

Dated: November 9, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01-30039 Filed 12-4-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin Liquid

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 an abbreviated new animal drug application (ANADA) filed by First Priority, Inc. The ANADA provides for oral use of ivermectin solution in horses for the treatment and control of various species of internal and cutaneous parasites.

DATES: This rule is effective December 5, 2001.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209.

SUPPLEMENTARY INFORMATION: First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123, filed ANADA 200-321 for PRIMECTIN™ (ivermectin) Equine Oral Liquid. The application provides for oral use of a 1.0 percent ivermectin solution in horses for the treatment and control of various species of gastrointestinal nematodes, lungworms, stomach bots, and cutaneous larvae and microfilariae. First Priority's PRIMECTIN™ Equine Oral Liquid is approved as a generic copy of Merial Ltd.'s EQVALAN® (ivermectin) Oral Liquid for Horses, approved under NADA 140-439. ANADA 200-321 is approved as of September 7, 2001, and 21 CFR 520.1195 is amended 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 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)(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 congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 520

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 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. Section 520.1195 is amended in paragraph (b) by adding "058829," after "051259"; by revising the heading of paragraph (c) and paragraph (c)(1); in paragraph (c)(2) by removing "It is used in horses"; and in paragraph (c)(3) by removing the first sentence to read as follows:

§ 520.1195 Ivermectin liquid.

* * * * *

(c) *Conditions of use in horses*—(1) *Amount.* 200 micrograms per kilogram of body weight as a single dose by stomach tube or as an oral drench.

Dated: November 9, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 70

[AZ060-OPP; FRL-7112-8]

Clean Air Act Full Approval of the Operating Permits Program for the Pinal County Air Quality Control District, AZ

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is taking final action to fully approve the Pinal County Air Quality Control District (Pinal or District) operating permits program. The Pinal program was submitted in response to the directive in the 1990 Clean Air Act (CAA) Amendments that permitting authorities develop, and submit to EPA, programs for issuing operating permits to all major stationary sources and to certain other sources within the permitting authorities' jurisdiction. On October 30, 1996, EPA granted interim approval to Pinal's operating permits program. The District revised its program to satisfy the conditions of the interim approval, and EPA proposed full approval in the **Federal Register** on September 20, 2001, contingent upon Pinal submitting the rules to EPA as a revision to its part 70 program. Pinal County did so, and EPA did not receive any comments on the proposed action. This action promulgates final full approval of the Pinal operating permits program.

EFFECTIVE DATE: This rule is effective on November 30, 2001.

ADDRESSES: Copies of Pinal's submittal and other supporting information used in developing this final full approval are available for inspection during normal business hours at the following location: U.S. Environmental Protection Agency, Region 9, 75 Hawthorne Street, San Francisco, California 94105. You may also see copies of the submitted title V program at the following location: Pinal County Air Quality Control District, Building F, 31 North Pinal Street, Florence, Arizona 85232.

FOR FURTHER INFORMATION CONTACT: Emmanuelle Rapicavoli, EPA Region 9, at (415) 972-3969 or rapicavoli.emmanuelle@epa.gov.

SUPPLEMENTARY INFORMATION: This section contains additional information about our final rulemaking, organized as follows:

- I. Background on the Pinal County Air Quality Control District operating permits program
- II. EPA's Final Action
- III. Effective date of EPA's full approval of the Pinal County Air Quality Control District operating permits program

I. Background on the Pinal County Air Quality Control District Operating Permits Program

The Clean Air Act (CAA) Amendments of 1990 required all state and local permitting authorities to develop operating permits programs that meet certain federal criteria. Pinal's operating permits program was submitted in response to this directive. Because the District program

substantially, but not fully, met the requirements of part 70, EPA granted interim approval to the program in a rulemaking published on October 30, 1996. See 61 FR 55910. The interim approval notice described the conditions that had to be met in order for the District program to receive full approval.

After Pinal revised its program to address the conditions of the interim approval, EPA promulgated a proposal to approve the District's title V operating permits program on

September 20, 2001, contingent upon Pinal submitting the rules that were adopted on September 5, 2001, as a revision to its part 70 program. See 66 FR 48402.

II. EPA's Final Action

EPA is granting full approval to the operating permits program submitted by the Pinal County Air Quality Control District based on the revisions adopted on September 5, 2001, and submitted to EPA on September 18, 2001, which satisfactorily address the program

deficiencies identified in EPA's October 30, 1996 interim approval (61 FR 55910). In addition, EPA is approving, as a title V operating permits program revision, additional changes to Pinal's rules. The deficiency corrections and the additional program revisions are described in detail in the September 20, 2001 proposal and its accompanying technical support document. See 66 FR 48402.

The rules for which we are granting final approval are listed below.

Rule No.	Rule title	Adoption date	Submittal date
PCR 1-3-140 (79)	Definitions (definition of stationary source only)	9/5/01	9/18/01
PCR 3-1-040	Applicability and Classes of Permits	9/5/01	9/18/01
PCR 3-1-045	Transition from Installation and Operating Permit Program	9/5/01	9/18/01
PCR 3-1-050	Permit Application Requirements	9/5/01	9/18/01
PCR 3-1-081	Permit Conditions	9/5/01	9/18/01
PCR 3-4-420	Standards of Conditional Orders	9/5/01	9/18/01
PCR 3-5-490	Application for Coverage under a General Permit	9/5/01	9/18/01
PCR 3-5-550	Revocations of Authority to Operate under a General Permit	9/5/01	9/18/01

In its program submission, Pinal County did not assert jurisdiction over Indian country. To date, no tribal government in Pinal County has applied to EPA for approval to administer a title V program in Indian country within the County. EPA regulations at 40 CFR part 49 govern how eligible Indian tribes may be approved by EPA to implement a title V program on Indian reservations and in non-reservation areas over which the tribe has jurisdiction. EPA's part 71 regulations govern the issuance of federal operating permits in Indian country. EPA's authority to issue permits in Indian country was challenged in *Michigan v. EPA*, (D.C. Cir. No. 99-1151). On October 30, 2001, the court issued its decision in the case, vacating a provision that would have allowed EPA to treat areas over which EPA determines there is a question regarding the area's status as if it is Indian country, and remanding to EPA for further proceedings. EPA will respond to the court's remand and explain EPA's approach for further implementation of part 71 in Indian country in a future action.

III. Effective Date of EPA's Full Approval of the Pinal County Air Quality Control District Operating Permits Program

EPA is using the good cause exception under the Administrative Procedure Act (APA) to make the full approval of the District's program effective on November 30, 2001. In relevant part, the APA provides that publication of "a substantive rule shall be made not less

than 30 days before its effective date, except—* * * (3) as otherwise provided by the agency for good cause found and published with the rule." 5 U.S.C. 553(d)(3). Section 553(b)(3)(B) of the APA provides that good cause may be supported by an agency determination that a delay in the effective date is impracticable, unnecessary, or contrary to the public interest. EPA finds that it is necessary and in the public interest to make this action effective sooner than 30 days following publication. In this case, EPA believes that it is in the public interest for the program to take effect before December 1, 2001. EPA's interim approval of Pinal County's program expires on December 1, 2001. In the absence of this full approval of Pinal County's amended program taking effect on November 30, the federal program under 40 CFR part 71 would automatically take effect in Pinal County and would remain in place until the effective date of the fully-approved state program. EPA believes it is in the public interest for sources, the public and Pinal County to avoid any gap in coverage of the state program, as such a gap could cause confusion regarding permitting obligations. Furthermore, a delay in the effective date is unnecessary because Pinal County has been administering the title V permit program for 5 years under an interim approval. Through this action, EPA is approving a few revisions to the existing and currently operational program. The change from the interim approved program which substantially met the

part 70 requirements, to the fully approved program is relatively minor, in particular if compared to the changes between a state-established and administered program and the federal program.

Administrative Requirements

Under Executive Order 12866, "Regulatory Planning and Review" (58 FR 51735, October 4, 1993), this final approval is not a "significant regulatory action" and therefore is not subject to review by the Office of Management and Budget. Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) the Administrator certifies that this final approval will not have a significant economic impact on a substantial number of small entities because it merely approves state law as meeting federal requirements and imposes no additional requirements beyond those imposed by state law. This rule does not contain any unfunded mandates and does not significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104-4) because it approves pre-existing requirements under state law and does not impose any additional enforceable duties beyond that required by state law. This rule also does not have tribal implications because it 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, "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000). This rule also does not have Federalism implications because it will 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, "Federalism" (64 FR 43255, August 10, 1999). This rule merely approves existing requirements under state law, and does not alter the relationship or the distribution of power and responsibilities between the State and the Federal government established in the Clean Air Act. This final approval also is not subject to Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997) or Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355 (May 22, 2001), because it is not a significant regulatory action under Executive Order 12866. This action will not impose any collection of information subject to the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., other than those previously approved and assigned OMB control number 2060-0243. For additional information concerning these requirements, see 40 CFR part 70. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

In reviewing State operating permit programs submitted pursuant to title V of the Clean Air Act, EPA will approve State programs provided that they meet the requirements of the Clean Air Act and EPA's regulations codified at 40 CFR part 70. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a State operating permit program for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews an operating permit program, to use VCS in place of a State program that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply.

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides

that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective on November 30, 2001.

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 4, 2002. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Operating permits, Reporting and recordkeeping requirements.

Dated: November 27, 2001.

Wayne Nastri,
Regional Administrator, Region 9.

40 CFR part 70, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 70—[AMENDED]

1. The authority citation for part 70 continues to read as follows:

Authority: 42 U.S.C. 7401, et seq.

2. Appendix A to part 70 is amended by adding paragraph (d)(3) under Arizona to read as follows:

Appendix A to Part 70—Approval Status of State and Local Operating Permits Programs

*	*	*	*	*
<i>Arizona</i>				
*	*	*	*	*
	(d)	*	*	*

(3) revisions submitted on September 18, 2001. Full approval is effective on November 30, 2001.

* * * * *

[FR Doc. 01-30100 Filed 12-4-01; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 70

[NJ002; FRL-7113-1]

Clean Air Act Final Full Approval of Operating Permit Program; New Jersey

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The EPA is promulgating final full approval of the operating permit program submitted by the State of New Jersey in accordance with Title V of the Clean Air Act (the Act) and its implementing regulations. This approved program allows New Jersey to issue federally enforceable operating permits to all major stationary sources and to certain other sources within the State's jurisdiction.

EFFECTIVE DATE: November 30, 2001.

ADDRESSES: Copies of the State's submittal and other supporting information used in developing the final full approval are available for inspection during normal business hours at the following location: U.S. Environmental Protection Agency, Region 2, 290 Broadway, 25th Floor, New York, New York 10007-1866.

FOR FURTHER INFORMATION CONTACT: Steven C. Riva, Chief, Permitting Section, Air Programs Branch, at the above EPA office in New York or at telephone number (212) 637-4074.

SUPPLEMENTARY INFORMATION: This section provides additional information by addressing the following questions:

1. What is the operating permits program?
2. What is being addressed in this document?
3. What are the program changes that EPA is approving?
4. What is involved in this final action?
5. What is the effective date of EPA's final full approval of the New Jersey title V program?

1. What Is the Operating Permits Program?

Title V of the Clean Air Act (CAA) and its implementing regulations at 40 CFR part 70 (part 70) direct all states to develop and implement operating permit programs that meet certain criteria. Operating permit programs are intended to consolidate into single