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Pamela Hamilton-Powell,

Director, Office of Rulemaking.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 601

[Docket No. FDA-2009-N-0100]

Revision of the Requirements for Publication of License Revocation; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of September 17, 2009, for the direct final rule that appeared in the **Federal Register** of May 5, 2009 (74 FR 20583). The direct final rule amends the biologics regulations to clarify the regulatory procedures for notifying the public about the revocation of a biologics license. The rule provides that FDA will publish a notice in the **Federal Register** following revocation of a biologics license under FDA regulations and will include a statement of the specific grounds for the revocation. This document confirms the effective date of the direct final rule.

DATES: *Effective date confirmed:* September 17, 2009.

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, Jr., Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 5, 2009 (74 FR 20583), FDA issued a direct final rule amending the biologics regulations for notifying the public about the revocation of a biologics license by clarifying that FDA will publish a notice of license revocation in cases where the Commissioner has made a finding that reasonable grounds for revocation exist under 21 CFR 601.5(b). The rule, as amended, does not affect other regulations or procedures for notification of license revocation. The rule, as amended, also does not affect existing FDA practices for publishing notices of voluntary withdrawal,

including notices of voluntary withdrawal of new drug applications.

FDA solicited comments concerning the direct final rule for a 75-day period ending July 20, 2009. FDA stated that the effective date of the direct final rule would be on September 17, 2009, 60 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comments.

Authority: Therefore, under the biological products provisions under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 601 is amended. Accordingly, the amendments issued thereby are effective.

Dated: August 14, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9-20119 Filed 8-20-09; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 55

[OAR-2004-0091; FRL-8941-3]

Outer Continental Shelf Air Regulations; Consistency Update for California

AGENCY: Environmental Protection Agency (“EPA”).

ACTION: Final rule.

SUMMARY: EPA is finalizing the update of the Outer Continental Shelf (“OCS”) Air Regulations proposed in the **Federal Register** on April 20, 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 Santa Barbara County Air Pollution Control District (Santa Barbara County APCD) is the designated COA. The intended effect of approving the requirements contained in the “Santa Barbara County Air Pollution Control District Requirements Applicable to OCS Sources” (June 2009) is to regulate emissions from OCS sources in accordance with the requirements onshore.

DATES: *Effective Date:* This rule is effective on September 21, 2009.

The incorporation by reference of certain publications listed in this rule is approved by the Director of the Federal Register as of September 21, 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.

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- I. Background
- II. Public Comment
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I. Background

On April 20, 2009 (74 FR 17934), EPA proposed to approve requirements into the OCS Air Regulations pertaining to Santa Barbara 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 action.

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 September 21, 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: June 24, 2009.

Jane Diamond,

Acting Regional Administrator, Region IX.

■ Title 40, chapter I of the Code of Federal Regulations is 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)(F) 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) * * *

(F) *Santa Barbara County Air Pollution Control District Requirements Applicable to OCS Sources*, June, 2009.

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■ 3. Appendix A to CFR Part 55 is amended by revising paragraph (b)(6) 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) * * *

* * * * *

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

- Rule 102 Definitions (Adopted 01/15/09)
- Rule 103 Severability (Adopted 10/23/78)
- Rule 106 Notice to Comply for Minor Violations (Repealed 01/01/2001)

- Rule 107 Emergencies (Adopted 04/19/01)
- Rule 201 Permits Required (Adopted 06/19/08)
- Rule 202 Exemptions to Rule 201 (Adopted 06/19/08)
- Rule 203 Transfer (Adopted 04/17/97)
- Rule 204 Applications (Adopted 04/17/97)
- Rule 205 Standards for Granting Permits (Adopted 04/17/97)
- Rule 206 Conditional Approval of Authority to Construct or Permit to Operate (Adopted 10/15/91)
- Rule 207 Denial of Application (Adopted 10/23/78)
- Rule 210 Fees (Adopted 03/17/05)
- Rule 212 Emission Statements (Adopted 10/20/92)
- Rule 301 Circumvention (Adopted 10/23/78)
- Rule 302 Visible Emissions (Adopted 10/23/78)
- Rule 304 Particulate Matter—Northern Zone (Adopted 10/23/78)
- Rule 305 Particulate Matter Concentration—Southern Zone (Adopted 10/23/78)
- Rule 306 Dust and Fumes—Northern Zone (Adopted 10/23/78)
- Rule 307 Particulate Matter Emission Weight Rate—Southern Zone (Adopted 10/23/78)
- Rule 308 Incinerator Burning (Adopted 10/23/78)
- Rule 309 Specific Contaminants (Adopted 10/23/78)
- Rule 310 Odorous Organic Sulfides (Adopted 10/23/78)
- Rule 311 Sulfur Content of Fuels (Adopted 10/23/78)
- Rule 312 Open Fires (Adopted 10/02/90)
- Rule 316 Storage and Transfer of Gasoline (Adopted 01/15/09)
- Rule 317 Organic Solvents (Adopted 10/23/78)
- Rule 318 Vacuum Producing Devices or Systems—Southern Zone (Adopted 10/23/78)
- Rule 321 Solvent Cleaning Operations (Adopted 09/18/97)
- Rule 322 Metal Surface Coating Thinner and Reducer (Adopted 10/23/78)
- Rule 323 Architectural Coatings (Adopted 11/15/01)
- Rule 324 Disposal and Evaporation of Solvents (Adopted 10/23/78)
- Rule 325 Crude Oil Production and Separation (Adopted 07/19/01)
- Rule 326 Storage of Reactive Organic Compound Liquids (Adopted 01/18/01)
- Rule 327 Organic Liquid Cargo Tank Vessel Loading (Adopted 12/16/85)
- Rule 328 Continuous Emission Monitoring (Adopted 10/23/78)
- Rule 330 Surface Coating of Metal Parts and Products (Adopted 01/20/00)
- Rule 331 Fugitive Emissions Inspection and Maintenance (Adopted 12/10/91)
- Rule 332 Petroleum Refinery Vacuum Producing Systems, Wastewater Separators and Process Turnarounds (Adopted 06/11/79)
- Rule 333 Control of Emissions from Reciprocating Internal Combustion Engines (Adopted 06/19/08)
- Rule 342 Control of Oxides of Nitrogen (NOx) from Boilers, Steam Generators and Process Heaters (Adopted 04/17/97)

- Rule 343 Petroleum Storage Tank Degassing (Adopted 12/14/93)
- Rule 344 Petroleum Sumps, Pits, and Well Cellars (Adopted 11/10/94)
- Rule 346 Loading of Organic Liquid Cargo Vessels (Adopted 01/18/01)
- Rule 352 Natural Gas-Fired Fan-Type Central Furnaces and Residential Water Heaters (Adopted 09/16/99)
- Rule 353 Adhesives and Sealants (Adopted 08/19/99)
- Rule 359 Flares and Thermal Oxidizers (Adopted 06/28/94)
- Rule 360 Emissions of Oxides of Nitrogen from Large Water Heaters and Small Boilers (Adopted 10/17/02)
- Rule 361 Small Boilers, Steam Generators, and Process Heaters (Adopted 01/17/08)
- Rule 370 Potential to Emit—Limitations for Part 70 Sources (Adopted 06/15/95)
- Rule 505 Breakdown Conditions Sections A., B.1., and D. only (Adopted 10/23/78)
- Rule 603 Emergency Episode Plans (Adopted 06/15/81)
- Rule 702 General Conformity (Adopted 10/20/94)
- Rule 801 New Source Review (Adopted 04/17/97)
- Rule 802 Nonattainment Review (Adopted 04/17/97)
- Rule 803 Prevention of Significant Deterioration (Adopted 04/17/97)
- Rule 804 Emission Offsets (Adopted 04/17/97)
- Rule 805 Air Quality Impact Analysis and Modeling (Adopted 04/17/97)
- Rule 808 New Source Review for Major Sources of Hazardous Air Pollutants (Adopted 05/20/99)
- Rule 1301 Part 70 Operating Permits—General Information (Adopted 06/19/03)
- Rule 1302 Part 70 Operating Permits—Permit Application (Adopted 11/09/93)
- Rule 1303 Part 70 Operating Permits—Permits (Adopted 11/09/93)
- Rule 1304 Part 70 Operating Permits—Issuance, Renewal, Modification and Reopening (Adopted 11/09/93)
- Rule 1305 Part 70 Operating Permits—Enforcement (Adopted 11/09/93)

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA–HQ–OPPT–2008–0252; FRL–8433–9]

RIN 2070–AB27

Certain Chemical Substances; Withdrawal of Significant New Use Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of final rules.

SUMMARY: EPA is withdrawing two significant new use rules (SNURs) promulgated under section 5(a)(2) of the