

weight gain in suckling beef calves. The supplemental NADA also adds the indication for use for increased rate of weight gain in steers fed in confinement for slaughter, previously approved at a lower dose, to the higher approved dose level. The supplemental NADA is approved as of January 19, 2006, and the regulations are amended in 21 CFR 522.841 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(c) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 522

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. In § 522.841, revise paragraph (d) to read as follows:

§ 522.841 Estradiol benzoate.

* * * * *

(d) *Conditions of use.* It is used by subcutaneous injection as follows:

(1) *Amount and indications for use—*
(i) *Suckling beef calves.* 10 mg (1 mL of product described in paragraph (a)(1) of this section or 0.5 mL of product described in paragraph (a)(2) of this section) for increased rate of weight gain.

(ii) *Cattle fed in confinement for slaughter.* 20 mg (1 mL of product described in paragraph (a)(2) of this section) for increased rate of weight gain and improved feed efficiency.

(2) *Limitations.* For subcutaneous injection in the ear only. Do not use in calves intended for reproduction or calves less than 30 days old. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

Dated: February 8, 2006.

David R. Newkirk,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

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BILLING CODE 4160-01-S

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 943

[Docket No. TX-055-FOR]

Texas Regulatory Program

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

ACTION: Final rule; approval of amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSM), are approving an amendment to the Texas regulatory program (Texas program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Texas proposed revisions to the Texas Surface Coal Mining and Reclamation Act (TSCMRA) and the Texas Administrative Code (TAC) regarding the State's annual fees that are required from coal mining permit holders. Texas proposed to change the requirement for the current annual fee and to add two new annual fees. Texas intends to revise its program to reduce the economic cost to the coal mining industry as a whole and to require coal mining permit holders that have ceased mining to pay annual fees. **EFFECTIVE DATE:** February 17, 2006.

FOR FURTHER INFORMATION CONTACT: Michael C. Wolfrom, Director, Tulsa Field Office. Telephone: (918) 581-6430. E-mail: mwolfrom@osmre.gov.

SUPPLEMENTARY INFORMATION:

- I. Background on the Texas Program
- II. Submission of the Amendment
- III. OSM's Findings
- IV. Summary and Disposition of Comments
- V. OSM's Decision

VI. Procedural Determinations

I. Background on the Texas 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 State 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 Texas program effective February 16, 1980. You can find background information on the Texas program, including the Secretary's findings, the disposition of comments, and the conditions of approval, in the February 27, 1980, **Federal Register** (45 FR 12998). You can find later actions on the Texas program at 30 CFR 943.10, 943.15, and 943.16.

II. Submission of the Amendment

By letter dated October 6, 2005 (Administrative Record No. TX-660), Texas sent us an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*). Texas sent the amendment at its own initiative.

We announced receipt of the proposed amendment in the November 29, 2005, **Federal Register** (70 FR 71441). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the adequacy of the amendment. We did not hold a public hearing or meeting because no one requested one. The public comment period ended on December 29, 2005. We received comments from one industry group.

III. OSM's Findings

Following are the findings we made concerning the amendment under SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17. We are approving the amendment as described below. Any revisions that we do not specifically discuss below concern nonsubstantive wording or editorial changes.

A. TSCMRA Section 134.055. Annual Fee

Section 134.055 of Texas' statute currently requires each permit holder to pay an annual fee for each acre of land in the permit area on which the permit holder actually conducted operations

for removing coal during the year (mined acreage fee). Presently, this fee can not be less than \$120.00 per acre. Texas proposed to revise section 134.055 by changing the section title from Annual Fee to Annual Fees. Texas also proposed to eliminate the \$120.00 per acre minimum fee for the mined acreage fee and to allow the Railroad Commission of Texas (Commission) to determine the amount of this fee. In addition, Texas proposed to add two new annual fees; a fee for mining permits in effect at the end of a calendar year (mining permit fee) and a fee for each acre of land in the bonded permit area (bond acreage fee). Texas proposed to allow the Commission to determine the amount of each of these two new annual fees. Furthermore, Texas stated in its letter dated October 6, 2005 (Administrative Record No. TX-660), that the proposed revised and new annual fees when coupled with the permit application fees are not expected to exceed 50 percent of the anticipated costs to administer the coal mining regulatory program for calendar year 2006.

The Federal statute at section 507(a) of SMCRA provides that each application for a surface coal mining and reclamation permit shall be accompanied by a fee as determined by the regulatory authority and that such fee may be less than, but shall not exceed the actual or anticipated cost of reviewing, administering, and enforcing such permit issued pursuant to a State program. The regulatory authority may also develop procedures to allow the fee to be paid over the term of the permit.

We find that Texas' proposed annual permit fees, including the current mined acreage fee and the two new fees (mining permit fee and bond acreage fee), are reasonable and consistent with the discretionary authority provided by the above Federal statute. Therefore, we are approving Texas' above revisions.

B. 16 TAC 12.108. Permit Fees

Texas proposed to revise its regulations at 16 TAC 12.108, regarding permit fees, to implement the above proposed statutory amendment.

Texas proposed to add the title, "Application Fees," and the title, "Annual Fees," to paragraph (a) and paragraph (b), respectively. In paragraph (b), Texas proposed to require the annual fees due and payable no later than March 15th of the year following the year for which these fees are applicable. Also, Texas proposed to add new paragraph (b)(1). This paragraph reduces the current annual mined acreage fee from \$390.00 to \$160.00 per acre for each acre of land within the

permit area on which coal or lignite was actually removed during the calendar year. In addition, Texas proposed to add new paragraph (b)(2) which adds a new bond acreage fee and proposed to set this fee at \$3.00 per acre for each acre of land within a permit area covered by a reclamation bond on December 31st of the year. Furthermore, Texas proposed to add new paragraph (b)(3) which adds a new mining permit fee and proposed to set this fee at \$3,550.00 for each permit in effect on December 31st of the year. Finally, Texas stated in its letter dated October 6, 2005 (Administrative Record No. TX-660), that the proposed revised and new annual fees, when coupled with the permit application fees, are not expected to exceed 50 percent of the anticipated costs to administer the coal mining regulatory program for calendar year 2006.

The Federal regulation at 30 CFR 777.17 provides that an application for a surface coal mining and reclamation permit shall be accompanied by a fee as determined by the regulatory authority and that such fee may be less than, but shall not exceed the actual or anticipated cost of reviewing, administering, and enforcing such permit issued pursuant to a State program. The regulatory authority may also develop procedures to allow the fee to be paid over the term of the permit.

We find that Texas' proposed annual permit fees, including the current mined acreage fee and the two new fees (mining permit fee and bond acreage fee), are reasonable and consistent with the discretionary authority provided by the Federal regulation. Therefore, we are approving the above revisions.

IV. Summary and Disposition of Comments

Public Comments

We asked for public comments on the amendment, and received one from TXU Power on behalf of TXU Mining Company LP (Administrative Record No. TX-660.03). The commenter stated that TXU strongly supports the proposed program amendment.

Federal Agency Comments

On October 26, 2005, under 30 CFR 732.17(h)(11)(i) and section 503(b) of SMCRA, we requested comments on the amendment from various Federal agencies with an actual or potential interest in the Texas program (Administrative Record No. TX-660.01). We did not receive any comments.

Environmental Protection Agency (EPA) Concurrence and Comments

None of the revisions that Texas proposed to make in this amendment

pertain to air or water quality standards. Therefore, we did not ask EPA to concur on the amendment.

On October 26, 2005, under 30 CFR 732.17(h)(11)(i), we requested comments on the amendment from the EPA (Administrative Record No. TX-660.01). The EPA did not respond to our request.

State Historical Preservation Officer (SHPO) and the Advisory Council on Historic Preservation (ACHP)

Under 30 CFR 732.17(h)(4), we are required to request comments from the SHPO and ACHP on amendments that may have an effect on historic properties. On October 26, 2005, we requested comments on Texas' amendment (Administrative Record No. TX-660.01), but neither responded to our request.

V. OSM's Decision

Based on the above findings, we approve the amendment Texas sent us on October 6, 2005.

To implement this decision, we are amending the Federal regulations at 30 CFR part 943, which codify decisions concerning the Texas program. We find that good cause exists under 5 U.S.C. 553(d)(3) to make this final rule effective immediately. Section 503(a) of SMCRA requires that the State's program demonstrate that the State has the capability of carrying out the provisions of the Act and meeting its purposes. Making this rule effective immediately will expedite that process. SMCRA requires consistency of State and Federal standards.

VI. 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 regulations.

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.

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. This determination is based on the fact that the Texas program does not regulate coal exploration and surface coal mining and reclamation operations on Indian lands. Therefore, the Texas program has no effect on Federally-recognized Indian tribes.

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 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 regulations did not impose an unfunded mandate.

List of Subjects in 30 CFR Part 943

Intergovernmental relations, Surface mining, Underground mining.

Dated: January 20, 2006.

Charles E. Sandberg,
Regional Director, Mid-Continent Region.

■ For the reasons set out in the preamble, 30 CFR part 943 is amended as set forth below:

PART 943—TEXAS

■ 1. The authority citation for part 943 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

■ 2. Section 943.15 is amended in the table by adding a new entry in chronological order by “Date of final publication” to read as follows:

§ 943.15 Approval of Texas regulatory program amendments.

* * * * *

Original amendment submission date	Date of final publication	Citation/description
* October 6, 2005	* February 17, 2006	* TSCMRA Section 134.055; and 16 TAC 12.108(a) and (b).

[FR Doc. 06-1397 Filed 2-16-06; 8:45 am]

BILLING CODE 4310-05-P

**ENVIRONMENTAL PROTECTION
AGENCY****40 CFR Part 52**

[EPA-R09-OAR-2006-0055; FRL-8030-7]

**Revisions to the California State
Implementation Plan, San Joaquin
Valley Unified Air Pollution Control
District****AGENCY:** Environmental Protection
Agency (EPA).**ACTION:** Final rule.**SUMMARY:** EPA is finalizing approval of
revisions to the San Joaquin Valley Air

Pollution Control District portion of the California State Implementation Plan (SIP). These revisions were proposed in the **Federal Register** on August 30, 2005 and concern particulate matter with an aerodynamic diameter less than or equal to a nominal 10 micrometers (PM-10) emissions from fugitive dust sources. We are approving local rules that regulate these emission sources under the Clean Air Act as amended in 1990 (CAA or the Act).

EFFECTIVE DATE: This rule is effective on March 20, 2006.**ADDRESSES:** EPA has established docket number EPA-R09-OAR-2006-0055 for this action. The index to the docket is available electronically at <http://www.regulations.gov> and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all

documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (e.g., copyrighted material), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT:
Andrew Steckel, EPA Region IX, (415)
947-4115, steckel.andrew@epa.gov.**SUPPLEMENTARY INFORMATION:**
Throughout this document, “we,” “us”
and “our” refer to EPA.**I. Proposed Action**

On August 30, 2005 (70 FR 51303), EPA proposed to approve the following rules into the California SIP:

TABLE 1.—SUBMITTED RULES

Rule No.	Rule title	Adopted	Submitted
8011	General Requirements	08/19/04	09/23/04
8021	Construction, Excavation, Extraction, and Other Earthmoving	08/19/04	09/23/04
8031	Bulk Materials	08/19/04	09/23/04
8041	Carryout and Trackout	08/19/04	09/23/04
8051	Open Areas	08/19/04	09/23/04
8061	Paved and Unpaved Roads	08/19/04	09/23/04
8071	Unpaved Traffic Areas	09/16/04	09/23/04
8081	Agricultural Sources	09/16/04	09/23/04

We proposed to approve these rules because we determined that they complied with the relevant CAA requirements. Our proposed action contains more information on the rules and our evaluation.

II. Public Comments

EPA’s proposed action provided a 30-day public comment period. During this period, we received comments supportive of our approval of the rules from the following parties:

1. Roger A. Isom, California Cotton Ginners and Growers Association (CCGGA); letter dated January 10, 2006.

2. San Joaquin Valley agricultural groups: California Citrus Mutual; California Grape and Tree Fruit League; Fresno County Farm Bureau; Kings County Farm Bureau; Merced County Farm Bureau; Nisei Farmers League; letter dated January 10, 2006.

We received no adverse comments on our proposed action.

III. EPA Action

No comments were submitted that change our assessment that the submitted rules comply with the relevant CAA requirements. Therefore, as authorized in section 110(k)(3) of the

Act, EPA is fully approving these rules into the California SIP.

**IV. Statutory and Executive Order
Reviews**

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a “significant regulatory action” and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that these rules 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.*). Because these rules approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described

in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

These rules also do not have tribal implications because they will not have a substantial direct effect 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, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves state rules implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. These rules also are not subject to Executive Order 13045 “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), because they are not economically significant.