

Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

V. How Does This Rule Comply With the Paperwork Reduction Act of 1995?

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 is not required.

The guidance for this final rule references previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB Control No. 0910–0120; the collections of information in 21 CFR part 814 have been approved under OMB Control No 0910–0231; the collections of information in 21 CFR part 809 have been approved under OMB Control No. 0910–0485.

VI. What References are on Display?

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Maine Molecular Quality Controls, Inc., dated August 10, 2006.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

- Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

- 1. The authority citation for 21 CFR part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

- 2. Section 866.5910 is added to subpart F to read as follows:

§ 866.5910 Quality Control Material for Cystic Fibrosis Nucleic Acid Assays.

(a) *Identification.* Quality control material for cystic fibrosis nucleic acid assays. A quality control material for cystic fibrosis nucleic acid assays is a device intended to help monitor reliability of a test system by detecting analytical deviations such as those that may arise from reagent or instrument variation in genetic testing. This type of device includes recombinant, synthetic, and cell line-based DNA controls.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled "Class II Special Controls Guidance Document: Quality Control Material for Cystic Fibrosis Nucleic Acid Assays." See § 866.1(e) for the availability of this guidance document.

Dated: December 21, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD11–06–048]

RIN 1625–AA09

Drawbridge Operation Regulations; Sacramento River, at Paintersville, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Eleventh Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Paintersville Drawbridge across the Sacramento River, mile 33.4, at Paintersville, CA. This deviation allows the bridge to remain in the closed-to-navigation position during the deviation period. The deviation is necessary for the bridge owner, the California Department of Transportation (Caltrans), to refurbish and replace aging operating machinery.

DATES: This deviation is effective from 7 a.m. on February 28, 2007 to 5 p.m. on March 8, 2007.

ADDRESSES: Materials referred to in this document are available for inspection or copying at Commander (dpw), Eleventh Coast Guard District, Building 50–2, Coast Guard Island, Alameda, CA

94501–5100, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: David H. Sulouff, Chief, Bridge Section, Eleventh Coast Guard District, telephone (510) 437–3516.

SUPPLEMENTARY INFORMATION: Caltrans requested a temporary change to the operation of the Paintersville Drawbridge, mile 33.4, over the Sacramento River, at Paintersville, CA. The Paintersville Drawbridge's navigation span provides a vertical clearance of 24 feet above Mean High Water in the closed-to-navigation position. The draw opens on signal from 9 a.m. to 5 p.m., November 1 through April 30, and at all other times if at least 4 hours notice is given as required by 33 CFR 117.189. Navigation on the waterway is recreational, search and rescue, and commercial traffic hauling materials for levee repair. Caltrans requested to secure the drawspan in the closed to navigation position from 7 a.m. on February 28, 2007 to 5 p.m. on March 8, 2007. During this time the drawspan motors will be refurbished and the control house replaced to ensure the continuing operation of the drawspan. This temporary deviation has been coordinated with waterway users. Caltrans has reduced the period of time the bridge will be closed to navigation to reduce the impact to levee repair in the area. Vessels that can transit the bridge while in the closed-to-navigation position may continue to do so at any time.

In accordance with 33 CFR 117.35(c), this work will be performed with all due speed in order to return the bridge to normal operation as soon as possible. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: December 29, 2006.

R.C. Lorigan,

Captain, U.S. Coast Guard, Acting Commander, Eleventh Coast Guard District.

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