

FIGURE 2 TO PART 1130—BACK OF REGISTRATION FORM

Dated: August 2, 2011.

Todd A. Stevenson,

Secretary, U.S. Consumer Product Safety Commission.

[FR Doc. 2011–19912 Filed 8–5–11; 8:45 am]

BILLING CODE 6355–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2011–N–0505]

Effective Date of Requirement for Premarket Approval for Cardiovascular Permanent Pacemaker Electrode

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the following class III preamendments device: Cardiovascular permanent pacemaker electrode. The Agency is also summarizing its proposed findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring this device to meet the statute's approval requirements and the benefits to the public from the use of the device. In addition, FDA is announcing the opportunity for interested persons to request that the Agency change the classification of the cardiovascular permanent pacemaker electrode based on new information. This action implements certain statutory requirements.

DATES: Submit either electronic or written comments by November 7, 2011. Submit requests for a change in classification by August 23, 2011. FDA intends that, if a final rule based on this proposed rule is issued, anyone who wishes to continue to market the device will need to submit a PMA within 90 days of the effective date of the final rule. Please see section XI of this document for the proposed effective date of any final rule that may publish based on this proposal.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2011–N–0505, by any of the following methods:

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:

- Fax: 301–827–6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD–ROM 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–2011–N–0505 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(s), 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.

FOR FURTHER INFORMATION CONTACT:

Elias Mallis, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 1538, Silver Spring, MD 20993–0002, 301–796–6216.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629), and the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), the Medical Devices Technical Corrections Act (Pub. L. 108–214), and the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), establish a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the

regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, 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. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices), are automatically classified by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless and until the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate 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.

A preamendments device that has been classified into class III may be marketed by means of premarket notification procedures (510(k) process) without submission of a PMA until FDA issues a final regulation under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval. Section 515(b)(1) of the FD&C Act (21 U.S.C. 360e(b)(1)) establishes the requirement that a preamendments device that FDA has classified into class III is subject to premarket approval. A preamendments class III device may be commercially distributed without an approved PMA or a notice of completion of a PDP until 90 days after FDA issues a final rule 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. Also, a preamendments device subject to the rulemaking procedure under section 515(b) of the FD&C Act is not required to have an approved investigational

device exemption (IDE) (see 21 CFR part 812) contemporaneous with its interstate distribution until the date identified by FDA in the final rule requiring the submission of a PMA for the device. At that time, an IDE is required only if a PMA has not been submitted or a PDP completed.

Section 515(b)(2)(A) of the FD&C Act provides that a proceeding to issue a final rule to require premarket approval shall be initiated by publication of a notice of proposed rulemaking containing: (1) The regulation; (2) 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 PDP and the benefit to the public from the use of the device; (3) an opportunity for the submission of comments on the proposed rule and the proposed findings; and (4) an opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

Section 515(b)(2)(B) of the FD&C Act provides that if FDA receives a request for a change in the classification of the device within 15 days of the publication of the notice, FDA shall, within 60 days of the publication of the notice, consult with the appropriate FDA advisory committee and publish a notice denying the request for change in reclassification or announcing its intent to initiate a proceeding to reclassify the device under section 513(e) of the FD&C Act. Section 515(b)(3) of the FD&C Act provides that FDA shall, after the close of the comment period on the proposed rule and consideration of any comments received, issue a final rule to require premarket approval or publish a document terminating the proceeding together with the reasons for such termination. If FDA terminates the proceeding, FDA is required to initiate reclassification of the device under section 513(e) of the FD&C Act, unless the reason for termination is that the device is a banned device under section 516 of the FD&C Act (21 U.S.C. 360f).

If a proposed rule to require premarket approval for a preamendments device is finalized, section 501(f)(2)(B) of the FD&C Act (21 U.S.C. 351(f)(2)(B)) requires that a PMA or notice of completion of a PDP for any such device be filed within 90 days of the date of issuance of the final rule or 30 months after the final classification of the device under section 513 of the FD&C Act, whichever is later. If a PMA or notice of completion of a PDP is not filed by the later of the two dates, commercial distribution of the device is

required to cease since the device would be deemed adulterated under section 501(f) of the FD&C Act.

The device may, however, be distributed for investigational use if the manufacturer, importer, or other sponsor of the device complies with the IDE regulations. If a PMA or notice of completion of a PDP is not filed by the later of the two dates, and the device does not comply with IDE regulations, the device is deemed to be adulterated within the meaning of section 501(f)(1)(A) of the FD&C Act, and subject to seizure and condemnation under section 304 of the FD&C Act (21 U.S.C. 334) if its distribution continues. Shipment of devices in interstate commerce will be subject to injunction under section 302 of the FD&C Act (21 U.S.C. 332), and the individuals responsible for such shipment will be subject to prosecution under section 303 of the FD&C Act (21 U.S.C. 333). In the past, FDA has requested that manufacturers take action to prevent the further use of devices for which no PMA or PDP has been filed and may determine that such a request is appropriate for the class III device that is the subject of this regulation.

The FD&C Act does not permit an extension of the 90-day period after issuance of a final rule within which an application or a notice is required to be filed. The House Report on the 1976 amendments states that: “[t]he thirty month grace period afforded after classification of a device into class III * * * is sufficient time for manufacturers and importers to develop the data and conduct the investigations necessary to support an application for premarket approval (H. Rept. 94–853, 94th Cong., 2d sess. 42 (1976)).”

The SMDA added section 515(i) to the FD&C Act requiring FDA to review the classification of preamendments class III devices for which no final rule requiring the submission of PMAs has been issued, and to determine whether or not each device should be reclassified into class I or class II or remain in class III. For devices remaining in class III, the SMDA directed FDA to develop a schedule for issuing regulations to require premarket approval. The SMDA does not, however, prevent FDA from proceeding immediately to rulemaking under section 515(b) of the FD&C Act on specific devices, in the interest of public health, independent of the procedures of section 515(i). Proceeding directly to rulemaking under section 515(b) of the FD&C Act is consistent with Congress’ objective in enacting section 515(i), i.e., that preamendments class III devices for which PMAs have not been previously required either be reclassified to class I

or class II or be subject to the requirements of premarket approval. Moreover, in this proposal, interested persons are being offered the opportunity to request reclassification of the device.

II. Dates New Requirements Apply

In accordance with section 515(b) of the FD&C Act, FDA is proposing to require that a PMA or a notice of completion of a PDP be filed with the Agency for class III devices within 90 days after issuance of any final rule based on this proposal. An applicant whose device was legally in commercial distribution before May 28, 1976, or whose device has been found to be substantially equivalent to such a device, will be permitted to continue marketing such class III devices during FDA’s review of the PMA or notice of completion of the PDP. FDA intends to review any PMA for the device within 180 days, and any notice of completion of a PDP for the device within 90 days of the date of filing. FDA cautions that under section 515(d)(1)(B)(i) of the FD&C Act, the Agency may not enter into an agreement to extend the review period for a PMA beyond 180 days unless the Agency finds that “the continued availability of the device is necessary for the public health.”

FDA intends that under § 812.2(d), the preamble to any final rule based on this proposal will state that, as of the date on which the filing of a PMA or a notice of completion of a PDP is required to be filed, the exemptions from the requirements of the IDE regulations for preamendments class III devices in § 812.2(c)(1) and (c)(2) will cease to apply to any device that is: (1) Not legally on the market on or before that date, or (2) legally on the market on or before that date but for which a PMA or notice of completion of a PDP is not filed by that date, or for which PMA approval has been denied or withdrawn.

If a PMA or notice of completion of a PDP for a class III device is not filed with FDA within 90 days after the date of issuance of any final rule requiring premarket approval for the device, commercial distribution of the device must cease. The device may be distributed for investigational use only if the requirements of the IDE regulations are met. The requirements for significant risk devices include submitting an IDE application to FDA for its review and approval. An approved IDE is required to be in effect before an investigation of the device may be initiated or continued under § 812.30. FDA, therefore, cautions that IDE applications should be submitted to FDA at least 30 days before the end of

the 90-day period after the issuance of the final rule to avoid interrupting investigations.

III. Proposed Findings With Respect to Risks and Benefits

As required by section 515(b) of the FD&C Act, FDA is publishing its proposed findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring that this device have an approved PMA or a declared completed PDP, and (2) the benefits to the public from the use of the device.

These findings are based on the reports and recommendations of the advisory committee (panel) for the classification of this device along with information submitted in response to the 515(i) order (74 FR 16214, April 9, 2009) and any additional information that FDA has encountered. Additional information regarding the risks as well as classification associated with this device type can be found in the following proposed and final rules and notices published in the **Federal Register** on these dates: (45 FR 7907 at 7971, February 5, 1980; 52 FR 17736, May 11, 1987; and 60 FR 41986, August 14, 1995).

IV. Device Subject to This Proposal

Cardiovascular Permanent or Temporary Pacemaker Electrode; Permanent Pacemaker Electrode (21 CFR 870.3680(b)).

A. Identification

A permanent pacemaker electrode is a device consisting of flexible insulated electrical conductors with one end connected to an implantable pacemaker pulse generator and the other end applied to the heart. The device is used to transmit a pacing electrical stimulus from the pulse generator to the heart and/or to transmit the electrical signal of the heart to the pulse generator.

B. Summary of Data

The Cardiovascular Devices Classification Panel recommended that this device be classified into class III as permanent pacemaker electrodes are permanent implants providing life-supporting or life-sustaining therapy. Over time, the devices that have been designed and developed have evolved and are widely variable from model to model as well as from manufacturer to manufacturer. These designs are generally more complex and of smaller sizes which may increase risk of failure and introduce new failure modes. Accordingly, this has limited the ability to develop comprehensive performance standards which would apply to all

aspects of pacemaker lead design, testing, and use. Adequate performance standards have not yet been developed. The potential safety and effectiveness risks, unsuitability of general and special controls, long-term use as permanent implants of life-sustaining therapy, and documented field failures warrant classification of this device as class III.

C. Risks to Health

- **Material risks.** The material properties of pacemaker leads, including mechanical, electrical, biostability, biocompatibility, corrosion and other characteristics can affect acute and chronic performance.

- **Design risks.** Lead designs may introduce features or geometries that depart from traditional designs, geometries, or sizes and which may result in degradation of performance and safety of use.

- **Manufacturing risks.** Manufacturing variation, the introduction of more complex and smaller designs, or quality system failures may introduce device defects that may not be identified with bench testing or acute in vivo studies.

- **Clinical-use risks.** Thromboembolism, perforation, tissue reaction (exit block), dislodgement, infection, air embolism, muscle/nerve stimulation, stenosis, and erosion/extrusion may occur as a result of the clinical use and/or device malfunction.

V. PMA Requirements

A PMA for this device must include the information required by section 515(c)(1) of the FD&C Act. Such a PMA should also include a detailed discussion of the risks identified previously, as well as a discussion of the effectiveness of the device for which premarket approval is sought. In addition, a PMA must include all data and information on: (1) Any risks known, or that should be reasonably known, to the applicant that have not been identified in this document; (2) the effectiveness of the device that is the subject of the application; and (3) full reports of all preclinical and clinical information from investigations on the safety and effectiveness of the device for which premarket approval is sought.

A PMA must include valid scientific evidence to demonstrate reasonable assurance of the safety and effectiveness of the device for its intended use (see § 860.7(c)(2) (21 CFR 860.7(c)(2))). Valid scientific evidence is “evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of

significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use.

* * * Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety or effectiveness.” (§ 860.7(c)(2)).

VI. PDP Requirements

A PDP for this device may be submitted instead of a PMA, and must follow the procedures outlined in section 515(f) of the FD&C Act. A PDP must provide: (1) A description of the device; (2) preclinical trial information (if any); (3) clinical trial information (if any); (4) a description of the manufacturing and processing of the device; (5) the labeling of the device; and (6) all other relevant information about the device. In addition, the PDP must include progress reports and records of the trials conducted under the protocol on the safety and effectiveness of the device for which the completed PDP is sought.

VII. Opportunity To Request a Change in Classification

Before requiring the filing of a PMA or notice of completion of a PDP for a device, FDA is required by section 515(b)(2)(A)(i) through (b)(2)(A)(iv) of the FD&C Act and 21 CFR 860.132 to provide an opportunity for interested persons to request a change in the classification of the device based on new information relevant to the classification. Any proceeding to reclassify the device will be under the authority of section 513(e) of the FD&C Act.

A request for a change in the classification of this device is to be in the form of a reclassification petition containing the information required by § 860.123 (21 CFR 860.123), including new information relevant to the classification of the device.

The Agency advises that to ensure timely filing of any such petition, any request should be submitted to the Division of Dockets Management (see **ADDRESSES**) and not to the address provided in § 860.123(b)(1). If a timely request for a change in the classification of this device is submitted, the Agency will, within 60 days after receipt of the petition, and after consultation with the appropriate FDA resources, publish an order in the **Federal Register** that either denies the request or gives notice of its intent to initiate a change in the

classification of the device in accordance with section 513(e) of the FD&C Act and § 860.139 (21 CFR 860.130) of the regulations.

VIII. 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.

IX. Analysis of Impacts

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 none of the manufacturers of affected products are small businesses, 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 \$136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any one-year expenditure that would meet or exceed this amount.

A. Costs of the Proposed Rule

Under the proposed rule, FDA would require producers in the cardiovascular permanent pacemaker electrode

industry to obtain PMA or establish a PDP before marketing new products. Similarly, producers of cardiovascular permanent pacemaker electrodes that are already on the market would need to submit PMA applications or establish PDPs in order to continue commercial distribution of these products. Based on an analysis of registration and listing data, manufacturer Web sites, and responses to previous **Federal Register** requests for comment; FDA estimates that 5 to 10 manufacturers are marketing approximately 18 to 23 devices that would be affected by this proposed rule. We therefore estimate that the proposed rule would generate between 18 and 23 PMA or PDP submissions. FDA has estimated an upper bound on the cost of PMA at approximately \$1,000,000 (see, for example, 73 FR 7501, February 8, 2008), and we assume that the cost of a PDP is roughly equal to that of a PMA; this yields a rule-induced upfront cost of between \$18 and \$23 million. We lack data with which to estimate how the burden of this cost would be distributed among device manufacturers, patients and insurance providers.

For a new product (*i.e.*, a cardiovascular permanent pacemaker electrode not currently on the market), the rule-induced cost would be the difference between the cost of preparing and submitting a premarket approval application and the cost of preparing and submitting a 510(k) application. However, FDA has not received any submissions for new devices of the type subject to the proposed rule since August 2004. We expect the recent pattern of zero submissions to continue; therefore, the proposed rule would not generate submission costs on an ongoing basis.

Some producers of devices that are subject to the proposed rule could be dissuaded from seeking approval by the cost of submitting a PMA application or by a low expectation that FDA would grant approval for their products. In these cases, producers would experience a rule-induced cost equal to the foregone expected profit on the withdrawn or withheld cardiovascular permanent pacemaker electrodes, which is necessarily less than the cost of PMA submission (otherwise, the producers in question would not be dissuaded from seeking PMA). Additionally, there would be a welfare loss experienced by consumers who would, in the absence of the proposed rule, use the cardiovascular permanent pacemaker electrodes that would be withdrawn or withheld from the market as a result of the call for PMA or PDP. Due to the lack of sufficient market data, we cannot

quantify these consumers' welfare loss. FDA requests comment on this issue and on all methods and results of our cost estimation.

In addition to the cost to industry of preparing and submitting PMAs or PDPs, the proposed rule would impose incremental review costs on FDA. Geiger (2005) (Ref. 1) estimated that, for devices reviewed by FDA's Center for Devices and Radiological Health in 2003 and 2004, review costs averaged \$563,000 per PMA. Updated for inflation (using U.S. Department of Commerce, 2011) (Ref. 2) to 2010 dollars, this average review cost becomes \$653,000 per PMA. Thus, the proposed rule's review-related costs are expected to be between \$11.8 million ($18 \times \$653,000$) and \$15.0 million ($23 \times \$653,000$). A portion of this total would be paid by industry in the form of user fees, with the remainder coming from general revenues. FDA's Data universal numbering system database reveals that the manufacturers affected by this proposed rule have annual revenues over \$100 million, so they would not be eligible for small business user fees. The standard user fee is currently set at \$236,298 for a premarket application (PMA or PDP) (75 FR 45632 at 45643), so user fees would likely cover \$4.3 million ($= 18 \times \$236,298$) to \$5.4 million ($= 23 \times \$236,298$) of FDA review costs, with the remaining \$7.5 to \$9.6 million coming from general revenues.

B. Benefits of the Proposed Rule

The proposed requirement for premarket approval applications or product development protocols for cardiovascular permanent pacemaker electrodes would produce social benefits equal to the value of the information generated by the safety and effectiveness tests that producers would be required to conduct as part of the PMA or PDP process. Provided first to FDA, this information would eventually assist physicians, patients and insurance providers in making more informed decisions about these devices. FDA expects there to be approximately 18 to 23 PMA or PDP submissions as a result of the proposed rule, but we are unable to quantify the value of information associated with each submission. We request comment on this issue.

X. Paperwork Reduction Act of 1995

This proposed rule refers to previously approved collections of information found in FDA regulations. These collections of information 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 collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subpart B have been approved under OMB control number 0910–0231; and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910–0485.

XI. Proposed Effective Date

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

XII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

XIII. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. Geiger, Dale R, “FY 2003 and 2004 Unit Costs for the Process of Medical Device Review,” September 2005, <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/umc109216>.
2. U.S. Department of Commerce, Bureau of Economic Analysis, National Income and Product Accounts Table 1.1.9, <http://www.bea.gov/national/nipaweb/SelectTable.asp>, accessed March 25, 2011.

List of Subjects in 21 CFR Part 870

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 870 be amended as follows:

PART 870—CARDIOVASCULAR DEVICES

1. The authority citation for 21 CFR part 870 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 870.3680 is amended by revising paragraph (c) to read as follows:

§ 870.3680 Cardiovascular permanent or temporary pacemaker electrode.

(c) *Date PMA or notice of completion of PDP is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before [A DATE WILL BE ADDED 90 DAYS AFTER DATE OF PUBLICATION OF A FUTURE FINAL RULE IN THE **FEDERAL REGISTER**], for any permanent pacemaker electrode that was in commercial distribution before May 28, 1976, or that has, on or before [A DATE WILL BE ADDED 90 DAYS AFTER DATE OF PUBLICATION OF A FUTURE FINAL RULE IN THE **FEDERAL REGISTER**], been found to be substantially equivalent to any permanent pacemaker electrode that was in commercial distribution before May 28, 1976. Any other permanent pacemaker electrode shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: August 2, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–19959 Filed 8–5–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA–2011–N–0504]

Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy Stimulator

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the Cranial Electrotherapy Stimulator. The Agency is also summarizing its proposed

findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring this device to meet the statute’s approval requirements and the benefits to the public from the use of the device. In addition, FDA is announcing the opportunity for interested persons to request that the Agency change the classification of the cranial electrotherapy stimulator based on new information. This action implements certain statutory requirements.

DATES: Submit either electronic or written comments by November 7, 2011. Submit requests for a change in classification by August 23, 2011. FDA intends that, if a final rule based on this proposed rule is issued, anyone who wishes to continue to market the device will need to submit a PMA within 90 days of the effective date of the final rule. Please see section XII of this document for the effective date of any final rule that may publish based on this proposal.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2011–N–0504 by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

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

Written Submissions

Submit written submissions in the following ways:

- Fax: 301–827–6870.
- Mail/Hand delivery/Courier (For paper, disk, or CD–ROM 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–2011–N–0504 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.