of information summary is provided to reflect the clarification.

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 re-delegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

2. Section 520.905a is amended by removing paragraph (a); by redesignating paragraphs (b) and (c) as paragraphs (a) and (b); by adding paragraph (c); by revising the heading of paragraph (d)(2); by redesignating paragraph (d)(3) as paragraph (d)(4); by redesignating paragraphs (d)(2)(ii), (d)(2)(ii)(A), and (d)(2)(ii)(B) as paragraphs (d)(3)(i), (d)(3)(ii), and (d)(3)(iii); by adding a heading for newly redesignated paragraph (d)(3); by redesignating paragraphs (d)(2)(ii)(A) and (d)(2)(ii)(B) as paragraphs (d)(2)(ii) and (d)(2)(iii) to read as follows:

§ 520.905a Fenbendazole suspension.
* * * * *
(c) Related tolerances. See § 556.275 of this chapter.
(d) * * *
(2) Cattle including dairy cows of breeding age—* * *
* * * * *
(3) Beef cattle—* * *
* * * * *

Dated: November 9, 1998.
Andrew J. Beaulieu,
Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 98–30750 Filed 11–17–98; 8:45 am]
BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52
[AK 15–1703a; FRL–6188–7]
Approval and Promulgation of State Implementation Plans; Alaska
AGENCY: Environmental Protection Agency.
ACTION: Final rule.

SUMMARY: Environmental Protection Agency (EPA) is approving in part and disapproving in part portions of the revisions to the State of Alaska Implementation Plan which were submitted to EPA by the Director of the Alaska Department of Environmental Conservation (ADEC) on January 8, 1997 and March 17, 1998. These revisions consist of certain changes to the ADEC rules for air quality control (18 AAC 50), updated Alaska statutes related to air pollution, and the "In Situ Burning Guideline for Alaska (revised 5/94)." These revisions were submitted in accordance with the requirements of section 110 and Part D of the Clean Air Act (hereinafter the Act).

DATES: This action is effective on January 19, 1999.
ADDRESSES: Copies of the State's request and other information supporting this proposed action are available for inspection during normal business hours at the following locations: EPA, Office of Air Quality (OAQ–107), 1200 Sixth Avenue, Seattle, Washington 98101, and State of Alaska, Department of Environmental Conservation, 410 Willoughby Avenue, Juneau, Alaska, 99801. Documents which are incorporated by reference are available for public inspection at the Air and Radiation Docket and Information Center, EPA, 401 M Street, SW, Washington, D.C. 20460, as well as the above addresses.

FOR FURTHER INFORMATION CONTACT: David C. Bray, Senior Air Pollution Scientist, Office of Air Quality (OAQ–107), EPA, Seattle, Washington, (206) 553–4253.

SUPPLEMENTARY INFORMATION:

I. Background

The Clean Air Act Amendments of 1990, Title V, require States to develop operating permit programs for most stationary sources. While Title V operating permit programs are not approved as part of the state implementation plan (SIP) under section 110 of the Act, many provisions of the SIP will interact closely with the Title V operating permit program. As
such, many States will be revising provisions of their SIPs to facilitate and improve the relationship between their SIP and their Title V operating permit program. The ADEC amended numerous provisions of its current rules for air pollution sources and submitted them to EPA on January 8, 1997, and March 17, 1998, as revisions to the Alaska SIP. ADEC also submitted updated Alaska statutes related to air pollution (specifically, the 1993 Alaska Act (Chapter 74 State Legislative Act 1993)), and the “In Situ Burning Guideline for Alaska (revised 5/94).”

On August 18, 1998 (63 FR 44208), EPA proposed to approve portions of the rules submitted by ADEC, along with portions of the updated Alaska statutes and the “In Situ Burning Guideline for Alaska (revised 5/94).” In that proposal, EPA indicated that it was taking no action at that time on the provisions relating to the permitting of stationary sources, including the construction of new and modified stationary sources. Part D New source review, and prevention of significant deterioration (PSD) permitting, but would propose action on those provisions in a separate notice. In addition, EPA indicated that it was taking no action on a number of provisions which are unrelated to the purposes of the implementation plan. See the August 18, 1998 Federal Register for complete descriptions of the portions of the ADEC submittals which were proposed for approval, the portions which will be acted on at a later date, and portions which will not be acted upon. The August 18, 1998 Federal Register also contains a discussion of EPA’s review of the ADEC submittals and its findings with regard to the portions of the submittals which EPA proposed for approval.

II. Response to Comments

EPA received comments from three entities on its proposed approval of portions of the ADEC submittal. One commenter (an Alaskan Industry) supported EPA’s proposed approval and encouraged EPA to complete its action on the provisions relating to the permitting of new and modified stationary sources. One commenter (the ADEC) supported EPA’s proposed approval, but pointed out that EPA had proposed to approve AS 46.14.110(e) and (g), which had been repealed by the Alaska Legislature and was no longer in effect. EPA agrees with the commenter that it cannot approve a repealed statutory provision and is correcting its error in this final action.

One commenter (representing three environmental organizations) opposed EPA’s proposed approval of the ADEC’s request to remove 18 AAC 50.110 “Air Pollution Prohibited” from the federally-approved Alaska SIP. The commenter disagreed with EPA’s characterization of this section as a general nuisance provision that is not relied upon to meet any requirement of the Clean Air Act or EPA regulations. The commenter indicated that 18 AAC 50.110 in fact provides a mechanism for regulating pollutants that are not otherwise regulated by ambient air quality standards and/or permitting requirements and equipment-specific standards, and cited examples of where this provision had been used in the past to regulate sources of criteria pollutants. The commenter also pointed out that neither ADEC nor EPA had provided an adequate justification for removing this section from the EPA-approved SIP.

EPA has considered the comments regarding its proposed approval of the removal of 18 AAC 50.110 from the SIP and has reevaluated the documentation submitted by ADEC in support of its request. In light of the information provided by the commenter and the lack of documentation submitted by ADEC, EPA finds the request for removal of 18 AAC 50.110 to be unapprovable. Specifically, ADEC has not demonstrated that the removal of 18 AAC 50.110 would comply with the requirements for SIP revisions set forth in sections 110(l) and 193 of the Act. EPA is therefore disapproving the ADEC request to remove 18 AAC 50.110 from the Alaska SIP. Note that EPA is not taking action at this time on the information provided by the commenter regarding whether 18 AAC 50.110 could be removed from the SIP, but only that ADEC has not submitted the necessary demonstrations required by the Act and EPA regulations for EPA to approve this specific SIP submittal.

III. Final Action

EPA is approving in part and disapproving in part portions of the rules submitted by ADEC, and is approving portions of the updated Alaska statutes and the “In Situ Burning Guideline for Alaska (revised 5/94).” Specifically, EPA is approving the following provisions of 18 AAC 50 as adopted by ADEC and effective on January 18, 1997: Section 005; Section 010, except for subsections (7) and (8); Section 025; Section 030; Section 035; Section 045; Section 050; Section 055, except for paragraph (d)(2)(B) (note that paragraph (a)(9) was not submitted by ADEC); Section 060; Section 065; Section 070; Section 075; Section 200; Section 201; Section 205; Section 220; Section 240; Section 245; Section 400; paragraphs (a), (b)(1), and (c); Section 410; Section 420; Section 430; Section 900; and Section 990, subsections (2), (3), (4), (5), (6), (8), (9), (10), (11), (12), (15), (16), (17), (19), (20), (23), (24), (25), (26), (29), (31), (32), (33), (34), (35), (37), (39), (40), (42), (43), (45), (47), (48), (50), (51), (53), (58), (59), (60), (61), (62), (63), (65), (66), (67), (69), (70), (71), (72), (74), (75), (78), (79), (80), (81), (83), (84), (85), (86), (89), (90), (91), (92), (93), (94), (95), (96), (97), (99), and (100). (Note that 18 AAC 50, Sections 700 through 735 were already approved by EPA on September 27, 1995 (60 FR 49765).) EPA is also disapproving the requested revocation of 18 AAC 50: Section 010 “Applicability of Local Government Regulations;” Section 070 “Motor Vehicle Emissions;” and Section 900 “Definitions;” subsections (19) “emission allowance,” (27) “maximum combustion efficiency,” (30) “opacity,” (45) “ug/m3,” (46) “regional supervisor,” and (48) “wood smoke control area.” EPA is approving as federally enforceable provisions of the SIP, the following provisions of the Alaska Statutes: AS 46.14.510(b); AS 46.14.520(a); AS 46.14.990(1), (2), (3), (6), (7), (8), (10), (13), (15), (16), (17), (18), (22), (24), and (25); and AS 45.45.400(a) (enacted 1993). Finally, EPA is approving the “In Situ Burning Guidelines for Alaska (revised 5/94).”

EPA is disapproving the ADEC request to remove 18 AAC 50.110 “Air Pollution Prohibited” (effective 5/26/72) from the EPA-approved SIP. EPA is taking no action at this time on the following provisions of 18 AAC 50 which relate to the permitting of new and modified stationary sources: Section 015; Section 020; Section 100; Section 210; Section 215; Section 225; Section 230; Section 250; Section 300; Section 310; Section 315; Section 320; Section 400, paragraphs (b)(2) through (b)(5); Section 910; and Section 990, subsections (1), (7), (13), (21), (22), (27), (28), (30), (36), (38), (41), (44), (46), (49), (52), (54), (55), (56), (57), (64), (68), (73), (76), (77), (82), and (98). Additionally, EPA is taking no action at this time on the revocation of Section 520 “Emission and Ambient Monitoring” (effective 7/21/91) and Section 900 “Definitions;” subsections (52) and (54) (effective 4/23/94). Finally, EPA is taking no action at this time on the following provisions of the Alaska Statutes which relate to the permitting of new and modified stationary sources: AS 46.14.120(a); AS 46.14.130(a); AS 46.14.240(a); AS 46.14.250(a); and AS 46.14.990(4), (5), (9), (11), (12), (14), (18), (20), (21), and (23) (enacted 1993).
the SIP under section 110 of the Act, or which implement other provisions of the Clean Air Act (e.g., NSPS, NESHAP, Title V); Section 010, subsections (7) and (8); Section 040; Section 055, paragraph (d)(2)(B); Section 080; Section 235; Section 300, paragraphs (f) and (h)(10); Section 310, paragraph (h); Section 315, paragraph (e)(6); Section 322; Sections 325 through 380; Section 400, paragraphs (b)(6) through (b)(10); Section 410; and Section 990, subsections (12), (18), (87), and (88).

IV. Administrative Requirements

A. Executive Order 12866 and 13045

The Office of Management and Budget (OMB) has exempted this regulatory action from review under E.O. 12866, entitled, “Regulatory Planning and Review” review.

The final rule is not subject to E.O. 13045, entitled, “Protection of Children from Environmental Health Risks and Safety Risks” because it is not an “economically significant” action under E.O. 12866.

B. Executive Order 12875: Enhancing the Intergovernmental Partnership

Under Executive Order 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 12875 requires EPA to provide to the Office of Management and Budget a description of the extent of EPA’s prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments “to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.”

Today’s rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of E.O. 13040 do not apply to this rule.

C. Executive Order 13084: Consultation and Coordination With Indian Tribal Governments

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA’s prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments “to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.”

Today’s rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

D. Regulatory Flexibility Act

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 Clean Air Act 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, the Administrator certifies 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 flexibility analysis would constitute Federal inquiry into the economic reasonableness of State action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. Union Electric Co. v. U.S. EPA, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

EPA’s disapproval of a portion of the State request under Section 110 and subchapter I, part D of the CAA does not affect any existing requirements applicable to small entities. Any pre-existing federal requirements remain in place after this disapproval. Federal disapproval of the state submittal does not affect its state-enforceability. Moreover, EPA’s disapproval of the submittal does not impose any new Federal requirements. Therefore, EPA certifies that this disapproval action does not have a significant impact on a substantial number of small entities because it does not remove existing requirements and impose any new Federal requirements.

E. Unfunded Mandates

Under Section 202 of the Unfunded Mandates Reform Act of 1995 (“Unfunded Mandates Act”), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate, or to the private sector, of $100 million or more. Under Section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

F. Submission to Congress and the Comptroller General

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. This rule is not a major rule as defined by 5 U.S.C. § 804(2).

G. Petitions for Judicial Review

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 January 19, 1999. 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).)

H. Alaska’s Audit Law

Nothing in this action should be construed as making any determination or expressing any position regarding Alaska’s audit privilege and penalty immunity law (Alaska Audit Act, AS 09.25.450 et seq., enacted in 1997) or its impact upon any approved provision in the SIP, including the revision at issue here. The action taken herein does not express or imply any viewpoint on the question of whether there are legal deficiencies in this or any other Clean Air Act program resulting from the effect of Alaska’s audit privilege and penalty immunity law. A state audit privilege and immunity law can affect only state enforcement and cannot have any impact on federal enforcement authorities. EPA may at any time invoke its authority under the Clean Air Act, including, for example, sections 113, 167, 205, 211 or 213, to enforce the requirements or prohibitions of the state plan, independently of any state audit or expressing any position regarding a state audit privilege or immunity law. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.


Chuck Findley,
Acting Regional Administrator, Region X.

Note: Incorporation by reference of the Implementation Plan for the State of Alaska was approved by the Director of the Office of the Federal Register on July 1, 1982.

Part 52, chapter 1, 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 et seq.

Subpart C—Alaska

2. Section 52.70 is amended by adding paragraph (c)(28) to read as follows:

§ 52.70 Identification of plan.

* * * * *

(c) * * * * *

(28) On January 8, 1997, the Director of the Alaska Department of Environmental Conservation submitted the Alaska air quality regulations, 18 Alaska Administrative Code (AAC) 50 (with the exception of 18 AAC 50.055(a)(9), 50.085, 50.090, 50.110, 50.300(g), and 50.310(l) which were not submitted), as effective on January 18, 1997. On March 17, 1998, the Director of the Alaska Department of Environmental Conservation resubmitted 18 AAC 50.055(a)(3) and (b)(6). EPA has approved the following provisions of 18 AAC 50, as effective on January 18, 1997: Section 005; Section 010, except for subsections (7) and (8); Section 025; Section 030; Section 035; Section 045; Section 050; except for paragraph (d)(2)(B) and (a)(9); 18 AAC 50.055; 18 AAC 50.055, except for paragraphs (d)(2)(B) and (a)(9); 18 AAC 50.060; 18 AAC 50.065; 18 AAC 50.070; 18 AAC 50.075; 18 AAC 50.200; 18 AAC 50.201; 18 AAC 50.205; 18 AAC 50.220; 18 AAC 50.240; 18 AAC 50.245; 18 AAC 50.400; paragraphs (a), (b)(1), and (c); 18 AAC 50.420; 18 AAC 50.430; 18 AAC 50.900; and 18 AAC 50.990, subsections (2), (3), (4), (5), (6), (8), (9), (10), (11), (14), (15), (16), (17), (19), (20), (23), (24), (25), (26), (29), (31), (32), (33), (34), (35), (37), (39), (40), (42), (43), (45), (47), (48), (50), (51), (53), (58), (59), (60), (61), (62), (63), (65), (66), (67), (69), (70), (71), (72), (74), (75), (78), (79), (80), (81), (83), (84), (85), (86), (89), (90), (91), (92), (93), (94), (95), (96), (97), (99), and (100); as effective on January 18, 1997.

B. Alaska’s state laws are likewise unaffected by this action. (A) 18 AAC 50.005; 18 AAC 50.10. (B) AS 46.14.510(b); AS 46.14.550; AS 46.14.560; AS 46.14.990(1), (2), (3), (6), (7), (8), (10), (13), (15), (16), (17), (18), (22), (24), and (25); and AS 45.45.400(a).

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[56 FR 6189] Availability of Federally-Enforceable State Implementation Plans for All States

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: Section 110(h) of the Clean Air Act, as amended in 1990 (the "Act"), requires EPA by November 15, 1995, and every three years thereafter, to identify the Federally-enforceable State Implementation Plans (SIPs) in each...