

Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7543, e-mail: melanie.berson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 556 Morris Ave., Summit, NJ 07901, filed a supplement to NADA 141-081 for the veterinary prescription use of ORBAX (orbifloxacin) Tablets for management of diseases in dogs and cats associated with bacteria susceptible to orbifloxacin. The supplemental NADA provides for revised animal safety labeling, specifically, the addition of postapproval adverse drug experience information and fluoroquinolone class statements regarding retinal toxicity in cats. The supplemental NADA is approved as of March 3, 2006, and the regulations are amended in 21 CFR 520.1616 to reflect a current format. 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(d)(5) 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 "articular 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 520

■ 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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

■ 2. Revise § 520.1616 to read as follows:

§ 520.1616 Orbifloxacin.

(a) *Specifications.* Each tablet contains 5.7, 22.7, or 68 milligrams (mg) orbifloxacin.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats—*(1) *Amount.* 2.5 to 7.5 mg per kilogram body weight once daily.

(2) *Indications for use.* For management of diseases associated with bacteria susceptible to orbifloxacin.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food producing animals.

Dated: March 14, 2006.

Steven D. Vaughn,

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

[FR Doc. 06-2791 Filed 3-22-06; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 950

[WY-033-FOR]

Wyoming Abandoned Mine Land Reclamation Plan

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

ACTION: Final rule; approval of amendment.

SUMMARY: We are approving an amendment to the Wyoming abandoned mine land reclamation (AMLR) plan (hereinafter referred to as the "Wyoming Plan" or "Plan") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Wyoming proposed revisions and additions to its abandoned mine land (AML) Plan by removing phrases concerning liens for reclamation on private lands and by removing and adding words concerning contract eligibility. Wyoming intended to revise its Plan in accordance with the amendments required by OSM to make it consistent with SMCRA.

DATES: *Effective Date:* March 23, 2006.

FOR FURTHER INFORMATION CONTACT: Richard W. Buckley, Acting Field Office Director, Telephone: 307/261-6550; E-mail address: RBuckley@osmre.gov.

SUPPLEMENTARY INFORMATION:

I. Background on the Wyoming Plan
II. Submission of the Proposed Amendment
III. Office of Surface Mining Reclamation and Enforcement's (OSM) Findings

IV. Summary and Disposition of Comments
V. OSM's Decision
VI. Procedural Determinations

I. Background on the Wyoming Plan

The Abandoned Mine Land Reclamation Program was established by Title IV of the Act (30 U.S.C. 1201 *et seq.*) in response to concerns over extensive environmental damage caused by past coal mining activities. The program is funded by a reclamation fee collected on each ton of coal that is produced. The money collected is used to finance the reclamation of abandoned coal mines and for other authorized activities. Section 405 of the Act allows States and Indian tribes to assume exclusive responsibility for reclamation activity within the State or on Indian lands if they develop and submit to the Secretary of the Interior for approval, a program (often referred to as a plan) for the reclamation of abandoned coal mines. On February 14, 1983, the Secretary of the Interior approved the Wyoming Plan. You can find general background information on the Wyoming Plan, including the Secretary's findings and the disposition of comments, in the February 14, 1983, **Federal Register** (48 FR 6536). You can also find later actions concerning Wyoming's Plan and plan amendments at 30 CFR 950.35 and outstanding required amendments at 30 CFR 950.36.

II. Submission of the Proposed Amendment

By letter dated September 1, 2005, Wyoming sent us an amendment to its Plan (Administrative Record No. WY-038-01) under SMCRA (30 U.S.C. 1201 *et seq.*). Wyoming sent the amendment in response to the required plan amendments at 30 CFR 950.36(a) and (b) to make its Plan consistent with SMCRA.

The provisions of the Wyoming Plan that it proposed to add to or revise were: Wyoming Statute (W.S.) 35-11-1206(a) and (b), liens for reclamation on private lands; and W.S. 35-11-1209, contract eligibility.

We announced receipt of the proposed amendment in the November 29, 2005, **Federal Register** (70 FR 71444). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the amendment's adequacy (Administrative Record No. WY-038-4). We did not hold a public hearing or meeting because no one requested one. The public comment period ended on December 29, 2005. We did not receive any comments.

III. Office of Surface Mining Reclamation and Enforcement's (OSM) Findings

Following are the findings we made concerning the amendment under SMCRA and the Federal regulations at 30 CFR 884.14 and 884.15. We are approving the amendment.

A. Revisions to Wyoming's Statute That Have the Same Meaning as the Corresponding Provisions of SMCRA

Wyoming proposed revisions to the following sections of its Plan to make it the same as, or similar to, the corresponding sections of SMCRA. These revisions are listed as a required amendment at 30 CFR 950.36(a):

1. W.S. 35-11-1206(a), remove language, "not to exceed the cost of reclamation work or" and "whichever is less" [sections 408(a) and (b) of SMCRA and the Federal regulations at 30 CFR part 882].

2. W.S. 35-11-1206(b), remove the language, "of but not exceeding the cost of reclamation" [see sections 408(a) and (b) of SMCRA and the Federal regulations at 30 CFR part 882].

Because these revisions in this Wyoming Statute make it substantively identical to SMCRA, no analysis is necessary. These revisions satisfy the required amendment at 30 CFR 950.36(a).

B. Revisions to Wyoming's Statute With No Corresponding Federal Regulations or Statute

1. W.S. 35-11-1209(a), remove the reference to "professional" and "construction" when referring to contractors.

2. W.S. 35-11-1209(a)(vii), added to read, "Unresolved notice of violation."

The Federal regulations at 30 CFR 874.16 and 875.20 indicate that bidder eligibility must be confirmed by OSM's Applicant Violator System (AVS) for each contract to be awarded. The existing version of W.S. 35-11-1209 did not include provisions for Wyoming to verify through AVS a contractor's eligibility; therefore we asked that Wyoming revise W.S. 35-11-1209 to indicate that any construction contractor or professional services contractor be confirmed through AVS as eligible to receive an AMLR contract prior to receiving the award. Wyoming is proposing here to not only add a reference to AVS' "unresolved notices of violation," but also to remove "professional" and "construction" when referring to contractors so that W.S. 35-11-1209 refers to all contractors.

These revisions therefore satisfy the required amendment at 30 CFR 950.36(b)(1) and (2).

IV. Summary and Disposition of Comments

Public Comments

We asked for public comments on the amendment (Administrative Record No. WY-038-03), but did not receive any.

Federal Agency Comments

Under 30 CFR 884.14(a)(2) and 884.15(a), we requested comments on the amendment from various Federal agencies with an actual or potential interest in the Wyoming Plan (Administrative Record No. WY-038-03). We received no comments from any Federal agency.

V. OSM's Decision

Based on the above findings, we approve Wyoming's September 1, 2005, proposed amendment to the following statutory provisions as discussed herein: W.S. 35-11-1206(a), and W.S. 35-11-1206(b), and W.S. 35-11-1209(a), and W.S. 35-11-1209(a)(vii).

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 regulation. The revisions made at the initiative of the State that do not have Federal counterparts have also been reviewed and a determination made that they do not have takings implications. This determination is based on the fact that the provisions are administrative and procedural in nature and are not expected to have a substantive effect on the regulated industry.

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 (Regulatory Planning and Review).

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, to the extent allowable by law, 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 AMLR plans and revisions thereof because each plan is drafted and promulgated by a specific State, not by OSM. Decisions on proposed State AMLR plans and revisions thereof submitted by a State are based on a determination of whether

the submittal meets the requirements of Title IV of SMCRA (30 U.S.C. 1231-1243) and the applicable Federal regulations at 30 CFR part 884.

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 rule does not involve or affect Indian Tribes in any way.

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

No environmental impact statement is required for this rule since agency decisions on proposed State AMLR plans and revisions thereof are categorically excluded from compliance with the National Environmental Policy

Act (42 U.S.C. 4332) by the Manual of the Department of the Interior (516 DM 6, appendix 8, paragraph 8.4B(29)).

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. The Department of the Interior also certifies that the provisions in this rule that are not based upon counterpart Federal regulations 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.*). This determination is based upon the fact that the provisions are administrative and procedural in nature and are not expected to have a substantive effect on the regulated industry.

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.
- 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. For the portion of the State provisions that is not based upon counterpart Federal regulations, this determination is based upon the fact that the State provisions are administrative and procedural in nature and are not expected to have a substantive effect on the regulated industry.

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. For the portion of the State provisions that is not based upon counterpart Federal regulations, this determination is based upon the fact that the State provisions are administrative and procedural in nature and are not expected to have a substantive effect on the regulated industry.

List of Subjects in 30 CFR Part 950

Abandoned mine reclamation programs, Intergovernmental relations, Surface mining, Underground mining.

Dated: February 24, 2006.

Allen D. Klein,

Regional Director, Western Region.

■ For the reasons set forth in the preamble, Title 30, Chapter VII, Subchapter T of the Code of Federal Regulations is amended as set forth below:

PART 950—WYOMING ABANDONED MINE LAND RECLAMATION PROGRAMS

■ 1. The authority citation for part 950 continues to read as follows:

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

■ 2. Section 950.35 is amended in the table by adding a new entry in chronological order by “Date of final publication” to read as follows:

§ 950.35 Approval of Wyoming abandoned mine land reclamation plan amendments.

* * * * *

Original amendment submission date	Date of final publication	Citation/description
* * *	* * *	* * *
September 1, 2005	March 23, 2006	W.S. 35–11–1206(a). W.S. 35–11–1206(b). W.S. 35–11–1209. W.S. 35–11–1209(vii).

■ 3. Amend § 950.36 by removing the text and revising the section heading as follows:

§ 950.36 Required abandoned mine land plan amendments. [Reserved]

[FR Doc. 06–2757 Filed 3–22–06; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[COTP San Francisco Bay 06–008]

RIN 1625–AA87

Security Zone; San Francisco Bay-Brooklyn Basin, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary fixed security zone surrounding a portion of Coast Guard Island within the navigable waters of the Brooklyn Basin during an official change of command ceremony. This security zone is needed for national security reasons to protect the ceremony participants and guests from potential subversive acts. Entry into this security zone is prohibited, unless specifically authorized by the Captain of the Port San Francisco, or his designated representative.