

<https://www.fda.gov/media/70844/download>), accessed February 5, 2020.

8. FDA, Draft Guidance for Industry, “Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices,” February 2014 (available at <https://www.fda.gov/media/88031/download>), accessed February 5, 2020.
9. FDA, Draft Guidance for Industry, “Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices,” December 2011 (available at <https://www.fda.gov/media/82660/download>), accessed February 5, 2020.
10. Eguale, T., D.L. Buckeridge, A. Verma, et al., “Association of Off-Label Drug Use and Adverse Drug Events in an Adult Population,” *Journal of American Medical Association Internal Medicine*, 176(1):55–63, 2016.

List of Subjects

21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR parts 201 and 801 be amended as follows:

PART 201—LABELING

- 1. The authority citation for part 201 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 343, 351, 352, 353, 355, 358, 360, 360b, 360ccc, 360ccc–1, 360ee, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

- 2. Revise § 201.128 to read as follows:

§ 201.128 Meaning of intended uses.

The words *intended uses* or words of similar import in §§ 201.5, 201.115, 201.117, 201.119, 201.120, 201.122, and 1100.5 of this chapter refer to the objective intent of the persons legally responsible for the labeling of an article (or their representatives). The intent may be shown by such persons’ expressions, the design or composition of the article, or by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. Objective intent may be shown, for example, by circumstances in which the article is, with the knowledge of such persons or their representatives, offered or used for a purpose for which it is neither labeled nor advertised; provided, however, that

a firm would not be regarded as intending an unapproved new use for an approved drug based solely on that firm’s knowledge that such drug was being prescribed or used by health care providers for such use. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he or she received the article, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses.

PART 801—LABELING

- 3. The authority citation for part 801 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360d, 360i, 360j, 371, 374.

- 4. Revise § 801.4 to read as follows:

§ 801.4 Meaning of intended uses.

The words *intended uses* or words of similar import in §§ 801.5, 801.119, 801.122, and 1100.5 of this chapter refer to the objective intent of the persons legally responsible for the labeling of an article (or their representatives). The intent may be shown by such persons’ expressions, the design or composition of the article, or by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. Objective intent may be shown, for example, by circumstances in which the article is, with the knowledge of such persons or their representatives, offered or used for a purpose for which it is neither labeled nor advertised; provided, however, that a firm would not be regarded as intending an unapproved new use for an approved or cleared device based solely on that firm’s knowledge that such device was being prescribed or used by health care providers for such use. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he or she received the article, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses.

Dated: September 8, 2020.

Stephen M. Hahn,

Commissioner of Food and Drugs.

[FR Doc. 2020–20437 Filed 9–22–20; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2020–0418; FRL–10013–74–Region 9]

Air Quality Implementation Plan; California; Northern Sierra Air Quality Management District; Stationary Source Permits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the Northern Sierra Air Quality Management District (NSAQMD or “District”) portion of the California State Implementation Plan (SIP). In this action, we are proposing to approve a rule submitted by the NSAQMD that governs the issuance of permits for stationary sources, which focuses on the preconstruction review and permitting of major sources and major modifications under part D of title I of the Clean Air Act (CAA or “the Act”). We are taking comments on this proposal and a final action will follow.

DATES: Written comments must be received on or before October 23, 2020.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2020–0418 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 the disclosure of which 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 and multimedia submissions, and general guidance on making effective comments, please visit <https://www2.epa.gov/dockets/commenting-epa-dockets>. If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT:
Amber Batchelder, EPA Region IX, 75

Hawthorne St., San Francisco, CA 94105; by phone: (415) 947-4174, or by email to batchelder.amber@epa.gov.

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

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I. The State’s Submittal

A. What rule did the State submit?

Table 1 lists the rule addressed by this proposal, including the date on which it was adopted by the District and the date on which it was submitted to the EPA by the California Air Resources Board (CARB or “the State”). The Northern Sierra Air Quality Management District (NSAQMD) is the air pollution control agency for Nevada, Sierra, and Plumas Counties.

TABLE 1—SUBMITTED RULES

District	Rule No.	Rule title	Adopted	Submitted ¹
NSAQMD	428	NSR Requirements for New and Modified Major Sources in Non-attainment Areas.	11/25/19	02/19/20

For areas designated nonattainment for one or more National Ambient Air Quality Standards (NAAQS), the applicable SIP must include preconstruction review and permitting requirements for new or modified major stationary sources of such nonattainment pollutant(s) under part D of title I of the Act, commonly referred to as Nonattainment New Source Review (NNSR). The rule listed in Table 1 contains the District’s NNSR permit program applicable to new and modified major sources located in areas within the District that are designated nonattainment for any NAAQS for ozone or particulate matter equal to or less than 2.5 micrometers (PM_{2.5}).

We find that the submittal for Rule 428 meets the completeness criteria in 40 CFR part 51 Appendix V, which must be met before formal EPA review.

B. Are there other versions of this rule?

There are no previous versions of NSAQMD Rule 428 in the California SIP.

C. What is the purpose of the submitted rule?

NSAQMD Rule 428 is intended to address the CAA’s statutory and regulatory requirements for NNSR permit programs for major sources emitting nonattainment air pollutants and their precursors.

II. The EPA’s Evaluation

A. What is the background for this proposal?

Because a part of Nevada County (“the western part”) is a federal ozone nonattainment area and part of Plumas County (“the Portola area”) is a federal PM_{2.5} nonattainment area,² the CAA requires the NSAQMD to have a SIP-approved NNSR program for new and modified major sources in the ozone and PM_{2.5} nonattainment areas that are under its jurisdiction. Below, we provide the area’s nonattainment designation history for the ozone and PM_{2.5} NAAQS, which forms the basis for the District’s NNSR program needed to satisfy the NNSR requirements applicable to Serious ozone nonattainment areas and Moderate PM_{2.5} nonattainment areas.

On July 18, 1997, the EPA issued a final rule revising the primary and secondary NAAQS for ozone to establish new 8-hour standards of 0.08 ppm.³ On April 30, 2004, the EPA issued a final rule designating the western part of Nevada County as nonattainment for the 1997 8-hour ozone NAAQS.⁴ On May 14, 2012, this area was reclassified as Moderate nonattainment for the 1997 ozone

NAAQS.⁵ On December 3, 2012, the EPA issued a final rule that determined that the western part of Nevada County had attained the 1997 ozone NAAQS by the extended attainment date.⁶

On March 27, 2008, the EPA issued a final rule revising the NAAQS for ozone, reducing the standards to a level of 0.075 ppm.⁷ On May 21, 2012, the EPA issued a final rule designating the western part of Nevada County as nonattainment for the 2008 8-hour ozone NAAQS, with a Marginal classification.⁸ On May 4, 2016, the EPA issued a final rule that determined that the western part of Nevada County had not attained the 2008 ozone NAAQS by the attainment date and was therefore reclassified as a Moderate nonattainment area.⁹ On August 23, 2019, the EPA issued a final rule that determined that the western part of Nevada County had not attained the 2008 ozone NAAQS by the attainment date and was therefore reclassified as a Serious ozone nonattainment area.¹⁰

On October 26, 2015, the EPA issued a final rule revising the NAAQS for ozone, reducing the standards to a level of 0.070 ppm.¹¹ On June 4, 2018, the EPA issued a final rule designating the western part of Nevada County as nonattainment for the 2015 8-hour

¹ The submittal was transmitted to the EPA via a letter from CARB dated February 6, 2020.

² While the NSAQMD includes all of Nevada, Sierra, and Plumas Counties, only the western part of Nevada County is nonattainment for ozone, and only a specific part of Plumas County is nonattainment for PM_{2.5}. See 40 CFR part 81.305.

³ 40 CFR 50.10; see 62 FR 38856, 38894–38895.
⁴ 69 FR 23858, 23889.

⁵ 77 FR 28424; see also 77 FR 43521 (July 25, 2012); 40 CFR 81.305.

⁶ 77 FR 71551.

⁷ 40 CFR 50.15; see 73 FR 16436, 16511.

⁸ 77 FR 30088, 30103.

⁹ 81 FR 26697.

¹⁰ 84 FR 44238; see 40 CFR 81.305.

¹¹ 40 CFR 50.19; see 80 FR 65292, 65452–53.

ozone NAAQS, with a Moderate classification.¹²

On January 15, 2013, the EPA issued a final rule revising the NAAQS for PM_{2.5}, reducing the primary annual standard to 12.0 micrograms per cubic meter.¹³ On January 15, 2015, the EPA issued a final rule designating the Portola area as nonattainment for the 2012 primary annual PM_{2.5} NAAQS, with a Moderate classification.¹⁴

The designations of the western part of Nevada County as a federal ozone nonattainment area and the Portola area as a federal PM_{2.5} nonattainment area triggered the requirement for the NSAQMD to develop and submit an NNSR program to the EPA for approval into the California SIP.¹⁵ The District's NNSR program must satisfy the NNSR requirements applicable to Moderate PM_{2.5} nonattainment areas and Serious ozone nonattainment areas, as these are the highest PM_{2.5} and ozone nonattainment classifications to which the District is subject.¹⁶

On February 19, 2020, CARB submitted to the EPA for SIP approval, via correspondence dated February 6, 2020, NSAQMD Rule 428, "NSR Requirements for New and Modified Major Sources in Nonattainment Areas," which was adopted by the District on November 25, 2019.

B. How is the EPA evaluating the rule?

The EPA reviewed NSAQMD Rule 428 for compliance with CAA requirements for: (1) Stationary source preconstruction permitting programs as set forth in CAA part D, including CAA sections 172(c)(5) and 173; (2) the review and modification of major sources in accordance with 40 CFR 51.160–51.165 as applicable in Serious ozone and Moderate PM_{2.5} nonattainment areas; (3) the review of new major stationary sources or major modifications in a designated nonattainment area that may have an impact on visibility in any mandatory Class I Federal Area in accordance with 40 CFR 51.307; (4) SIPs in general as set forth in CAA section 110(a)(2), including 110(a)(2)(A) and

110(a)(2)(E)(i);¹⁷ and (5) SIP revisions as set forth in CAA section 110(l)¹⁸ and 193.¹⁹ Our review evaluated the submittals for compliance with the NNSR requirements applicable to nonattainment areas designated Serious for ozone and nonattainment areas designated Moderate for PM_{2.5}, and ensured that the submittals addressed the NNSR requirements for the 1997, 2008 and 2015 ozone NAAQS, and the 2012 Annual PM_{2.5} NAAQS.

C. Does the rule meet the evaluation criteria?

With respect to procedural requirements, CAA sections 110(a)(2) and 110(l) require that revisions to a SIP be adopted by the state after reasonable notice and public hearing. Based on our review of the public process documentation included in the February 19, 2020 submittal of NSAQMD Rule 428, we find that the NSAQMD has provided sufficient evidence of public notice, opportunity for comment and a public hearing prior to adoption and submittal of these rules to the EPA.

With respect to the substantive requirements found in CAA sections 172(c)(5) and 173, and 40 CFR 51.160–51.165, we have evaluated NSAQMD Rule 428 in accordance with the applicable CAA and regulatory requirements that apply to NNSR permit programs under part D of title I of the Act for all relevant ozone and PM_{2.5} NAAQS, including the 2015 ozone NAAQS. We find that NSAQMD Rule 428 satisfies these requirements as they apply to sources subject to NNSR permit program requirements for ozone nonattainment areas classified as Serious and PM_{2.5} nonattainment areas classified as Moderate. We have also determined that this rule satisfies the related visibility requirements in 40 CFR 51.307. In addition, we have determined that Rule 428 satisfies the requirement in CAA section 110(a)(2)(A) that requires regulations submitted to

the EPA for SIP approval to be clear and legally enforceable, and have determined that the submittal demonstrates in accordance with CAA section 110(a)(2)(E)(i) that the District has adequate personnel, funding, and authority under state law to carry out these proposed SIP revisions.

Our Technical Support Document, which can be found in the docket for this rule, contains a more detailed discussion of our analysis of Rule 428.

III. Proposed Action and Public Comment

As authorized in section 110(k)(3) of the Act, the EPA is proposing to approve the submitted rule because it fulfills all relevant CAA requirements. We have concluded that our approval of the submitted rule would comply with the relevant provisions of CAA sections 110(a)(2), 110(l), 172(c)(5), 173, and 193, and 40 CFR 51.160–51.165 and 40 CFR 51.307.

In support of this proposed action, we have concluded that our action would comply with section 110(l) of the Act because approval of NSAQMD Rule 428 will not interfere with any applicable requirement concerning attainment and reasonable further progress, or any other CAA applicable requirement. In addition, our approval of Rule 428 will not relax any pre-November 15, 1990 requirement in the SIP, and therefore changes to the SIP resulting from this action ensure greater or equivalent emission reductions of ozone, PM_{2.5}, and their respective precursors in the District; accordingly, we have concluded that our action is consistent with the requirements of CAA section 193.

If we finalize this action as proposed, our action will be codified through revisions to 40 CFR 52.220a (Identification of plan-in part).

We will accept comments from the public on this proposal until October 23, 2020.

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

¹² 83 FR 25776, 25788; see 40 CFR 81.305.

¹³ 40 CFR 50.18; see 78 FR 3086, 3277.

¹⁴ 80 FR 2206, 2218; see 40 CFR 81.305.

¹⁵ 40 CFR 51.1003(a)(1), 51.1100(o)(14), 51.1105(a) and (f), 51.1114, 51.1314. We note that, as a result of the EPA's determination that an area has attained a NAAQS by the attainment date, those SIP elements related to attaining the NAAQS are suspended for so long as the area continues to attain the standard; however, the requirement for an NNSR program is not one of the SIP elements suspended as a result of such a determination. See, e.g., 40 CFR 51.1118.

¹⁶ See 40 CFR 51.1003(a)(1), 51.1105(f), 51.1114.

¹⁷ CAA section 110(a)(2)(A) requires that regulations submitted to the EPA for SIP approval be clear and legally enforceable, and CAA section 110(a)(2)(E)(i) requires that states have adequate personnel, funding, and authority under state law to carry out their proposed SIP revisions.

¹⁸ CAA section 110(l) requires SIP revisions to be subject to reasonable notice and public hearing prior to adoption and submittal by states to EPA and prohibits EPA from approving any SIP revision that would interfere with any applicable requirement concerning attainment and reasonable further progress, or any other applicable requirement of the CAA.

¹⁹ CAA section 193 prohibits the modification of any SIP-approved control requirement in effect before November 15, 1990 in a nonattainment area, unless the modification ensures equivalent or greater emission reductions of the relevant pollutants.

V. Statutory and Executive Order Reviews

Under the CAA, 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 Act. Accordingly, this proposed action merely proposes to approve state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed 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);
- Is not an Executive Order 13771 (82 FR 9339, February 3, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- 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 disproportionate human health or environmental effects with practical, appropriate, 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, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

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

Dated: August 28, 2020.

John Busterud,

Regional Administrator, Region IX.

[FR Doc. 2020-19587 Filed 9-22-20; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS-R4-ES-2018-0062; FXES11130900000-189-FF0932000]

RIN 1018-BD02

Endangered and Threatened Wildlife and Plants; Removal of the Nashville Crayfish From the Federal List of Endangered and Threatened Wildlife

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; reopening of comment period and announcement of public hearing.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), proposed to remove the Nashville crayfish (*Orconectes shoupi*) from the Federal List of Endangered and Threatened Wildlife (List). This determination is based on the best available scientific and commercial data, which indicate that the threats to the species have been eliminated or reduced to the point that the species has recovered and no longer meets the definition of an endangered species or a threatened species under the Endangered Species Act of 1973, as amended (Act). We announced a 60-day public comment period on the proposed rule, ending January 27, 2020. We now reopen the public comment period on the proposed rule to allow all interested parties additional time to comment on the proposed rule. Comments

previously submitted need not be resubmitted and will be fully considered in preparation of the final rule. We also announce a public informational meeting and public hearing on the proposed rule.

DATES:

Written comments: The comment period on the proposed rule that published November 26, 2019 (84 FR 65098), is reopened. We will accept comments received or postmarked on or before October 23, 2020. Please note that comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. Eastern Time on the closing date, and comments submitted by U.S. mail must be postmarked by that date to ensure consideration.

Public informational meeting and public hearing: On October 8, 2020, we will hold a public informational meeting from 6 to 7 p.m., Central Time, followed by a public hearing from 7 to 8:30 p.m., Central Time.

ADDRESSES:

Availability of documents: You may obtain copies of the November 26, 2019, proposed rule and associated documents on the internet at <http://www.regulations.gov> under Docket No. FWS-R4-ES-2018-0062.

Written comments: You may submit written comments by one of the following methods:

(1) **Electronically:** Go to the Federal eRulemaking Portal: <http://www.regulations.gov>. In the Search box, enter FWS-R4-ES-2018-0062, which is the docket number for the proposed rule. Then, click on the Search button. On the resulting page, in the Search panel on the left side of the screen, under the Document Type heading, check the Proposed Rule box to locate this document. You may submit a comment by clicking on "Comment Now!" Please ensure you have found the correct document before submitting your comments. If your comments will fit in the provided comment box, please use this feature of <http://www.regulations.gov>, as it is most compatible with our comment review procedures. If you attach your comments as a separate document, our preferred file format is Microsoft Word. If you attach multiple comments (such as form letters), our preferred format is a spreadsheet in Microsoft Excel.

(2) **By hard copy:** Submit by U.S. mail to: Public Comments Processing, Attn: FWS-R4-ES-2018-0062, U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041-3803.