

11. Horowitz, S. and R. P. Scalici, "Results of Sensory Panel Tests on Slim-Mint Chewing Gum," in OTC Vol. 170010, Docket No. FDA-1981-N-0012 (formerly 1981N-0022), Division of Dockets Management.
12. Rosner, L., "To Determine the Effect of Chewing Slim-Mint Gum Upon Taste Perception, Particularly Toward Sweetness," in OTC Vol. 170010, Docket No. FDA-1981-N-0012 (formerly 1981N-0022), Division of Dockets Management.
13. Summary Minutes of the 11th meeting of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products held on May 9-10, 1976 in OTC Vol. 170010, Docket No. FDA-1981-N-0012 (formerly 1981N-0022), Division of Dockets Management.
14. Gould, W. L., "On the Use of a Medicament to Reduce the Appetite in the Treatment of Obesity and Other Conditions," *New York State Journal of Medicine*, 47:981-983, 1947.
15. Gould, W. L., "Obesity and Hypertension: The Importance of a Safe Compound to Control Appetite," *North Carolina Medical Journal*, 11:327-334, 1950.
16. Plotz, M., "Obesity," *Medical Times*, 86:860-863, 1958.
17. McClure, C. W. and C. A. Bruschi, "Treatment of Oral Syndrome Obesity with Non traditional Appetite Control Plan," *Journal of the American Women's Medical Association*, 28:239-248, 1973.

List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

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 310 be amended as follows:

PART 310—NEW DRUGS

1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b-360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b-263n.

2. Section 310.545 is amended by adding paragraphs (a)(20)(i), (a)(20)(ii), and (a)(20)(iii); by revising paragraph (d) introductory text; and by adding paragraph (d)(40) to read as follows:

§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

(a) * * *

(20) * * *

(i) [Reserved]

(ii) [Reserved]

(iii) Approved as of [DATE 30 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**].

Benzocaine

* * * * *

(d) Any OTC drug product that is not in compliance with this section is subject to regulatory action if initially introduced or initially delivered for introduction into interstate commerce after the dates specified in paragraphs (d)(1) through (d)(40) of this section.

* * * * *

(40) [DATE 30 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**], for products subject to paragraph (a)(20)(iii) of this section.

Dated: March 2, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-5145 Filed 3-8-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 938

[PA-157-FOR; OSM 2010-0011]

Pennsylvania Regulatory Program

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

ACTION: Proposed rule; public comment period and opportunity for public hearing on removal of required amendment.

SUMMARY: We are announcing receipt of a request to remove a required amendment to the Pennsylvania regulatory program (the "Pennsylvania program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). In response to a required program amendment codified in the Federal regulations, Pennsylvania has submitted rationale that it believes supports its position that current program provisions are sufficient to render its program no less effective than the Federal requirements and, therefore, no amendment is necessary. The required amendment pertains to regulatory exemptions for coal extraction incidental to the extraction of other minerals.

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: We will accept written comments until 4 p.m., local time April 8, 2011. If requested, we will hold a public hearing on April 4, 2011. We will accept requests to speak until 4 p.m., local time on March 24, 2011.

ADDRESSES: You may submit comments, identified by "PA-157-FOR; Docket ID: OSM-2010-0011" by either of the following two methods:

Federal eRulemaking Portal: <http://www.regulations.gov>. The proposed rule has been assigned Docket ID: OSM-2010-0011. If you would like to submit comments through the Federal eRulemaking Portal, go to <http://www.regulations.gov> and follow the instructions.

Mail/Hand Delivery/Courier: Mr. George Rieger, Chief, Pittsburgh Field Division, Office of Surface Mining Reclamation and Enforcement, Harrisburg Transportation Center, 415 Market St., Suite 304, Harrisburg, PA 17101.

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 of this document.

Docket: In addition to obtaining copies of documents at <http://www.regulations.gov>, information may also be obtained at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSM's Pittsburgh Field Division Office.

George Rieger, 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, *E-mail:* grieger@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) 787-5103, *E-mail:* tcallaghan@state.pa.us.

FOR FURTHER INFORMATION CONTACT: George Rieger, *Telephone:* (717) 782-4036. *E-mail:* grieger@osmre.gov.

SUPPLEMENTARY INFORMATION:

- I. Background on the Pennsylvania Program
- II. Description of the Request
- III. Public Comment Procedures
- IV. Procedural Determinations

I. Background on the Pennsylvania Program

Section 503(a) of the Act permits a State to assume primacy for the

regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its program includes, among other things, “a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of this Act * * *; and rules and regulations consistent with regulations issued by the Secretary pursuant to this Act.” See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Pennsylvania program on July 30, 1982. You can find background information on the Pennsylvania program, including the Secretary’s findings, the disposition of comments, and conditions of approval of the Pennsylvania program in the July 30, 1982, **Federal Register** (47 FR 33050). You can also find later actions concerning the Pennsylvania program and program amendments at 30 CFR 938.11, 938.12, 938.13, 938.15, and 938.16.

II. Description of the Request

By letter dated August 6, 2010 (Administrative Record Number PA 892.12), Pennsylvania sent us a response to a program amendment that was required by OSMRE in a final rule notice published in the **Federal Register** on November 7, 1997, (62 FR 60177) and codified in the Federal Regulations at 30 CFR 938.16(uuu). This required amendment provided that Pennsylvania submit an amendment to provide counterparts to the Federal regulations at 30 CFR 702.15(d), (e), (f), and 702.17(c)(2), and (c)(3). The Federal regulations pertain to (1) conditions of exemption and right of inspection and entry; and (2) revocation and enforcement. Pennsylvania submits that its regulatory program already contains counterparts to the Federal regulations and, therefore, is no less effective than the Federal regulations pertaining to incidental coal extraction. Pennsylvania requests that we remove the condition found at 30 CFR 938.16(uuu) on this basis.

Pennsylvania is submitting the request that includes three parts: (1) Environmental Hearing Board Act (35 P.S. Sections 7511–7516); (2) 25 Pa Code Chapter 1021; and (3) 25 Pa Code 77.352. In summary, the Federal regulations and PADEP rationale are provided as follows:

Federal Regulations: 30 CFR 702.15, Conditions of Exemption and Right of Inspection and Entry, provides with regard to exemptions for coal extraction incidental to the extraction of other minerals, authorized representatives of

the regulatory authority and Secretary the right to conduct inspections of operations claiming exemption. The representatives have the right of entry to any mining and reclamation operations without advance notice or search warrants, access to and copies of any relevant records, and to gather physical and photographic evidence. A search warrant may be required for entry into a building.

PADEP Response: OSM’s review of 25 Pennsylvania Code (Pa Code) Section 86.5 in the 1997 rulemaking did not include a discussion of the need for 25 Pa Code Section 86.5 to be revised to add counterparts to the Federal regulations at 30 CFR 702.15(d), (e), and (f). Thus, it is not clear why OSM considered 25 Pa Code Section 86.5 to be less effective than the Federal regulations with respect to the right to conduct inspections and right of entry for operations extracting coal incidental to surface mining.

Pennsylvania submits that its regulatory program, upon approval of the program amendment incorporating 25 Pa Code Section 77.352, will contain counterparts to 30 CFR 702.15(d), (e), and (f), and, therefore, is no less effective than the Federal regulations pertaining to incidental coal extraction.

Section 86.5(a) requires that a person who intends to extract coal incidental to the extraction of other minerals “shall do so under the provisions of a noncoal surface mining permit issued under Chapter 77 (relating to noncoal mining) and subject to the conditions described in this section.” A person who seeks to engage in incidental coal extraction is required to obtain a noncoal surface mining permit pursuant to Pennsylvania’s Noncoal Surface Mining Conservation and Reclamation Act, 52 P.S. Section 3301 *et seq.* (NSMCRA) and the regulations in 25 Pa Code Chapter 77 which implement NSMCRA. Thus, all persons conducting incidental coal extraction under Chapter 86.5 must comply with, and are subject to, the provision of NSMCRA and 25 Pa Code Chapter 77. Section 3314 of NSMCRA provides: “The department shall have the right to enter and inspect all surface mining operations for the purpose of determining conditions of health or safety and for compliance with the provisions of this act and all rules and regulations promulgated pursuant thereto.” 52 P.S. Section 3314. According to Pennsylvania, this statutory provision and the implementing regulations in Chapter 77.352, clearly constitute a counterpart to 30 CFR 702.15(d) that is at least no less effective than the Federal regulation.

Sections 702.15(e) and (f) elaborate on the right of authorized representatives of the regulatory authority to conduct inspections of sites conducting incidental coal extraction.

Pennsylvania’s noncoal mining regulations in 25 Pa Code Chapter 77, (which persons claiming exemption under 25 Pa Code Section 86.5 are subject to pursuant to 25 Pa Code Section 86.5(a)), provide counterparts to the Federal regulations at 30 CFR 702.15(d), (e), and (f). Section 77.352(a)(1) states that the Department and its agents and employees “will have access to, and require the production of, books and papers, documents, and physical evidence pertinent to a matter under investigation.” Further 77.352(a)(2) states that Department representatives have the right to “enter a building, property, premises, or place where noncoal mining activities are conducted for the purpose of making an investigation or inspection as may be necessary to ascertain the compliance or noncompliance by a person with the environmental acts and the act and regulations thereunder.” These provisions in 25 Pa Code Chapter 77 provide counterparts to 30 CFR 702.15(d), (e), and (f), and, according to Pennsylvania, provide broader authority to Pennsylvania’s authorized representatives given that they may enter a building at a surface mine site for the purposes of inspection or investigation without being required to obtain a search warrant. These requirements extend to OSM in their role as oversight agent for the primacy coal mining program. Pennsylvania therefore submits that its regulatory program, upon approval of the program amendment incorporating 25 Pa Code 77.352, will contain counterparts to 30 CFR 702.15(d), (e), and (f) which are no less effective than the Federal regulations.

Federal Regulations: 30 CFR 702.17, Revocation and Enforcement, provides that the regulatory authority may revoke the exemption, if the operator has not established that the activities conducted in the mining area qualify for an exemption. An administrative review of a decision whether to revoke an exemption may be requested by any adversely affected person within 30 days of notification. Lastly, the petition for administrative review will not suspend the effect of the decision of whether to revoke an exemption.

PADEP’s Response: OSM’s required amendment at 30 CFR 938.16(uuu) with respect to Pennsylvania counterparts for 30 CFR 702.17(c)(2) and (c)(3) also was not discussed in the 1997 rulemaking. More importantly, this part of the

required amendment actually conflicts with OSM's own findings in the 1997 rulemaking.

In the 1997 rulemaking, OSM determined that 25 Pa Code Section 86.5(o) is identical in meaning to 30 CFR 702.17(c)(2); and that 25 Pa Code Section 86.5(n) is identical in meaning to 30 CFR 702.17(c)(3). *See Federal Register* (62 FR 60169–70 and Table A). OSM then concluded: "Because the above proposed revisions (listed in Table A) are identical in meaning to the corresponding Federal regulations, the Director finds that Pennsylvania's proposed rules are no less effective than the Federal rules." Thus, the portion of 30 CFR 938.16(uuu) pertaining to counterparts to 30 CFR 702.17(c)(2) and (c)(3) appears to be an error and should be rescinded by OSM on that basis alone.

In any event, Pennsylvania submits that its regulatory program already contains counterparts to 30 CFR 702.17(c)(2) and (c)(3). As previously recognized by OSM in the 1997 Rulemaking, Pennsylvania has regulations which provide for administrative review of Department determinations concerning exemption for incidental coal extraction. *See Federal Register* (62 FR 60170). A Department determination to revoke an exemption for incidental coal extraction under Chapter 86.5 would constitute a final action of the Department, which would be appealable to the Environmental Hearing Board. *See* 35 P.S. 7511–7516 (Environmental Hearing Board Act); 35 P.S. 7514 ("no action of the department adversely affecting a person shall be final as to that person until the person has had the opportunity to appeal the action to the board"); 25 Pa. Code Chapter 1021 (Environmental Hearing Board procedural rules); 25 Pa. Code Chapter 1021.2 (defining "action" of the department), Chapter 1021.51 (commencement of an appeal). These statutory and regulatory sections regarding the right of appeal to the Pennsylvania Environmental Hearing Board provide counterparts to 30 CFR 702.17(c)(2).

Pennsylvania also has counterparts to 30 CFR 702.17(c)(3). The Environmental Hearing Board Act states: "No appeal shall act as an automatic supersedeas." 35 P.S. 7514(d). *See* also 25 Pa. Code Chapter 1021.61. In the 1997 Rulemaking, OSM stated as follows with respect to Chapter 86.5(I)(3): In its letter dated March 28, 1997, Pennsylvania stated that appeals to the Environmental Hearing Board (EHB) under the provisions of Chapter 21 [now Chapter 1021] do not stay the effect of the Department of Environmental

Protection's (Department) actions. If an appellant wishes to stay the effect of such an action, the appellant must petition the EHB which, in turn, must issue a supersedeas. The Director finds the proposed Pennsylvania regulation no less effective than the Federal regulations, since Pennsylvania law provides, generally, that an appeal does not, by itself, suspend the effect of the decision appealed from. *See Federal Register* (62 FR 60170). Pennsylvania contends that this same rationale applies to the required counterpart to 30 CFR 702.17(c)(3). Pennsylvania law provides, generally, that an appeal does not, by itself, suspend the effect of the decision appealed from. Therefore, Pennsylvania submits that its regulatory program, upon approval of the program amendment incorporating, will contain counterparts to 30 CFR 702.17(c)(2) and (c)(3), which are no less effective than the Federal regulations.

III. 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.

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 appreciate any and all comments, but those most useful and likely to influence decisions on the final regulations will be those that either involve personal experience or include citations to and analyses of SMCRA, its legislative history, its implementing regulations, case law, other pertinent Tribal or Federal laws or regulations, technical literature, or other relevant publications. 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.

Public Availability of Comments

Before including your address, phone number, e-mail 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 will not consider anonymous comments.

Public Hearing

If you wish to speak at the public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4 p.m., local time March 24, 2011. If you are disabled and need reasonable accommodations to attend a public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT**. We will arrange the location and time of the hearing with those persons requesting the hearing. If no one requests an opportunity to speak, we will not hold the hearing. To assist the transcriber and ensure an accurate record, we request, if possible, that each person who speaks at a public hearing provide us with a written copy of his or her comments. The public hearing will continue on the specified date until everyone scheduled to speak has been given an opportunity to be heard. If you are in the audience and have not been scheduled to speak and wish to do so, you will be allowed to speak after those who have been scheduled. We will end the hearing after everyone scheduled to speak and others present in the audience who wish to speak, have been heard.

Public Meeting

If there is only limited interest in participating in a public hearing, we may hold a public meeting rather than a public hearing. If you wish to meet with us to discuss the submission, please request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings are open to the public and, if possible, we will post notices of meetings at the locations listed under **ADDRESSES**. We will make a written summary of each meeting a part of the administrative record.

IV. Procedural Determinations

Executive Order 12866—Regulatory Planning and Review

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866.

Other Laws and Executive Orders Affecting Rulemaking

When a State submits a program amendment to OSM for review, our regulations at 30 CFR 732.17(h) require us to publish a notice in the **Federal Register** indicating receipt of the proposed amendment, its text or a summary of its terms, and an opportunity for public comment. We conclude our review of the proposed amendment after the close of the public comment period and determine whether

the amendment should be approved, approved in part, or not approved. At that time, we will also make the determinations and certifications required by the various laws and executive orders governing the rulemaking process and include them in the final rule.

List of Subjects in 30 CFR Part 938

Intergovernmental relations, Surface mining, Underground mining.

Dated: November 24, 2010.

Thomas D. Shope,

Regional Director, Appalachian Region.

[FR Doc. 2011-5404 Filed 3-8-11; 8:45 am]

BILLING CODE 4310-05-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA-HQ-OAR-2008-0708, FRL-9277-4]

RIN 2060-AQ78

National Emission Standards for Hazardous Air Pollutants for Reciprocating Internal Combustion Engines

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; amendments.

SUMMARY: EPA is taking action to propose amendments to a final rule that provided national emission standards for hazardous air pollutants for existing stationary spark ignition reciprocating internal combustion engines. The final rule was published on August 20, 2010. This action proposes to amend certain regulatory text to clarify compliance requirements related to continuous parameter monitoring systems. EPA is also proposing to correct minor typographical errors in the regulatory text to the August 20, 2010, action.

DATES: *Comments.* Comments must be received on or before April 8, 2011, or 30 days after date of public meeting if one is requested.

Public Meeting. If anyone contacts us requesting to speak at a public meeting by March 16, 2011, a public meeting will be held on March 24, 2011. If you are interested in attending the public meeting, contact Ms. Pamela Garrett at (919) 541-7966 to verify that a meeting will be held.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2008-0708, by one of the following methods:

- <http://www.regulations.gov>: Follow the on-line instructions for submitting comments.

- *E-mail:* a-and-r-docket@epa.gov.
- *Fax:* (202) 566-1741.
- *Mail:* Air and Radiation Docket and Information Center, Environmental Protection Agency, Mailcode: 6102T, 1200 Pennsylvania Ave., NW., Washington, DC 20460. Please include a total of two copies. EPA requests a separate copy also be sent to the contact person identified below (*see FOR FURTHER INFORMATION CONTACT*).

- *Hand Delivery:* Air and Radiation Docket and Information Center, U.S. EPA, Room B102, 1301 Constitution Avenue, NW., Washington, DC. 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-HQ-OAR-2008-0708. EPA's policy is that all comments received will be included in the public docket without change and may be made available on-line 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.

Public Meeting: If a public meeting is held, it will be held at EPA's campus located at 109 T.W. Alexander Drive in Research Triangle Park, NC or an alternate site nearby.

Docket: All documents in the docket are listed in the <http://www.regulations.gov> index. EPA also relies on documents in Docket ID Nos.

EPA-HQ-OAR-2002-0059, EPA-HQ-OAR-2005-0029, and EPA-HQ-OAR-2005-0030, and incorporated those dockets into the record for this action. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at the Air and Radiation Docket, EPA/DC, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Air Docket is (202) 566-1742.

FOR FURTHER INFORMATION CONTACT: Ms. Melanie King, Energy Strategies Group, Sector Policies and Programs Division (D243-01), Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number (919) 541-2469; facsimile number (919) 541-5450; e-mail address king.melanie@epa.gov.

SUPPLEMENTARY INFORMATION:

Organization of This Document. The following outline is provided to aid in locating information in the preamble.

- I. General Information
 - A. What entities are potentially affected by this action?
 - B. What should I consider as I prepare my comments for EPA?
- II. Direct Final Rule
- III. Statutory and Executive Order Reviews
 - A. Executive Order 12866: Regulatory Planning and Review
 - B. Paperwork Reduction Act
 - C. Regulatory Flexibility Act
 - D. Unfunded Mandates Reform Act of 1995
 - E. Executive Order 13132: Federalism
 - F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
 - G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks
 - H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
 - I. National Technology Transfer and Advancement Act
 - J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations