Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 40

[NRC–2009–0079 and NRC–2011–0080]

RIN 3150–AI50

Domestic Licensing of Source Material—Amendments/Integrated Safety Analysis; Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Extension of public comment period and public meeting; correction.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is correcting a notice appearing in the **Federal Register** on July 27, 2011 (76 FR 44865), that extended the public comment period and provided a date for a public meeting for the proposed rule, ''Domestic Licensing of Source Material—Amendments/Integrated Safety Analysis.'' This action is necessary to correct the date of the public meeting in the **DATES** section, and to correct the Docket ID information for accessing publicly available documents related to the proposed rule and draft guidance document in the **ADDRESSES** section.

FOR FURTHER INFORMATION CONTACT: Cindy Bladey, Chief, Rules, Announcements and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–492–3667 or e-mail: *Cindy.Bladey@nrc.gov.*

SUPPLEMENTARY INFORMATION: On page 44865 of **Federal Register** document 2011–14060, published July 27, 2011 (76 FR 44865), in the third column, under the section titled **DATES**, second paragraph, ''August 7, 2011'' is corrected to read ''August 17, 2011.'' Also, on page 44866 of the same document, in the first column, the last bulleted item before the section titled **FOR FURTHER INFORMATION CONTACT** is removed and the following bulleted item is added in its place:

• *Federal Rulemaking Web site:* Public comments and supporting materials related to the proposed rule and proposed draft guidance document can be found at *http://www.regulations.gov* by searching on Docket ID NRC–2009–0079 for the proposed rule and Docket ID NRC–2011–0080 for the proposed draft guidance document.

Dated at Rockville, Maryland, this 29th day of July 2011.

For the Nuclear Regulatory Commission.

Cindy Bladey,

Chief, Rules, Announcements and Directives Branch, Division of Administrative Services, Office of Administration.

[FR Doc. 2011–19726 Filed 8–3–11; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2011–N–0526]

Effective Date of Requirement for Premarket Approval for a Pacemaker Programmer

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 pacemaker programmers. 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 devices. 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 November 2, 2011. Submit requests for a change in classification by August 19, 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–0526], 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 and Regulatory Information Number (RIN) (if a RIN number has been assigned) 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, 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 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 21 CFR 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 21 CFR 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 21 CFR 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**: 44 FR 13382, March 9, 1979; 45 FR 7907–7971, February 5, 1980; and 52 FR 17736, May 11, 1987.

IV. Device Subject to This Proposal—Pacemaker Programmers (21 CFR 870.3700)

A. Identification

A pacemaker programmer is a device used to change noninvasively one or more of the electrical operating characteristics of a pacemaker.

B. Summary of Data

The Cardiovascular Device Classification Panel recommended that this device be classified as class III because the panel also recommended that pacemakers be classified into class III. The panel believed that premarket approval was necessary to assure the safety and effectiveness of pacemakers, which are life-supporting devices, and that the same level of control was necessary for both devices because pacemaker programmers must be designed to operate with a specific pacemaker as a system. The panel believed that general controls alone would not provide sufficient control over the performance characteristics of this device, that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device, and, moreover, that there are insufficient data to establish a standard to provide such assurance. 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. Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias.
2. Improper pacemaker operation: Inadequate design of the device's programming function can cause the pacemaker to lose its sensing or pacing ability, or to pace at an improper rate.
3. Misdiagnosis: Inadequate design of the device's ability to sense pacemaker function can lead to the generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.
4. Inability to change pacing therapy: Inadequate matching of the programmer to the pacemaker could lead to a situation where the pacemaker could not be programmed, thereby preventing a needed change in pacing therapy and placing the patient at risk unnecessarily.

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 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. 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, 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.

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 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs 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 the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. There has been only one 510(k) submission assigned to this product code within the past 15 years. Upon review of this record, the agency determined that this was done in error, which has been corrected. Accordingly, since it has been determined that all of the affected devices have fallen into disuse; 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.

FDA proposes to certify that this proposed rule, if issued as a final rule, would not have a significant economic impact. We base this determination on an analysis of registration and listing and other data for the device. There have been no 510(k) submissions for pacemaker programmers since 1995 with the exception of one 510(k) submission cleared in 2009 for a Pacing System Analyzer cleared for use with a PMA approved programmer. This device was inappropriately reviewed as a 510(k) submission, because this device should have been regulated under PMA. Programmers currently marketed are capable of programming all implantable cardiac devices including pacemakers and defibrillators. Because these programmers interact with products covered under several class III product codes including adaptive rate pacemakers (LWP); implantable defibrillators (LWS); cardiac resynchronization pacemakers (CRT–P, NKE) and implantable defibrillators (CRT–D, NIK) they have been entirely reviewed within the PMA program for more than a decade.

This information is summarized in table 1 below as follows:

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?
Pacemaker Programmer	KRG	510(k)	2011	1990s	Yes

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.

X. 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.

XI. 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 No. 0910–0078; the collections of information in 21 CFR part 807 subpart E have been approved under OMB Control No. 0910–0120; the collections of information in 21 CFR 814 subpart B have been approved under OMB Control No. 0910–0231; and the collections of information under 21 CFR 801 have been approved under OMB Control No. 0910–0485.

XII. 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.

XIII. 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.

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 870.3700 is amended by revising paragraphs (a) and (c) to read as follows:

§ 870.3700 Pacemaker programmers.

(a) *Identification.* A pacemaker programmer is a device used to noninvasively change one or more of the electrical operating characteristics of a pacemaker.

(b) * * *

(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 November 2, 2011, for any pacemaker programmer that was in commercial distribution before May 28, 1976, or that has, on or before November 2, 2011, been found to be substantially equivalent to any pacemaker programmer that was in commercial distribution before May 28, 1976. Any other pacemaker programmer shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: July 29, 2011.

Nancy K. Stade,

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

[FR Doc. 2011–19733 Filed 8–3–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Chapter III

Regulatory Review Schedule; Cancellation of Consultation Meetings

AGENCY: National Indian Gaming Commission.

ACTION: Notice.

SUMMARY: On November 18, 2010, the National Indian Gaming Commission (NIGC) issued a Notice of Inquiry and Notice of Consultation advising the public that the NIGC was conducting a comprehensive review of its regulations and requesting public comment on the process for conducting the regulatory review. On April 4, 2011, after holding eight consultations and reviewing all comments, NIGC published a Notice of Regulatory Review Schedule setting out a consultation schedule and process for review. The purpose of this document is to cancel four scheduled tribal consultations.

DATES: See **SUPPLEMENTARY INFORMATION** below for dates and locations of cancelled consultations.

FOR FURTHER INFORMATION CONTACT: Lael Echo-Hawk, National Indian Gaming Commission, 1441 L Street NW., Suite 9100 Washington, DC 20005. Telephone: 202–632–7003; e-mail: *reg.review@nigc.gov.*

SUPPLEMENTARY INFORMATION: On November 18, 2010, the National Indian Gaming Commission (NIGC) issued a Notice of Inquiry and Notice of Consultation advising the public that it was conducting a review of its regulations promulgated to implement 25 U.S.C. 2701–2721 of the Indian Gaming Regulatory Act (IGRA) and requesting public comment on the process for conducting the regulatory review. On April 4, 2011, after holding eight consultations and reviewing all