

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 860

[Docket No. FDA-2013-N-1529]

Medical Device Classification Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations governing classification and reclassification of medical devices to conform to the applicable provisions in the Food and Drug Administration Safety and Innovation Act (FDASIA). FDA is also proposing changes unrelated to the new FDASIA requirements to update its regulations governing classification and reclassification of medical devices. FDA is taking this action to codify the procedures and criteria that apply to classification and reclassification of medical devices and to provide for classification of devices in the lowest regulatory class consistent with the public health and the statutory scheme for device regulation.

DATES: Submit either electronic or written comments on the proposed rule by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (the PRA) by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. FDA-2013-N-1529 by any of the following methods, except that comments on information collection issues under the

Paperwork Reduction Act of 1995 must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the “Paperwork Reduction Act of 1995” section of this document).

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2013-N-1529 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the “Comments” heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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SUPPLEMENTARY INFORMATION:

I. Background

FDA is proposing to revise the regulations in part 860 (21 CFR part 860) to conform to recent changes made in FDASIA to sections 513(e) and 515(b) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(e) and 360e(b)), which became effective on July

9, 2012. These provisions established processes for reclassification of devices by administrative order instead of by regulation. FDA also proposes to update other reclassification provisions and to clarify the meaning of certain terms related to device classification and reclassification.

II. Legal Authority

The FD&C Act (21 U.S.C. 301 et seq.) establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act established 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). For simplicity, FDA will refer to “reasonable assurance of safety and effectiveness,” the basic concept of device regulation, as “RASE.” Under section 513(d) of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments in May 28, 1976 (generally referred to as preamendments devices), are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel’s recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device.

Section 513(e) of the FD&C Act provides that FDA may, by administrative order published in the Federal Register, reclassify a device based upon “new information.” FDA can initiate a reclassification under section 513(e) of the FD&C Act, or an interested person may petition FDA to reclassify a device. The term “new information,” as used in section 513(e) of the FD&C Act, includes information developed as a result of a reevaluation of the data before the Agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., Holland-Rantos v. United States Dep’t. of

Health, Educ., & Welfare, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); Upjohn v. Finch, 422 F.2d 944 (6th Cir. 1970); Bell v. Goddard, 366 F.2d 177 (7th Cir. 1966).)

Section 608 of FDASIA amends section 513(e) of the FD&C Act and changes the procedure to reclassify a device under section 513(e). Under the new procedures, when FDA reclassifies devices under section 513(e), it must do so through administrative order. Prior to the publication of a final order, FDA must also publish a proposed order in the Federal Register and consider any comments submitted on the proposed order. FDA must, in addition, hold a device classification panel meeting (21 U.S.C. 360c(b)). The panel meeting must occur before the final order is published, and may occur either before or after the proposed order is published. The proposed order must include the following: (1) A substantive summary of valid scientific evidence, including the public health benefits and risks of the device, (2) when reclassifying from class II to class III, an explanation that general and special controls are insufficient to reasonably assure safety and effectiveness, and (3) when reclassifying from class III to class II, an explanation that general and special controls are sufficient to reasonably assure safety and effectiveness.

Section 608 of FDASIA also amends section 515(b) of the FD&C Act. Under section 515(b) of the FD&C Act as amended, preamendments devices that have been classified into class III and devices found substantially equivalent by means of premarket notification (510(k)) procedures to such preamendments devices or to devices within that generic device type may be marketed without submission of a premarket approval application (PMA) until FDA issues a final order requiring premarket approval. The process to require approval of a PMA for a preamendments class III device requires that FDA publish a proposed order in the Federal Register, hold an advisory committee meeting, and consider comments on the proposed order.

Under section 515(b)(2) of the FD&C Act as amended, a proposed order to support the call for PMAs must: (1) Contain proposed findings with respect to 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 (PDP) under section 515(f)) and the benefit to the public from the use of the device; (2) provide an opportunity for the submission of comments on the proposed order and the proposed findings; and (3) provide an opportunity to request a change in the classification of the device based on new information relevant to the classification of the device. After consideration of comments on the proposed order and findings, FDA must issue: (1) An administrative order requiring approval of a PMA and publish in the Federal Register findings with respect to 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 PDP and the benefit to the public from the use of the device or (2) publish in the Federal Register a notice terminating the process to require approval of a PMA together with reasons for such termination, and initiate reclassification under section 513(e) of the FD&C Act.

Under section 501(f) of the FD&C Act (21 U.S.C. 351(f)), a preamendments class III device may be commercially distributed without a PMA or a notice of completion of a PDP until 90 days after FDA issues a final order requiring premarket approval for the device, or 30 months after final classification of the device under section 513 of the FD&C Act, whichever is later.

FDA refers to devices that were not in commercial distribution before May 28, 1976, as “postamendments devices.” These devices are classified automatically under section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require the filing of a PMA, 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 under section 513(f)(2) of

the FD&C Act; or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the FD&C Act, to a predicate device that does not require the filing of a PMA. FDA determines whether new devices are substantially equivalent to previously cleared devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and 21 CFR part 807.

Section 513(f)(3) of the FD&C Act provides for reclassification of postamendments devices. Under this section, FDA may initiate, or the manufacturer or importer of a device may petition for the reclassification of a device classified into class III by operation of law under section 513(f)(1) of the FD&C Act.

Reclassification of transitional devices is governed by section 510(l)(2) of the FD&C Act. Under section 520(l)(2) of the FD&C Act (21 U.S.C. 360j(l)(2)), FDA may initiate, or the manufacturer or importer of a device may petition for the reclassification of a device classified into class III by operation of law under section 520(l)(1). The 1976 amendments broadened the definition of “device” in section 201(h) of the FD&C Act (21 U.S.C. 321(h)) to include certain articles that were once regulated as drugs. Under the 1976 amendments, Congress classified all those devices previously regulated as new drugs into class III (generally referred to as transitional devices). Congress amended section 520(l) of the FD&C Act to direct FDA to collect certain safety and effectiveness information from the manufacturers of transitional devices still remaining in class III to determine whether the devices should be reclassified into class II (special controls and general controls) or class I (general controls).

Although combination products retain the regulatory identities of their constituent parts, the FD&C Act also recognizes combination products as a category of products that are distinct from products that are solely drugs, devices, or biological products, and that could be subject to

specialized regulatory controls. See, e.g., section 503(g)(4)(A) of the FD&C Act (21 U.S.C. 353(g)(4)(A)) and section 563(a) of the FD&C Act (21 U.S.C. 360bbb-2(a)).

In addition, section 701(a) of the FD&C Act (21 U.S.C. 371(a)) provides authority to issue regulations for the efficient enforcement of the FD&C Act. This includes the authority to develop regulations to ensure sufficient and appropriate ongoing assessment of the risks associated with devices and combination products.

III. Proposed Revisions

FDASIA changed the procedures for reclassification of devices under section 513(e) of the FD&C Act, and for requiring PMAs for preamendments class III devices from notice and comment rulemaking under section 553 of the Administrative Procedure Act to an administrative order process. FDA is proposing these revisions to update its regulations to reflect these and other changes, and to ensure classification of devices in the lowest regulatory class consistent with the protection of the public health and the statutory scheme for device regulation.

A. Proposed Amendments to 21 CFR 860.3--Definitions

This section provides the key definitions for part 860. FDA proposes to amend § 860.3 to remove the paragraph designations and to list the definitions alphabetically. This proposed amendment would simplify adding any new definitions to this part. FDA is also proposing to change the term from “life-supporting or life-sustaining device” to the term “supporting or sustaining human life” to conform to the language of section 513 of the FD&C Act.

1. Definitions of Class I, II, and III

FDA proposes to amend the definitions of class I, class II, and class III by revising the definitions to reflect a key principle underlying device classification, namely, that a reasonable assurance of safety and effectiveness is necessary for all three device classes; however, the level

of regulation necessary to provide such assurance should be closely tailored to the risk presented by a type of device. Explanatory language about general and special controls has been removed from the definitions of class I and II, respectively, to avoid repetition with the new proposed definitions for the terms “general controls” and “special controls”. Other minor changes are intended to improve the clarity and structure of these definitions.

FDA is also proposing changes to the definition of class III to provide greater clarity regarding which devices fall within this class, and to improve transparency and predictability in device classification and reclassification decisions. Section 513(a)(1)(C) of the FD&C Act provides a definition for class III devices.

An important aspect of this definition is that FDA must first determine that a device falls into one of the three categories that make the device potentially high risk to be eligible to be classified by FDA in class III because the FD&C Act explicitly reserves class III to devices that are intended for use in supporting or sustaining human life, of substantial importance in preventing impairment of health, or that present a potential unreasonable risk of illness or injury. The proposed definition retains this concept, reserving class III for devices that present heightened potential risks because they fall into one of three statutory categories. As a shorthand, this preamble will refer to devices described by section 513(a)(1)(C)(ii) of the FD&C Act as potentially high risk devices, although in some cases, such devices may be known to be high risk. Importantly, the proposed definition of class III refers to the initial statutory classification of postamendment (21 U.S.C. 360c(f)) and transitional devices (21 U.S.C. 360j(1)(1)) to make clear that such devices are placed into class III automatically, rather than by operation of the definition of class III at section 513(a)(1)(C) of the FD&C Act. Thus, the second part of the proposed definition of class III (under paragraph (b)) will apply to initial

classification of preamendments devices and reclassification decisions for a type of device, but will not control classification decisions FDA renders in reviewing a premarket notification under section 510(k) of the FD&C Act.

The current regulatory definition closely tracks the statute, but it does not further explain the key statutory concept that determines which potentially high risk devices will be classified in class III--namely, the concept of when insufficient information exists to determine that general and special controls would provide RASE. FDA's experience has shown that different stakeholders interpret this language differently. In some instances, FDA's stakeholders have suggested that premarket and postmarket controls typically associated with class III devices, such as requiring clinical trials to provide an independent assessment of the safety and effectiveness of a device, can be established as special controls. In other instances, FDA's stakeholders have suggested that all high risk devices should be classified in class III, even if those risks are well understood and may be able to be controlled through premarket studies showing equivalence to a marketed device, labeling, and other general or special controls.

To address the need for greater clarity and promote consistent expectations about device classification, FDA is proposing to identify those potentially high risk devices for which insufficient information exists to determine that special and general controls would provide RASE. Under section 513(a)(2)(C) of the FD&C Act, the safety and effectiveness of a device are determined by evaluating its risks and benefits; thus, after FDA has determined a device is potentially high risk, FDA must still determine the risks, benefits, and appropriate regulatory controls to determine whether the device should be classified into class III. The proposed regulation would identify five categories of devices for classification into class III based on the risks, benefits, and available controls for the three device classes:

Devices that present known risks that cannot be controlled. This category encompasses devices that have a favorable benefit- risk profile even though they present significant risks that cannot be adequately controlled through general and special controls. Because special controls cannot fully address the risks presented, the highest level of regulation is necessary to minimize those risks.

Devices for which the risk-benefit profile is unknown or unfavorable. For most devices that enter the market each year after premarket review by FDA, FDA evaluates the safety and effectiveness of the device--and its risks and benefits--by determining in the context of the review of a premarket notification under section 510(k) of the FD&C Act whether the device is substantially equivalent to a legally marketed predicate device; thus, FDA assesses safety and effectiveness through a comparison to a predicate. FDA believes comparison to a predicate device is appropriate for the overwhelming majority of devices subject to premarket review, including many devices that are intended for use in supporting or sustaining human life, of substantial importance in preventing impairment of health, or that present a potential unreasonable risk of illness or injury.

For certain potentially high risk technologies, however, the risks or benefits may not be sufficiently well understood to allow meaningful comparison of a device to a predicate device. If the risks and benefits of a device are unknown, FDA may be unable to identify the performance parameters relevant to risks and benefits that would allow FDA to assess safety and effectiveness through a comparison to a predicate. On the other hand, if FDA does have information concerning the risks and/or benefits of a type of device, but the known benefits do not justify the known risks, there cannot be sufficient information to determine that general controls and special controls are sufficient to provide RASE, unless the applicant provides additional valid scientific

evidence independently establishing a favorable benefit/risk profile for the device. The proposed rule would provide clear language classifying into class III potentially high risk devices for which the risk/benefit profile is unknown or unfavorable.

Devices for which a full review of manufacturing information is necessary. Even when the risk/benefit profile of a device is well-established, for certain potentially high risk devices, the risks may be of a type or degree that can only be adequately addressed by relatively stringent controls. Among the relatively stringent controls applied to class III devices are, in addition to the requirement for approval of an application containing valid scientific evidence independently establishing RASE for the device, the requirement to provide full manufacturing information about a device for FDA review before it may enter the market. FDA may be aware, for example, from experience with a particular device type, that certain aspects of the manufacturing process are critical to the safety or effectiveness of the device, which makes review of the manufacturing process necessary prior to marketing.

Because the statutory provision concerning special controls provides only an illustrative list of controls, leaving open the possibility other controls could be available as special controls, FDA believes it is important to identify those controls that are appropriate only for class III devices. FDA believes the flexibility provided by the statutory definition of special controls--and retained in the proposed regulatory definition--is appropriate and facilitates the goal of regulating device classes in the lowest regulatory class consistent with the protection of the public health. FDA also believes, however, that the statutory classification scheme contemplates that certain regulatory controls are appropriately reserved to class III devices subject to approval under section 515 of the FD&C Act. For example, section 515(c) of the FD&C Act specifically provides that a PMA is to include a full description of the methods used in, and the facilities and

controls used for, the manufacture, processing, and, when relevant, packing and installation, of [a] device. This provision is in stark contrast to section 513(i) of the FD&C Act, which limits FDA's review of a premarket notification to a review of the intended use and technology of a device. In addition, section 513(f)(5), provides that FDA may not withhold a determination of the initial classification of a device under section 513(f)(1) because of a failure to comply with any provision of this chapter unrelated to a substantial equivalence decision, including a finding that the facility in which the device is manufactured is not in compliance with good manufacturing requirements as set forth in regulations of the Secretary under section 360j(f) of this title (other than a finding that there is a substantial likelihood that the failure to comply with such regulations will potentially present a serious risk to human health).

Differences in the types of information FDA reviews in 510(k)s and PMAs correspond to different review timeframes for these two application types; indeed, on the rare occasions that FDA has required a manufacturing inspection before clearance of a premarket notification for a device, FDA has found scheduling the inspection within the 90-day statutory timeframe for 510(k)s challenging. For all of these reasons, when a review of a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation, of a device is necessary to provide RASE for a potentially high risk device, general and special controls are inadequate to provide RASE and the device thus meets the statutory definition of class III.

Devices for which premarket review of any change affecting safety or effectiveness is necessary. Similarly, when approval of a premarket submission for any change to a device that affects safety or effectiveness is necessary to provide RASE, general and special controls are insufficient to provide RASE, and classification in class III is necessary. Section 515(d)(6) of

the FD&C Act provides explicit authority to require premarket approval of a supplemental application for any change to an approved device that affects safety or effectiveness (with the exception of changes to certain manufacturing methods or procedures, for which a notice to FDA must be submitted 30 days prior to implementation). FDA considers this to be a regulatory control reserved for class III devices. For higher risk devices with unique design characteristics or manufacturing processes, it is essential for FDA to assess any change that affects safety or effectiveness premarket to ensure that RASE is maintained, for example because of the cumulative impact that multiple changes may have on the safety or effectiveness of the device over time. FDA proposes that devices for which premarket review of any change that affects safety or effectiveness is necessary to provide RASE be classified in class III.

Combination products. The last proposed category of class III devices are devices that provide the primary mode of action for combination products that include a drug constituent part for which a finding is required that the drug constituent part be safe and effective, or include a biological product constituent part for which a finding is required that the biological product constituent part be safe, pure, and potent, and such a finding has not been made. Accordingly, the proposed rule would classify such devices in class III, subject to premarket approval.

2. Other Definitions

FDA proposes to amend the definition of generic type of device to address confusion about the inter-relationship among product code (procode), generic type, and classification regulation. In general, these represent levels of device categorization, with the lowest range of differences at the procode level and the highest range of differences at the classification regulation level, though sometimes the levels are coextensive. The terms “device,” “device type,” and “generic device type” are often used in the FD&C Act and implementing regulations

interchangeably. As explained in the guidance entitled “Medical Device Classification Product Codes--Guidance for Industry and Food and Drug Administration Staff,” CDRH assigns three letter “procodes” to devices to group and track them for various purposes. FDA proposes to amend the definition of “generic type of device” to make clear that a generic type may include one or more procodes, and a single classification regulation may include one or more generic types of device and may even, in some instances, straddle device classes.

FDA proposes to remove the definitions for classification questionnaire and supplemental data sheet because FDA is proposing to remove the requirement that this form be included as part of the reclassification procedures under § 860.84 and a reclassification petition under § 860.123. FDA believes the proposed definitions, when finalized, will clarify the classification criteria for panels, FDA, and all stakeholders and thus obviate the need for this form.

FDA proposes to add a definition of general controls for medical devices that harmonizes with the definition in section 513(a)(1)(A) of the FD&C Act. While explanations of general controls have been provided in guidance, adding the definition to this regulation will provide another opportunity to clarify which controls are included as general controls.

FDA proposes to replace the term “implant” with the term “implantable device,” which FDA proposes to have the same definition as “implant.”

FDA proposes to add a definition of special controls to clarify the regulatory significance of special controls as the controls necessary to provide RASE for a type of device classified in class II, which must be met for a device to be in class II.

FDA proposes to add a definition of “special controls guideline.” Under section 513(a) of the FD&C Act, a special controls guideline is a means for providing RASE for a class II device. While the guideline establishes a mandatory level of regulatory controls that must be met

for the device to be in class II, manufacturers may comply with the guideline either by following the particular controls described in the guideline or by using alternative mitigation measures but demonstrating to the Agency's satisfaction that those alternative measures provide the same or greater level of assurance of safety and effectiveness.

B. Proposed Amendments to 21 CFR 860.7--Determination of Safety and Effectiveness

This section provides the relevant factors FDA and classification panels will consider in reviewing evidence of device safety and effectiveness. The proposed provision clarifies class II classification or reclassification requirements for safety and effectiveness. FDA proposes to amend § 860.7(b) and (g)(1) to include establishment of special controls for class II devices, replacing the term performance standards because special controls include performance standards. Under section 513(a)(1)(B) of the FD&C Act, special controls includes the issuance of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification of submissions in accordance with section 510(k)), recommendations and other appropriate actions as the FDA deems necessary to provide such assurance.

FDA is proposing additional minor changes in paragraphs § 860.7(c)(2) and (d)(2) to update terminology and to reflect changes in the FD&C Act.

C. Proposed Amendments to 21 CFR Part 860.84--Classification Procedures for
"Preamendments Devices"

This section explains the procedures and criteria for original classification of preamendments devices. FDA proposes to amend § 860.84 by removing the term "old devices" as a reference to medical devices in commercial distribution before May 28, 1976. The

terminology FDA more commonly uses is “preamendments devices.” May 28, 1976, is the date of enactment of the Medical Device Amendments of 1976.

FDA further proposes removing the requirement to answer the classification questionnaire and provide information using the supplemental data sheet. The classification questionnaire provides recommendations and information for FDA to consider during the classification process. The supplemental data sheet is information compiled by a classification panel or submitted in a petition for reclassification. As FDA has gained experience with the classification processes, questions concerning the utility of the classification questionnaire and supplemental data sheet have arisen. FDA believes that a more efficient use of FDA and petitioner resources would be to focus on the information the petitioner provides concerning review of available valid scientific evidence, appropriate regulatory controls given the risks presented by the device, and regulatory standards to understand whether general controls are sufficient to provide RASE or whether general controls and special controls are sufficient to provide RASE.

FDA proposes to amend § 860.84(d)(5) and (g)(2) to include establishment of special controls for class II devices. “Special controls” is the more inclusive term. Under section 513(a)(1)(B) of the FD&C Act, special controls includes the issuance of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification of submissions in accordance with section 510(k)), recommendations, and other appropriate actions as the FDA deems necessary to provide such assurance.

FDA proposes additional minor changes to § 860.84(a), (d)(4), (d)(6), (e), and (g)(3) to reflect the changes in the FD&C Act and to update terminology.

D. Proposed New 21 CFR 860.90--Consultation With Panels

FDA proposes to add a new section to explain how FDA consults with panels regarding classification of preamendments devices. This provision for the most part mirrors § 860.125, which outlines the means by which FDA consults with panels for reclassifications.

E. Proposed Amendments to 21 CFR 860.93--Classification of Implantable Devices and Devices Intended for a Use in Supporting or Sustaining Human Life

This section explains the special requirements for classifying any implantable device or device intended for a use in supporting or sustaining human life. FDA proposes to replace the term “implant” with the newly proposed term “implantable device” throughout this section. We also propose to add clarifying provisions that any class II classification recommendation for any implantable device or device intended for a use in supporting or sustaining human life from a classification device panel must identify and describe any special controls that are necessary to provide RASE. For any implantable device or device intended for a use in supporting or sustaining human life the Commissioner of Food and Drugs classifies or reclassifies into class II, the Commissioner must identify and describe any special controls that are necessary to provide RASE.

F. Proposed Amendments to 21 CFR 860.95--Exemptions From Sections 510, 519, and 520(f) of the FD&C Act

This section discusses exemptions from registration, product listing, and premarket notification in section 510 of the FD&C Act, records and reports in section 519 of the FD&C Act (21 U.S.C. 360i), and good manufacturing practice requirements in section 520(f) of the FD&C Act. FDA proposes additional changes to paragraphs § 860.95(a) and (b) to reflect changes in the FD&C Act that a class II device may be exempted from the premarket notification

requirements if premarket notification is not necessary to assure the safety and effectiveness of the device.

G. Proposed Amendments to 21 CFR 860.120--General

This section explains the criteria for reclassifying medical devices under sections 513(e), 513(f), 514(b) (21 U.S.C. 360d(b)), 515(b), and 520(l) of the FD&C Act. FDA proposes to remove the term “substantial equivalence” in § 860.120(b) to clarify that reclassifying one device within a generic type of device reclassifies all devices within a generic type of device. As clarified in the proposed amendment to the definition of “generic type of device,” a classification may include more than one generic type. Thus a reclassification may reclassify all of the devices within a classification (either because a classification only includes one generic type or because FDA has decided to reclassify more than one generic type) or only one or more generic types within a classification. FDA proposes to revise § 860.120(c) to clarify that the Commissioner may reclassify class I, class II, and class III devices into any of the other of the three classes and to add provisions that list the sections of the FD&C Act under which the Commissioner may initiate reclassification of a medical device.

H. Proposed Amendments to 21 CFR 860.123--Reclassification Petition: Content and Form

This section provides the form and content of reclassification petitions. FDA proposes to remove the requirement to include in a reclassification petition a completed classification questionnaire and supplemental data sheet. The classification questionnaire provides recommendations and information for FDA to consider during the classification process. The supplemental data sheet is information compiled by a classification panel or submitted in a petition for reclassification. As FDA has gained experience with the classification processes, questions concerning the utility of the classification questionnaire and supplemental data sheet

have arisen. FDA believes that a more efficient use of FDA and petitioner resources would be to focus on the information the petitioner provides concerning review of available valid scientific evidence, appropriate regulatory controls given the risks presented by the device, and regulatory standards to understand whether general controls are sufficient to provide RASE or whether general controls and special controls are sufficient to provide a reasonable assurance of safety and effectiveness.

In paragraph § 860.123(b)(2), FDA proposes to clarify a reference to section 513(f) in the FD&C Act to the more specific section 513(f)(3).

I. Proposed Amendments to 21 CFR 860.125--Consultation With Panels

This section provides the procedures under which FDA's Commissioner consults with classification panels in the context of reclassification. FDA proposes to add language to clarify when consultation with a panel is required and when consultation is optional. In particular, FDA proposes to add language to § 860.125(c) to reflect the FDASIA change that requires FDA to convene a classification panel meeting prior to reclassifying a device under section 513(e) of the FD&C Act.

J. Proposed Amendments to 21 CFR 860.130--General Procedures Under Section 513(e) of the FD&C Act

This section provides the procedures for reclassifying a device based on new information under section 513(e) of the FD&C Act. FDA proposes to revise the procedure in § 860.130(c) to reflect the FDASIA requirement that devices reclassified under section 513(e) of the FD&C Act be reclassified using an administrative order procedure. FDA also proposes to add language to clarify that the Commissioner may reclassify class I, class II, and class III devices into any of the other of the three classes under the criteria set forth in § 860.3 for each class of device.

In § 860.130(d) FDA proposes revisions to reflect the FDASIA process that FDA will use to reclassify a device under section 513(e) of the FD&C Act. Prior to the publication of a final order, FDA must also publish a proposed order in the Federal Register and consider any comments submitted on the proposed order. FDA must, in addition, hold a device classification panel meeting (21 U.S.C. 360c(b)). The panel meeting must occur before the final order is published, and may occur either before or after the proposed order is published. The proposed order must include the following: (1) A substantive summary of valid scientific evidence, including the public health benefits and risks of the device; (2) when reclassifying from class II to class III, an explanation that general and special controls are insufficient to reasonably assure safety and effectiveness; and (3) when reclassifying from class III to class II an explanation that general and special controls are sufficient to reasonably assure safety and effectiveness.

FDA proposes revisions to § 860.130 (f) and (g) to reflect the change to an administrative order process. FDA further proposes to revise § 860.130(g) to reflect that the administrative order may establish special controls to provide RASE of the device.

K. Proposed Amendments to 21 CFR 860.132--Procedures When the Commissioner Initiates a Performance Standard or Premarket Approval Proceeding Under Sections 514(b) or 515(b) of the

FD&C Act

This section explains the procedures for an interested person to request reclassification of a device after FDA initiates a proceeding for the establishment of a performance standard or for requiring premarket approval. FDA proposes removing premarket approval proceedings from the process currently outlined in § 860.132(b) since the corresponding statutory requirement was removed by FDASIA (pre-FDASIA section 515(b)(2)(B)) of the FD&C Act). Instead, FDA proposes new § 860.132(b) and (c), providing that reclassification requests received during

premarket approval proceedings will either be denied, if FDA does not agree that a change in classification is warranted, or granted, in which case FDA will follow the reclassification process under section 513(e) of the FD&C Act.

FDA proposes new § 860.132(d) for requests for reclassification during a performance standard proceeding, the process for which would remain largely unchanged. FDA proposes to remove the requirement in current § 860.132(b)(3) that a grant or denial of a petition to reclassify a device must be by order published in the Federal Register. Publishing the administrative order in the Federal Register is not required by statute and adds an unnecessary step to the process. FDA proposes to extend the time for filing a petition for reclassification in § 860.132(b)(1) to 30 days.

L. Proposed Addition of 21 CFR 860.133--Procedures When the Commissioner Initiates a Proceeding to Require Premarket Approval Under Section 515(b) of the FD&C Act

FDA proposes to add § 860.133 to describe the process for requiring the filing of a PMA for class III preamendments devices under section 515(b) of the FD&C Act (also referred to as a “call for PMAs”). FDASIA changes the process that FDA uses to require the filing of PMAs or completion of PDPs from a rulemaking process to an administrative order process. Under proposed § 860.133(b), a final order will include any recommendation to the Commissioner from a classification panel regarding the classification. Prior to the publication of a final order, FDA must also publish a proposed order in the Federal Register and consider any comments submitted on the proposed order. FDA must, in addition, hold a device classification panel meeting (21 U.S.C. 360c(b)). The panel meeting must occur before the final order is published, and may occur either before or after the proposed order is published. The proposed order must include the following: (1) A substantive summary of valid scientific evidence, including the public health

benefits and risks of the device; (2) when reclassifying from class II to class III, an explanation that general and special controls are insufficient to reasonably assure safety and effectiveness; and (3) when reclassifying from class III to class II an explanation that general and special controls are sufficient to reasonably assure safety and effectiveness.

M. Proposed Amendments to 21 CFR 860.134--Procedures for “Postamendment Devices” Under Section 513(f)(3) of the FD&C Act and Reclassification of Certain Devices

This section explains the procedures for reclassifying postamendments devices that are class III by operation of section 513(f)(1) of the FD&C Act. FDA proposes to amend § 860.134 by removing the term “new devices” as a reference to medical devices in commercial distribution after May 28, 1976. The terminology FDA more commonly uses is “postamendment devices.” May 28, 1976, is the date of enactment of the Medical Device Amendments of 1976. FDA further proposes to clarify a reference to section 513(f) in the FD&C Act to the more specific section 513(f)(3) and to add a reference to “de novo” classification under section 513(f)(2) to § 860.134(a) to reflect a change made by FDASIA to section 513(f)(1).

FDA proposes to add new § 860.134(c), detailing the process where reclassification is initiated by FDA rather than a petition. This process would 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. FDA further proposes to add new paragraph 860.134(d) to reflect that the administrative order may establish special controls to provide RASE of the device

N. Proposed Amendments to 21 CFR 860.136--Procedures for Transitional Products Under
Section 520(l) of the FD&C Act

FDA proposes to revise § 860.136(a) to add reclassification initiated by FDA and proposes to revise § 860.136(b) to apply to reclassification initiated by manufacturer or importer.

FDA proposes to add new § 860.136(c), detailing the process where reclassification is initiated by FDA rather than a petition. This process would 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. The proposed amendments to § 860.136 also include provisions making clear that reclassification orders under this section may establish special controls for a device reclassified into class II to provide RASE of the device. FDA also proposes to remove the requirement for a part 16 hearing because we believe the process providing for a proposed order, panel consultation, consideration of comments, and final order provide sufficient opportunity for participation and review of reclassifications of transitional devices.

IV. Environmental Impact

The Agency has determined under 21 CFR 25.30(h) 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.

V. Analysis of Impacts

A. Introduction

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct

Agencies 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). The Agency believes that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule imposes no significant new burdens, the Agency proposes to certify that the final rule would not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “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 \$141 million, using the most current (2012) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

B. Summary

The reclassification process provides manufacturers a pathway to reclassify medical devices (e.g., reclassify from class III to class II). Although the process is intended to be straightforward, FDA has found that certain aspects of it lack clarity and as a result petitions have been submitted for devices that are not suitable candidates for reclassification. To make the process clearer, the rule proposes the following changes: (1) Removing repetitive sentences in

the regulatory language; (2) using definitions that are consistent with the current statutory language; (3) and adding clarity to the definition of class III devices, which would make it more clear which devices currently regulated in class III are not suitable for down-classification.

Adopting the proposed rule is expected to impose a modest net monetized benefit (estimated benefits minus estimated costs) on society. Benefits are attributed to making the reclassification process clearer, which would reduce the costs associated with preparing and reviewing reclassification petitions. We estimate annual benefits to roughly range from \$1,535 to \$2,880 per year. Using a 20-year time period, we estimate present discounted benefits to range between \$22,837 to \$42,847 at a 3 percent discount rate and \$16,262 to \$30,511 at a 7 percent discount rate.

FDA also examined the economic implications of the final rule as required by the Regulatory Flexibility Act. If a rule will have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires Agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. This proposed rule would impose no new burdens on small entities, and thus would not impose a significant economic impact on a substantial number of small entities.

VI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would 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, the Agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as

defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Paperwork Reduction Act of 1995

This proposed 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 (the PRA) (44 U.S.C. 3501-3520). A description of these provisions is given in the “Description” section of this document 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.

FDA invites comments on the following topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Reclassification Petitions for Medical Devices

Description: This proposed rule would eliminate the requirement for petitioners to complete Form FDA 3429 (Classification Questionnaire) and Form FDA 3427 (Supplemental Data Sheet).

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.

Requirements Reflected in the Burden Estimates: FDA has identified the following requirements as having burdens that must be accounted for under the PRA; the burdens associated with these requirements are summarized in the tables that follow:

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Section	No. of Respondents	No of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
860.123 Supporting data for reclassification	6	1	6	497	2,982

¹There 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).

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.

This proposed rule also refers to previously approved collections of information found in FDA regulations. The collections of information in § 860.123 have been approved under OMB control number 0910-0138.

To ensure that comments on these revised information collection requirements are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the title “Reclassification Petitions for Medical Devices.” In compliance with the PRA (44 U.S.C. 3507(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the Federal Register.

VIII. Proposed Effective Date

FDA is proposing that any final rule based on this proposal become effective 90 days after date of publication of a final rule in the Federal Register or at a later date if stated in the final rule.

IX. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to submit one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

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, it is proposed that 21 CFR part 860 be amended as follows:

PART 860--MEDICAL DEVICE CLASSIFICATION PROCEDURES

1. The authority citation for 21 CFR part 860 continues to read as follows:

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

2. Section 860.3 is revised to read as follows:

§ 860.3 Definitions.

For the purposes of this part:

Act means the Federal Food, Drug, and Cosmetic Act.

Class means one of the three categories of regulatory controls for medical devices. Class I, class II, and class III are defined below.

Class I means the class of devices that are subject to only the general controls of the Federal Food, Drug, and Cosmetic Act. A device is in class I if:

(1) General controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, or

(2) There is insufficient information from which to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but the device:

(i) Is not intended for a use in supporting or sustaining human life;

(ii) Is not intended for a use that is of substantial importance in preventing impairment of human health; and

(iii) Does not present a potential unreasonable risk of illness or injury.

Class II means the class of devices for which general controls alone are insufficient to provide reasonable assurance of safety and effectiveness and for which sufficient information exists to establish special controls to provide such assurance. For a device that is intended for a use in supporting or sustaining human life, the Commissioner shall examine and establish the special controls, if any, that are necessary to provide a reasonable assurance of safety and effectiveness and describe how such controls provide such assurance.

Class III means the class of devices for which premarket approval is or will be required in accordance with section 515 of the Federal Food, Drug, and Cosmetic Act.

(1) A device is in class III:

(i) If so classified by the Federal Food, Drug, and Cosmetic Act under section 513(f)(1) or section 520(l)(1); or

(ii) If the device:

(A) Is intended for a use in supporting or sustaining human life, or

(B) Is intended for a use that is of substantial importance in preventing impairment of human health, or

(C) Presents a potential unreasonable risk of illness or injury; and

(D) Insufficient information exists to determine that general controls and/or special controls are sufficient to provide reasonable assurance of safety and effectiveness.

(2) The Commissioner may find that there is insufficient information to determine that general controls and/or special controls are sufficient to provide reasonable assurance of a device's safety and effectiveness. For example, the Commissioner may make this finding when any of the following apply:

(i) The device presents known risks that cannot be adequately controlled by general and special controls;

(ii) Evaluation under section 513(i) of the Federal Food, Drug, and Cosmetic Act is not adequate to establish that the benefit to health from use of the device justifies the risk of illness or injury from use of the device because:

(A) The benefits of the device are unknown;

(B) The risks of the device are unknown; or

(C) The known benefits do not justify the known risks;

(iii) Review of a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, each device within the generic type is necessary to provide a reasonable assurance of safety and effectiveness;

(iv) Review of a supplemental application in accordance with section 515(d)(6) of the Federal Food, Drug, and Cosmetic Act for any change to the device that affects safety or effectiveness is necessary to provide a reasonable assurance of safety and effectiveness; or

(v) The device is part of a combination product as defined in section 3.2(e) of this chapter, the device constituent part provides the primary mode of action under section 503(g) of the Federal Food, Drug, and Cosmetic Act and part 3 of this chapter, and a finding is required that the drug constituent part be safe and effective or that the biological product constituent part be safe, pure, and potent, but such a finding has not been made.

Classification panel means one of the advisory committees established by the Commissioner under section 513 of the Federal Food, Drug, and Cosmetic Act and part 14 of this chapter for the purpose of making recommendations to the Commissioner on the

classification and reclassification of devices and for other purposes prescribed by the Federal Food, Drug, and Cosmetic Act or by the Commissioner.

Commissioner means the Commissioner of Food and Drugs, Food and Drug Administration, United States Department of Health and Human Services, or the Commissioner's designee.

General controls mean the controls authorized by or under sections 501 (adulteration), 502 (misbranding), 510 (registration, listing, premarket notification, etc.), 516 (banned devices), 518 (notification and other remedies), 519 (records, reports, and unique device identification) and 520 (general provisions) of the Federal Food, Drug, and Cosmetic Act.

Generic type of device means a grouping of devices that do not differ significantly in purpose, design, materials, energy source, 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. Devices within a generic type of device are sometimes, but not always, grouped together under the same product code. Devices within a single classification sometimes, but not always, form a generic type of device.

Implantable device means a device that is intended to be placed in a surgically or naturally formed cavity of the human body. A device is regarded as an implantable device for the purpose of this part only if it is intended to remain implanted continuously for a period of 30 days or more, unless the Commissioner determines otherwise in order to protect human health.

Petition means a submission seeking reclassification of a device in accordance with § 860.123.

Special controls mean the controls necessary to provide a reasonable assurance of safety and effectiveness for a generic type of device within class II and that must be met to establish

and maintain classification within the generic type. Special controls can include a wide variety of regulatory controls necessary to provide reasonable assurance of the safety and effectiveness of the device, such as the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 510(k) of the Federal Food, Drug, and Cosmetic Act), recommendations, and other appropriate actions as the Commissioner deems necessary to provide such assurance.

Special controls guideline is a type of document referenced in the codified text of the applicable classification regulation that establishes the special controls necessary to provide a reasonable assurance of safety and effectiveness for a generic type of class II device, such as the type and level of data (clinical or other performance data) to be included in premarket notification submissions, labeling, postmarket reporting, and/or other controls. Special controls guidelines establish a mandatory level of regulatory control, but permit flexibility in how to meet the level of control necessary to provide a reasonable assurance of safety and effectiveness. A manufacturer of a device subject to a special controls guideline must comply with the guideline, in order for the device to be in class II, by complying with the particular mitigation measures described in the guideline or by using alternative mitigation measures but demonstrating to the Agency's satisfaction that those alternative measures provide at least an equivalent assurance of safety and effectiveness.

Supporting or sustaining human life means essential to, or yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.

3. Section 860.7 is amended 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, and 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. Section 860.84 is amended by revising the section heading and paragraph (a), removing paragraphs (c)(3) and (4), redesignating paragraph (c)(5) as paragraph (c)(3), and 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). 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 device under this section, 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 exempt 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) in accordance with § 860.95, 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;

(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;

(6) In the case of a recommendation for classification of an implantable device or a device intended for a use in supporting or sustaining human life 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, accompanied by references to supporting documentation and data satisfying the requirements of § 860.7, and an identification of the risks to health, if any, presented by the device.

(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 in the Division of Dockets Management's office upon receipt and are available to the public and posted on FDA's Web site at <http://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;

(3) If classifying an implantable device, or a device intended for a use in supporting or sustaining human life, comply with § 860.93(b).

5. Section 860.90 is added 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; 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.

6. Revise § 860.93 to read as follows:

§ 860.93 Classification of implantable devices and devices intended for a use in supporting or sustaining human life.

(a) A classification panel will recommend classification into class III of any implantable device or device intended for a use in supporting or sustaining human life 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, are necessary to provide a reasonable assurance of safety and effectiveness of the device and how such controls provide such assurance.

(b) The Commissioner will classify an implantable device or a device intended for a use in supporting or sustaining human life 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, are necessary to provide a reasonable assurance of safety and effectiveness of the device and how such controls provide such assurance.

7. Section 860.95 is amended by revising the section heading and paragraphs (a) and (b) to read as follows:

§ 860.95 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 exempt 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.

* * * * *

8. Section 860.120 is amended 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. 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 device other than a device classified under section 513(f) 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).

9. Section 860.123 is amended by removing paragraphs (a)(3) and (4), redesignating paragraphs (a)(5) through (10) as paragraphs (a)(3) through (8), respectively; and 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”;

* * * * *

10. Section 860.125 is amended by revising paragraphs (a) introductory text and (a)(2), redesignating paragraph (c) as paragraph (d) and revising it, and adding a new paragraph (c) to 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 under § 860.132(d) or § 860.136, 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:

* * * * *

(2) Consultation by mail with at least a majority of current voting panel members and, when possible, nonvoting panel members; or

* * * * *

(c) The Commissioner will consult with a classification panel prior to changing the classification of a device 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 ("new 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, § 860.132, or § 860.136, the Commissioner may or may not obtain a formal recommendation.

11. Section 860.130 is amended 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 II to class III if the Commissioner determines that the device meets the criteria set forth in § 860.3 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 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 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. The meeting of a device classification panel may take place at any time before or after the publication of a proposed reclassification order in the Federal Register.

(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 classification 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.

12. Amend § 860.132 as follows:

- a. Revise the section heading and paragraph (a);
- b. Redesignate paragraph (b) as paragraph (d);
- c. Revise newly redesignated paragraphs (d) introductory text, (d)(1), and (d)(3); and
- d. Add new paragraph (b) and paragraph (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 request a change in 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 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.

13. 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 meeting of a device classification panel may take place at any time before or after the publication of a proposed order in the Federal Register. Any 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.

14. Section 860.134 is amended by revising the section heading and paragraph (a)(3), adding paragraph (a)(4), revising paragraphs (b) introductory text and (b)(4) and (6), and adding paragraphs (c) and (d) to 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.

(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 in the Division of Dockets Management upon receipt and are available to the public and posted at <http://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 and subject to the applicable requirements of § 860.93, relating to the classification of implantable devices and devices intended for a use in supporting or sustaining human life, and

§ 860.95, 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 are as follows:

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

(2) Before or after the publication of a proposed reclassification order, 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.

15. Amend § 860.136 as follows:

- a. Revise the section heading, paragraph (a), and paragraph (b) introductory text;
- b. Remove paragraph (b)(3);
- c. Redesignate paragraphs (b)(4) through (6) as paragraphs (b)(3) through (5),

respectively;

- d. Revise newly redesignated paragraph (b)(4); and
- e. Add 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) 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 are as follows:

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

(2) Before or after the publication of a proposed reclassification order, 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: March 18, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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