

Unfunded Mandates Reform Act of 1995 is not required.

VI. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no information that is subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995.

VII. Submission of Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this proposed rule by July 5, 2002. Two copies of any comments are to be submitted, except that individuals may submit one 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. 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**.

VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Transcript of the Dental Products Panel Meeting, November 3–5, 1997.
2. Menn, S. et al., "The Mandibular Repositioning Device: Role in the Treatment of Obstructive Sleep Apnea," *Sleep*, vol. 19, no. 10, pp. 794–800, 1996.
3. Schmidt-Nowara, W. et al., "Oral Appliances for the Treatment of Snoring and Obstructive Sleep Apnea: A Review," *Sleep*, vol. 18, no. 6, pp. 501–510, 1995.
4. Bliwise, D. L. et al., "Sleep Apnea and Mortality in an Aged Cohort," *American Journal of Public Health*, vol. 78, no. 5, pp. 544–547, 1988.
5. Lavie, P. et al., "Sleep Apnea Research Mortality in Sleep Apnea Patients: A Multivariate Analysis of Risk Factors," *Sleep*, vol. 18, no. 3, pp. 149–157, 1995.
6. Ferguson, K. A. et al., "A Randomized Crossover Study of an Oral Appliance vs. Nasal-Continuous Positive Airway Pressure in the Treatment of Mild-Moderate Obstructive Sleep Apnea," *Chest*, vol. 109, no. 5, pp. 1269–1275, 1996.

List of Subjects in 21 CFR Part 872

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 872 be amended in subpart F as follows:

PART 872—DENTAL DEVICES

1. The authority citation for 21 CFR part 872 continues to read as follows:

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

2. Section 872.5570 is added to subpart F to read as follows:

§ 872.5570 Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea.

(a) *Identification.* Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea are devices that are worn during sleep to reduce the incidence of snoring and to treat obstructive sleep apnea. The devices are designed to increase the patency of the airway and to decrease air turbulence and airway obstruction. The classification includes palatal lifting devices, tongue retaining devices, and mandibular repositioning devices.

(b) *Classification.* Class II (special controls). The special control for these devices is the FDA guidance document entitled "Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Draft Guidance for Industry and FDA."

Dated: February 28, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–8347 Filed 4–4–02; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 936

[OK–029–FOR]

Oklahoma Regulatory Program

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

ACTION: Proposed rule; reopening and extension of public comment period on proposed amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSM), are announcing receipt of revisions to a previously proposed amendment to the Oklahoma regulatory program (Oklahoma program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The Oklahoma Department of Mines (Department or Oklahoma) added a new definition for "community or institutional building," revised the procedures for making a valid existing rights determination, and corrected various editorial-type errors throughout

the amendment. Oklahoma intends to revise its program to be consistent with the corresponding Federal regulations.

This document gives the times and locations that the Oklahoma program and proposed amendment to that program are available for your inspection and the comment period during which you may submit written comments on the revisions to the amendment.

DATES: We will accept written comments until 4 p.m., c.s.t., April 22, 2002.

ADDRESSES: You should mail or hand deliver written comments to Michael C. Wolfrom, Director, Tulsa Field Office at the address listed below.

You may review copies of the Oklahoma program, the amendment, 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 receive one free copy of the amendment by contacting OSM's Tulsa Field Office.

Michael C. Wolfrom, Director, Tulsa Field Office, Office of Surface Mining Reclamation and Enforcement, 5100 East Skelly Drive, Suite 470, Tulsa, Oklahoma 74135–6547, Telephone: (918) 581–6430, Internet: mwolfrom@osmre.gov.

Mary Ann Pritchard, Director, Oklahoma Department of Mines, 4040 N. Lincoln Blvd., Suite 107, Oklahoma City, Oklahoma 73105, Telephone: (405) 521–3859, Internet: maryann@guinan.osmre.gov.

FOR FURTHER INFORMATION CONTACT:

Michael C. Wolfrom, Director, Tulsa Field Office. Telephone: (918) 581–6430. Internet: mwolfrom@osmre.gov.

SUPPLEMENTARY INFORMATION:

I. Background on the Oklahoma 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 Oklahoma program on January 19, 1981. You can find background information on the

Oklahoma program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the Oklahoma program in the January 19, 1981, **Federal Register** (46 FR 4902). You can also find later actions concerning Oklahoma's program and program amendments at 30 CFR 936.15 and 936.16.

II. Description of the Proposed Amendment

By letter dated November 20, 2001 (Administrative Record No. OK-988.02), Oklahoma sent us an amendment to its program under SMCRA and the Federal regulations at 30 CFR 732.17(b). Oklahoma sent the amendment in response to an August 23, 2000, letter (Administrative Record No. 988) that we sent to Oklahoma in accordance with 30 CFR 732.17(c).

We announced receipt of the proposed amendment in the December 21, 2001, **Federal Register** (66 FR 65858) and invited public comment on its adequacy. The public comment period ended January 22, 2002.

During our review of the amendment, we identified concerns relating to definitions at OAC 460:20-7-3, procedures at OAC 460:20-7-5, and various editorial errors. We notified Oklahoma of the concerns by letter dated December 13, 2001, and January 16, 2002 (Administrative Record Nos. OK-988.06 and OK-988.08). On February 21, 2002, Oklahoma sent us a revised amendment (Administrative Record No. OK-988.10).

Below is a summary of the revisions proposed by Oklahoma. The full text of the revised amendment is available for you to read at the locations listed above under **ADDRESSES**.

A. OAC 460:20-7-3 Definitions

Oklahoma proposes the following new definition for "community or institutional building":

"Community or institutional building" means any structure, other than a public building or an occupied dwelling, which is used primarily for meetings, gatherings, or functions of local civic organizations or other community groups; functions as an educational, cultural, historic, religious, scientific, correctional, mental-health, or physical-health care facility; or is used for public services, including, but not limited to, water supply, power generation, or sewage treatment.

B. OAC 460:20-7-5 Procedures

1. At OAC 460:20-7-5(f)(1), Oklahoma proposes to remove the phrase "or eligible for listing" from the first sentence.

2. At OAC 460:20-7-5(h)(2)(C), Oklahoma proposes to replace the

originally proposed provision with the following new provision:

(C) If the information that the Department requests under Paragraph (h)(2)(A) of this Section is not provided within the time specified or as subsequently extended, the Department shall issue a determination that the applicant has not demonstrated valid existing rights, as provided in Paragraph (h)(6)(C) of this Section.

3. At OAC 460:20-7-5(h)(7), Oklahoma proposes to replace the originally proposed provision with the following new provision:

(7) The Department shall make a copy of the request subject to notice and comment under Subsection (h)(3) of this Section available to the public in the same manner as the Department makes permit applications available to the public under Section 460:20-15-5(d) of this Chapter. In addition, the Department shall make records associated with that request, and any subsequent determination under Subsection (h)(6) of this Section, available to the public in accordance with the requirements and procedures of Section 460:20-57-7 of this Chapter.

C. Editorial Corrections

Oklahoma proposes to correct typographical errors and citation references in OAC 460:20-7-3, 460:20-7-4, and 460:20-7-5.

III. Public Comment Procedures

We are reopening the comment period on the proposed Oklahoma program amendment to provide the public an opportunity to reconsider the adequacy of the proposed amendment in light of the additional materials submitted. In accordance with the provisions of 30 CFR 732.17(h), we are seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If we approve the amendment, it will become part of the Oklahoma program.

Written Comments: If you submit written or electronic comments on the proposed rule during the 15-day comment period, they should be specific, should be confined to issues pertinent to the notice, and should explain the reason for your recommendation(s). We may not be able to consider or include in the Administrative Record comments delivered to an address other than the one listed above (see **ADDRESSES**).

Electronic Comments: Please submit Internet comments as an ASCII or Word file avoiding the use of special characters and any form of encryption. Please also include "Attn: OK-029-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 Tulsa Field Office at (918) 581-6430.

Availability of Comments: Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours at OSM's Tulsa Field Office (see **ADDRESSES**). Individual respondents may request that we withhold their home address from the administrative record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the administrative record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous 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.

IV. Procedural Determinations

Executive Order 12630—Takings

In this rule, the State is adopting valid existing rights standards that are similar to the standards in the Federal definition at 30 CFR 761.5. Therefore, this rule has the same takings implications as the Federal valid existing rights rule. The takings implications assessment for the Federal valid existing rights rule appears in Part XXIX.E of the preamble to that rule. See 64 FR 70766, 70822-27, December 17, 1999.

Executive Order 12866—Regulatory Planning and Review

This rule is exempted 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. Section 503(a)(7) requires that State programs contain rules and regulations “consistent with” regulations issued by the Secretary pursuant to SMCRA.

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 governmental 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 fact that the State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation was not considered a major rule.

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 fact that the State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation did not impose an unfunded mandate.

List of Subjects in 30 CFR Part 936

Intergovernmental relations, Surface mining, Underground mining.

Dated: March 2, 2002.

Charles E. Sandberg,

Acting Regional Director, Mid-Continent Regional Coordinating Center.

[FR Doc. 02–8231 Filed 4–4–02; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[FRL–7156–1]

National Emission Standards for Hazardous Air Pollutants: Solvent Extraction for Vegetable Oil Production

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; amendments.

SUMMARY: We are proposing to amend the national emission standards for hazardous air pollutants (NESHAP) for solvent extraction for vegetable oil production plants, which were promulgated on April 12, 2001 (66 FR 19006) under the authority of section 112 of the Clean Air Act (CAA). These amendments would clarify the startup, shutdown and malfunction requirements for owners and operators of sources subject to the Vegetable Oil Production NESHAP. These amendments would also clarify the applicability of the NESHAP General Provisions.

In the Rules and Regulations section of this **Federal Register**, we are taking direct final action on the proposed amendments, because we view these actions as noncontroversial, and we anticipate no adverse comments. We have explained our reasons for these actions in the preamble to the direct final rule.

If we receive no adverse comments, we will take no further action on this proposed rule. If we receive adverse comments, we will withdraw only those provisions on which we received adverse comments. We will publish a timely withdrawal in the **Federal Register** indicating which provisions will become effective and which provisions are being withdrawn. If part or all of the direct final rule in the Rules and Regulations section of this **Federal Register** is withdrawn, all public comments pertaining to those provisions will be addressed in a subsequent final rule based on this proposed rule. We will not institute a second comment period on that subsequent final rule. If you are interested in commenting, you must do so at this time.