that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. All received comments will be considered comments regarding the proposed rule and this direct final rule.

List of Subjects

21 CFR Part 10

Administrative practice and procedure, News media.

21 CFR Part 12

Administrative practice and procedure.

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 10, 12, and 510 be amended as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

1. The authority citation for 21 CFR part 10 continues to read as follows:

Authority: 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

§ 10.20 [Amended]

2. Section 10.20 *Submission of documents to Dockets Management Branch; computation of time; availability for public disclosure* is amended by adding in paragraph (c)(1)(iii) the word ''or'' after the word ''available;'', by removing in paragraph (c)(1)(iv) the words ''agency; or'' and adding in its place the word ''agency.'', and by removing paragraph (c)(1)(v).

PART 12—FORMAL EVIDENTIARY PUBLIC HEARING

3. The authority citation for 21 CFR part 12 continues to read as follows:

Authority: 21 U.S.C. 141–149, 321–393, 467f, 679, 821, 1034; 42 U.S.C. 201, 262, 263b–263n, 264; 15 U.S.C. 1451–1461; 5 U.S.C. 551–558, 701–721; 28 U.S.C. 2112.

§ 12.22 [Amended]

4. Section 12.22 *Filing objections and requests for a hearing on a regulation or order* is amended by adding in paragraph (a)(5)(i)(*a*) the word ''or'' after the word ''available;'', by removing in paragraph (a)(5)(i)(*b*) the words ''agency; or'' and adding in its place the word ''agency.'', and by removing paragraph (a)(5)(i)(*c*).

PART 510—NEW ANIMAL DRUGS

5. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.3 [Amended]

6. Section 510.3 *Definitions and interpretations* is amended by removing paragraph (l).

§ 510.95 [Removed and Reserved]

7. Section 510.95 *Designated journals* is removed and reserved.

Dated: November 30, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–31908 Filed 12–9–99; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA–222–0198; FRL–6506–7]

Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision, South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to disapprove revisions to the California State Implementation Plan (SIP). The revisions provide for the exemption of sources from visible emission limits in the South Coast Air Quality Management District. EPA has evaluated these revisions and is proposing to disapprove these revisions to the California SIP because the revisions are not consistent with applicable Clean Air Act (Act) requirements.

DATES: Comments must be received on or before December 27, 1999.

ADDRESSES: Comments must be submitted to Andrew Steckel at the Region IX office listed below. Copies of the rule and EPA's evaluation report for the rule are available for public inspection at EPA's Region IX office during normal business hours. Copies of the submitted rule are available for inspection at the following locations:

Rulemaking Office (AIR–4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105

Environmental Protection Agency, Air Docket (6102), 401 ''M'' Street, S.W., Washington, D.C. 20460

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 ''L'' Street, Sacramento, CA 95812

South Coast Air Quality Management District, 21865 E. Copley Drive, Diamond Bar, CA 91765

FOR FURTHER INFORMATION CONTACT: Patricia Bowlin, Rulemaking Office (AIR–4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105, Telephone: (415) 744–1188.

SUPPLEMENTARY INFORMATION:

I. Applicability of EPA's Proposed Action

This document addresses EPA's proposed disapproval of South Coast Air Quality Management District (SCAQMD) Rule 401, Visible Emissions, as adopted by SCAQMD on September 11, 1998. SCAQMD Rule 401 was submitted by the California Air Resources Board to EPA on January 12, 1999.

This **Federal Register** action for the SCAQMD excludes the Los Angeles County portion of the Southeast Desert AQMA, otherwise known as the Antelope Valley Region in Los Angeles County, which is now under the jurisdiction of the Antelope Valley Air Pollution Control District as of July 1, 1997.[1]

II. Background of the State Submittal

On January 29, 1985 EPA approved into the SIP a version of SCAQMD Rule 401, Visible Emissions, that had been adopted by SCAQMD on March 2, 1984. Revisions to this rule were subsequently adopted on April 7, 1989 and submitted to EPA on March 26, 1990. EPA did not act on the 1990 submittal of Rule 401, which is now superseded by the January 12, 1999 submittal.

EPA found the January 12, 1999 submittal of SCAQMD Rule 401, Visible

[1] The State has recently changed the names and boundaries of the air basins located within the Southeast Desert Modified AQMA. Pursuant to State regulation the Coachella-San Jacinto Planning Area is now part of the Salton Sea Air Basin (17 Cal. Code. Reg. § 60114); the Victor Valley/Barstow Region in San Bernardino County and the Antelope Valley Region in Los Angeles County are a part of the Mojave Desert Air Basin (17 Cal. Code. Reg. § 60109). In addition, in 1996 the California Legislature established a new local air agency, the Antelope Valley Air Pollution Control District, to have the responsibility for local air pollution planning and measures in the Antelope Valley Region (California Health & Safety Code § 40106).

Emissions, to be complete on March 19, 1999, pursuant to EPA's completeness criteria that are set forth in 40 CFR part 51, Appendix V.[2]

The submitted version of SCAQMD Rule 401 includes the following revisions to the version of Rule 401 approved into the federally enforceable SIP in 1985:

- Adds temporary provision that establishes Ringelmann 2 standard for commercial underfired charbroilers
- Adds operational requirements for diesel pile-driving hammers subject to Ringelmann 2 versus Ringelmann 1 standard
- Adds exemption for visible emission generating equipment used in training visible emission evaluators
- Adds exemption for ships performing emergency boiler shutdowns, tests required by governmental agencies, or maneuvers for safety purposes
- Adds exemption for agricultural operations

The following provides a brief discussion of EPA's evaluation of SCAQMD Rule 401. A more detailed discussion of EPA's evaluation of the submitted rule can be found in the Technical Support Document (November 1999), which is available from the EPA Region IX office.

III. EPA's Analysis of State's Submittal

In determining the approvability of a submitted rule, EPA must evaluate the rule for consistency with the requirements of the CAA and EPA regulations, as found in section 110 and part D of the CAA and 40 CFR part 51 (Requirements for Preparation, Adoption, and Submittal of Implementation Plans). These provisions require that submitted rules are enforceable and strengthen or maintain the SIP's control strategy.

EPA has evaluated SCAQMD Rule 401, Visible Emissions, as submitted on January 12, 1999, against the relevant requirements of the CAA and federal regulations. EPA has interpreted some aspects of the CAA and regulations in policy and guidance. EPA has identified several deficiencies with the State's submittal, as follows:

A. The State Has Not Demonstrated Compliance With Section 193 of the CAA

For SIP provisions which EPA approved before November 15, 1990, section 193 prohibits SIP modifications applicable within a nonattainment area unless the modification ensures equivalent or greater emissions reductions of the pollutant for which the area is designated nonattainment.

EPA approved an earlier version of SCAQMD Rule 401 as part of the SIP in 1985, prior to the enactment of the 1990 amendments to the Act (i.e., prior to November 15, 1990). SCAQMD has jurisdiction over the South Coast Air Basin and the Coachella Valley Planning Area, which are serious nonattainment areas for PM–10. Thus, the prohibition in section 193 applies to Rule 401.

SCAQMD states, in documents accompanying the 1999 submittal of Rule 401, that the revisions to the rule would have no net effect on emissions of particulate matter. However, SCAQMD does not provide an analyis or any data to support this conclusion, and EPA does not agree with SCAQMD's conclusion with regard to the new exemption for agricultural operations. Under submitted Rule 401, agricultural sources which were subject to a 20% opacity limit are no longer subject to any visible emissions standard and may now emit up to 100% opacity.

Increases in visible emissions correlate to increases in particulate matter emissions. Therefore, particulate matter emissions would likely increase from agricultural operations. For this reason, SCAQMD has failed to show that the SIP revision will insure equivalent or greater reductions of PM–10 as required by section 193 of the CAA.

B. The State Has Not Demonstrated Compliance With Section 110(l) of the CAA

Section 110(l) of the Act provides that EPA cannot approve a revision to a SIP if the revision would interfere with any applicable requirement concerning attainment and reasonable further progress, or any other applicable requirement of the Act. Section 110(l) applies to SIP revisions affecting both attainment or unclassifiable areas, as well as nonattainment areas.

As discussed above, the revisions to SCAQMD Rule 401, particularly the new exemption for agricultural operations, would likely allow increased particulate matter emissions into the air. Therefore, EPA cannot approve the revisions to Rule 401 unless SCAQMD provides an adequate demonstration that the SIP revisions will not interfere with attainment of the NAAQS or any other applicable requirement of the Act.

C. The SIP Revision Does Not Meet the Requirements of Section 189 of the CAA

Section 189(a) of the CAA requires moderate PM–10 nonattainment areas to adopt reasonably available control measures (RACM), including reasonably available control technology (RACT) for stationary sources of PM–10. Section 189(b) of the CAA requires serious nonattainment areas to adopt best available control measures (BACM), including best available control technology (BACT).

As a serious PM–10 nonattainment area, SCAQMD must apply the requirements for RACT and BACT to stationary sources of PM–10. EPA believes that the requirement to implement RACT and BACT would preclude broadly exempting agricultural sources of particulate matter from visible emissions limits, where such exemption would likely result in increased particulate matter emissions. Therefore, EPA finds the submitted revisions to SCAQMD Rule 401 to be inconsistent with the requirements of CAA section 189.

III. Proposed Action

For the reasons discussed above, EPA is proposing to disapprove California's January 12, 1999 submittal of SCAQMD Rule 401, Visible Emissions. The effect of this action, once final, will be that the version of Rule 401 that was approved by EPA into the SIP in 1985 will remain in the federally enforceable SIP. Specifically, this means that agricultural operatons will be subject to federally enforceable 20% opacity limits. Because the 1985 SIP-approved Rule 401 will remain federally enforceable, this disapproval action does not trigger sanctions or FIP clocks under section 179 of the CAA.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

V. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this proposed regulatory action from Executive Order 12866, Regulatory Planning and Review.

B. Executive Order 13132

Federalism (64 FR 43255, August 10, 1999) revokes and replaces Executive Order 12612, Federalism, and Executive

[2] EPA adopted the completeness criteria on February 16, 1990 (55 FR 5830) and, pursuant to section 110(k)(1)(A) of the CAA, revised the criteria on August 26, 1991 (56 FR 42216).

Order 12875, Enhancing the Intergovernmental Partnership. Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in Executive Order 13132 to include regulations that 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.'' Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This proposed rule 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. Thus, the requirements of section 6 of Executive Order 13132 do not apply to this rule.

C. Executive Order 13045

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. This rule is not subject to Executive Order 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

D. Executive Order 13084

Under Executive Order 13084, Consultation and Coordination with Indian Tribal Governments, 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 proposed rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This proposed rule will not have a significant impact on a substantial number of small entities because disapprovals of SIP revisions under section 110 and subchapter I, part D of the Clean Air Act do not affect any existing requirements applicable to small entities. Any existing Federal requirements will remain in place. Federal disapproval of the State SIP submittal will not affect State-enforceability. Moreover, EPA's disapproval of the submittal would not impose any new Federal requirements. Therefore, I certify that this action will not have a significant economic impact on a substantial number of small entities.

F. 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 annual costs to State, local, or tribal governments in the aggregate; or to 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 proposed disapproval action does not include a Federal mandate that may result in estimated annual costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. The proposed disapproval will not change existing requirements and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this proposed action.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

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

Dated: November 24, 1999.

Laura Yoshii,

Deputy Regional Administrator, Region IX.

[FR Doc. 99–32076 Filed 12–9–99; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 68c

RIN 0925–AA19

National Institutes of Health Contraception and Infertility Research Loan Repayment Program

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice of proposed rulemaking.