

paragraph (b)(2)(ii)(a) and by adding new paragraph (b)(2)(ii)(b) as follows:

§ 314.81 Other postmarketing reports.

* * * * *

(b) * * *

(2) * * *

(ii) * * *

(b) *Authorized generic drugs.* If applicable, the date each authorized generic drug (as defined in § 314.3) entered the market, the date each authorized generic drug ceased being distributed, and the corresponding trade or brand name. Each dosage form and/or strength is a different authorized generic drug and should be listed separately. The first annual report submitted on or after January 25, 2010 must include the information listed in this paragraph for any authorized generic drug that was marketed during the time period covered by an annual report submitted after January 1, 1999. If information is included in the annual report with respect to any authorized generic drug, a copy of that portion of the annual report must be sent to the Food and Drug Administration, Center for Drug Evaluation and Research, Office of New Drug Quality Assessment, Bldg. 21, rm. 2562, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, and marked "Authorized Generic Submission" or, by e-mail, to the Authorized Generics electronic mailbox at AuthorizedGenerics@fda.hhs.gov with "Authorized Generic Submission" indicated in the subject line. However, at such time that FDA has required that annual reports be submitted in an electronic format, the information required by this paragraph must be submitted as part of the annual report, in the electronic format specified for submission of annual reports at that time, and not as a separate submission under the preceding sentence in this paragraph.

* * * * *

Dated: April 7, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9-17963 Filed 7-27-09; 8:45 am]

BILLING CODE 4160-01-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R04-OAR-2009-0303(a); FRL-8936-2]

Approval and Promulgation of Implementation Plans; South Carolina; Transportation Conformity Memorandum of Agreement Update

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve a revision to the South Carolina State Implementation Plan (SIP) submitted on November 28, 2008, through the South Carolina Department of Health and Environmental Control (SC DHEC). This revision consists of transportation conformity criteria and procedures related to interagency consultation and enforceability of certain transportation-related control measures and mitigation measures. The intended effect of this approval is to update the transportation conformity criteria and procedures in the South Carolina SIP.

DATES: This direct final rule is effective September 28, 2009 without further notice, unless EPA receives adverse comment by August 27, 2009. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R04-OAR-2009-0303, by one of the following methods:

a. <http://www.regulations.gov>: Follow the on-line instructions for submitting comments.

b. *E-mail:* Wood.amanetta@epa.gov.

c. *Fax:* (404) 562-9019.

d. *Mail:* EPA-R04-OAR-2009-0303, Air Quality Modeling and Transportation Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960.

e. *Hand Delivery or Courier:* Amanetta Wood, Air Quality Modeling and Transportation Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960. Such deliveries are only accepted during the Regional Office's normal hours of

operation. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA-R04-OAR-2009-0303. EPA's policy is that all comments received 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 information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through <http://www.regulations.gov> or e-mail, information that you consider to be CBI or otherwise protected. The <http://www.regulations.gov> Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through <http://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. 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. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

Docket: All documents in the electronic docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at the Air Quality Modeling and Transportation Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960. EPA

requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Amanetta Wood, Air Quality Modeling and Transportation Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960. Ms. Wood's telephone number is 404-562-9025. She can also be reached via electronic mail at Wood.amanetta@epa.gov.

SUPPLEMENTARY INFORMATION:

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I. Transportation Conformity

Transportation conformity (hereafter referred to as "conformity") is required under section 176(c) of the Clean Air Act ("CAA" or "Act") to ensure that Federally supported highway, transit projects, and other activities are consistent with ("conform to") the purpose of the SIP. Conformity currently applies to areas that are designated nonattainment, and to areas that have been redesignated to attainment after 1990 (maintenance areas) with plans developed under section 175A of the Act, for the following transportation related criteria pollutants: Ozone, particulate matter (e.g., PM_{2.5} and PM₁₀), carbon monoxide, and nitrogen dioxide.

Conformity to the purpose of the SIP means that transportation activities will not cause new air quality violations, worsen existing violations, or delay timely attainment of the relevant criteria pollutants, also known as national ambient air quality standards (NAAQS). The conformity regulation is found in 40 CFR part 93 and provisions related to conformity SIPs are found in 40 CFR 51.390.

II. Background for This Action

A. Federal Requirements

EPA promulgated the Federal transportation conformity criteria and procedures ("Conformity Rule") on November 24, 1993 (58 FR 62188). Among other things, the rule required

States to address all provisions of the conformity rule in their SIPs frequently referred to as "conformity SIPs." Under 40 CFR 51.390, most sections of the conformity rule were required to be copied verbatim. States were also required to tailor all or portions of the following three sections of the conformity rule to meet their State's individual circumstances: 40 CFR 93.105, which addresses consultation procedures; 40 CFR 93.122(a)(4)(ii), which addresses written commitments to control measures that are not included in a metropolitan planning organization's (MPO's) transportation plan and transportation improvement program that must be obtained prior to a conformity determination, and the requirement that such commitments, when they exist, must be fulfilled; and 40 CFR 93.125(c), which addresses written commitments to mitigation measures that must be obtained prior to a project-level conformity determination, and the requirement that project sponsors must comply with such commitments, when they exist.

On August 10, 2005, the "Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users" (SAFETEA-LU) was signed into law. SAFETEA-LU revised section 176(c) of the CAA transportation conformity provisions. One of the changes streamlines the requirements for conformity SIPs. Under SAFETEA-LU, States are required to address and tailor only three sections of the rule in their conformity SIPs: 40 CFR 93.105, 40 CFR 93.122(a)(4)(ii), and, 40 CFR 93.125(c), described above. In general, States are no longer required to submit conformity SIP revisions that address the other sections of the conformity rule. These changes took effect on August 10, 2005, when SAFETEA-LU was signed into law.

B. South Carolina Transportation Conformity SIP

Effective June 15, 2004, EPA designated Rock Hill, a portion of York County, as a nonattainment area for the 1997 8-hour ozone standard as part of the bi-State Charlotte-Gastonia-Rock Hill NC-SC nonattainment area. The current designation status for the bi-State Charlotte-Rock Hill Area for the 1997 8-hour ozone standard is nonattainment. See, 40 CFR 81 for more information on designations.

The Rock Hill-Fort Mill Area Transit Study (RFATS) is the MPO for the entire portion of York County that is included in the 1997 8-hour ozone area. Per the Transportation Conformity Rule, the MPO's conformity determination is not complete without a regional analysis

that considers the projects in the MPO area. For the purposes of 8-hour conformity, the RFATS MPO serves as the lead agency for the preparation, consultation, and distribution of the conformity determinations.

Previously, South Carolina had established a conformity SIP. In 2004, EPA approved the State of South Carolina's SIP revision which incorporated by reference 40 CFR 93 Subpart A, 67 FR 50808, and customized 40 CFR 93.105, 93.122(a)(4)(ii), and 93.125(c) for all of the MPOs in the entire State and for the South Carolina Department of Transportation (SC DOT). Specifically, the State of South Carolina established a Memorandum of Agreement (MOA) for implementing the conformity Criteria and Consultation Procedure for all transportation-related pollutants. The new conformity SIP (the subject of this rulemaking) removed any incorporation by reference and has revised the MOA to be consistent with the SAFETEA-LU revisions to the CAA (Pub. L. 109-59) and subsequent regulations published on January 24, 2008 (73 FR 4420). While South Carolina currently has only one nonattainment area (*i.e.* a portion of York County) for the 1997 standard its MOA covers all of the MPOs in the State should new areas become subject to conformity requirements for a transportation-related pollutant in the future.

The State of North Carolina will establish conformity procedures for the counties that make up the North Carolina portion of the bi-State Charlotte-Rock Hill nonattainment area in the individual conformity SIPs.

III. State Submittal and EPA Evaluation

On November 19, 2008, the State of South Carolina, through SC DHEC, submitted the Statewide conformity and consultation interagency SIP, based on an MOA signed by all of the MPOs in the State and SC DOT, to EPA as a revision to the SIP. The South Carolina conformity SIP establishes procedures for interagency consultation and supersedes the November 19, 2003, incorporation into the SIP of the MOA (which included previous procedures for interagency consultation). Prior to today, the MOA incorporated EPA regulations in 40 CFR 93 Subpart A (July 1, 1997), and 62 FR 43780 (August 15, 1997) by reference. The revision to the MOA that EPA is approving now no longer incorporates the Federal conformity rules by reference. Additionally, as was the case with the previous MOA, it applies to all counties in South Carolina.

The State of South Carolina developed its consultation SIP based on the elements contained in 40 CFR 93.105, 93.122(a)(4)(ii), and 93.125(c) and included it in the SIP. As a first step, the State worked with the existing transportation planning organization's interagency committees that included representatives from the SC DHEC; SC DOT; all of the MPOs in the State; Federal Highway Administration—South Carolina Division; Federal Transit Administration; and the Region 4 office of EPA. The interagency committee met regularly and drafted the consultation procedures considering elements in 40 CFR Part 93.105, 93.122(a)(4)(ii), and 93.125(c), and integrated the local procedures and processes into the MOA. The resulting consultation process developed is unique to the State of South Carolina. On April 28, 2008, SC DHEC held a public hearing for the transportation conformity MOA. The final MOA was issued by South Carolina on November 19, 2008, and subsequently submitted to EPA as a SIP revision.

EPA has evaluated this SIP revision and has determined that the State has met the requirements of Federal transportation conformity rules as described in 40 CFR Part 51, Subpart T and 40 CFR Part 93, Subpart A. SC DHEC has satisfied the public participation and comprehensive interagency consultation requirement during development and adoption of the MOA at the local level. Therefore, EPA is approving the MOA as a revision to the South Carolina SIP. EPA's rule requires the States to develop their own processes and procedures for interagency consultation among the Federal, State, and local agencies and resolution of conflicts meeting the criteria in 40 CFR 93.105. The SIP revision must include processes and procedures to be followed by the MPO, State DOT, and U.S. DOT in consulting with the State and local air quality agencies and EPA before making conformity determinations. The conformity SIP revision must also include processes and procedures for the State and local air quality agencies and EPA to coordinate the development of applicable SIPs with MPOs, State DOTs, and the U.S. DOT.

EPA has reviewed the submittal to assure consistency with the CAA as amended by SAFETEA-LU and EPA regulations (40 CFR part 93 and 40 CFR 51.390) governing State procedures for transportation conformity and interagency consultation and has concluded that the submittal is approvable. Details of our review are set forth in a technical support document

(TSD), which has been included in the docket for this action. Specifically, in the TSD, we identify how the submitted procedures satisfy our requirements under 40 CFR 93.105 for interagency consultation with respect to the development of transportation plans and programs, SIPs, and conformity determinations, the resolution of conflicts, and the provision of adequate public consultation, and our requirements under 40 CFR 93.122(a)(4)(ii) and 93.125(c) for enforceability of control measures and mitigation measures.

IV. Public Comment and Final Action

For the reasons set forth above, EPA is taking action under section 110 of the Act to approve the rule implementing the conformity criteria and consultation procedures revision to the South Carolina SIP pursuant to the CAA, as a revision to the South Carolina SIP. As a result of this action, South Carolina's previously SIP-approved conformity procedures for South Carolina 69 FR 4245, January 29, 2004, will be replaced by the procedures submitted to EPA on November 19, 2008 for approval and adopted by the State of South Carolina on November 28, 2008. This action also establishes consultation procedures for all counties in South Carolina.

EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should adverse comments be filed. This rule will be effective September 28, 2009 without further notice unless the Agency receives adverse comments by August 27, 2009.

If EPA receives such comments, then EPA will publish a document withdrawing the final rule and informing the public that the rule will not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period. Parties interested in commenting should do so at this time. If no such comments are received, the public is advised that this rule will be effective on September 28, 2009 and no further action will be taken on the proposed rule.

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, EPA's role is to approve State choices, provided that they meet the criteria of the CAA. 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 CAA; 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.

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the

agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 28, 2009. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition

for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the Proposed Rules section of today’s **Federal Register**; rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Intergovernmental relations, Incorporation by reference, Intergovernmental relations, Incorporation by reference, Nitrogen

dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: July 8, 2009.
Beverly H. Banister,
Acting Regional Administrator, Region 4.

■ 40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

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

Subpart (PP)—South Carolina

■ 2. Section 52.2120(e) is amended by adding a new entry at the end of the table for “Transportation Conformity SIP” to read as follows:

§ 52.2120 Identification of plan.

*	*	*	*	*
(e)	*	*	*	*

EPA-APPROVED SOUTH CAROLINA NON-REGULATORY PROVISIONS

Provision	State effective date	EPA approval date	Explanation
South Carolina Transportation Conformity Air Quality Implementation Plan.	11/28/2008	7/28/2009 [Insert citation of publication].

[FR Doc. E9-17818 Filed 7-27-09; 8:45 am]
BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R05-OAR-2008-0812, EPA-R05-OAR-2009-0292; FRL-8932-4]

Approval and Promulgation of Implementation Plans; Ohio; Volatile Organic Compound Emission Control Measures for Cleveland

AGENCY: Environmental Protection Agency (EPA).
ACTION: Final rule.

SUMMARY: EPA is approving several volatile organic compound (VOC) control rules that were submitted on September 4, 2008, and March 23, 2009, into the Ohio State Implementation Plan (SIP). The purpose of these rules is to satisfy the VOC reasonably available control technology (RACT) requirement for the Cleveland-Akron 8-hour ozone nonattainment area. These rules are approvable because they satisfy the control and enforceability requirements of RACT, including Ohio’s requirement

to adopt VOC RACT rules for the Control Technique Guideline (CTG) documents issued by EPA in 2006 and 2007. EPA proposed these rules for approval on May 7, 2009, and received no comments.

DATES: This final rule is effective on August 27, 2009.

ADDRESSES: EPA has established a docket for this action under Docket ID Nos. EPA-R05-OAR-2008-0812 and EPA-R05-OAR-2009-0292. All documents in the docket are listed on the <http://www.regulations.gov> Web site. Although listed in the index, some information is not publicly available, *i.e.*, Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through <http://www.regulations.gov> or in hard copy at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding

Federal holidays. We recommend that you telephone Steven Rosenthal, Environmental Engineer, at (312) 886-6052 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Steven Rosenthal, Environmental Engineer, Criteria Pollutant Section, Air Programs Branch (AR-18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886-6052, rosenthal.steven@epa.gov.

SUPPLEMENTARY INFORMATION: Throughout this document whenever “we,” “us,” or “our” is used, we mean EPA. This supplementary information section is arranged as follows:

- I. What Public Comments Were Received on the Proposed Approval and What Is EPA’s Response?
- II. What Action Is EPA Taking?
- III. What Is the Purpose of This Action?
- IV. Statutory and Executive Order Reviews

I. What Public Comments Were Received on the Proposed Approval and What Is EPA’s Response?

No comments were received.

II. What Action Is EPA Taking?

EPA is approving several revised and new VOC rules into the Ohio SIP.