

analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VIII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does 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 has concluded that the 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.

IX. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520) is not required.

FDA also tentatively concludes that the special controls guidance document does not contain new information collection provisions that are subject to review and clearance by OMB under the PRA. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of the draft guidance document entitled “Class II Special Controls Guidance Document: Tinnitus Masker Devices.”

X. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this proposed rule. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two paper copies of any written comments, except that individuals may submit one paper copy. Comments are to be identified 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.

XI. Proposed Implementation Plan

FDA proposes that any final regulation that may issue based on this proposal become effective 30 days after its date of publication in the **Federal Register**. Following the effective date of a final rule exempting the device, manufacturers of TMDs will need to address the issues covered in this

special controls guidance. However, the manufacturer need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

List of Subjects in 21 CFR Part 874

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 874 be amended as follows:

PART 874—EAR, NOSE, AND THROAT DEVICES

■ 1. The authority citation for 21 CFR part 874 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 874.1 is amended by revising paragraph (e) to read as follows:

§ 874.1 Scope.

* * * * *

(e) Guidance documents in this part may be obtained on the Internet at <http://www.fda.gov/cdrh/guidance.html>.

■ 3. Section 874.3400 is amended by revising paragraph (b) to read as follows:

§ 874.3400 Tinnitus masker.

* * * * *

(b) *Classification.* Class II (special controls). The special control for these devices is FDA’s “Class II Special Controls Guidance Document: Tinnitus Masker Devices.”

Dated: October 7, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 948

[WV–108–FOR]

West Virginia Regulatory Program

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

ACTION: Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: We are announcing receipt of a proposed amendment to the West Virginia regulatory program (the West

Virginia program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). West Virginia proposes to revise its Code of State Regulations (CSR) concerning surety bonds. The amendment is intended to provide the State with an alternative source of reliable financial information about the surety, and to allow sureties that are licensed and in good financial condition but are not currently listed with the U.S. Department of the Treasury as an acceptable surety of Federal bonds to provide surety bonds to the coal industry in West Virginia. The proposed amendment was authorized by the West Virginia Secretary of State as an emergency rule under the State’s Administrative Procedures Act.

DATES: We will accept written comments on this amendment until 4 p.m. (local time), on December 8, 2005. If requested, we will hold a public hearing on the amendment on December 5, 2005. We will accept requests to speak at a hearing until 4 p.m. (local time), on November 23, 2005.

ADDRESSES: You may submit comments, identified by WV–108–FOR, by any of the following methods:

- E-mail: chfo@osmre.gov. Include WV–108–FOR in the subject line of the message;
- Mail/Hand Delivery: Mr. Roger W. Calhoun, Director, Charleston Field Office, Office of Surface Mining Reclamation and Enforcement, 1027 Virginia Street, East, Charleston, West Virginia 25301; or
- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency docket number for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the “Public Comment Procedures” heading in the **SUPPLEMENTARY INFORMATION** section of this document. You may also request to speak at a public hearing by any of the methods listed above or by contacting the individual listed under **FOR FURTHER INFORMATION CONTACT**.

Docket: You may review copies of the West Virginia program, this amendment, a listing of any scheduled public hearings, and all written comments received in response to this document at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. You may also receive one free copy of this amendment by contacting OSM’s Charleston Field Office listed below.

Mr. Roger W. Calhoun, Director, Charleston Field Office, Office of

Surface Mining Reclamation and Enforcement, 1027 Virginia Street, East, Charleston, West Virginia 25301, Telephone: (304) 347-7158. E-mail: chfo@osmre.gov.

West Virginia Department of Environmental Protection, 601 57th Street, SE, Charleston, WV 25304, Telephone: (304) 926-0490.

In addition, you may review a copy of the amendment during regular business hours at the following locations:

Office of Surface Mining Reclamation and Enforcement, Morgantown Area Office, 75 High Street, Room 229, P.O. Box 886, Morgantown, West Virginia 26507, Telephone: (304) 291-4004. (By Appointment Only)

Office of Surface Mining Reclamation and Enforcement, Beckley Area Office, 313 Harper Park Drive, Suite 3, Beckley, West Virginia 25801, Telephone: (304) 255-5265.

FOR FURTHER INFORMATION CONTACT: Mr. Roger W. Calhoun, Director, Charleston Field Office, Telephone: (304) 347-7158. Internet: chfo@osmre.gov.

SUPPLEMENTARY INFORMATION:

- I. Background on the West Virginia Program
- II. Description of the Proposed Amendment
- III. Public Comment Procedures
- IV. Procedural Determinations

I. Background on the West Virginia 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 the Act * * *; and rules and regulations consistent with regulations issued by the Secretary pursuant to the 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 West Virginia program on January 21, 1981. You can find background information on the West Virginia program, including the Secretary’s findings, the disposition of comments, and conditions of approval of the West Virginia program in the January 21, 1981, **Federal Register** (46 FR 5915). You can also find later actions concerning West Virginia’s program and program amendments at 30 CFR 948.10, 948.12, 948.13, 948.15, and 948.16.

II. Description of the Proposed Amendment

By letter dated October 17, 2005 (Administrative Record Number WV-

1441), the West Virginia Department of Environmental Protection (WVDEP) submitted an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*). The amendment consists of a proposed revision to CSR 38-2-11.3.a.3 concerning surety bonds, a briefing document, an emergency rule justification, which includes an affidavit that was submitted in support of the emergency rule package, and a decision by the Secretary of State dated October 11, 2005, approving the emergency rule.

In its submittal of this amendment, the WVDEP stated that its current rule at CSR 38-2-11.3.a.3 requires that after July 1, 2001, a surety must be recognized by the Treasurer of the State as holding a certificate of authority from the United States Department of the Treasury as an acceptable surety on Federal bonds (otherwise referred to as being “T-Listed”). The WVDEP stated that the original standard was adopted to address concerns about the financial solvency of sureties providing reclamation bonds in West Virginia. The WVDEP did not have the necessary resources or expertise to regularly and timely monitor the financial condition of sureties doing business in West Virginia. However, a surety that is T-Listed is required to provide, on a regular basis, financial information to the U.S. Department of Treasury, which reviews this information and provides its findings to state regulatory agencies. While this information provided by the Department of Treasury has been helpful, WVDEP stated, this restriction has prevented sureties that are not T-Listed, and that are otherwise in good financial condition, from providing reclamation bonds in West Virginia. The WVDEP stated that this, along with other reasons, has adversely impacted the market for reclamation bonds in West Virginia. Further, WVDEP stated, since a surety must have at least two years experience providing surety bonds before it can be T-Listed, a new insurance company or an existing insurance company that has not previously issued surety bonds cannot offer surety bonds in West Virginia.

The WVDEP stated that the proposed amendment to CSR 38-2-11.3.a.3 not only addresses the concerns noted above by providing an alternative source of reliable financial information about the surety, but it also allows sureties that are licensed and in good financial condition but are not T-Listed to provide surety bonds in West Virginia.

The WVDEP stated that an “emergency” exists under the State’s Administrative Procedures Act because there is presently a great demand for reclamation bonds from the coal

industry in West Virginia that is not being met by the limited number of sureties currently offering surety bonds in West Virginia. As a result, alternative more expensive means are being used by coal companies to comply with the State’s bonding requirements. Among other things, this has greatly restricted the availability of capital for the development of new coal mines and the creation of new jobs. The State acknowledges that at a time when coal is so important to West Virginia’s economy, this dearth of surety bonds is having a significant negative impact on West Virginia’s coal industry. The proposed amendment to 38 CSR 2 is thus necessary “to prevent substantial harm to the public interest.”

Specifically, West Virginia proposes the following amendment.

CSR 38-2-11.3.a.3 Surety

The existing rule currently provides that surety received after July 1, 2001, must be recognized by the treasurer of the state as holding a current certificate of authority from the U.S. Department of the Treasury as an acceptable surety on Federal bonds. This provision is proposed to be amended by adding new language at the end of the existing requirement. As amended, CSR 38-2-11.3.a.3 provides as follows:

11.3.a.3. Surety received after July 1, 2001 must: (i) Be recognized by the treasurer of state as holding a current certificate of authority from the United States Department of the Treasury as an acceptable surety on federal bonds; Or (ii) submit to the Secretary proof that the surety holds a valid license issued by the basis a certificate of good standing or other evidence demonstrating that the surety remains licensed or otherwise in good standing with the West Virginia Insurance Commissioner and the insurance regulator of its domiciliary state and within four (4) years take all steps necessary to obtain a certificate of authority from the United States Department of the Treasury as an acceptable surety on federal bonds.

The WVDEP filed the emergency rule with the West Virginia Secretary of State on September 21, 2005. The Secretary of State approved the rule on an emergency basis pursuant to W. Va. Code 29A-3-15a on October 11, 2005.

The WVDEP also filed a legislative rule containing the same language with the Secretary of State on September 21, 2005 (Administrative Record Number WV-1442). At the same time, the State announced a public comment period on the legislative rule. The public comment period commenced on September 21, 2005, and closed on October 27, 2005. A public hearing was held at the WVDEP office in Kanawha City prior to the close of the comment period.

On October 3, 2005, WVDEP provided OSM a copy of the proposed rule for informal review. Unlike the State's existing surety bond provisions at CSR 38-2-11.3.a.1 and the Federal surety bond requirements at 30 CFR 800.20(a), OSM notified the State that the proposed revision at CSR 38-2-11.3.a.3 did not appear to require the surety to be licensed to do business in the State. To resolve this concern and to make additional clarifications without altering the purpose or intent of either the emergency or the legislative rule, on October 14, 2005 (Administrative Record Number WV-1443) OSM recommended that the language in both rules be revised as follows:

11.3.a.3. Any company that executes surety bonds in the State after July 1, 2001, must: (i) be recognized by the treasurer of the state as holding a current certificate of authority from the United States Department of the Treasury as an acceptable surety on federal bonds by being included on the Treasury Department's listing of approved sureties (Department Circular 570); or (ii) submit proof to the Secretary that it holds a valid license issued by the West Virginia Insurance Commissioner, and agree to submit to the Secretary on at least a quarterly basis a certificate of good standing from the West Virginia Insurance Commissioner and such other evidence from the insurance regulator of its domiciliary state, if other than West Virginia, demonstrating that it is also in good standing in that state. Companies not included on the United States Treasury Department's listing of approved sureties must diligently pursue application for listing, submit evidence on a semi-annual basis demonstrating that they are pursuing such listing, and within four (4) years, obtain a certificate of authority from the United States Department of the Treasury as an acceptable surety on federal bonds.

State officials agreed that while the recommended technical revisions offered by OSM were better and further clarified the intent of their initial rule, they needed to wait until after the close of their comment period before making any changes to the rule. The WVDEP intends to submit these changes and any additional revisions to OSM after the close of the State's comment period on October 27, 2005. This provision is expected to be in the form of both an emergency and a legislative rule. If the revised rules contain language identical to the language recommended by OSM and included herein, that revision will be acted upon by OSM in this rulemaking. If substantive changes beyond or other than those recommended by OSM are included in the revised rules, we may need to reopen the comment period.

The legislative rule will be submitted to the Legislative Rulemaking Review Committee after the close of the

comment period, and it is to be acted upon by the West Virginia Legislature during the upcoming 2005-2006 regular legislative session. If that rule is adopted with the identical language recommended by OSM as described above, no further action will be required by OSM, and it will become part of West Virginia's permanent regulatory program upon submission by the State.

Given that an emergency situation exists in West Virginia with regard to surety bonds and to avoid any unnecessary delays in approving the proposed State rule, OSM is requesting comments on both the proposed State rule and the suggested revisions to that rule as described above. Any changes adopted by the State after the close of its public comment period will result in the revision to both its emergency and legislative rules. As mentioned above, any substantive changes in the proposed State rules that go beyond those described herein will be subject to further rulemaking.

III. Public Comment Procedures

Under the provisions of 30 CFR 732.17(h), we are seeking your comments on whether these amendments satisfy the applicable program approval criteria of 30 CFR 732.15. If we approve these revisions they will become part of the West Virginia program.

Written Comments

Send your written or electronic comments to OSM at the address given above. Your written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of your recommendations. We may not consider or respond to your comments when developing the final rule if they are received after the close of the comment period (see **DATES**). We will make every attempt to log all comments into the administrative record, but comments delivered to an address other than the Charleston Field Office may not be logged in.

Electronic Comments

Please submit Internet comments as an ASCII, Word file avoiding the use of special characters and any form of encryption. Please also include "Attn: SATS NO. WV-108-FOR" and your name and return address in your Internet message. If you do not receive a confirmation that we have received your Internet message, contact the Charleston Field office at (304) 347-7158.

Availability of Comments

We will make comments, including names and addresses of respondents, available for public review during normal business hours. We will not consider anonymous comments. If individual respondents request confidentiality, we will honor their request to the extent allowable by law. Individual respondents who wish to withhold their name or address from public review, except for the city or town, must state this prominently at the beginning of their comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

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), on November 23, 2005. If you are disabled and need special 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 a hearing.

To assist the transcriber and ensure an accurate record, we request, if possible, that each person who speaks at the 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 only one person requests an opportunity to speak, we may hold a public meeting rather than a public hearing. If you wish to meet with us to discuss the amendment, please request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings will be 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 12630—Takings

This rule does not have takings implications. This determination is based on the analysis performed for the counterpart Federal regulation.

Executive Order 12866—Regulatory Planning and Review

This rule is exempt from review by the Office of Management and Budget under Executive Order 12866.

Executive Order 12988—Civil Justice Reform

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 and has determined that this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments because each program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731, and 732 have been met.

Executive Order 13132—Federalism

This rule does not have Federalism implications. SMCRA delineates the roles of the Federal and State governments with regard to the regulation of surface coal mining and reclamation operations. One of the purposes of SMCRA is to “establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations.” Section 503(a)(1) of SMCRA requires that State laws regulating surface coal mining and reclamation operations be “in accordance with” the requirements of SMCRA, and section 503(a)(7) requires that State programs contain rules and regulations “consistent with”

regulations issued by the Secretary pursuant to SMCRA.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

In accordance with Executive Order 13175, we have evaluated the potential effects of this rule on Federally-recognized Indian tribes and have determined that the rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. The basis for this determination is that our decision is on a State regulatory program and does not involve a Federal regulation involving Indian lands.

Executive Order 13211—Regulations That Significantly Affect the Supply, Distribution, or Use of Energy

On May 18, 2001, the President issued Executive Order 13211 which requires agencies to prepare a Statement of Energy Effects for a rule that is (1) considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866 and is not expected to have a significant adverse effect on the supply, distribution, or use of energy, a Statement of Energy Effects is not required.

National Environmental Policy Act

This rule does not require an environmental impact statement because section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior certifies that this rule will not have a

significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule: (a) Does not have an annual effect on the economy of \$100 million; (b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. This determination is based upon the analysis performed under various laws and executive orders for the counterpart Federal regulations.

Unfunded Mandates

This rule will not impose an unfunded mandate on State, local, or tribal governments or the private sector of \$100 million or more in any given year. This determination is based upon the analysis performed under various laws and executive orders for the counterpart Federal regulations.

List of Subjects in 30 CFR Part 948

Intergovernmental relations, Surface mining, Underground mining.

Dated: October 21, 2005.

Brent Wahlquist,

Regional Director, Appalachian Region.

[FR Doc. 05–22194 Filed 11–7–05; 8:45 am]

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