

Reason: The provision of law which “Marketing Exclusivity and Patent Provisions for Certain Antibiotic Drugs” (Proposed Rule) was intended to implement, section 125(d) of the Medicare Modernization Act (Public Law 105–115), was superseded by the enactment of Public Law 110–379 (S. 3560) on October 8, 2008, which included new provisions on marketing exclusivity and patent provisions for certain antibiotic drugs.

The withdrawal of the proposals identified in this document does not preclude the agency from reinstating rulemaking concerning the issues addressed in the proposals listed in the previous paragraphs. Should we decide to undertake such rulemakings in the future, we will re-propose the actions and provide new opportunities for comment. Furthermore, this notice is only intended to address the specific actions identified in this document, and not any other pending proposals that the agency has issued or is considering.

The agency notes that withdrawal of a proposal does not necessarily mean that the preamble statement of the proposal no longer reflects the current position of FDA on the matter addressed. You may wish to review the agency’s Web site (<http://www.fda.gov>) for any current guidance on the matter.

**III. Withdrawal of the Proposed Rules and ANPRM**

For the reasons described in this document, FDA is withdrawing the aforementioned proposed rules and ANPRM.

Dated: December 3, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

[EPA–R09–OAR–2008–0863; FRL–8751–5]

**Revisions to the California State Implementation Plan, Approval of the Ventura County Air Pollution Control District—Reasonably Available Control Technology Analysis**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to approve revisions to the Ventura County Air Pollution Control District (VCAPCD) portion of the California State Implementation Plan (SIP). These revisions concern the District’s analysis of whether its rules meet Reasonably Available Control Technology (RACT) under the 8-hour ozone National Ambient Air Quality Standard (NAAQS). We are approving the analysis under the Clean Air Act as amended in 1990 (CAA or the Act). We are taking comments on this proposal and plan to follow with a final action.

**DATES:** Any comments must arrive by January 12, 2009.

**ADDRESSES:** Submit comments, identified by docket number EPA–R09–OAR–2008–0863, by one of the following methods:

1. *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions.
2. *E-mail:* [steckel.andrew@epa.gov](mailto:steckel.andrew@epa.gov).
3. *Mail or deliver:* Andrew Steckel (Air-4), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

*Instructions:* All comments will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through <http://www.regulations.gov> or e-mail.

<http://www.regulations.gov> is an “anonymous access” system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send e-mail directly to EPA, your e-mail address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

*Docket:* The index to the docket for this action is available electronically at <http://www.regulations.gov> and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (e.g., copyrighted material), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

**FOR FURTHER INFORMATION CONTACT:** Stanley Tong, EPA Region IX, (415) 947–4122, [tong.stanley@epa.gov](mailto:tong.stanley@epa.gov).

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

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**I. The State’s Submittal**

*A. What document did the State submit?*

Table 1 lists the document addressed by this proposal with the date that it was adopted by the local air agency and submitted by the California Air Resources Board.

**TABLE 1—SUBMITTED DOCUMENT**

Local agency	Document	Adopted	Submitted
VCAPCD .....	2006 Reasonably Available Control Technology Analysis .....	06/27/06	01/31/07

This submittal became complete by operation of law on July 31, 2007.

*B. Are there other versions of this document?*

There is no previous version of this document in the SIP.

*C. What is the purpose of the submitted RACT SIP analysis?*

VOCs and NO<sub>x</sub> help produce ground-level ozone and smog, which harm human health and the environment. Section 110(a) of the CAA requires States to submit regulations that control VOC and NO<sub>x</sub> emissions. Section 172(c)(1) and 182 require areas that are designated as moderate or above for ozone non-attainment to adopt RACT. The VCAPCD falls under this requirement as it is designated as a moderate ozone non-attainment area under the 8-hour NAAQS for ozone (40 CFR 81.305; 69 FR 23858, at 23889, April 30, 2004). On May 20, 2008, EPA granted California's request for voluntary reclassification of the Ventura County ozone non-attainment area from "moderate" to "serious". (73 FR 29073). Therefore, under both the 2004 classification as a moderate ozone non-attainment area, and the 2008 reclassification as a serious ozone non-attainment area, the VCAPCD must, at a minimum, adopt RACT-level controls for sources covered by a Control Techniques Guidelines (CTG) document and for any major non-CTG source. EPA evaluated VCAPCD's submittal based on a moderate ozone non-attainment area classification since the District adopted its 2006 certification based on this classification. We note, however, that the VCAPCD still has an obligation to submit a RACT SIP certification for the serious classification.

Section IV.G. of EPA's final rule to implement the 8-hour ozone NAAQS (70 FR 71612, November 29, 2005) discusses RACT requirements. It states in part that where a RACT SIP is required, State SIPs implementing the 8-hour standard generally must assure that RACT is met, either through a certification that previously required RACT controls represent RACT for 8-hour implementation purposes or through a new RACT determination.

The submitted document provides VCAPCD's analysis of their RACT rules for the 8-hour NAAQS for ozone. EPA's technical support document (TSD) has more information about VCAPCD's RACT analysis.

**II. EPA's Evaluation and Action**

*A. How is EPA evaluating the RACT SIP analysis?*

Rules, guidance and policy documents that we use to evaluate whether the analysis fulfills RACT include the following:

1. Final Rule to Implement the 8-Hour Ozone National Ambient Air Quality Standard (70 FR 71612; November 29, 2005).

2. Letter from William T. Harnett to Regional Air Division Directors, (May 18, 2006), "RACT Qs & As—Reasonably Available Control Technology (RACT) Questions and Answers".

3. State Implementation Plans, General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990 (57 FR 13498; April 16, 1992).

4. RACT SIPs, Letter dated March 9, 2006 from EPA Region IX (Andrew Steckel) to CARB (Kurt Karperos) describing Region IX's understanding of what constitutes a minimally acceptable RACT SIP.

5. RACT SIPs, Letter dated April 4, 2006 from EPA Region IX (Andrew Steckel) to CARB (Kurt Karperos) listing EPA's current CTGs, ACTs, and other documents which may help to establish RACT.

6. Comment letter dated June 5, 2006 from EPA Region IX (Andrew Steckel) to VCAPCD (Chuck Thomas) on the 8-hour Ozone Reasonably Available Control Technology—State Implementation Plan (RACT SIP) Analysis, draft staff report dated May 2006.

*B. Does the analysis meet the evaluation criteria?*

VCAPCD's staff report included a listing of all CTG source categories and matched those categories with the corresponding District rule which implemented RACT. Given its designation as a moderate ozone non-attainment area, VCAPCD was also

required to analyze RACT for all sources that emit or have the potential to emit at least 100 tons per year (tpy) of VOC or NO<sub>x</sub>. VCAPCD staff searched their permitting database for all facilities that emitted at least 25 tpy of VOC or NO<sub>x</sub>, identified approximately 27 such facilities, and listed them in Table B of their staff report. Table B also provides a matrix of the major sources of VOC and NO<sub>x</sub> emissions in Ventura County and the district rules applicable to those facilities. We reviewed the California Air Resources Board's (CARB) emissions database and did not identify any major sources in VCAPCD for which there was no corresponding District rule. Generally, VCAPCD's certification is based on the District's conclusion that District rules met RACT because their rule development process requires them to analyze CARB and EPA publications, including CTGs, to assess the feasibility and the cost of control techniques, and California State regulations require them to apply RACT and Best Available Retrofit Technology (BARCT) because VCAPCD is classified as a severe ozone non-attainment area for the State ozone standard. Based on a comparison of a sampling of VCAPCD's rules with rules in other air districts and States, we conclude that the VCAPCD rules meet RACT.

Table A-2 of VCAPCD's staff report includes a listing of source categories and CTG/ACTs for which there are no applicable District Rules and no stationary sources within the District. The table lists not only CTGs, but also ACTs and other documents relevant to establishing RACT at major sources. Negative declarations are only required for CTG source categories for which the District has no sources covered by the CTGs. A negative declaration is not required for ACTs or for major non-CTG source categories. Table 1 below lists the CTG source categories that remain after excluding the ACTs and non-CTG source categories from VCAPCD's Table A-2. EPA is acting on the negative declarations listed in Table 1 below instead of VCAPCD's Table A-2 which includes both CTGs and non-CTG source categories.

TABLE 1—VCAPCD NEGATIVE DECLARATIONS

CTG source category	CTG reference document
Automobile Coatings; Metal Coil, Container, and Closure.	EPA-450/2-77-008—Control of Volatile Organic Emissions from Existing Stationary Sources—Volume II: Surface Coating of Cans, Coils, Paper, Fabrics, Automobiles, and Light-Duty Trucks.
Wood Coating .....	EPA-450/2-78-032—Control of Volatile Organic Emissions from Existing Stationary Sources, Volume VII: Factory Surface of Flat Wood Paneling.
Large Appliances, Surface Coating .....	EPA-450/2-77-034—Control of Volatile Organic Emissions from Existing Stationary Sources, Volume V: Surface Coating of Large Appliances.

TABLE 1—VCAPCD NEGATIVE DECLARATIONS—Continued

CTG source category	CTG reference document
Magnetic Wire .....	EPA-450/2-77-033—Control of Volatile Organic Emissions from Existing Stationary Sources, Volume IV: Surface Coating of Insulation of Magnet Wire.
Synthetic Organic Chemical .....	EPA-450/3-84-015—Control of VOC Emissions from Air Oxidation Processes in Synthetic Organic Manufacturing Industry. EPA-450/4-91-031—Control of VOC Emissions from Reactor Processes and Distillation Operations in SOCM.
Pharmaceutical Products .....	EPA-450/2-78-029—Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products.
Rubber Tires .....	EPA-450/2-78-030—Control of Volatile Organic Emissions from Manufacture of Pneumatic Rubber Tires.
Polyester Resin .....	EPA-450/3-83-006—Control of VOC Fugitive Emissions from Synthetic Organic Chemical Polymer and Resin Manufacturing Equipment. EPA-450/3-83-008—Control of VOC Emissions from Manufacture of High-Density Polyethylene, Polypropylene, and Polystyrene Resins.

VCAPCD's staff report indicates the District has a large agricultural industry and that agricultural pesticide use is a substantial source of VOCs in the county. The District points out, however, that agricultural pesticide usage is regulated by the State of California and not under the District's jurisdiction. EPA agrees the California Department of Pesticide Regulation (DPR), and not the VCAPCD, has jurisdiction over pesticide regulations in California. VCAPCD is not required, therefore, to adopt RACT rules for these activities.

VCAPCD's RACT SIP analysis was made available for public comment prior to being adopted by the District. The District did not receive any public comments during the public comment period. We propose to find that the RACT SIP analysis performed by the VCAPCD is reasonable and demonstrates their rules meet RACT. We also propose to find that the analysis is consistent with the CAA, EPA regulations and the relevant policy and guidance documents listed above. The TSD has more information on our evaluation.

#### C. EPA Recommendation To Strengthen the SIP

The TSD describes recommendations for further strengthening the VCAPCD SIP by reviewing and tightening controls in the following rules as appropriate: Rule 71.3, "Transfer of Organic Reactive Compound Liquids"; Rule 74.26, Crude Oil Storage, Degassing Operations; and Rule 74.27, Gasoline and ROC Liquid Storage Tank Degassing Operations.

EPA further notes that due to the recent reclassification of VCAPCD to a serious ozone non-attainment area, it will need to certify in a future action that District rules meet CTGs issued since 2006.

#### D. Public Comment and Final Action

Because EPA believes the submitted analysis fulfills all relevant requirements, we are proposing to fully approve it as described in section 110(k)(3) of the Act. We will accept comments from the public on this proposal for the next 30 days. Unless we receive convincing new information during the comment period, we intend to publish a final approval action that will incorporate this document into the federally enforceable SIP.

#### III. 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, 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 Order 12866 (58 FR 51735, October 4, 1993);
- 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 EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

#### List of Subjects in 40 CFR Part 52

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

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

Dated: November 20, 2008.

**Jane Diamond,**

*Acting Regional Administrator, Region IX.*

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