

# Rules and Regulations

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 600

[Docket No. FDA-2013-N-0011]

#### Change of Address; Biologics License Applications; Technical Amendment

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is amending its regulations to update the address for applicants to submit biologics license applications (BLAs) and BLA amendments and supplements regulated by the Center for Drug Evaluation and Research (CDER). This action is being taken to ensure accuracy and clarity in the Agency's regulations.

**DATES:** This rule is effective April 2, 2013.

#### FOR FURTHER INFORMATION CONTACT:

Scott E. Zeiss, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 1120, Silver Spring, MD 20993-0002, 301-796-0639.

**SUPPLEMENTARY INFORMATION:** FDA is amending 21 CFR 600.2(b) to update the address for applicants to submit BLAs and BLA amendments and supplements regulated by CDER. The new address for all these submissions is CDER Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901B Ammendale Rd., Beltsville, MD 20705. This action is being taken to ensure accuracy and clarity in the Agency's regulations.

Publication of this document constitutes final action on these changes

under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment to the regulations provides only technical changes to update an address for the submission of BLAs and BLA amendments and supplements.

#### List of Subjects for 21 CFR Part 600

Biologics, 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 600 is amended as follows:

#### PART 600—BIOLOGICAL PRODUCTS: GENERAL

■ 1. The authority citation for 21 CFR part 600 continues to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 353, 355, 360, 360i, 371, 374; 42 U.S.C. 216, 262, 263, 263a, 264, 300aa-25.

#### § 600.2 [Amended]

■ 2. Section 600.2 is amended in the first sentence of paragraph (b) by removing "CDER Therapeutic Biological Products Document Room" and adding in its place "CDER Central Document Room", and by removing "12229 Wilkins Ave., Rockville, MD 20852" and adding in its place "5901B Ammendale Rd., Beltsville, MD 20705".

Dated: March 27, 2013.

**Peter Lurie,**

*Acting Associate Commissioner for Policy and Planning.*

[FR Doc. 2013-07578 Filed 4-1-13; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 117

[Docket No. USCG-2013-0142]

#### Drawbridge Operation Regulations; China Basin, San Francisco, CA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of deviation from drawbridge regulation.

**SUMMARY:** The Coast Guard has issued a temporary deviation from the operating

schedule that governs the Third Street Drawbridge across the China Basin, mile 0.0, at San Francisco, CA. The deviation is necessary to allow the public to cross the bridge to participate in the scheduled CycleSF, a community event. This deviation allows the bridge to remain in the closed-to-navigation position during the deviation period.

**DATES:** This deviation is effective from 6 a.m. until 10 a.m. on April 28, 2013.

**ADDRESSES:** The docket for this deviation, [USCG-2013-0142], is available at <http://www.regulations.gov>. Type the docket number in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this deviation. You may also visit the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary deviation, call or email David H. Sulouff, Chief, Bridge Section, Eleventh Coast Guard District; telephone 510-437-3516, email [David.H.Sulouff@uscg.mil](mailto:David.H.Sulouff@uscg.mil). If you have questions on viewing the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone 202-366-9826.

**SUPPLEMENTARY INFORMATION:** The City of San Francisco requested a temporary change to the operation of the Third Street Drawbridge, mile 0.0, over China Basin, at San Francisco, CA. The Third Street Drawbridge navigation span provides a vertical clearance of 7 feet above Mean High Water in the closed-to-navigation position. The draw opens on signal if at least one hour notice is given as required by 33 CFR 117.149. Navigation on the waterway is recreational.

The drawspan will be secured in the closed-to-navigation position 6 a.m. until 10 a.m. on April 28, 2013, to allow participants in the CycleSF to cross the bridge during the event. This temporary deviation has been coordinated with the waterway users. No objections to the proposed temporary deviation were raised. The drawspan can be operated upon one hour advance notice for emergencies requiring the passage of waterway traffic.