

information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

See the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

**FOR FURTHER INFORMATION CONTACT:** Samir Assar, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1636.

#### **SUPPLEMENTARY INFORMATION:**

#### **I. Background**

In the **Federal Register** of November 27, 2015 (80 FR 74353), we issued a final rule entitled “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” (the final rule) that establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption. The final rule, which is codified at 21 CFR part 112, became effective January 26, 2016, but has staggered compliance dates starting January 26, 2017.

We examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-612) and determined that the final rule will have a significant economic impact on a substantial number of small entities. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104-121, as amended by Pub. L. 110-28), we are making available the SECG to reduce the burden of determining how to comply by further explaining and clarifying the actions that a small entity must take to comply with the rule.

We are issuing the SECG consistent with our good guidance practices

regulation (21 CFR 10.115(c)(2)). The SECG represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This is not a significant regulatory action subject to Executive Order 12866 and does not impose any additional burden on regulated entities.

#### **II. Paperwork Reduction Act of 1995**

This guidance refers to 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 part 112 have been approved under OMB control number 0910-0816.

#### **III. Electronic Access**

Persons with access to the Internet may obtain the SECG at either <https://www.fda.gov/FoodGuidances>, or <https://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: August 30, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017-18811 Filed 9-5-17; 8:45 am]

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### **DEPARTMENT OF HOMELAND SECURITY**

#### **Coast Guard**

#### **33 CFR Part 117**

**[Docket No. USCG-2017-0807]**

#### **Drawbridge Operation Regulation; Newtown Creek, New York, NY**

**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 Pulaski Bridge across Newtown Creek, mile 0.6 at New York City, New York. This deviation is necessary to facilitate planned repairs and will allow the owner to temporarily close the draw during weeknights for periods not to exceed five hours.

**DATES:** This deviation is effective from 12:01 a.m. on September 19, 2017 through 5 a.m. on December 30, 2017.

**ADDRESSES:** The docket for this deviation, USCG-2017-0807, 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.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary deviation, call or email James M. Moore, Bridge Management Specialist, First District Bridge Branch, U.S. Coast Guard; telephone 212-514-4334, email [James.M.Moore2@uscg.mil](mailto:James.M.Moore2@uscg.mil).

**SUPPLEMENTARY INFORMATION:** The owner of the bridge, the New York City Department of Transportation, requested a temporary deviation in order to facilitate planned repairs of the bridge including replacement of the grease piping system as well as installation of new span lock shoes, steel shims and horizontal/vertical bolts.

The Pulaski Bridge across Newtown Creek, mile 0.6 at New York City, New York is a double-leaf bascule bridge with a vertical clearance of 39 feet at mean high water and 43 feet at mean low water in the closed position. The existing drawbridge operating regulations are listed at 33 CFR 117.801(g)(1)-(2).

The temporary deviation will allow the Pulaski Bridge to remain closed each Tuesday, Wednesday, Thursday, Friday and Saturday from 12:01 a.m. to 5 a.m. beginning September 19, 2017 until December 30, 2017. The waterway is transited by tug/barge traffic of various sizes. Coordination with waterway users has indicated no objections to the proposed closure of the draw.

Vessels that can pass under the bridge without an opening may do so at all times. The bridge will not be able to open for emergencies. There is no alternate route for vessels to pass.

The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so vessel operators may arrange their transits to minimize any impact caused by the temporary deviation.

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 31, 2017.

**Christopher J. Bisignano,**

*Supervisory Bridge Management Specialist, First Coast Guard District.*

[FR Doc. 2017-18822 Filed 9-5-17; 8:45 am]

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