

in part 522 (21 CFR part 522) by adding § 522.1367 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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning November 12, 2003.

The agency has determined under 21 CFR 25.33(d)(1) 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. Section 522.1367 is added to read as follows:

§ 522.1367 Meloxicam.

(a) *Specifications.* Each milliliter of solution contains 5.0 milligrams (mg) meloxicam.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* Administer 0.2 mg/kilogram (kg) body weight by intravenous or subcutaneous injection on the first day of treatment. For treatment after day 1, administer meloxicam suspension orally

at 0.1 mg/kg body weight once daily as in § 520.1350(c) of this chapter.

(2) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: November 21, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 948

[WV-095-FOR]

West Virginia Regulatory Program

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

ACTION: Final rule; approval of amendment.

SUMMARY: We are approving, with one exception, amendments to the West Virginia surface coal mining regulatory program (the West Virginia program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). The amendments we are approving concern blasting, and amend the Code of State Regulations (CSR) by adding the Surface Mining Blasting Rule, and amend the Code of West Virginia (W. Va. Code) blasting provisions as contained in Enrolled Senate Bill 689. The amendments are intended to improve the operational efficiency of the West Virginia program, and to render the West Virginia program consistent with SMCRA and the Federal regulations.

EFFECTIVE DATE: December 10, 2003.

FOR FURTHER INFORMATION CONTACT: Mr. Roger W. Calhoun, Director, Charleston Field Office, 1027 Virginia Street East, Charleston, West Virginia 25301. Telephone: (304) 347-7158, Internet address: chfo@osmre.gov.

SUPPLEMENTARY INFORMATION:

- I. Background on the West Virginia 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 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. Submission of the Amendment

By letter dated October 30, 2000, West Virginia sent us an amendment to its program (Administrative Record Number WV-1187) under SMCRA (30 U.S.C. 1201 *et seq.*). The amendment added to the West Virginia regulations new Title 199, Series 1, entitled Surface Mining Blasting Rule. These regulations consist of some new blasting provisions and many blasting provisions that were relocated or derived from previously-approved West Virginia blasting provisions. The amendment is intended to revise the State's blasting rules to implement statutory revisions concerning blasting that we approved, with certain exceptions, on November 12, 1999 (64 FR 61507) (Administrative Record Number WV-1143).

We announced receipt of the proposed amendment in the December 5, 2000, **Federal Register** (65 FR 75889) (Administrative Record Number WV-1190). In the same document, we opened the public comment and provided an opportunity for a public hearing or meeting on the amendment's adequacy. We did not hold a hearing or a meeting because no one requested one. The public comment period ended on January 4, 2001. We received comments from one Federal agency and one professional organization.

By letter dated November 28, 2001 (Administrative Record Number WV-