

is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

List of Subjects in 21 CFR Part 514

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

Therefore under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 514 is amended as follows:

PART 514—NEW ANIMAL DRUG APPLICATIONS

■ 1. The authority citation for 21 CFR part 514 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 356a, 360b, 371, 379e, 381.

■ 2. In § 514.11, revise paragraphs (b), (d), (e) introductory text, and (e)(2)(ii) introductory text to read as follows:

§ 514.11 Confidentiality of data and information in a new animal drug application file.

* * * * *

(b) The existence of an NADA file will not be disclosed by the Food and Drug Administration before the application has been approved, unless it has been previously disclosed or acknowledged.

* * * * *

(d) If the existence of an NADA file has been publicly disclosed or acknowledged before the application has been approved, no data or information contained in the file is available for public disclosure, but the Commissioner may, in his discretion, disclose a summary of such selected portions of the safety and effectiveness data as are appropriate for public consideration of a specific pending issue, i.e., at an open session of a Food and Drug Administration advisory committee or pursuant to an exchange of important regulatory information with a foreign government.

(e) After an application has been approved, the following data and information in the NADA file are immediately available for public disclosure unless extraordinary circumstances are shown:

* * * * *

(2) * * *

(ii) For an NADA approved after July 1, 1975, a summary of such data and

information prepared in one of the following two alternative ways shall be publicly released when the application is approved.

* * * * *

Dated: March 7, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-05430 Filed 3-14-14; 8:45 am]

BILLING CODE 4160-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R06-OAR-2013-0439; FRL-9907-55-Region 6]

Approval and Promulgation of Air Quality Implementation Plans; Texas; Stage II Vapor Recovery Program and Control of Air Pollution From Volatile Organic Compounds

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving revisions to the Texas State Implementation Plan (SIP) that control emissions of volatile organic compounds (VOCs) at gasoline dispensing facilities (GDFs) in Texas. The revisions were submitted to the EPA by the Texas Commission on Environmental Quality (TCEQ) on October 31, 2013 and address the maintenance and removal of Stage II vapor recovery equipment at GDFs. The EPA is also approving related revisions to the Stage II SIP narrative that pertain to the maintenance and removal of Stage II vapor recovery equipment and demonstrate that the absence of Stage II equipment in the Beaumont-Port Arthur (BPA), Dallas-Fort Worth (DFW) and Houston-Galveston Brazoria (HGB) areas, and in El Paso County would not interfere with attainment of the national ambient air quality standards, reasonable further progress or any other requirement of the Clean Air Act (CAA or Act). The EPA is approving these revisions pursuant to sections 110 and 202 of the Act and consistent with the EPA's guidance.

DATES: This final rule is effective on April 16, 2014.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA-R06-OAR-2013-0439. 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, e.g., Confidential Business Information

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 Air Planning Section (6PD-L), Environmental Protection Agency, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202-2733. To inspect the hard copy materials, please schedule an appointment with the person listed in the **FOR FURTHER INFORMATION CONTACT** paragraph below or Mr. Bill Deese at 214-665-7253.

FOR FURTHER INFORMATION CONTACT: Ms. Carrie Paige, Air Planning Section (6PD-L); telephone (214) 665-6521; email address paige.carrie@epa.gov.

SUPPLEMENTARY INFORMATION: Throughout this document, “we,” “us,” and “our” means EPA.

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I. Background

The background for today's final rule is discussed in our December 30, 2013 proposal to approve revisions to the Texas SIP (78 FR 79340). In that action, we proposed to approve the Texas SIP revisions submitted by the TCEQ on October 31, 2013, which specify that new GDFs would not be required to install Stage II equipment and provide removal (decommissioning) procedures that existing GDFs in the 16 counties¹ must complete by August 31, 2018. The revisions to the Stage II SIP describe the removal of Stage II equipment at GDFs and require maintenance of the Stage II equipment until decommissioning occurs. The revisions to the SIP narrative also include a demonstration that the removal of, or failure to install, Stage II equipment in the 16 counties is consistent with section 110(l) of the Act which precludes approval of revisions to the SIP that contribute to nonattainment or interfere with maintenance of any National Ambient Air Quality Standard.

Our December 30, 2013 proposal provides a detailed description of the revisions and the rationale for EPA's proposed actions, together with a

¹ The four areas in Texas where Stage II is required comprise 16 counties: BPA, containing Hardin, Jefferson and Orange counties; DFW, involving Collin, Dallas, Denton and Tarrant counties; El Paso County; and HGB, containing Brazoria, Chambers, Fort Bend, Galveston, Harris, Liberty, Montgomery, and Waller counties.

discussion of the opportunity to comment. The public comment period for these actions closed on January 29, 2014. See the Technical Support Document in the docket for this rulemaking and our proposal at 78 FR 79340 for more information. We did not receive any comments regarding our proposal. Therefore, we are finalizing our action as proposed.

II. Final Action

The EPA is approving revisions to the Texas SIP that control emissions of VOCs and pertain to the maintenance and removal of Stage II vapor recovery equipment submitted on October 31, 2013. We are approving revisions to the following sections within 30 TAC 115: 115.240, 115.241, 115.242, 115.243, 115.244, 115.245, 115.246, 115.247, and 115.249. The EPA is also approving related revisions to the Stage II SIP narrative that address the maintenance and removal of Stage II equipment, and demonstrate that the removal of, or failure to install Stage II equipment in the BPA, DFW, and HGB areas, and in El Paso County, meets section 110(l) of the Act. The EPA is approving these revisions in accordance with sections 110 and 202 of the Act and consistent with the EPA's guidance.

III. 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 May 16, 2014. 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. 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, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: February 25, 2014.

Ron Curry,

Regional Administrator, Region 6.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart SS—Texas

- 2. In § 52.2270:
 - a. In paragraph (c) the table titled "EPA Approved Regulations in the Texas SIP" is amended by revising the entries for Sections 115.240—115.247 and Section 115.249.
 - b. In paragraph (e) the second table titled "EPA Approved Nonregulatory Provisions and Quasi-Regulatory Measures in the Texas SIP" is amended by adding a new entry to the end of the table for "Stage II Vapor Recovery Program SIP."

The revisions and additions read as follows:

§ 52.2270 Identification of plan.

*	*	*	*	*
(c)	*	*	*	

EPA APPROVED REGULATIONS IN THE TEXAS SIP

State citation	Title/subject	State approval/submittal date	EPA approval date	Explanation
* * * * *				
Section 115.240	Stage II Vapor Recovery Definitions and List of California Air Resources Board Certified Stage II Equipment.	10/9/2013	3/17/14 [Insert FR page number where document begins].	
Section 115.241	Emission Specifications	10/9/2013	3/17/14 [Insert FR page number where document begins].	
Section 115.242	Control Requirements	10/9/2013	3/17/14 [Insert FR page number where document begins].	
Section 115.243	Alternate Control Requirements	10/9/2013	3/17/14 [Insert FR page number where document begins].	
Section 115.244	Inspection Requirements	10/9/2013	3/17/14 [Insert FR page number where document begins].	
Section 115.245	Testing Requirements	10/9/2013	3/17/14 [Insert FR page number where document begins].	
Section 115.246	Recordkeeping Requirements	10/9/2013	3/17/14 [Insert FR page number where document begins].	
Section 115.247	Exemptions	10/9/2013	3/17/14 [Insert FR page number where document begins].	
* * * * *				
Section 115.249	Counties and Compliance Schedules.	10/9/2013	3/17/14 [Insert FR page number where document begins].	
* * * * *				

(e) * * *

EPA APPROVED NONREGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES IN THE TEXAS SIP

Name of SIP provision	Applicable geographic or non-attainment area	State submittal/effective date	EPA approval date	Comments
* * * * *				
Stage II Vapor Recovery Program SIP.	Statewide	10/9/2013	3/17/14 [Insert FR page number where document begins].	

[FR Doc. 2014-05100 Filed 3-14-14; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Parts 52, 62, and 70****[EPA-R07-OAR-2013-0724; FRL-9907-79-Region 7]****Approval and Promulgation of Implementation Plans, State Plans for Designated Facilities and Pollutants, and Operating Permits Program; State of Missouri****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Direct final rule.**SUMMARY:** The Environmental Protection Agency (EPA) is taking direct final action to approve revisions to the

Missouri State Implementation Plan (SIP), the 40 CFR part 62 state plans (111(d)), and the 40 CFR part 70 operating permits program, which were received on August 25, 2011, May 8, 2012, and February 11, 2013, respectively. The revisions submitted by the state move definitions currently in individual rules into one rule and eliminates the risk of the same term being defined differently for different rules. This action provides more clarity for the regulated public. These revisions do not have an adverse affect on air quality. EPA's approval of these rule revisions is being done in accordance with the requirements of the Clean Air Act (CAA).

DATES: This direct final rule is effective May 16, 2014, without further notice, unless EPA receives adverse comment by April 16, 2014. If EPA receives adverse comment, we will publish a

timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R07-OAR-2013-0724, by one of the following methods:

1. *www.regulations.gov*. Follow the on-line instructions for submitting comments.

2. *Email:* higbee.paula@epa.gov.

3. *Mail or Hand Delivery:* Paula Higbee, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219.

Instructions: Direct your comments to Docket ID No. EPA-R07-OAR-2013-0724. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at