to provide reasonable assurance of the safety and effectiveness of the device and there is sufficient information to establish special controls to provide such assurance, or to class I if the Commissioner determines that general controls alone would provide reasonable assurance of the safety and effectiveness of the device. The procedures for the reclassification proceeding under this paragraph (c) are as follows:

(1) The Commissioner publishes a proposed reclassification order in the **Federal Register** seeking comment on the proposed reclassification.

(2) The Commissioner may consult with the appropriate classification panel with respect to the reclassification of the device. The panel will consider reclassification in accordance with the consultation procedures of § 860.125.

(3) Following consideration of comments to a public docket and any panel recommendations or comments, the Commissioner may change the classification of a device by final administrative order published in the **Federal Register**.

(d) An administrative order under this section changing the classification of a device from class III to class II may establish the special controls necessary to provide reasonable assurance of the safety and effectiveness of the device.

Dated: December 7, 2018.

Scott Gottlieb,

Commissioner of Food and Drugs.

[FR Doc. 2018–27015 Filed 12–13–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9842]

RIN 1545–BO63

Tax Return Preparer Due Diligence Penalty Under Section 6695(g); Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains a correction to final regulations (TD 9842) that were published in the **Federal Register** on Wednesday, November 7, 2018. The final regulations relate to the tax return preparer penalty.

DATES: This correction is effective December 17, 2018 and applicable November 7, 2018.

FOR FURTHER INFORMATION CONTACT: Marshall French at (202) 317–6845 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9842) that are the subject of this correction are