

1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning on the date of approval.

FDA has determined under 21 CFR 25.33 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Add § 520.2475 to read as follows:

§ 520.2475 Toceranib.

(a) *Specifications.* Each tablet contains 10, 15, or 50 milligrams (mg) toceranib as toceranib phosphate.

(b) *Sponsor.* See No. 000009 in § 510.600 of this chapter.

(c) *Conditions of use—(1) Dogs—(i) Amount.* Administer an initial dose of 3.25 mg per kilogram (1.48 mg per pound) body weight, orally every other day.

(ii) *Indications for use.* For the treatment of Patnaik grade II or III, recurrent, cutaneous mast cell tumors with or without regional lymph node involvement.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved].

Dated: June 12, 2009.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E9–14299 Filed 6–17–09; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 55

[OAR–2004–0091; FRL–8912–7]

Outer Continental Shelf Air Regulations Consistency Update for California

AGENCY: Environmental Protection Agency (“EPA”).

ACTION: Final rule—consistency update.

SUMMARY: EPA is finalizing the update of the Outer Continental Shelf (“OCS”) Air Regulations proposed in the **Federal Register** on March 17, 2009. Requirements applying to OCS sources located within 25 miles of states’ seaward boundaries must be updated periodically to remain consistent with the requirements of the corresponding onshore area (“COA”), as mandated by section 328(a)(1) of the Clean Air Act Amendments of 1990 (“the Act”). The portion of the OCS air regulations that is being updated pertains to the requirements for OCS sources for which the Ventura County Air Pollution Control District (Ventura County APCD) is the designated COA. The intended effect of approving the requirements contained in the “Ventura County Air Pollution Control District Requirements Applicable to OCS Sources” (May 2009) is to regulate emissions from OCS sources in accordance with the requirements onshore.

DATES: *Effective Date:* This rule is effective on July 20, 2009.

The incorporation by reference of certain publications listed in this rule is approved by the Director of the Federal Register as of July 20, 2009.

ADDRESSES: EPA has established docket number OAR–2004–0091 for this action. The index to the docket 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: Cynthia G. Allen, Air Division, U.S. EPA Region IX, (415) 947–4120, allen.cynthia@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document, the terms “we,” “us,” or “our” refer to U.S. EPA.

Organization of this document: The following outline is provided to aid in locating information in this preamble.

Table of Contents

- I. Background
- II. Public Comment
- III. EPA Action
- IV. Statutory and Executive Order Reviews

I. Background

On March 17, 2009 (74 FR 11330), EPA proposed to approve requirements into the OCS Air Regulations pertaining to Ventura County APCD. These requirements are being promulgated in response to the submittal of rules from this California air pollution control agency. EPA has evaluated the proposed requirements to ensure that they are rationally related to the attainment or maintenance of federal or state ambient air quality standards or Part C of title I of the Act, that they are not designed expressly to prevent exploration and development of the OCS and that they are applicable to OCS sources. 40 CFR 55.1. EPA has also evaluated the rules to ensure that they are not arbitrary or capricious. 40 CFR 55.12(e). In addition, EPA has excluded administrative or procedural rules.

Section 328(a) of the Act requires that EPA establish requirements to control air pollution from OCS sources located within 25 miles of states’ seaward boundaries that are the same as onshore requirements. To comply with this statutory mandate, EPA must incorporate applicable onshore rules into 40 CFR part 55 as they exist onshore. This limits EPA’s flexibility in deciding which requirements will be incorporated into part 55 and prevents EPA from making substantive changes to the requirements it incorporates. As a result, EPA may be incorporating rules into part 55 that do not conform to all of EPA’s state implementation plan (SIP) guidance or certain requirements of the Act. Consistency updates may result in the inclusion of state or local rules or regulations into part 55, even though the same rules may ultimately be disapproved for inclusion as part of the SIP. Inclusion in the OCS rule does not imply that a rule meets the requirements of the Act for SIP approval, nor does it imply that the rule will be approved by EPA for inclusion in the SIP.

II. Public Comment

EPA’s proposed actions provided a 30-day public comment period. During this period, we received no comments on the proposed actions.

III. EPA Action

In this document, EPA takes final action to incorporate the proposed changes into 40 CFR part 55. No changes were made to the proposed action. EPA is approving the proposed action under section 328(a)(1) of the Act, 42 U.S.C. 7627. Section 328(a) of the Act requires that EPA establish requirements to control air pollution from OCS sources located within 25 miles of states' seaward boundaries that are the same as onshore requirements. To comply with this statutory mandate, EPA must incorporate applicable onshore rules into Part 55 as they exist onshore.

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to establish requirements to control air pollution from OCS sources located within 25 miles of States' seaward boundaries that are the same as onshore air control requirements. To comply with this statutory mandate, EPA must incorporate applicable onshore rules into part 55 as they exist onshore. 42 U.S.C. 7627(a)(1); 40 CFR 55.12. Thus, in promulgating OCS consistency updates, EPA's role is to maintain consistency between OCS regulations and the regulations of onshore areas, provided that they meet the criteria of the Clean Air Act. Accordingly, this action simply updates the existing OCS requirements to make them consistent with requirements onshore, without the exercise of any policy discretion by EPA. 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);
- 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 it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, nor does it impose substantial direct compliance costs on tribal governments, nor preempt tribal law.

Under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, OMB has approved the information collection requirements contained in 40 CFR part 55 and, by extension, this update to the rules, and has assigned OMB control number 2060-0249. Notice of OMB's approval of EPA Information Collection Request ("ICR") No. 1601.06 was published in the **Federal Register** on March 1, 2006 (71 FR 10499-10500). The approval expires January 31, 2009. As EPA previously indicated (70 FR 65897-65898 (November 1, 2005)), the annual public reporting and recordkeeping burden for collection of information under 40 CFR part 55 is estimated to average 549 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information

unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9 and are identified on the form and/or instrument, if applicable. In addition, the table in 40 CFR part 9 of currently approved OMB control numbers for various regulations lists the regulatory citations for the information requirements contained in 40 CFR part 55.

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 Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by August 17, 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. 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 55

Environmental protection, Administrative practice and procedures, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Nitrogen oxides, Outer Continental Shelf, Ozone, Particulate matter, Permits, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: May 1, 2009.

Laura Yoshii,

Acting Regional Administrator, Region IX.

■ Title 40 of the Code of Federal Regulations, part 55, is to be amended as follows:

PART 55—[AMENDED]

■ 1. The authority citation for part 55 continues to read as follows:

Authority: Section 328 of the Clean Air Act (42 U.S.C. 7401 *et seq.*) as amended by Public Law 101–549.

■ 2. Section 55.14 is amended by revising paragraph (e)(3)(ii)(H) to read as follows:

§ 55.14 Requirements that apply to OCS sources located within 25 miles of States' seaward boundaries, by State.

* * * * *

(e) * * *
(3) * * *
(ii) * * *

(H) *Ventura County Air Pollution Control District Requirements Applicable to OCS Sources*, May, 2009.

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■ 3. Appendix A to CFR Part 55 is amended by revising paragraph (b)(8) under the heading “California” to read as follows:

Appendix A to Part 55—Listing of State and Local Requirements Incorporated by Reference Into Part 55, by State

* * * * *

California

* * * * *

(b) * * *

(8) The following requirements are contained in *Ventura County Air Pollution Control District Requirements Applicable to OCS Sources*:

Rule 2 Definitions (Adopted 04/13/04)
 Rule 5 Effective Date (Adopted 04/13/04)
 Rule 6 Severability (Adopted 11/21/78)
 Rule 7 Zone Boundaries (Adopted 06/14/77)
 Rule 10 Permits Required (Adopted 04/13/04)
 Rule 11 Definition for Regulation II (Adopted 03/14/06)
 Rule 12 Applications for Permits (Adopted 06/13/95)
 Rule 13 Action on Applications for an Authority to Construct (Adopted 06/13/95)
 Rule 14 Action on Applications for a Permit to Operate (Adopted 06/13/95)
 Rule 15.1 Sampling and Testing Facilities (Adopted 10/12/93)
 Rule 16 BACT Certification (Adopted 06/13/95)
 Rule 19 Posting of Permits (Adopted 05/23/72)
 Rule 20 Transfer of Permit (Adopted 05/23/72)
 Rule 23 Exemptions from Permits (Adopted 04/08/08)
 Rule 24 Source Recordkeeping, Reporting, and Emission Statements (Adopted 09/15/92)
 Rule 26 New Source Review—General (Adopted 03/14/06)
 Rule 26.1 New Source Review—Definitions (Adopted 11/14/06)
 Rule 26.2 New Source Review—Requirements (Adopted 05/14/02)

Rule 26.3 New Source Review—Exemptions (Adopted 03/14/06)
 Rule 26.6 New Source Review—Calculations (Adopted 03/14/06)
 Rule 26.8 New Source Review—Permit To Operate (Adopted 10/22/91)
 Rule 26.10 New Source Review—PSD (Adopted 01/13/98)
 Rule 26.11 New Source Review—ERC Evaluation At Time of Use (Adopted 05/14/02)
 Rule 26.12 Federal Major Modifications (Adopted 06/27/06)
 Rule 28 Revocation of Permits (Adopted 07/18/72)
 Rule 29 Conditions on Permits (Adopted 03/14/06)
 Rule 30 Permit Renewal (Adopted 04/13/04)
 Rule 32 Breakdown Conditions: Emergency Variances, A., B.1., and D. only. (Adopted 02/20/79)
 Rule 33 Part 70 Permits—General (Adopted 09/12/06)
 Rule 33.1 Part 70 Permits—Definitions (Adopted 09/12/06)
 Rule 33.2 Part 70 Permits—Application Contents (Adopted 04/10/01)
 Rule 33.3 Part 70 Permits—Permit Content (Adopted 09/12/06)
 Rule 33.4 Part 70 Permits—Operational Flexibility (Adopted 04/10/01)
 Rule 33.5 Part 70 Permits—Time frames for Applications, Review and Issuance (Adopted 10/12/93)
 Rule 33.6 Part 70 Permits—Permit Term and Permit Reissuance (Adopted 10/12/93)
 Rule 33.7 Part 70 Permits—Notification (Adopted 04/10/01)
 Rule 33.8 Part 70 Permits—Reopening of Permits (Adopted 10/12/93)
 Rule 33.9 Part 70 Permits—Compliance Provisions (Adopted 04/10/01)
 Rule 33.10 Part 70 Permits—General Part 70 Permits (Adopted 10/12/93)
 Rule 34 Acid Deposition Control (Adopted 03/14/95)
 Rule 35 Elective Emission Limits (Adopted 11/12/96)
 Rule 36 New Source Review—Hazardous Air Pollutants (Adopted 10/06/98)
 Rule 42 Permit Fees (Adopted 04/08/08)
 Rule 44 Exemption Evaluation Fee (Adopted 04/08/08)
 Rule 45 Plan Fees (Adopted 06/19/90)
 Rule 45.2 Asbestos Removal Fees (Adopted 08/04/92)
 Rule 47 Source Test, Emission Monitor, and Call-Back Fees (Adopted 06/22/99)
 Rule 50 Opacity (Adopted 04/13/04)
 Rule 52 Particulate Matter-Concentration (Grain Loading)(Adopted 04/13/04)
 Rule 53 Particulate Matter-Process Weight (Adopted 04/13/04)
 Rule 54 Sulfur Compounds (Adopted 06/14/94)
 Rule 56 Open Burning (Adopted 11/11/03)
 Rule 57 Incinerators (Adopted 01/11/05)
 Rule 57.1 Particulate Matter Emissions from Fuel Burning Equipment (Adopted 01/11/05)
 Rule 62.7 Asbestos—Demolition and Renovation (Adopted 09/01/92)
 Rule 63 Separation and Combination of Emissions (Adopted 11/21/78)
 Rule 64 Sulfur Content of Fuels (Adopted 04/13/99)

Rule 67 Vacuum Producing Devices (Adopted 07/05/83)
 Rule 68 Carbon Monoxide (Adopted 04/13/04)
 Rule 71 Crude Oil and Reactive Organic Compound Liquids (Adopted 12/13/94)
 Rule 71.1 Crude Oil Production and Separation (Adopted 06/16/92)
 Rule 71.2 Storage of Reactive Organic Compound Liquids (Adopted 09/26/89)
 Rule 71.3 Transfer of Reactive Organic Compound Liquids (Adopted 06/16/92)
 Rule 71.4 Petroleum Sumps, Pits, Ponds, and Well Cellars (Adopted 06/08/93)
 Rule 71.5 Glycol Dehydrators (Adopted 12/13/94)
 Rule 72 New Source Performance Standards (NSPS) (Adopted 09/9/08)
 Rule 73 National Emission Standards for Hazardous Air Pollutants (NESHAPS) (Adopted 09/9/08)
 Rule 74 Specific Source Standards (Adopted 07/06/76)
 Rule 74.1 Abrasive Blasting (Adopted 11/12/91)
 Rule 74.2 Architectural Coatings (Adopted 11/13/01)
 Rule 74.6 Surface Cleaning and Degreasing (Adopted 11/11/03—effective 07/01/04)
 Rule 74.6.1 Batch Loaded Vapor Degreasers (Adopted 11/11/03—effective 07/01/04)
 Rule 74.7 Fugitive Emissions of Reactive Organic Compounds at Petroleum Refineries and Chemical Plants (Adopted 10/10/95)
 Rule 74.8 Refinery Vacuum Producing Systems, Waste-water Separators and Process Turnarounds (Adopted 07/05/83)
 Rule 74.9 Stationary Internal Combustion Engines (Adopted 11/08/05)
 Rule 74.10 Components at Crude Oil Production Facilities and Natural Gas Production and Processing Facilities (Adopted 03/10/98)
 Rule 74.11 Natural Gas-Fired Residential Water Heaters-Control of NO_x (Adopted 04/09/85)
 Rule 74.11.1 Large Water Heaters and Small Boilers (Adopted 09/14/99)
 Rule 74.12 Surface Coating of Metal Parts and Products (Adopted 04/08/08)
 Rule 74.15 Boilers, Steam Generators and Process Heaters (Adopted 11/08/94)
 Rule 74.15.1 Boilers, Steam Generators and Process Heaters (Adopted 06/13/00)
 Rule 74.16 Oil Field Drilling Operations (Adopted 01/08/91)
 Rule 74.20 Adhesives and Sealants (Adopted 01/11/05)
 Rule 74.23 Stationary Gas Turbines (Adopted 1/08/02)
 Rule 74.24 Marine Coating Operations (Adopted 11/11/03)
 Rule 74.24.1 Pleasure Craft Coating and Commercial Boatyard Operations (Adopted 01/08/02)
 Rule 74.26 Crude Oil Storage Tank Degassing Operations (Adopted 11/08/94)
 Rule 74.27 Gasoline and ROC Liquid Storage Tank Degassing Operations (Adopted 11/08/94)
 Rule 74.28 Asphalt Roofing Operations (Adopted 05/10/94)
 Rule 74.30 Wood Products Coatings (Adopted 06/27/06)
 Rule 75 Circumvention (Adopted 11/27/78)

Rule 101 Sampling and Testing Facilities
(Adopted 05/23/72)

Rule 102 Source Tests (Adopted 04/13/04)

Rule 103 Continuous Monitoring Systems
(Adopted 02/09/99)

Rule 154 Stage 1 Episode Actions (Adopted
09/17/91)

Rule 155 Stage 2 Episode Actions (Adopted
09/17/91)

Rule 156 Stage 3 Episode Actions (Adopted
09/17/91)

Rule 158 Source Abatement Plans (Adopted
09/17/91)

Rule 159 Traffic Abatement Procedures
(Adopted 09/17/91)

Rule 220 General Conformity (Adopted 05/
09/95)

Rule 230 Notice to Comply (Adopted 9/9/
08)

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