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 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:


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.

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
comments, NIGC published a Notice of Regulatory Review Schedule in the Federal Register setting out consultation schedules and review processes. (76 FR 18457, April 4, 2011).

The Commission’s regulatory review process establishes a tribal consultation schedule with a description of the regulation groups to be covered at each consultation. This document advises the public that the following tribal consultations have been cancelled.

<table>
<thead>
<tr>
<th>Consultation date</th>
<th>Event</th>
<th>Location</th>
<th>Regulation group(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>August 25–26, 2011</td>
<td>NIGC Consultation—Southwest</td>
<td>Wild Horse Resort Casino, Scottsdale, AZ</td>
<td>1, 2, 3, 4, 5</td>
</tr>
<tr>
<td>September 19–20, 2011</td>
<td>NIGC Regional Training</td>
<td>Sky Ute Casino Resort Ignacio, CO</td>
<td>3, 4, 5</td>
</tr>
<tr>
<td>November 7–12, 2011</td>
<td>USET Annual Meeting</td>
<td>Mississippi Choctaw, MS</td>
<td>3, 4, 5</td>
</tr>
</tbody>
</table>

For additional information on consultation locations and times, please refer to the Web site of the National Indian Gaming Commission, http://www.nigc.gov.

Dated: August 1, 2011, Washington, DC.

Tracie L. Stevens, Chairwoman.
Stefanni A. Cochran, Vice-Chairwoman.
Daniel J. Little, Associate Commissioner.

[FR Doc. 2011–19808 Filed 8–3–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52


Approval and Promulgation of Air Quality Implementation Plans; Maryland; Preconstruction Permitting Requirements for Electric Generating Stations in Maryland

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the Maryland Department of the Environment (MDE) on May 13, 2011 and July 15, 2011. This SIP revision revises and supplements the preconstruction permitting requirements for electric generating stations that are required to receive a Certificate of Public Convenience and Necessity (CPCN) from the Maryland Public Service Commission (PSC) before commencing construction. The SIP revision also requires electric generating stations to obtain a preconstruction permit from the MDE when a CPCN is not required under the PSC regulations and statutes. This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before September 6, 2011.

ADDRESSES: Identify your comments, identified by Docket ID Number EPA–R03–OAR–2011–0623 by one of the following methods:


2. E-mail: cox.kathleen@epa.gov.


4. Hand Delivery: At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket’s normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R03–OAR–2011–0623. EPA’s policy is that all comments received will be included in the public docket without change, and may be made available online at http://www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through http://www.regulations.gov or e-mail. The http://www.regulations.gov Web site is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through http://www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the http://www.regulations.gov index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in http://www.regulations.gov or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Maryland Department of the Environment, 1800 Washington Boulevard, Suite 705, Baltimore, Maryland 21230.

FOR FURTHER INFORMATION CONTACT: David Talley at 215–814–2117, or e-mail at talley.david@epa.gov.

SUPPLEMENTARY INFORMATION: Throughout this document, whenever “we,” “us,” or “our” is used, we mean EPA. EPA is proposing approval of this SIP revision because it corrects the deficiencies in the Maryland SIP and eliminates inconsistencies between State statutory and regulatory requirements for preconstruction permitting for electric generating stations in Maryland. It will also ensure that the SIP is adequate to prevent significant deterioration of air quality in areas designated as attainment or unclassifiable as required by Sections 110(a) and 161 of the CAA and 40 CFR...