October 15, 1998, the comment period on a proposal rule that was published in the **Federal Register** of May 22, 1998 (63 FR 28301). The document proposed to amend the drug and biologics regulations by adding provisions that would clarify the evaluation and approval of in vivo radiopharmaceuticals used in the diagnosis or monitoring of diseases. The agency is taking this action to provide interested persons additional time to submit comments to FDA on the proposed rule.

DATES: Written comments by October 15, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Dano B. Murphy, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210, or Brian L. Pendleton, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5649.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 22, 1998 (63 FR 28301), FDA published a proposed rule to amend the drug and biologics regulations by adding provisions that would clarify the evaluation and approval of in vivo radiopharmaceuticals used in the diagnosis and monitoring of diseases. The proposed regulations would describe certain types of indications for which FDA may approve diagnostic radiopharmaceuticals. The proposed rule would also include criteria that the agency would use to evaluate the safety and effectiveness of a diagnostic radiopharmaceutical under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. Interested persons were given until August 5, 1998, to submit comments on the proposed rule. Due to the technical nature of the proposed rule, FDA has decided to extend the comment period until October 15, 1998, to allow interested persons additional time to submit comments on the proposed rule.

Interested persons may, on or before October 15, 1998, submit to the Dockets Management Branch (address above) written comments regarding this proposed rule. Two copies of any comments are to be submitted, except 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.

Dated: July 28, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–20596 Filed 7–31–98; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 095–0083; FRL–6133–7]

Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision, Ventura County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing a limited approval and limited disapproval of revisions to the California State Implementation Plan (SIP) which concern the control of the sulfur content of fuels within the Ventura County Air Pollution Control District.

The intended effect of proposing limited approval and limited disapproval of this rule is to regulate emissions of sulfur dioxide (SO_2) in accordance with the requirements of the Clean Air Act, as amended in 1990 (CAA or the Act). EPA's final action on this proposed rule will incorporate it into the federally approved SIP. EPA has evaluated the rule and is proposing a simultaneous limited approval and limited disapproval under provisions of the CAA regarding EPA action on SIP submittals and general rulemaking authority because these revisions, while strengthening the SIP, also do not fully meet the CAA provisions regarding plan submissions.

DATES: Comments must be received on or before September 2, 1998.

ADDRESSES: Comments may be mailed to: Andrew Steckel, Rulemaking Office [AIR–4], Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Copies of the rule and EPA's evaluation report of the rule is available for public inspection at EPA's Region IX office during normal business hours. Copies of the submitted rule are also available for inspection at the following locations:

Environmental Protection Agency, Air Docket, 401 ''M'' Street, SW., Washington, DC 20460.

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

Ventura County Air Pollution Control District, 669 County Square Drive, Ventura, CA 93003.

FOR FURTHER INFORMATION CONTACT: Stanley Tong, Rulemaking Office, [AIR–4], Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901; Telephone: (415) 744–1191.

SUPPLEMENTARY INFORMATION:

I. Applicability

The rule being proposed for approval into the California SIP is Ventura County Air Pollution Control District (VCAPCD) Rule 64, Sulfur Content of Fuels. This rule was submitted by the California Air Resources Board (CARB) to EPA on July 13, 1994.

II. Background

40 CFR 81.305 provides the attainment status designations for air districts in California. Ventura County Air Pollution Control District is listed as being in attainment for the national ambient air quality standards for sulfur dioxide (SO_2). Sulfur dioxide is formed by the combustion of fuels containing sulfur compounds.

VCAPCD adopted Rule 64, Sulfur Content of Fuels, on June 14, 1994. On July 13, 1994 the State of California submitted many rules for incorporation into its SIP, including the rule being acted on in this document. VCAPCD Rule 64 was found to be complete on September 12, 1994 pursuant to EPA's completeness criteria that are set forth in 40 CFR part 51, appendix V [1] and is being proposed for limited approval and limited disapproval. The following is EPA's evaluation and proposed action for this rule.

III. EPA Evaluation and Proposed Action

In determining the approvability of an SO_2 rule, EPA must evaluate the rule for consistency with the requirements of the CAA and EPA regulations, as found in section 110 and 40 CFR part 51 (Requirements for Preparation, Adoption, and Submittal of Implementation Plans).

While the VCAPCD is in attainment with the SO_2 NAAQS, many of the

[1] EPA adopted completeness criteria on February 16, 1990 (55 FR 5824) and, pursuant to section 110(k)(1)(A) of the CAA, revised the criteria on August 26, 1991 (56 FR 42216).

general SIP requirements regarding enforceability, for example, are still appropriate for the rule. In determining the approvability of this rule, EPA evaluated it in light of the ''SO_2 Guideline Document'', EPA–452/R–94–008.

On April 17, 1987, EPA approved into the SIP a version of Rule 64, Sulfur Content of Fuels, that had been adopted by the VCAPCD on July 5, 1983. VCAPCD submitted an amendment to Rule 64 on July 13, 1994 which includes the following significant changes from the current SIP:

- Adds a section on applicability of the rule.
- Adds a section on test methods for determining the sulfur content of fuels.
- Removes incineration of waste gases whose gross heating value is less than 300 BTUs per cubic foot from the list of exemptions to Rule 64.
- Exempts flare gas combustion and places it under the requirements of Rule 54: Sulfur Compounds.

EPA has evaluated VCAPCD's submitted Rule 64 for consistency with the CAA, EPA regulations, and EPA policy and has found that the revisions result in a clearer, more enforceable rule. Although VCAPCD's Rule 64 will strengthen the SIP, this rule contains the following deficiency which should be corrected.

- The rule does not explicitly state those records which sources are required to keep on site and made available to inspectors to assess compliance. The rule also does not state the minimum length of time for retaining data on site.

A detailed discussion of the rule deficiency can be found in the Technical Support Document for Rule 64 (7/1/98), which is available from the U.S. EPA, Region IX office. Because of this deficiency, the rule is not approvable and may lead to rule enforceability problems.

Because of the above deficiency, EPA cannot grant full approval of this rule under section 110(k)(3). Also, because the submitted rule is not composed of separable parts which meet all the applicable requirements of the CAA, EPA cannot grant partial approval of the rule under section 110(k)(3). However, EPA may grant a limited approval of the submitted rule under section 110(k)(3) in light of EPA's authority pursuant to section 301(a) to adopt regulations necessary to further air quality by strengthening the SIP. The approval is limited because EPA's action also contains a simultaneous limited disapproval. In order to strengthen the SIP, EPA is proposing a limited approval of VCAPCD Rule 64 under sections 110(k)(3) and 301(a) of the CAA. At the same time, EPA is also proposing a limited disapproval of this rule because it contains a deficiency. There will be no sanctions clock as VCAPCD is in attainment for SO_2.

It should be noted that the rule covered by this proposed rulemaking has been adopted by the VCAPCD and is currently in effect in the VCAPCD. EPA's final limited disapproval action will not prevent the VCAPCD or EPA from enforcing this rule.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any state 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.

IV. Administrative Requirements

A. Executive Orders 12866 and 13045

The Office of Management and Budget (OMB) has exempted this regulatory action from E.O. 12866 review.

The proposed 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. 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 sections 110 and 301, 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 flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its action 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).

C. 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 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 proposed 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 Federal requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

List of Subjects in 40 CFR Part 52

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

Authority: 42 U.S.C. 7401–7671q.

Dated: July 22, 1998.

Sally Seymour,

Acting Regional Administrator, Region IX.

[FR Doc. 98–20609 Filed 7–31–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL–6133–8]

Designation of Areas for Air Quality Planning Purposes: State of Idaho and the Fort Hall Indian Reservation and Clean Air Act Reclassification; Fort Hall Indian Reservation Particulate Matter Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).