

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice entitled “Standards for Future Opioid Analgesic Approvals and Incentives for New Therapeutics To Treat Pain and Addiction; Public Hearing” that appeared in the **Federal Register** of June 21, 2019. The document was published with incorrect presenter registration and slide deck submission deadlines. This document corrects those deadlines.

FOR FURTHER INFORMATION CONTACT: Nicole Zelenak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6429, Silver Spring, MD 20993-0002, 301-796-9030.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Friday, June 21, 2019 (84 FR 29112), in FR Doc. 2019-13219, on page 29114, the following correction is made:

On page 29114, in the first column, in the “Presenter” bulleted paragraph, the fourth and fifth sentences “Presenters must register no later than August 9, 2019. Slide decks are due to *CDER-PublicMeeting@fda.hh.gov* in PDF or PowerPoint format no later than August 23, 2019.” are corrected to read “Presenters must register no later than September 6, 2019. Slide decks are due to *CDER-PublicMeeting@fda.hh.gov* in PDF or PowerPoint format no later than September 6, 2019.”

Dated: August 16, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-18090 Filed 8-21-19; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R09-OAR-2018-0713; FRL-9998-36-Region 9]

Revisions to California State Implementation Plan; Antelope Valley Air Quality Management District and Ventura County Air Pollution Control District; Nonattainment New Source Review Requirements for the 2008 8-Hour Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve two state implementation plan (SIP) revisions submitted by the State of California addressing the nonattainment new source review (NNSR) requirements for the 2008 8-hour ozone National Ambient Air Quality Standards (NAAQS) and one SIP revision regarding a permit rule. These SIP revisions address the Antelope Valley Air Quality Management District (AVAQMD or District) and Ventura County Air Pollution Control District (VCAPCD or District) portions of the California SIP. This action is being taken pursuant to the Clean Air Act (CAA or “Act”) and its implementing regulations.

DATES: Any comments must arrive by September 23, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R09-OAR-2018-0713 at <https://www.regulations.gov>, or via email to R9AirPermits@epa.gov. For comments submitted at [Regulations.gov](https://www.regulations.gov), follow the online instructions for submitting comments. Once submitted, comments cannot be removed or edited from [Regulations.gov](https://www.regulations.gov). For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www2.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT: Manny Aquitania, EPA Region IX, 75 Hawthorne St., San Francisco, CA

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SUPPLEMENTARY INFORMATION:

Throughout this document, the terms “we,” “us,” and “our” refer to EPA.

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I. Background and Purpose

On May 10, 2019, EPA published a notice of proposed rulemaking regarding the NNSR requirements for the 2008 8-hour ozone NAAQS and one SIP revision regarding a permit rule. The EPA received one comment, stating that Section V, Incorporation by Reference of the proposed rule, contained a minor administrative error regarding what provisions were to be incorporated by reference. In response, Section V of today’s **Federal Register** notice now clearly states we are proposing to incorporate into the SIP Ventura County Rule 10, “Required Permits”.

On March 12, 2008, the EPA promulgated a revised 8-hour ozone NAAQS of 0.075 parts per million (ppm).¹ Upon promulgation of a new or revised NAAQS, the CAA requires the EPA to designate as nonattainment any area that is violating the NAAQS based on the three most recent years of ambient air quality data. The two California air districts that are subject to this action were designated nonattainment for the 2008 8-hour ozone NAAQS on April 30, 2012, using years 2009–2011 ambient air quality data.² At the time of designation, the AVAQMD was classified as a severe ozone nonattainment area as part of the Mojave Desert Air Basin and VCAPCD was classified as a serious ozone nonattainment area as part of the South Central Coast Air Basin.

¹ 73 FR 16436 (March 27, 2008).

² 77 FR 30088 (May 21, 2012).

On March 6, 2015, the EPA issued a final rule entitled, “Implementation of the 2008 National Ambient Air Quality Standards for Ozone: State Implementation Plan Requirements” (“SIP Requirements Rule”), which establishes the requirements and deadlines that state, tribal, and local air quality management agencies must meet as they develop implementation plans for areas where ozone concentrations exceed the 2008 8-hour ozone NAAQS.³ Based on the initial nonattainment designations for the 2008 8-hour ozone standard, each District was required to make a SIP revision addressing NNSR no later than July 20, 2015.⁴ This requirement may be met by submitting a SIP revision consisting of a new or

revised NNSR permit program, or an analysis demonstrating that the existing SIP-approved NNSR permit program meets the applicable 2008 ozone requirements and a letter certifying the analysis.

On February 3, 2017, the EPA issued a final rule entitled, “Findings of Failure to Submit State Implementation Plan Submittals for the 2008 Ozone National Ambient Air Quality Standards” (“FFS Rule”). The rule found that certain state and local air agencies, including the AVAQMD and VCAPCD, had failed to submit a SIP revision in a timely manner to satisfy specific New Source Review requirements that apply to nonattainment areas. The rule

established certain deadlines for the imposition of sanctions, if a state does not submit a timely SIP revision addressing the requirements for which the finding was made, and for the EPA to promulgate a federal implementation plan (FIP) to address any outstanding SIP requirements.

II. The State’s Submittal

A. What did the State submit?

Table 1 lists the dates the submitted 2008 Ozone Certification letters and permit rule addressed by this proposal were adopted by each air District and submitted by the California Air Resources Board (CARB), the agency responsible for California SIP submittals.

TABLE 1—SIP SUBMITTALS

District	Rule No.	Rule title	Adoption/ amend date	Submittal date
AVAQMD	N/A	2008 Ozone Certification	7/17/2018	8/31/2018
VCAPCD	N/A	2008 Ozone Certification	7/31/2018	8/31/2018
VCAPCD	10	Permits Required	4/13/2004	7/19/2004

On August 10, 2004, CARB’s July 19, 2004 submittal of VCAPCD’s Rule 10 was deemed to meet the completeness criteria in 40 CFR part 51, appendix V, which must be met before formal EPA review. On September 6, 2018, CARB’s August 31, 2018 submittal of AVAQMD’s and VCAPCD’s 2008 Certification letters were also deemed to meet the completeness criteria in 40 CFR part 51, appendix V.

B. What is the purpose of the submitted certification letters?

The submittal from each District is intended to satisfy the SIP Requirement Rule that requires states to make a SIP revision addressing NNSR and the FFS Rule that requires each District to make a SIP submittal by September 6, 2018. The SIP for each District currently contains approved NNSR permit programs based on their nonattainment classification for the 1997 8-hour ozone NAAQS. The submitted certification letters provide a mechanism for each District to satisfy the 40 CFR 51.1114 submittal requirements based on their 2008 8-hr ozone nonattainment designations. EPA’s analysis of how these SIP revisions address the NNSR requirements for the 2008 8-hour ozone NAAQS is provided below.

C. What is the purpose of the submitted permit rule?

The submittal of Rule 10 by the VCAPCD is intended to clarify the expiration date of a Part 70 permit. The District revised Section 3 of Rule 10, pertaining to the expiration of a “Permit to Operate” to clarify that a Part 70 permit does not expire annually. This revision clarifies that a Part 70 permit expires only if not renewed in accordance with the requirements of VCAPCD’s Rule 30, “Permit Renewal”.

III. Analysis of Nonattainment New Source Review Requirements

The minimum SIP requirements for NNSR permitting programs for the 2008 8-hour ozone NAAQS are contained in 40 CFR 51.165. These NNSR program requirements include those promulgated in the “Phase 2 Rule” implementing the 1997 8-hour ozone NAAQS⁵ and the SIP Requirements Rule implementing the 2008 8-hour ozone NAAQS. Under the Phase 2 Rule, the SIP for each ozone nonattainment area must contain NNSR provisions that: (1) Set major source thresholds for nitrogen oxides (NO_x) and volatile organic compounds (VOC) pursuant to 40 CFR 51.165(a)(1)(iv)(A)(1)(i)–(iv) and (2); (2) classify physical changes at a major

source if the change would constitute a major source by itself pursuant to 40 CFR 51.165(a)(1)(iv)(A)(3); (3) consider any significant net emissions increase of NO_x as a significant net emissions increase for ozone pursuant to 40 CFR 51.165(a)(1)(v)(E); (4) consider any increase of VOC emissions in extreme ozone nonattainment areas as significant net emissions increases and major modifications for ozone pursuant to 40 CFR 51.165(a)(1)(v)(F); (5) set significant emissions rates for VOC and NO_x as ozone precursors pursuant to 40 CFR 51.165(a)(1)(x)(A)–(C) and (E); (6) contain provisions for emissions reductions credits pursuant to 40 CFR 51.165(a)(3)(ii)(C)(1)–(2); (7) provide that the requirements applicable to VOC also apply to NO_x pursuant to 40 CFR 51.165(a)(8); and (8) set offset ratios for VOC and NO_x pursuant to 40 CFR 51.165(a)(9)(ii)–(iv). Under the SIP Requirements Rule, the SIP for each ozone nonattainment area designated nonattainment for the 2008 8-hour ozone NAAQS and designated nonattainment for the 1997 ozone NAAQS as of April 6, 2015, must also contain NNSR provisions that include the anti-backsliding requirements at 40 CFR 51.1105.

also revokes the 1997 ozone NAAQS and establishes anti-backsliding requirements.

⁴ 40 CFR 51.1114.

⁵ 70 FR 71612 (November 29, 2005).

³ 80 FR 12263 (March 6, 2015). The SIP Requirements Rule addresses a range of nonattainment area SIP requirements for the 2008 ozone NAAQS, including requirements pertaining to attainment demonstrations, reasonable further

progress (RFP), reasonably available control technology, reasonably available control measures, major new source review, emission inventories, and the timing of SIP submissions and of compliance with emission control measures in the SIP. The rule

A. Antelope Valley Air Quality Management District (AVAQMD)

The AVAQMD's longstanding SIP-approved NNSR program,⁶ established in Regulation XIII, "New Source Review," of the AVAQMD's Rules and Regulations, applies to the construction and modification of stationary sources, including major stationary sources in nonattainment areas under its jurisdiction. In addition, the District has submitted revisions to their NSR program that update and clarify certain provisions.⁷ The AVAQMD's submitted SIP revision includes a demonstration, consisting of a table listing each of the Phase 2 Rule and SIP Requirements Rule NNSR program requirements, and a citation to the specific provision of the SIP-approved or SIP-submitted rule satisfying the requirement. The submittal also includes a certification by the AVAQMD that the cited rules meet the federal NNSR requirements for the applicable ozone nonattainment designation. These documents are available in the docket for this action. EPA has reviewed the demonstration and cited program elements intended to meet the federal NNSR requirements and is proposing to approve the AVAQMD's submittal because the current SIP-approved or SIP-submitted NSR program contains all the Phase 2 Rule and SIP Requirements Rule NNSR program requirements for a severe ozone nonattainment area.

B. Ventura County Air Pollution Control District (VCAPCD)

The VCAPCD's longstanding SIP-approved NNSR program,⁸ established in Rules 26–26.11, applies to the construction and modification of stationary sources, including major stationary sources in nonattainment areas under its jurisdiction. The VCAPCD's submitted SIP revision includes a demonstration, consisting of a table listing each of the Phase 2 Rule and SIP Requirements Rule NNSR program requirements, and a citation to the specific provision of the rule satisfying the requirement. The submittal also includes a certification by the VCAPCD that the cited rules meet the federal NNSR requirements for the applicable ozone nonattainment designation. These documents are available in the docket for this action. The EPA has reviewed the

demonstration and cited program elements intended to meet the federal NNSR requirements and is proposing to approve the VCAPCD's submittal because the current SIP-approved NSR program contains all the Phase 2 Rule and SIP Requirements Rule NNSR program requirements for a serious ozone nonattainment area.

The EPA has determined that the revision to Rule 10 provides clarity pertaining to the expiration of permits issued by the District. Therefore, we find this revision acceptable for incorporation into the SIP by reference.

IV. Proposed Action and Public Comment

The EPA is proposing to approve SIP revisions addressing the NNSR requirements for the 2008 8-hour ozone NAAQS for the AVAQMD and VCAPCD, as well as VCAPCD Rule 10. In support of this proposed action, we have concluded that our approval would comply with section 110(l) of the Act because the submittals will not interfere with continued attainment of the NAAQS in each District. The EPA has concluded that the State's submission fulfills the 40 CFR 51.1114 revision requirement and meets the requirements of CAA section 110 and the minimum SIP requirements of 40 CFR 51.165. The intended effect of our proposed action is to approve the submitted certifications as meeting the applicable Phase 2 Rule requirements. If we finalize this action as proposed, our action would incorporate these certifications and Rule 10 into the federally-enforceable SIP and be codified through revisions to 40 CFR 52.220 (Identification of plan—in part).

We will accept comments from the public on this proposal until September 23, 2019.

In addition, the FFS Rule issued by the EPA on February 3, 2017, started an 18-month sanctions clock and a 24-month FIP clock.⁹ The 18-month sanctions clock was stopped upon receipt of California's SIP revisions and our determination that the submittals were complete. We determined the submittals for AVAQMD and VCAPCD were complete on September 6, 2018. The 24-month FIP clock will stop upon the effective date of our final approval.

V. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference

the VCAPCD rule listed in Table 1 of this preamble. The EPA has made, and will continue to make, this material available electronically through <https://www.regulations.gov> and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

VI. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, The EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using

⁶ 61 FR 64291 (December 4, 1996).

⁷ New Rule 1305—Emission Offsets was submitted to the EPA by CARB on October 30, 2001 and rule revisions were submitted on December 29, 2006.

⁸ 65 FR 76567 (December 7, 2000), 68 FR 9561 (February 28, 2003), 75 FR 1284 (January 11, 2010).

⁹ 82 FR 9158, (February 3, 2017).

practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

- In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

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

Dated: August 6, 2019.

Michael Stoker,

Regional Administrator, Region IX.

[FR Doc. 2019-17804 Filed 8-21-19; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R07-OAR-2019-0468; FRL-9998-40-Region 7]

Air Plan Approval; Iowa; Revisions to Regional Haze Plan and Visibility Requirements in Infrastructure State Implementation Plans for the 2006 PM_{2.5}, 2012 PM_{2.5}, 2010 NO₂, 2010 SO₂, 2008 Ozone, and 2015 Ozone NAAQS

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve Iowa's request on four actions regarding the Iowa State Implementation Plan (SIP). The four SIP actions relate to Iowa's Regional Haze Plan and infrastructure SIPs for the 2006 Fine Particulate Matter (PM_{2.5}), 2012 PM_{2.5}, 2010 Nitrogen Dioxide (NO₂), 2010 Sulfur Dioxide (SO₂), 2008 Ozone, and 2015 Ozone National Ambient Air Quality Standards (NAAQS).

DATES: Comments must be received on or before September 23, 2019.

ADDRESSES: You may send comments, identified by Docket ID No. EPA-R07-OAR-2019-0468 to <https://www.regulations.gov>. Follow the online instructions for submitting comments.

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received will be posted without change to <https://www.regulations.gov/>, including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the "Written Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Jed D. Wolkins, Environmental Protection Agency, Region 7 Office, Air Quality Planning Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219 at telephone number (913) 551-7588; email address wolkins.jed@epa.gov.

SUPPLEMENTARY INFORMATION: Throughout this document "we," "us," and "our" refer to EPA.

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- V. Statutory and Executive Order Reviews

I. Written Comments

Submit your comments, identified by Docket ID No. EPA-R07-OAR-2019-0468, at <https://www.regulations.gov>. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>.

II. What is being addressed in this document?

On May 14, 2019, the State of Iowa submitted a request to revise the State of Iowa's Regional Haze Plan, changing from reliance on the Clean Air Interstate Rule (CAIR) to reliance on the Cross State Air Pollution Rule (CSAPR) for certain regional haze requirements; removing EPA's Federal Implementation Plan (FIP) for reliance on CSAPR for certain regional haze requirements, converting EPA's limited approval/limited disapproval of Iowa's Regional Haze Plan for the first regional haze planning period to a full approval; and approving the states' submissions addressing the Clean Air Act (CAA or the Act) section 110(a)(2)(D)(i)(II) provision (prong 4) that prohibits emissions activity in one state from interfering with measures to protect visibility in another state of Iowa's infrastructure SIP submittals for the 2006 PM_{2.5}, 2012 PM_{2.5}, 2010 NO₂, 2010 SO₂, 2008 Ozone, and 2015 Ozone NAAQS. The EPA is proposing approve these requests.

A. Regional Haze SIPs and Their Relationship With CAIR and CSAPR

Section 169A(b)(2)(A) of the CAA requires states to submit Regional Haze SIPs that contain such measures as may be necessary to make reasonable progress towards the natural visibility goal at Class I areas, including a requirement that certain categories of existing major stationary sources built between 1962 and 1977 procure, install, and operate Best Available Retrofit Technology (BART) as determined by the state. Under the Regional Haze Rule (RHR), adopted in 1999, states are directed to conduct BART determinations for such "BART-eligible" sources that may be anticipated to cause or contribute to visibility impairment in a Class I area.¹ Rather than requiring source-specific BART controls, states also have the flexibility to adopt an emissions trading program or other alternative program as long as the alternative provides greater reasonable progress towards improving visibility than BART.² The EPA provided states with this flexibility in the 1999 RHR, and further refined the criteria for assessing whether an alternative program provides for greater reasonable progress in two subsequent rulemakings.³

The EPA demonstrated that CAIR would achieve greater reasonable

¹ See 64 FR 35714 (July 1, 1999).

² See 40 CFR 51.308(e)(2).

³ See 70 FR 39104 (July 6, 2005) and 71 FR 60612 (October 13, 2006).