

US EPA ARCHIVE DOCUMENT

(including any ester or salt of the active ingredient) has been approved in any other application under section 512(b)(1) of the act.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. New § 522.1362 is added to read as follows:

§ 522.1362 Melarsomine dihydrochloride for injection.

(a) *Specifications.* The drug consists of a vial of lyophilized powder containing 50 milligrams of melarsomine dihydrochloride which is reconstituted with the provided 2 milliliters of sterile water for injection.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* For asymptomatic to moderate (class 1 to class 2) heartworm disease: 2.5 milligrams per kilogram of body weight (1.1 milligram per pound) twice, 24 hours apart. The series can be repeated in 4 months depending on the response to the first treatment and the condition, age, and use of the dog. For severe (class 3) heartworm disease: Single injection of 2.5 milligrams per kilogram followed, approximately 1 month later, by 2.5 milligrams per kilogram administered twice, 24 hours apart.

(2) *Indications.* Treatment of stabilized, class 1, 2, and 3 heartworm disease (asymptomatic to mild, moderate, and severe, respectively) caused by immature (4 month-old, stage L₅) to mature adult infections of *Dirofilaria immitis* in dogs.

(3) *Limitations.* Administer only by deep intramuscular injection in the lumbar muscles (L₃-L₅). Use a 23 gauge 1 inch needle for dogs less than or equal to 10 kilograms (22 pounds) and a 22 gauge 1 1/2 inch needle for dogs greater than 10 kilograms (22 pounds). Use alternate sides with each administration. The drug is contraindicated in dogs with class 4 (very severe) heartworm disease (Caval Syndrome). Not for use in breeding animals and lactating or pregnant bitches. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: September 1, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95-23603 Filed 9-22-95; 8:45 am]

BILLING CODE 4160-01-F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MO-21-1-6443(a); FRL-5289-6]

Approval and Promulgation of Implementation Plans and Delegation of 112(l) Authority; State of Missouri

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: Missouri submitted its Rule 10 CSR 10-6.065, entitled "Operating Permits," for Federal approval. The rule would establish a mechanism for creating federally enforceable limitations that would reduce sources' potential to emit such that sources could avoid major source permitting requirements. This action approves this rule as satisfying the criteria set forth in the Federal Register of June 28, 1989, for EPA approval of federally enforceable state operating permit programs (FESOP). In addition, this action addresses Missouri's program covering both criteria pollutants (regulated under section 110 of the Clean Air Act (CAA)) and hazardous air pollutants (HAP) (regulated under section 112).

DATES: This final rule is effective November 24, 1995, unless by October 25, 1995 adverse or critical comments are received.

ADDRESSES: Written comments should be addressed to: Joshua A. Tapp, Air Planning and Development Section, United States Environmental Protection Agency, 726 Minnesota Avenue, Kansas City, Kansas 66101.

Copies of the State Implementation Plan (SIP) revision request and EPA's analysis are available for public inspection during normal business hours at the following address: United States Environmental Protection Agency, Region VII, Air and Toxics Division, 726 Minnesota Avenue, Kansas City Kansas 66101.

FOR FURTHER INFORMATION CONTACT:

Joshua A. Tapp, Air Planning and Development Section, United States Environmental Protection Agency, Region VII, Kansas City, Kansas 66101 ((913) 551-7606).

SUPPLEMENTARY INFORMATION:

I. Review of State Submittal

For many years, Missouri has been issuing permits for major new sources and for major modifications of existing sources. Throughout this time, Missouri has also been issuing permits establishing limitations on the potential emissions from new sources so as to avoid major source permitting requirements. This latter type of permitting has been the subject of various guidance from EPA, most notably the memorandum entitled "Guidance on Limiting Potential to Emit in New Source Permitting" dated June 13, 1989.

The operating permit provisions in title V of the Clean Air Act Amendments of 1990 have created interest in mechanisms for limiting sources' potential-to-emit, thereby allowing the sources to avoid being defined as "major" with respect to title V operating permit programs. A key mechanism for such limitations is the use of FESOPs. EPA issued guidance on FESOPs in the Federal Register of June 28, 1989 (54 FR 27274). On April 6, 1994, Missouri submitted its newly adopted rule 10 CSR 10-6.065 to provide for FESOPs in Missouri. This rule would supplement the preexisting mechanism for establishing federally enforceable limitations on potential-to-emit (i.e., new source permits). This document evaluates whether Missouri has satisfied the requirements for this type of federally enforceable limitation on potential-to-emit.

As specified in the Federal Register of June 28, 1989, the first provision necessary for an FESOP program is that the state must have approved operating permit regulations. Rule 10 CSR 10-6.065 sections 1, 2, 3, 4(C)-(P), 5, and 7 serve as the foundation for the FESOP rule and the rule defines the "intermediate" permitting program. EPA approval of the program will satisfy the first provision for Federal enforceability.

The second provision is that sources have a legal obligation to comply with permit terms, and that EPA may deem as "not federally enforceable" those permits which it finds fail to satisfy applicable requirements. Rule 10 CSR 10-6.065 requires sources to obtain permits to operate, authorizes Missouri to establish terms and conditions in these permits "to ensure compliance with applicable requirements," and authorizes the state to suspend or revoke permits if the source violates the terms or conditions. In addition, Missouri's definition of "federally enforceable" states that an operating permit is federally enforceable only if it establishes terms and conditions which require adherence to its requirements (10 CSR 10-6.020(2)F(2)). Thus, this rule imposes a legal obligation on sources to comply with permit terms.

The third requirement for FESOPs is that the program require all limits to be at least as stringent as other applicable federally enforceable provisions. Rule 10 CSR 10-6.065(5)(C)1 provides that terms and conditions in permits must "be at least as stringent as any other applicable limitations and requirements contained in the implementation plan or enforceable under the implementation plan." These rules contain no provisions authorizing terms and conditions any less stringent than the applicable requirements.

The fourth requirement is that the permit provisions must be permanent, quantifiable, and otherwise enforceable as a practical matter. Permit "permanence" does not mean never providing for a modification, reissuance, or revocation, for these elements are fundamental in all air permit programs. Permanence instead is considered in terms of provisions having continuing mandates, i.e., that EPA has assurance that the provisions are in effect through the life of the permit. In this case, the limitations on potential-to-emit will generally be sought by sources so as to be redefined from "major" to "minor" for permitting purposes. Sources that obtain such limitations must keep these limitations in effect, so as never to be a "major" source violating the requirement for a "major" source permit. The requirement for permit provisions to be quantifiable and practically enforceable must be met on a permit-by-permit basis. Missouri's rules do provide in section 10 CSR 10-6.065(5)(C)2 for the issuance of permanent, quantifiable, and enforceable permits. Thus, Missouri's rules provide for legally enforceable permits that EPA may evaluate for practical enforceability.

The fifth requirement is that the permits must be subject to public notice and review. Rules 10 CSR 10-6.065(5)(C)3 and 10 CSR 10-6.065(7) provide that permits intended to establish federally enforceable limitations on potential-to-emit may not be issued without first providing opportunity for public comment.

Missouri has requested that EPA authorize federally enforceable limitations on potential-to-emit for both pollutants regulated under section 110 of the Act ("criteria pollutants") and pollutants regulated under section 112 (HAPs). As discussed above, the June 28, 1989, Federal Register document provided five specific criteria for approval of state operating permit programs for the purpose of establishing federally enforceable limits on a source's potential-to-emit. This 1989 document addressed only SIP programs to control criteria pollutants. Federally enforceable limits on criteria pollutants (especially volatile organic compounds (VOC) and particulate matter) may have the incidental effect of limiting certain HAPs listed pursuant to section 112(b). This situation would occur when a pollutant classified as an HAP is also classified as a criteria pollutant (e.g., benzene).¹ As a legal matter, no additional program approval by EPA is required in order for these criteria pollutant limits to be recognized for this purpose.

EPA has determined that the five approval criteria for approving FESOP programs into the SIP, as specified in the June 28, 1989, Federal Register document, are also appropriate for evaluating and approving the programs under section 112(l). Hence, the five criteria discussed above are applicable to FESOP approvals under section 112(l) as well as under section 110.

In addition to meeting the criteria in the June 28, 1989, document, an FESOP program for HAPs must meet the statutory criteria for approval under section 112(l)(5). This section allows EPA to approve a program only if it: (1) Contains adequate authority to ensure compliance with any section 112 standards or requirements; (2) provides for adequate resources; and (3) provides for an expeditious schedule for ensuring compliance with section 112 requirements.

EPA plans to codify the approval criteria for programs limiting potential-to-emit HAPs in subpart E of part 63, the regulations promulgated to implement

¹ EPA intends to issue guidance addressing the technical aspects of how these criteria pollutant limits may be recognized for purposes of limiting a source's potential-to-emit of HAPs to below section 112 major source levels.

section 112(l) of the Act. EPA currently anticipates that these criteria, as they apply to FESOP programs, will mirror those set forth in the June 28, 1989, document, with the addition that the state's authority must extend to HAPs instead of, or in addition to, VOCs and particulate matter. EPA currently anticipates that FESOP programs that are approved pursuant to section 112(l) prior to the subpart E revisions will have had to meet these criteria and, hence, will not be subject to any further approval action.

EPA believes it has authority under section 112(l) to approve programs to limit potential-to-emit HAPs directly under section 112(l) prior to this revision to subpart E. Section 112(l)(5) requires EPA to disapprove programs that are inconsistent with guidance required to be issued under section 112(l)(2). This might be read to suggest that the "guidance" referred to in section 112(l)(2) was intended to be a binding rule. Even under this interpretation, EPA does not believe that section 112(l) requires this rulemaking to be comprehensive. That is, it need not address all instances of approval under section 112(l). EPA has already issued regulations under section 112(l) that would satisfy this requirement. Given the severe timing problems posed by impending deadlines under section 112 and title V, EPA believes it is reasonable to read section 112(l) to allow for approval of programs to limit potential-to-emit prior to issuance of a rule specifically addressing this issue.

Missouri's satisfaction of the criteria published in the Federal Register of June 28, 1989, has been discussed above. In addition, Missouri's FESOP program meets the statutory criteria for approval under section 112(l)(5). EPA believes that Missouri has adequate authority to ensure compliance with section 112 requirements since the third criteria of the June 28, 1989, document is met—that is, since the program does not provide for waiving any section 112 requirement. Nonmajor sources would still be required to meet applicable section 112 requirements.

Regarding adequate resources, Missouri has included in its request for approval under section 112(l) a commitment to provide adequate resources to implement and enforce the program, which will be obtained from fees collected under title V. EPA believes that this mechanism will be sufficient to provide for adequate resources to implement this program, and will monitor the state's implementation of the program to ensure that adequate resources continue to be available.

Missouri's FESOP program also meets the requirement for an expeditious schedule for ensuring compliance. A source seeking a voluntary limit on potential-to-emit is probably doing so to avoid a Federal requirement applicable on a particular date. Nothing in this program would allow a source to avoid or delay compliance with the Federal requirement if it fails to obtain the appropriate federally enforceable limit by the relevant deadline.

II. Rulemaking Action

EPA finds that the criteria for Missouri to be able to issue FESOPs are met, and is today approving Rule 10 CSR 10-6.065 sections 1, 2, 3, 4(C)-(P), 5, and 7. It is important to note that Missouri's rule 10 CSR 10-6.065 contains the requirements for a part 70 permit program, an intermediate permit program which EPA is approving in this action, and a basic permit program which applies to minor sources. To some extent, the requirements for these programs overlap within the rule. EPA wants to make clear that it is only approving the language and requirements of this rule as they apply to Missouri's intermediate operating permit program.

EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in a separate document in the Federal Register publication, EPA is proposing to approve the SIP revision should adverse or critical comments be filed.

If EPA receives such comments, this action will be withdrawn before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on this action serving as a proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time.

Under sections 202, 203, and 205 of the Unfunded Mandates Reform Act of 1995 ("Unfunded Mandates Act"), signed into law on March 22, 1995, EPA must undertake various actions in association with proposed or final rules that include a Federal mandate that may result in estimated costs of \$100 million or more to the private sector, or to state, local, or tribal governments in the aggregate.

Through submission of this SIP revision, the state has elected to adopt the program provided for under section 110 of the CAA. These rules may bind state and local governments to perform

certain actions and also require the private sector to perform certain duties. To the extent that the rules being finalized for approval by this action will impose new requirements, sources are already subject to these regulations under state law. Accordingly, no additional costs to state or local governments, or to the private sector, result from this final action. EPA has also determined that this final action does not include a mandate that may result in estimated costs of \$100 million or more to state or local governments in the aggregate or to the private sector.

Nothing in this action should be construed as permitting, allowing, or establishing a precedent for any future request for revision to any SIP. EPA shall consider each request for revision to the SIP in light of specific technical, economic, and environmental factors, and in relation to relevant statutory and regulatory requirements.

The Office of Management and Budget has exempted these regulatory actions from review under Executive Order 12866.

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities (5 U.S.C. 603 and 604). Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under section 110 and subchapter I, part D of the CAA do not create any new requirements, but simply approve requirements that the state is already imposing. Therefore, because the Federal SIP approval does not impose any new requirements, I certify that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-state relationship under the CAA, preparation of a regulatory flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The CAA forbids EPA to base its actions concerning SIPs on such grounds (*Union Electric Co. v. United States*, EPA, 427 U.S. 246, 256-66 (S.Ct. 1976); 42 U.S.C. 7410(a)(2)).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 24, 1995. 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 52

Environmental Protection, Air pollution control, Hydrocarbons, Incorporation by reference, Lead, Nitrogen dioxide, Ozone, Particulate matter, Volatile organic compounds.

Dated: August 9, 1995.

Dennis Grams,

Regional Administrator.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401-7671q.

Subpart AA—Missouri

2. Section 52.1320 is amended by adding paragraph (c)(88) to read as follows:

§ 52.1320 Identification of plan.

* * * * *

(c)* * *

(88) This revision submitted by the Missouri Department of Natural Resources on March 31, 1994, relates to intermediate sources, and the EPA is not approving the basic operating permit program. This revision establishes a mechanism for creating federally enforceable limitations. Emission limitations and related provisions which are established in Missouri operating permits as federally enforceable conditions shall be enforceable by EPA. EPA reserves the right to deem permit conditions not federally enforceable. Such a determination will be made according to appropriate procedures and be based upon the permit, permit approval procedures, or permit requirements which do not conform with the operating permit program requirements or the requirements of EPA's underlying regulations.

(i) Incorporation by reference.

(A) 10 C.S.R. 10-6.065 (sections 1, 2, 3, 4(C)-(P), 5, and 7) Operating Permits, effective May 9, 1994.

(ii) Additional material.

(A) Letter from Missouri to EPA Region VII dated November 7, 1994, regarding how Missouri intends to

satisfy the requirements set forth in the Clean Air Act Amendments at sections 112(l)(5)(A), (B), and (C).

(B) Two letters from Missouri to EPA Region VII dated October 3, 1994, and February 10, 1995, supplementing the November 7, 1994, letter and clarifying that Missouri does have adequate authority to limit potential-to-emit of hazardous air pollutants through the state operating permit program.

* * * * *

3. Section 52.1323 is amended by adding paragraph (i) to read as follows:

§ 52.1323 Approval status.

* * * * *

(i) Emission limitations and related provisions which are established in Missouri's operation permits as federally enforceable conditions shall be enforceable by EPA. EPA reserves the right to deem permit conditions not federally enforceable. Such a determination will be made according to appropriate procedures, and be based upon the permit, permit approval procedures, or permit requirements which do not conform with the operating permit program requirements or the requirements of EPA's underlying regulations.

[FR Doc. 95-23719 Filed 9-22-95; 8:45 am]

BILLING CODE 6560-50-F

40 CFR Part 70

[FL-95-01; FRL-5302-5]

Clean Air Act Final Interim Approval of Operating Permit Program; State of Florida

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final interim approval.

SUMMARY: EPA is promulgating interim approval of the operating permit program submitted by the Florida Department of Environmental Protection for the purpose of complying with Federal requirements for an approvable State program to issue operating permits to all major stationary sources, and to certain other sources.

EFFECTIVE DATE: October 25, 1995.

ADDRESSES: Copies of Florida's submittal and the other supporting information used in developing the final interim approval are available for inspection during normal business hours at the following location: U.S. Environmental Protection Agency, Region 4, 345 Courtland Street NE., Atlanta, GA 30365. Interested persons wanting to examine these documents, contained in EPA docket number FL-

95-01, should make an appointment at least 24 hours before the visiting day.

FOR FURTHER INFORMATION CONTACT: Kim Gates, Title V Program Development Team, Air Programs Branch, Air Pesticides & Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 345 Courtland Street NE., Atlanta, GA 30365, (404) 347-3555, Ext. 4146.

SUPPLEMENTARY INFORMATION:

I. Background and Purpose

Title V of the 1990 Clean Air Act Amendments (sections 501-507 of the Clean Air Act (the Act) and the implementing regulations at 40 Code of Federal Regulations (CFR) part 70 require that States develop and submit operating permits programs to EPA by November 15, 1993, and that EPA act to approve or disapprove each program within one year after receiving the submittal. If the State's submission is materially changed during the one-year review period, 40 CFR 70.4(e)(2) allows EPA to extend the review period for no more than one year following receipt of the additional materials. EPA received Florida's title V operating permit program submittal on November 16, 1993. The State provided EPA with additional materials in supplemental submittals dated July 8, 1994, November 28, 1994, December 21, 1994, December 22, 1994, and January 11, 1995. Because the supplements materially changed the State's title V program submittal, EPA extended the one-year review period.

EPA reviews state operating permit programs pursuant to section 502 of the Act and the part 70 regulations, which together outline criteria for approval or disapproval. Where a program substantially, but not fully, meets the requirements of part 70, EPA may grant the program interim approval for a period of up to two years. If EPA has not fully approved a program by November 15, 1995, or by the end of an interim program, it must establish and implement a Federal operating permit program for that state.

On June 21, 1995, EPA proposed interim approval of Florida's operating permit program. See 60 FR 32292. The June 21, 1995 notice also proposed approval of Florida's interim mechanism for implementing section 112(g) and for delegation of section 112 standards and programs that are unchanged from the Federal rules as promulgated. Public comment was solicited on these proposed actions. In this notice, EPA is responding to the comments received and taking final action to promulgate interim approval of Florida's operating permit program.

II. Final Action and Implications

A. Analysis of State Submission and Response to Public Comments

On June 21, 1995, EPA proposed interim approval of Florida's title V operating permit program. See 60 FR 32292. The program elements discussed in the proposal notice are unchanged from the proposal notice and continue to substantially meet the requirements of title V and part 70. For detailed information on EPA's analysis of Florida's program submittal, please refer to the Technical Support Document (TSD) contained in the docket at the address noted above.

EPA received three letters during the 30-day public comment period held on the proposed interim approval of Florida's program. One respondent requested a 90-day extension of the public comment period based on the guidance memorandum entitled "White Paper for Streamlined Development of Part 70 Permit Applications" issued by EPA on July 10, 1995. The respondent suggested that the White Paper memorandum provides more flexibility for insignificant activities than allowed for in part 70 and in the proposal notice. EPA denied the extension request because the policies set forth in the White Paper memorandum are intended solely as guidance and do not change the current part 70 requirements.

EPA received two comment letters on the proposed interim approval of Florida's program, one from an industry commenter and the other from the State. In response to the comments, several of the conditions for full program approval discussed in the proposal notice are being revised. The changes are discussed below along with the conditions for full approval that remain unchanged.

1. Definition of "Major Source"

Florida's definition of "major source" in the original program submittal (see Rule 62-213.200(19)(a), F.A.C.) implied that emissions of criteria pollutants from any oil or gas exploration or production well (with its associated equipment) and emissions from any pipeline compressor or pump station would not be aggregated with emissions of criteria pollutants from other similar units. Since Florida's definition of "major source" conflicted with the part 70 definition, revision of the State's definition was identified in the proposal notice as a condition of full program approval.

In its comment letter, the State indicated that the definition of "major source" in Rule 62-213.200(19)(a), F.A.C., has been amended to clarify that