

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. FDA-2018-N-3066]

Medical Devices; Classification of Accessories Distinct From Other Devices; Finalized List of Accessories Suitable for Class I; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final classification action; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that appeared in the **Federal Register** of April 12, 2019. That document was published with the instruction to add a section to the incorrect subpart. This correction is being made to improve the accuracy of the final classification action.

DATES: Effective May 20, 2019, and applicable May 13, 2019.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy and Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993, 301-796-9115.

SUPPLEMENTARY INFORMATION: In FR Doc. 2019-07290 appearing on page 14865 in the **Federal Register** of Friday, April 12, 2019, the following correction is made:

§ 886.4355 [Corrected]

■ 1. On page 14870, in the second column, in part 886, amendatory instruction 11 is corrected to read as follows:

“11. “Add § 886.4355 to subpart E to read as follows:”

Dated: May 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-10399 Filed 5-17-19; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2018-0228]

RIN 1625-AA09

Drawbridge Operation Regulation; Delaware River, Burlington, NJ and Bristol, PA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is temporarily modifying the operating schedule that governs the SR 413/Burlington-Bristol Bridge across the Delaware River, mile 117.8, between Burlington, NJ and Bristol, PA. This temporary modification will allow the drawbridge to be maintained closed-to-navigation and is necessary to accommodate bridge maintenance.

DATES: This temporary final rule is effective from June 19, 2019, through 7:59 a.m. on September 17, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>. Type USCG-2018-0228 in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rulemaking.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Michael Thorogood, Bridge Administration Branch Fifth District, Coast Guard, telephone 757-398-6557, email Michael.R.Thorogood@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
FR Federal Register
OMB Office of Management and Budget
NPRM Notice of Proposed Rulemaking
(Advance, Supplemental)
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

On April 26, 2018, the Coast Guard published a temporary deviation entitled “Drawbridge Operation Regulation; Delaware River, Burlington NJ and Bristol, PA” in the **Federal Register** (83 FR 18226). This temporary deviation was in place to facilitate bridge maintenance and painting of the vertical lift span of the drawbridge from May 1, 2018, through September 30, 2018. During the planned maintenance period, a work platform reduced one half of the bridge span vertical clearance to approximately 58 feet above mean high water in the closed position and approximately 132 feet above mean high water in the open position.

On August 9, 2018, the Coast Guard published a cancellation of the temporary deviation entitled “Drawbridge Operation Regulation; Delaware River, Burlington NJ and Bristol, PA” in the **Federal Register** (83 FR 18226). The temporary deviation was cancelled due to delays in performing bridge maintenance outside the navigation span, thereby eliminating the

need for maintaining the temporary deviation. Due to the cancellation of the work, the platform was not installed and the bridge is operating under its regular operating schedule in 33 CFR 117.716(a). In accordance with 33 CFR 117.35(e), the drawbridge was returned to its regular operating schedule immediately at the end of the cancellation date of the temporary deviation.

On March 1, 2019, the Coast Guard published a notice for proposed rulemaking entitled “Drawbridge Operation Regulation; Delaware River, Burlington, NJ and Bristol, PA” in the **Federal Register** (84 FR 6992). We received no comments on this rule.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority 33 U.S.C. 499.

The SR 413/Burlington-Bristol Bridge across the Delaware River, mile 117.8, between Burlington, NJ and Bristol, PA, is a vertical lift span bridge, and has a vertical clearance of 61 feet above mean high water in the closed position and 135 feet above mean high water in the open position. The current operating schedule for the drawbridge is published in 33 CFR 117.716(a).

The Burlington County Bridge Commission, who owns and operates the SR 413/Burlington-Bristol Bridge across the Delaware River, mile 117.8, between Burlington, NJ and Bristol, PA, has requested this modification to allow the drawbridge to be maintained in the closed-to-navigation position to facilitate maintenance and painting of the vertical lift span of the drawbridge.

Under this temporary final rule, the drawbridge will be maintained in the closed-to-navigation position and open on signal if at least a two-hour notice is given, from June 19, 2019, through 7:59 a.m. on September 17, 2019. At all other times, the drawbridge will operate per 33 CFR 117.716 (a).

This temporary final rule is necessary to facilitate safe and effective bridge maintenance and painting of the vertical lift span of the drawbridge, while providing for the reasonable needs of navigation. Multiple work platforms will reduce the entire bridge span vertical clearance to approximately 58 feet above mean high water in the closed position and approximately 132 feet above mean high water in the open position. Maintenance personnel, equipment and materials will be located inside the work platforms while maintenance and painting is being performed. To facilitate an opening of the bridge, equipment and materials will need to be secured inside or removed from the work platforms and

personnel will need to vacate the work platforms.

IV. Discussion of Comments, Changes and the Temporary Final Rule

The Coast Guard provided a comment period of 30 days and no comments were received. No changes were made to the regulatory text of this temporary final rule.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive Orders, and we discuss First Amendment rights of protesters.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget (OMB) and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the fact that vessels can still transit the bridge on signal if at least two-hour notice is given.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rule. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the bridge may be small entities, for the reasons stated in section V.A. above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards.

The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Government

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In

particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year.

Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.1D, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a determination that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule simply promulgates the operating regulations or procedures for drawbridges. This action is categorically excluded from further review, under figure 2–1, paragraph (32)(e), of the Instruction. A Record of Environmental Consideration and a Memorandum for the Record are not required for this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; and Department of Homeland Security Delegation No. 0170.1.

■ 2. Amend § 117.716 by adding paragraph (c) to read as follows:

§ 117.716 Delaware River.

* * * * *

(c) The draw of the SR 413 (Burlington-Bristol) Bridge, mile 117.8, between Burlington, NJ and Bristol, PA, shall open on signal if at least a two-hour notice is given from June 19, 2019,

through 7:59 a.m. on September 17, 2019.

K.M. Smith,

Rear Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.

[FR Doc. 2019-10462 Filed 5-17-19; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2019-0343]

Safety Zone; Marine Events Within the Eighth Coast Guard District

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a Safety Zone for the St. John the Baptist Independence day fireworks display from 8:45 p.m. through 9:45 p.m. on July 3, 2019, to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the Eighth Coast Guard District identifies the regulated area for this event on the Lower Mississippi River, by Reserve Louisiana. During the enforcement periods, the operator of any vessel in the regulated area must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

DATES: The regulations in 33 CFR 165.801, Table 5, line 2 will be enforced from 8:45 p.m. through 9:45 p.m. on July 3, 2019.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Lieutenant Commander Benjamin Morgan, Sector New Orleans, U.S. Coast Guard; telephone 504-365-2281, email Benjamin.P.Morgan@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone described in 33 CFR 165.801, Table 5, line 2, as the St. John the Baptist Independence day fireworks display event from 8:45 p.m. through 9:45 p.m. on July 3, 2019. This action is being taken to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the Eighth Coast Guard District, § 165.801, specifies the location of the regulated area for the St. John the Baptist Independence day fireworks display between mile markers 137.5 and 138.5 on the Mississippi River near Reserve, Louisiana. During the

enforcement period, as reflected in § 165.801(a)-(d), if you are the operator of a vessel in the safety zone, you must comply with directions from the Captain of the Port Sector New Orleans or a designated representative.

In addition to this notice of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the local notice to mariners and marine information broadcasts.

Dated: May 14, 2019.

K.M. Luttrell,

Captain, U.S. Coast Guard, Captain of the Port Sector New Orleans.

[FR Doc. 2019-10353 Filed 5-17-19; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2019-0358]

RIN 1625-AA00

Safety Zone; Kanawha River, Charleston, WV

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all navigable waters of the Kanawha River from mile marker 58.1 to mile marker 59.1. This temporary safety zone is necessary to protect persons, vessels, and the marine environment from potential hazards associated with the Live on the Levee fireworks display. Entry into this safety zone is prohibited unless specifically authorized by the Captain of the Port Sector Ohio Valley or a designated representative.

DATES: This rule is effective from 9:15 p.m. through 10:15 p.m. on May 24, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2019-0358 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Wesley Cornelius, Marine Safety Unit Huntington, U.S. Coast Guard; telephone 304-733-0198, email Wesley.P.Cornelius@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. It is impracticable to publish an NPRM because we must establish this safety zone by May 24, 2019, and we lack sufficient time to provide reasonable comment period and then consider those comments before issuing the rule. The NPRM process would delay the establishment of the safety zone until after the date of the event and compromise public safety.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable and contrary to public interest because immediate action is necessary to protect persons, vessels and the marine environment from the potential hazards associated with the fireworks display.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Sector Ohio Valley (COTP) has determined that potential hazards associated with a fireworks display taking place over this section of the Kanawha River will be a safety concern for anyone within a one-mile stretch of the waterway. This rule is needed to protect persons, vessels, and the marine environment in the navigable waters within the safety zone before, during, and after the scheduled fireworks display.

IV. Discussion of the Rule

This rule establishes a temporary safety zone for the Live on the Levee fireworks display from 9:15 p.m. until 10:15 p.m. on May 24, 2019. The safety