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Nancy B. Shelton,

Acting Manager, Air Traffic Division,  
Southern Region.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 558

#### New Animal Drugs for Use in Animal Feeds; Chlortetracycline Hydrochloride

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by PennField Oil Co. The supplemental NADA provides for a revised withdrawal period of 1-day following feeding of Type B and Type C chlortetracycline feeds to cattle.

**EFFECTIVE DATE:** May 3, 1999

#### FOR FURTHER INFORMATION CONTACT:

Dianne T. McRae, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0212.

**SUPPLEMENTARY INFORMATION:** PennField Oil Co., 14040 Industrial Rd., Omaha, NE 68144, is the sponsor of NADA 138-935 that provides for feeding Type B and Type C chlortetracycline medicated feeds to poultry cattle, swine, and sheep. The firm has filed a supplemental NADA that provides for a revised withdrawal period of 1-day in cattle. The supplemental NADA is approved as of March 24, 1999, and the regulations are amended in 21 CFR 558.128 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Dockets Management Branch (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(a)(3) 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.

#### List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.  
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 558 is amended as follows:

#### PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

**Authority:** 21 U.S.C. 360b, 371.

#### § 558.128 [Amended]

2. Section 558.128 *Chlortetracycline* is amended in the table in paragraph (d)(1) in entries (xi) and (xvii) by revising the entry under the "Limitations" column, and in entry (xii) by revising the entry under the "Indications for use" column to read as follows:

(d)(1) \* \* \*

Chlortetracycline amount	Combination	Indications for use	Limitations	Sponsor
(xi) * * *	* * *	* * *	Withdraw 48 h prior to slaughter. For sponsor 000004 zero withdrawal time. For sponsor 053389 1 d withdrawal time.	* * *
(xii) * * *	* * *	1. Calves, beef and nonlactating dairy cattle; treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>P. multocida</i> organisms susceptible to chlortetracycline. For sponsor 053389 1 d withdrawal time. 2. * * *	* * *	* * *
(xvii) * * *	* * *	* * *	Withdraw 48 h prior to slaughter. For sponsor 000004 zero withdrawal time. For sponsor 053389 1 d withdrawal time.	* * *
* * *	* * *	* * *	* * *	* * *

\* \* \* \* \*

Dated: April 22, 1999.

**Margaret Ann Miller,**

Acting Director, Office of New Animal Drug  
Evaluation, Center for Veterinary Medicine.  
[FR Doc. 99-10983 Filed 4-30-99; 8:45 am]

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**DEPARTMENT OF THE INTERIOR****Office of Surface Mining Reclamation  
and Enforcement****30 CFR Part 943**

[SPATS No. TX-045-FOR]

**Texas Regulatory Program**

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

**ACTION:** Final rule; approval of  
amendment.

**SUMMARY:** OSM is approving an amendment to the Texas regulatory program (Texas program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Texas proposed deletions, revisions, and addition of regulations concerning air pollution control plans; reclamation plans: general requirements; air resources protection; stabilization of surface areas; and coal processing plants: performance standards. Texas intends to bring its regulations into alignment with Federal regulations that were revised in 1983.

**EFFECTIVE DATE:** May 3, 1999.

**FOR FURTHER INFORMATION CONTACT:**  
Michael C. Wolf from, Director, Tulsa  
Field Office, Office of Surface Mining,  
5100 East Skelly Drive, Suite 470, Tulsa,  
Oklahoma 74135-6548. Telephone:

(918) 581-6430. Internet:  
mwolf from@mcr gw.osmre.gov.

**SUPPLEMENTARY INFORMATION:**

- I. Background on the Texas Program
- II. Submission of the Proposed Amendment
- III. Director's Findings
- IV. Summary and Disposition of Comments
- V. Director's Decision
- VI. Procedural Determinations

**I. Background on the Texas Program**

On February 16, 1980, the Secretary of the Interior conditionally approved the Texas program. 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 concerning the Texas program at 30 CFR 943.10, 943.15, and 943.16.

**II. Submission of the Proposed Amendment**

By letter dated January 28, 1999 (Administrative Record No. TX-647), Texas sent us an amendment to its program under SMCRA. The amendment included changes to the Texas Administrative Code (TAC) made at Texas' own initiative.

We announced receipt of the amendment in the February 12, 1999 **Federal Register** (64 FR 7145). 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 proposed amendment. The public comment period closed on March 15, 1999. Because no one requested a public hearing or meeting, we did not hold one.

**III. Director's Findings**

Following, under SMCRA and the Federal regulations at 30 CFR 732.15

and 732.17, are our findings concerning the amendment.

**A. Regulations Deleted From Texas' Program**

1. Sections 12.379 and 12.546, Air Resources Protection (Surface and Underground Mining, Respectively)

Texas proposed to delete the above regulations. The Federal counterparts to these State regulations were previously found at 30 CFR 816.95 and 817.95 for surface and underground mining, respectively. We deleted these Federal counterpart regulations from our own regulations. See the **Federal Register** dated January 10, 1983 (48 FR 1163). Therefore, we are approving the deletion of the above Texas regulations.

2. Sections 12.389 and 12.554, Regrading or Stabilizing Rills and Gullies (Surface and Underground Mining, Respectively)

Texas proposed to delete the above regulations. The Federal counterparts to these State regulations were previously found at 30 CFR 816.106 and 817.106 for surface and underground mining, respectively. We deleted these Federal counterpart regulations from our own regulations. See the **Federal Register** dated January 10, 1983 (48 FR 1163). Therefore, we are approving the deletion of the above Texas regulations.

**B. Revisions to Texas' Regulations That Have the Same Meaning as the Corresponding Provisions of the Federal Regulations**

The State regulations listed in the table below contain language that is the same as or similar to the corresponding sections of the Federal regulations. Differences between the State regulations and the Federal regulations are minor.

Topic	State regulation (TAC)	Federal counterpart regulation (30 CFR)
Air pollution control plan .....	Sections 12.143(a)(2), (b)(1) and (b)(2); 12.199(2).	780.15(a)(2), (b)(1) and (b)(2); 784.26(b).
Stabilization of surface areas .....	Sections 12.389 and 12.554 .....	816.95 and 817.95.
Coal processing plants: performance standards.	Section 12.651(9) .....	827.12(j).

Because the above State regulations have the same meaning as the corresponding Federal regulations, we find that they are no less effective than the Federal regulations.

**C. Revisions to Texas' Regulations That Are Not the Same as the Corresponding Provisions of the Federal Regulations**

1. Sections 12.145 and 12.187, Reclamation Plan: General Requirements (Surface and Underground Mining, Respectively) [30 CFR 780.18(a)(3) and 784.13(b)(3)]

Texas proposed to update and change one of the reference citation titles in

paragraph (b)(3) from "Regrading or Stabilizing Rills and Gullies" to "Stabilization of Surface Areas." We are approving this change because it is not inconsistent with our Federal regulations at 30 CFR 780.18(a)(3) and 784.13(b)(3).