

§ 814.39 PMA supplements.

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(c) * * *

(2) The supplement must include the following information:

(i) Information concerning pediatric uses as required under § 814.20(b)(13).

(ii) If information concerning the device that is the subject of the supplement was previously submitted under § 814.20(b)(13) or under this section in a previous supplement, the applicant is not required to resubmit the information, but may include the information by referring to the previous application or submission that contains the information. However, if additional information required under § 814.20(b)(13) has become readily available to the applicant since the previous submission, the applicant must submit that information as part of the supplement.

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■ 7. In § 814.44, redesignate paragraphs (e)(1)(ii) through (iv) as paragraphs (e)(1)(iii) through (v), respectively, and add new paragraph (e)(1)(ii) to read as follows:

§ 814.44 Procedures for review of a PMA.

* * * * *

(e) * * *

(1) * * *

(ii) The submission of additional information concerning pediatric uses required by § 814.20(b)(13);

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■ 8. Amend § 814.100 as follows:

■ a. Redesignate paragraphs (b) through (e) as paragraphs (d) through (g), respectively.

■ b. Redesignate paragraph (a) as paragraph (b), and remove the first sentence of newly redesignated paragraph (b); and

■ c. Add new paragraphs (a) and (c) to read as follows:

§ 814.100 Purpose and scope.

(a) This subpart H implements sections 515A and 520(m) of the act.

* * * * *

(c) Section 515A of the act is intended to ensure the submission of readily available information concerning:

(1) Any pediatric subpopulations (neonates, infants, children, adolescents) that suffer from the disease or condition that the device is intended to treat, diagnose, or cure; and

(2) The number of affected pediatric patients who are 21 years of age or younger.

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■ 9. Amend § 814.104 as follows:

■ a. Revise the last sentence of paragraph (b)(4)(ii);

■ b. Revise the last sentence of paragraph (b)(5); and

■ c. Add paragraph (b)(6).

The revisions and addition read as follows:

§ 814.104 Original applications.

* * * * *

(b) * * *

(4) * * *

(ii) * * * The effectiveness of this device for this use has not been demonstrated;

(5) * * * If the amount charged is \$250 or less, the requirement for a report by an independent certified public accountant or an attestation by a responsible individual of the organization is waived; and

(6) Information concerning pediatric uses of the device, as required by § 814.20(b)(13).

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■ 10. In 814.116, redesignate paragraphs (c)(2) through (4) as paragraphs (c)(3) through (5), respectively, and add new paragraph (c)(2) to read as follows:

§ 814.116 Procedures for review of an HDE.

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(c) * * *

(2) The submission of additional information concerning pediatric uses of the device, as required by § 814.20(b)(13);

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Dated: February 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-03647 Filed 2-15-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF THE INTERIOR**Office of Surface Mining Reclamation and Enforcement****30 CFR Part 938**

[SATS No. PA-159-FOR; Docket ID: OSM 2010-0017]

Pennsylvania Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: We are reopening the public comment period on the proposed amendment to the Pennsylvania regulatory program (the "Pennsylvania program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act) published on

February 7, 2011. In response to a required program amendment codified in the Federal regulations, Pennsylvania submitted information that it believes demonstrates that sufficient funds exist to guarantee coverage of the full cost of land reclamation at all sites originally permitted and bonded under its now-defunct alternative bonding system. Pennsylvania requested that the program amendment be removed based on the information provided. The comment period is being reopened to incorporate subsequent information that we received from Pennsylvania regarding one permit involving land reclamation obligations. This document gives the times and locations that the Pennsylvania program and this submittal are available for your inspection, the comment period during which you may submit written comments, and the procedures that we will follow for the public hearing, if one is requested.

DATES: The comment period for the proposed rule published February 7, 2011 (76 FR 6587), and extended on June 13, 2011 (76 FR 64048), is reopened. We will accept written comments until 4 p.m., local time March 6, 2013.

ADDRESSES: You may submit comments, identified by "PA-159-FOR; Docket ID: OSM-2010-0017" by either of the following two methods:

Federal eRulemaking Portal:
www.regulations.gov. The proposed rule has been assigned Docket ID: OSM-2010-0017. If you would like to submit comments through the Federal eRulemaking Portal, go to www.regulations.gov and follow the instructions.

Mail/Hand Delivery/Courier:
Mr. Ben Owens, Chief, Pittsburgh Field Division, Office of Surface Mining Reclamation and Enforcement, Harrisburg Transportation Center, 415 Market St., Suite 304, Harrisburg, Pennsylvania 17101, Telephone: (717) 782-4036, Email: bowens@osmre.gov.

Thomas Callaghan, P.G., Director, Bureau of Mining and Reclamation, Pennsylvania Department of Environmental Protection, Rachel Carson State Office Building, P.O. Box 8461, Harrisburg, Pennsylvania 17105-8461, Telephone: (717) 787-5015, Email: tcallaghan@state.pa.us
mailto:

Instructions: For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Public Comment Procedures" heading of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Ben Owens, Telephone: (717) 782-4036. Email: bowens@osmre.gov

SUPPLEMENTARY INFORMATION: On February 7, 2011, (76 FR 6587), we published a proposed rule that was in response to a required program amendment codified in the Federal regulations. The submission included budgetary information that Pennsylvania had submitted to demonstrate that sufficient funds exist to guarantee coverage of the full cost of land reclamation at all sites originally permitted and bonded under the now-defunct alternative bonding system. Pennsylvania requested that the program amendment be removed based on the information provided.

On June 13, 2011, (76 FR 64048), we published a proposed rule to extend the public comment period and incorporate additional information from Pennsylvania regarding developments involving one permit that was transferred to another company, resulting in the posting of full-cost bond in an amount to cover the land reclamation obligation.

On November 6, 2012, (Administrative Record Number PA 802.85), we received additional information from Pennsylvania regarding recent developments involving another permit and its bonding status. Pennsylvania requested that the required amendment be removed based on the information provided.

We are reopening the comment period to incorporate the above-referenced subsequent information that we received from Pennsylvania on November 6, 2012.

Public Comment Procedures

Under the provisions of 30 CFR 732.17(h), we are seeking your comments on whether the submission satisfies the applicable program approval criteria of 30 CFR 732.15. If we approve the amendment, it will become part of the Pennsylvania program.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. We cannot ensure that comments received after the close of the comment period (see **DATES**) or sent to an address

other than those listed above (see **ADDRESSES**) will be included in the docket for this rulemaking and considered.

Electronic or Written Comments

If you submit written comments, they should be specific, confined to issues pertinent to the proposed regulations, and explain the reason for any recommended change(s). We would appreciate all comments relating to this specific issue, but those most useful and likely to influence decisions on the final rule will be those that either involve personal experience or include citations to and analysis of the Surface Mining Control and Reclamation Act of 1977, its legislative history, its implementing regulations, case law, other State or Federal laws and regulations, data, technical literature, or other relevant publications.

List of Subjects in 30 CFR Part 938

Intergovernmental relations, Surface mining, Underground mining.

Dated: January 25, 2013.

Thomas D. Shope,

Regional Director, Appalachian Region.

[FR Doc. 2013-03567 Filed 2-15-13; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R04-OAR-2012-0888; FRL-9780-7]

Approval and Promulgation of Implementation Plans Tennessee: Revisions to Volatile Organic Compound Definition

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve changes to the Tennessee State Implementation Plan (SIP), submitted by the State of Tennessee, through the Tennessee Department of Environment and Conservation on September 3, 1999. Tennessee's September 3, 1999, SIP revision adds 17 compounds to the list of compounds excluded from the definition of "Volatile Organic Compound". EPA is approving this SIP revision because the State has demonstrated that it is consistent with the Clean Air Act.

In the Final Rules Section of this **Federal Register**, EPA is approving the State's implementation plan revision as a direct final rule without prior proposal because the Agency views this as a

noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

DATES: Written comments must be received on or before March 21, 2013.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R04-OAR-2012-0888, by one of the following methods:

1. *www.regulations.gov*: Follow the on-line instructions for submitting comments.

2. *Email*: R4-RDS@epa.gov.

3. *Fax*: (404) 562-9019.

4. *Mail*: "EPA-R04-OAR-2012-0888," Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960.

5. *Hand Delivery or Courier*: Lynorae Benjamin, Chief, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding federal holidays.

Please see the direct final rule which is located in the Rules section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT: Sean Lakeman, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960. The telephone number is (404) 562-9043. Mr. Lakeman can be reached via electronic mail at lakeman.sean@epa.gov.

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule which is published in the