separate corporate identity, common boards of directors and employees, control of one entity over another, and lack of separate books and records. The legal advice may be provided by independent legal counsel of the investing FICU or the CUSO.

§ 712.9 [Removed and Reserved]

6. Remove and reserve § 712.9

7. Revise § 712.10 to read as follows:

§ 712.10 How can a state supervisory authority obtain an exemption for FISCUs from compliance with § 712.3(d)?

(a) The NCUA Board may exempt FISCUs in a given state from compliance with §§ 712.3(d)(1), (2), and (3) if the NCUA Board determines the laws and procedures available to the supervisory authority in that state are sufficient to provide NCUA with the degree of access and information it believes is necessary to evaluate the safety and soundness of FICUs having business relationships with CUSOs owned by FISCUs in that state.

(b) To obtain the exemption, the state supervisory authority must submit a copy of the legal authority pursuant to which it secures the information required in §§ 712.3(d)(1), (2), and (3) of this part to NCUA's regional office having responsibility for that state, along with all procedural and operational documentation supporting and describing the actual practices by which it implements and exercises the authority.

(c) The state supervisory authority must provide the regional director with an assurance that NCUA examiners will be provided with co-extensive authority and will be allowed direct access to CUSO books and records at such times as NCUA, in its sole discretion, may determine necessary or appropriate. For purposes of this section, access includes the right to make and retain copies of any CUSO record, as to which NCUA will accord the same level of control and confidentiality that it uses with respect to all other examination-related materials it obtains in the course of its duties.

(d) The state supervisory authority must also provide the regional director with an assurance that NCUA, upon request, will have access to copies of any financial statements or reports, which a CUSO has provided to the state supervisory authority.

(e) The regional director will review the applicable authority, procedures and assurances and forward the exemption request, along with the regional director's recommendation, to the NCUA Board for a final determination.

(f) For purposes of this section, whether an entity is a CUSO shall be determined in accordance with the definition set out in § 741.222 of this chapter.

8. Add § 712.11 to read as follows:

712.11 What requirements apply to subsidiary CUSOs?

(a) *FCUs investing in a CUSO that invests in a CUSO.* The requirements of this part apply to all tiers or levels of a CUSO's structure and FCUs may only invest in or loan to a CUSO, which has an investment in another CUSO, if the subsidiary CUSO satisfies all of the requirements of this part.

(b) *FISCUs investing in a CUSO that invests in a CUSO.* FISCUs may only invest in or loan to a CUSO, which has an investment in another CUSO, if the subsidiary CUSO complies with the following:

(1) All of the requirements of this part that apply to FISCUs, which are listed in § 712.1; and

(2) All applicable state laws and rules regarding CUSOs.

(c) For purposes of this section, a subsidiary CUSO is any entity in which a CUSO invests.

PART 741—REQUIREMENTS FOR INSURANCE

1. The authority citation for part 741 continues to read as follows:

Authority: 12 U.S.C. 1757, 1766(a), 1781–1790, and 1790d; 31 U.S.C. 3717.

2. Revise § 741.222 to read as follows:

§ 741.222. Credit Union Service Organizations.

(a) Any credit union that is insured pursuant to Title II of the Act must adhere to the requirements in §§ 712.2 (d)(3), 712.3(d), 712.4 and 712.11 of this chapter concerning permissible investment limits for less than adequately capitalized credit unions, agreements between credit unions and their credit union service organizations (CUSOs), the requirement to maintain separate corporate identities, and investments and loans to CUSOs investing in other CUSOs. For purposes of this section, a CUSO is any entity in which a credit union has an ownership interest or to which a credit union has extended a loan and that is engaged primarily in providing products or services to credit unions or credit union members, or, in the case of checking and currency services, including check cashing services, sale of negotiable checks, money orders, and electronic transaction services, including international and domestic electronic fund transfers, to persons eligible for membership in any credit union having a loan, investment or contract with the entity. A CUSO also includes any entity in which a CUSO invests.

(b) This section shall have no preemptive effect with respect to the laws or rules of any state providing for access to CUSO books and records or CUSO examination by credit union regulatory authorities.

[FR Doc. 2011–18906 Filed 7–26–11; 8:45 am]

BILLING CODE 7535–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2011–N–0522]

Effective Date of Requirement for Premarket Approval for an Implantable Pacemaker Pulse Generator

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 class III preamendments device implantable pacemaker pulse generator. 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 the 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 aforementioned device based on new information. This action implements certain statutory requirements.

DATES: Submit either electronic or written comments by October 25, 2011. Submit requests for a change in classification by August 11, 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 XIII 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–0522, 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 Number 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.

FOR FURTHER INFORMATION CONTACT: Elias Mallis, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1538, Silver Spring, MD 20993, 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 of 2004 (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 part 807 (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 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 part 812 (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 devices that are the subjects 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 any of the devices.

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 committees (panels) for the classification of these devices along with information submitted in response to the 515(i) Order that published in the **Federal Register** of April 9, 2009 (74 FR 16214), and any additional information that FDA has encountered. Additional information regarding the risks as well as classification associated with these device types can be found in the following proposed and final rules published in the **Federal Register** on the following dates: March 9, 1979 (44 FR 13373); February 5, 1980 (45 FR 7907); and May 11, 1987 (52 FR 17736).

IV. Device Subject to This Proposal—Implantable Pacemaker Pulse Generator (21 CFR 870.3610)

A. Identification

An implantable pacemaker pulse generator is a device that has a power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart. The power supply may be a pacemaker battery although, as discussed in section X of this document, FDA has no record of the pacemaker battery ever being marketed. This device is used as a substitute for the heart's intrinsic pacing system to correct both intermittent and continuous cardiac rhythm disorders. This device may include triggered, inhibited, and asynchronous devices implanted in the human body.

B. Summary of Data

The Cardiovascular Devices Panel recommended that the implantable pacemaker pulse generator (which includes the internal pacemaker battery) be classified into class III because the device is implanted and life-supporting and presented a potential unreasonable risk of illness or injury. The power supply may be a pacemaker battery although, as discussed under section X of this document, FDA has no record of the pacemaker battery ever being marketed. The panel indicated that

although a proposed standard had been written, it did not cover all of the performance characteristics of the device and that this standard was not widely accepted. The panel indicated that general controls alone would not provide sufficient control over the performance characteristics of the device and that sufficient scientific and medical data did not exist to establish a complete standard to assure the safety and effectiveness of particular aspects of the device. Consequently, the panel believed that premarket approval was necessary to assure the safety and effectiveness of the device. FDA continues to agree with the panel's recommendation.

C. Risks to Health

1. Failure To Pace

A failure of the electronic circuitry or early battery depletion can cause failure to pace the patient's heart. Failure to pace could result in a dangerously slow heart rate (or in extreme cases, no heart beat at all), which could result in weakness, dizziness, fainting or even death.

2. Improper Pacing Rate

An electronic circuit failure or an inaccurate rate controller in the circuit can cause improper pacing rates, which could be too fast or too slow. Improper pacing rates may result in symptoms of fatigue, chest discomfort, shortness of breath, dizziness, or fainting.

3. Arrhythmias

A sensing failure of the pacemaker during vulnerable periods of the cardiac cycle can induce cardiac arrhythmias, in particular, dangerously fast arrhythmias. In this case, dangerously fast arrhythmias may lead to chest pain, shortness of breath, dizziness, fainting or even death.

4. Improper Sensing

Electromagnetic interference with pacemaker electronics, loose connections, or sensing circuitry failures may cause improper sensing by the pacemaker, which can lead to failure to pace, improper pacing cycle, and/or arrhythmias.

5. Tissue Damage

If the materials, surface finish, or cleanliness of this device are inadequate, tissue damage can occur.

6. Unintended Stimulation

Pacing pulses may stimulate unintended nerve or muscle, resulting in uncomfortable contractions of the chest wall muscles or of the diaphragm.

7. Development of Pacemaker Syndrome

Pacemaker syndrome may result from suboptimal atrioventricular (AV) synchrony or AV dyssynchrony; this could cause an uncomfortable cardiac awareness including palpitations, fatigue, dizziness, shortness of breath and near-fainting.

8. Other Complications

Other risks of pacemaker implantation include infection, erosion, fibrotic tissue formation, body rejection phenomena, hematoma, myopotential sensing, and additional surgery for replacement. Risks are also associated with pacemaker lead implantation. These are not discussed in this document.

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 the following: (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 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.'' (21 CFR 860.7(c)(2)).

VI. PDP Requirements

A PDP for this device may be submitted in lieu 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. 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.

VIII. 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 these devices 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 21 CFR 860.130 of the regulations.

IX. 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.

X. 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. There have been no 510(k) submissions for implantable pacemaker devices since 1999, there is no record of pacemaker batteries ever being marketed, and both of these devices are in a state of disuse. Accordingly, FDA has concluded that there is little or no interest in marketing these devices in the future. Therefore, the Agency proposes to certify that the proposed rule, if issued as a final rule, would not have a significant economic impact on a substantial number of small entities. We specifically request detailed comment regarding the appropriateness of our assumptions regarding the potential economic impact of this proposed rule.

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 1-year expenditure that would meet or exceed this amount.

This proposed rule, if issued as a final rule, would be likely to have no significant impact. We base this determination on an analysis of our Registration and Listing, 510(k) and Premarket Approval Application (PMA) database information. There have been no 510(k) submissions for implantable pacemaker pulse generators since 1999, with the exception of one 510(k) submission cleared in 2001 that was erroneously coded as an implantable pacemaker pulse generator (product code DXY), but is actually for an external pacemaker and is being corrected. Current pacemakers have newer features and capabilities that have rendered them not substantially equivalent to the devices cleared under 510(k) prior to 1999, which are obsolete. Current pacemakers are marketed under a PMA; in some cases the product code DXY has been erroneously applied. In addition, there have been no valid 510(k) submissions for pacemaker batteries for implantable pacemakers, which also fall under the product code DSZ also under 21 CFR 870.3610. Two 510(k) submissions have been received for DSZ devices since 1976, but they are believed to be miscoded. The Agency has no record of pacemaker batteries ever being marketed.

This information is summarized in table 1 of this document.

TABLE 1—SUMMARY OF ELECTRONIC REGISTRATION AND LISTING INFORMATION

Device name	Product code	510(k) or PMA?	Last listed	Last marketed	Replaced by approved technology?
Implantable Pacemaker Pulse Generator	DXY	Both	2011	1990s	Yes.[1]
Pacemaker Battery	DSZ	510(k)	No Record	No Record	No.[2]

[1] Implantable pacemaker pulse generators have been submitted as PMAs since the early 1980s. The product code DXY has been erroneously applied to many of these PMA products. The last 510(k) submission for a DXY device was cleared in 1999.
[2] Pacemaker batteries are not separately marketed products. They are internal to implantable pacemakers.

Based on our review of electronic product registration and listing and other data, FDA concludes that there is currently little or no interest in marketing the affected devices and that the proposed rule would not have a significant economic impact. We specifically request detailed comment regarding the appropriateness of our assumptions regarding the potential economic impact of this proposed rule.

XI. 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.

XII. Paperwork Reduction Act of 1995

This proposed rule refers to currently 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 part 812 are currently approved under OMB Control No. 0910–0078; the collections of information in part 807, subpart E are currently approved under OMB Control No. 0910–0120; the collections of information in 21 CFR Part 814, subpart B are currently approved under OMB Control No. 0910–0231; and the collections of information under 21 CFR Part 801 are currently approved under OMB Control No. 0910–0485.

XIII. 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.

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 870.3610 is amended by revising paragraphs (a) and (c) to read as follows:

§ 870.3610 Implantable pacemaker pulse generator.

(a) *Identification.* An implantable pacemaker pulse generator is a device that has a power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart. This device is used as a substitute for the heart's intrinsic pacing system to correct both intermittent and continuous cardiac rhythm disorders. This device may include triggered, inhibited, and asynchronous modes and is implanted in the human body.

* * * * *

(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 implantable pacemaker pulse generator 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 implantable pacemaker pulse generator that was in commercial distribution before May 28, 1976. Any other implantable pacemaker pulse generator shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: July 22, 2011.

Nancy K. Stade,

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

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2011–0629]

RIN 1625–AA08

Special Local Regulations for Marine Events; Temporary Change of Dates for Recurring Marine Events in the Fifth Coast Guard District, Wrightsville Channel; Wrightsville Beach, NC

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to temporarily change the enforcement period of one special local regulation for a recurring marine event in the Fifth Coast Guard District. The ''Wilmington YMCA Triathlon,'' conducted on the waters of Wrightsville Channel near Wrightsville Beach, North Carolina normally would take place on September 24, 2011; this year, the sponsor would like to have the event on September 17, 2011. This Special Local Regulation is necessary to provide for the safety of life on navigable waters during the event, which has been rescheduled from the last Saturday in September to the second-to-last Saturday in September. This action is intended to restrict vessel traffic on Wrightsville Channel during the swimming portion of this event.

DATES: Comments and related material must be received by the Coast Guard on or before August 26, 2011.

ADDRESSES: You may submit comments identified by docket number USCG–2011–0629 using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* 202–493–2251.

(3) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or e-mail BOSN3 Joseph M. Edge, Coast Guard Sector North Carolina, Coast Guard; telephone 252–247–4525, e-mail *Joseph.M.Edge@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2011–0629), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (via *http://www.regulations.gov*) or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via *http://www.regulations.gov,* it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an e-mail address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* click on the ''submit a comment'' box, which will then become highlighted in blue. In the ''Document Type'' drop down menu select ''Proposed Rule'' and insert ''USCG–2011–0629'' in the ''Keyword'' box. Click ''Search'' then click on the balloon shape in the ''Actions'' column.