

VIII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to “construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.” Federal law includes an express preemption provision that preempts certain state requirements “different from or in addition to” certain Federal requirements applicable to devices. 21 U.S.C. 360k; See *Medtronic Inc., v. Lohr* 518 U.S. 470 (1996); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). The special controls established by this final rule create “requirements” for specific medical devices under 21 U.S.C. 360k, even though products sponsors have some flexibility in how they meet those requirements. Cf. *Papike v. Tambrands, Inc.*, 107 F. 3d 737, 740–742 (9th Cir. 1991).

IX. Paperwork Reduction Act of 1995

This final rule contains no new collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520) is not required. This final rule establishes as special controls a guidance document that refers to currently approved collections of information found in other FDA regulations. These collections of information are subject to review by OMB under the PRA. The analysis of the paperwork burden for the guidance document is included in its notice of availability.

List of Subjects in 21 CFR Part 866

Biologics, Laboratory, 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 866.3305 is amended by revising paragraph (b) to read as follows:

§ 866.3305 Herpes simplex virus serological assays.

* * * * *

(b) *Classification.* Class II (special controls). The device is classified as class II (special controls). The special control for the device is FDA’s revised guidance document entitled “Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays.” For availability of the guidance revised document, see § 866.1(e).

Dated: August 3, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2011–0759]

Drawbridge Operation Regulations; Long Island, New York Inland Waterway From East Rockaway Inlet to Shinnecock Canal, NY

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Loop Parkway Bridge, mile 0.7, across Long Creek, and the Captree State Parkway (Robert Moses Causeway) Bridge, mile 30.7, across the State Boat Channel, at Long Island, New York. This deviation is necessary to facilitate the 2011 March of Dimes Motorcycle Run. The deviation allows the two bridges listed above to remain in the closed position during this public event.

DATES: This deviation is effective from 10:51 a.m. through 1:49 p.m. on September 25, 2011.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2011–0759 and are available online at <http://www.regulations.gov>, inserting USCG–2011–0759 in the “Keyword” box and then clicking “Search”. They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 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 rule, call or e-mail Ms. Judy Leung-Yee, Project Officer, First Coast Guard District, telephone (212) 668–7165, judy.k.leung-ye@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

The Loop Parkway Bridge, mile 0.7, across Long Creek has a vertical clearance in the closed position of 21 feet at mean high water and 25 feet at mean low water. The existing drawbridge operation regulations are listed at 33 CFR 117.799(f).

The Captree State Parkway (Robert Moses Causeway) Bridge, mile 30.7, across the State Boat Channel has a vertical clearance in the closed position of 29 feet at mean high water and 31 feet at mean low water. The existing drawbridge operation regulations are listed at 33 CFR 117.799(i).

Long Creek and the State Boat Channel both are both transited by commercial fishing and recreational vessel traffic.

The owner of the two bridges, the State New York Department of Transportation, requested bridge closures to facilitate a public event, the March of Dimes Charity Motorcycle Run.

Under this temporary deviation the Loop Parkway Bridge may remain in the closed position from 10:51 a.m. through 11:49 a.m. and from 12:21 p.m. through 1:49 p.m. on September 25, 2011, and the Captree State Parkway Bridge (Robert Moses Causeway) may remain in the closed position from 11 a.m. through 1 p.m. on September 25, 2011, to facilitate a public event, the 2011 March of Dimes Motorcycle Run.

Vessels that can pass under the closed draws during each respective closure may do so at any time.

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

Dated: July 29, 2011.

Gary Kassof,

Bridge Program Manager, First Coast Guard District.

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