

nor an environmental impact statement is required.

III. Paperwork Reduction Act of 1995

This final administrative order establishes special controls that refer to previously approved collections of information found in other 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 part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR parts 801 and 809 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 862

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 862 is amended as follows:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 862 continues to read as follows:

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

■ 2. Add § 862.1373 to subpart B to read as follows:

§ 862.1373 Hemoglobin A1c test system.

(a) *Identification.* A hemoglobin A1c test system is a device used to measure the percentage concentration of hemoglobin A1c in blood. Measurement of hemoglobin A1c is used as an aid in the diagnosis of diabetes mellitus and as an aid in the identification of patients at risk for developing diabetes mellitus.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The device must have initial and annual standardization verification by a certifying glycohemoglobin standardization organization deemed acceptable by FDA.

(2) The premarket notification submission must include performance testing to evaluate precision, accuracy, linearity, and interference, including the following:

(i) Performance testing of device precision must, at a minimum, use

blood samples with concentrations near 5.0 percent, 6.5 percent, 8.0 percent, and 12 percent hemoglobin A1c. This testing must evaluate precision over a minimum of 20 days using at least three lots of the device and three instruments, as applicable.

(ii) Performance testing of device accuracy must include a minimum of 120 blood samples that span the measuring interval of the device and compare results of the new device to results of a standardized test method. Results must demonstrate little or no bias versus the standardized method.

(iii) Total error of the new device must be evaluated using single measurements by the new device compared to results of the standardized test method, and this evaluation must demonstrate a total error less than or equal to 6 percent.

(iv) Performance testing must demonstrate that there is little to no interference from common hemoglobin variants, including Hemoglobin C, Hemoglobin D, Hemoglobin E, Hemoglobin A2, and Hemoglobin S.

(3) When assay interference from Hemoglobin F or interference with other hemoglobin variants with low frequency in the population is observed, a warning statement must be placed in a black box and must appear in all labeling material for these devices describing the interference and any affected populations.

Dated: August 19, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–20022 Filed 8–22–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 862, 864, 866, and 872

[Docket No. FDA–2014–N–0011]

Medical Devices; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending certain medical device regulations to correct minor errors in the Code of Federal Regulations (CFR). This action is editorial in nature and is intended to correct outdated Web site addresses.

DATES: This rule is effective August 25, 2014.

FOR FURTHER INFORMATION CONTACT:

Aaron Josephson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5449, Silver Spring, MD 20993–0002, 301–796–5178.

SUPPLEMENTARY INFORMATION: FDA is amending certain regulations in parts 862, 864, 866, and 872 (21 CFR parts 862, 864, 866, and 872). This action updates certain Web site addresses that have been changed due to recent FDA Web site changes.

Publication of this document constitutes final action of these changes under the Administrative Procedure Act (5 U.S.C. 553). These amendments are merely correcting nonsubstantive errors. FDA therefore, for good cause, finds under 5 U.S.C. 553(b)(3)(B) and (d)(3) that notice and public comment are unnecessary.

FDA has determined under 21 CFR 25.30(i) that this final rule 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. In addition, FDA has determined that this final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects

21 CFR Part 862

Medical devices.

21 CFR Part 864

Blood, Medical devices, Packaging and containers.

21 CFR Part 866

Biologics, Laboratories, Medical devices.

21 CFR Part 872

Medical devices.

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

PARTS 862, 864, 866, AND 872 [AMENDED]

■ 1. The authority citation for parts 862, 864, 866, and 872 continues to read as follows:

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

§§ 862.1, 864.1, 866.1, and 872.1 [Amended]

■ 2. In the following table, for each section indicated in the left column,

remove the Web site address indicated in the middle column from wherever the Web site address appears in the

section, and add the Web site address indicated in the right column:

Section	Remove	Add
862.1	http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHombudsman/default.htm .	http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm .
864.1	http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHombudsman/default.htm .	http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm .
866.1	http://www.fda.gov/cdrh.guidance.html	http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm .
872.1	http://www.fda.gov/cdrh.guidance.html	http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm .

Dated: August 19, 2014.
Peter Lurie,
Associate Commissioner for Policy and Planning.
 [FR Doc. 2014–20107 Filed 8–22–14; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2014–0755]

Drawbridge Operation Regulation; Tennessee River, Decatur, AL

AGENCY: Coast Guard, DHS.
ACTION: Notice of deviation from drawbridge regulations.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Southern Railroad Drawbridge across the Tennessee River, mile 304.4, at Decatur, Alabama. The deviation is necessary to allow the bridge owner time to replace and adjust the down haul operating ropes that are essential to the continued safe operation of the drawbridge. This deviation allows the bridge to remain in the closed-to-navigation position and not open to vessel traffic.

DATES: This deviation is effective from 8 a.m. to 10 p.m., September 17, 2014 and September 24, 2014.

ADDRESSES: The docket for this deviation, (USCG–2014–0755) 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 Eric A. Washburn, Bridge Administrator, Western Rivers, Coast Guard; telephone 314–269–2378, email Eric.Washburn@uscg.mil. If you have questions on viewing the docket, call Cheryl F. Collins, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: The Norfolk Southern Railroad requested a temporary deviation for the Southern Railroad Drawbridge, across the Tennessee River, mile 304.4, at Decatur, Alabama to remain in the closed-to-navigation position on two days for 14 hours each day from 8 a.m. to 10 p.m. on September 17, 2014 and September 24, 2014 in order to replace and adjust the down haul operation ropes.

The Southern Railroad Drawbridge currently operates in accordance with 33 CFR 117.5, which states the general requirement that drawbridge shall open promptly and fully for the passage of vessels when a request to open is given in accordance with the subpart.

There are no alternate routes for vessels transiting this section of the Tennessee River.

The Southern Railroad Drawbridge, in the closed-to-navigation position, provides a vertical clearance of 10.52 feet above normal pool. Navigation on the waterway consists primarily of commercial tows and recreational watercraft and will not be significantly impacted. This temporary deviation has been coordinated with waterway users. No objections were received.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: August 13, 2014.
Eric A. Washburn,
Bridge Administrator, Western Rivers.
 [FR Doc. 2014–20184 Filed 8–22–14; 8:45 am]
BILLING CODE 9110–04–P

LIBRARY OF CONGRESS

U.S. Copyright Office

37 CFR Part 201

[Docket No. 2014–06]

Exemption to Prohibition on Circumvention of Copyright Protection Systems for Wireless Telephone Handsets

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Final rule.

SUMMARY: Pursuant to an act of Congress, the Librarian of Congress is amending applicable regulations to provide that the prohibition against circumvention of technological measures that effectively control access to copyrighted works set forth in the United States Code shall not apply to persons who engage in such circumvention to enable used wireless telephone handsets to connect to wireless telecommunications networks when the circumvention is initiated either by the owner of the handset or certain other persons, and when connection to the network is authorized by the operator of the network.

DATES: Effective August 25, 2014.