

Issued in Washington, DC, on August 17, 2009.

**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]

**BILLING CODE 4160-01-S**

## 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](mailto: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
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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