

**Instructions:** All submissions received must include the Docket No. FDA–2019–D–2011 for “Section 503A Bulks List Final Rule Questions and Answers; Guidance for Industry; Small Entity Compliance Guide; Availability.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the SECG to the Division of Drug Information, Center for Drug Evaluation and Research, Food and

Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

#### FOR FURTHER INFORMATION CONTACT:

Rosilend Lawson, Center for Drug Evaluation and Research, Office of Unapproved Drugs and Labeling Compliance, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5197, Silver Spring, MD 20993–0002, 240–402–6223, [Rosilend.Lawson@fda.hhs.gov](mailto:Rosilend.Lawson@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of February 19, 2019 (84 FR 4696), we issued a final rule establishing the list of bulk drug substances that can be used in compounding under section 503A of the FD&C Act (the final rule) (21 U.S.C. 353a). The final rule, entitled “List of Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act,” is codified at 21 CFR 216.23 and became effective March 21, 2019.

We examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612) and, because we do not have enough information about the effect of the final rule on small entities, 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 explain 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). The SECG represents the current thinking of FDA on the final rule. 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 guidance is not subject to Executive Order 12866.

##### II. Electronic Access

Persons with access to the internet may obtain the SECG at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or [https://](https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm)

[www.regulations.gov](https://www.regulations.gov). Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: May 21, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–10953 Filed 5–23–19; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 100

[Docket No. USCG–2019–0357]

#### Special Local Regulations; Marine Events Within the Captain of the Port Zone Columbia River

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of enforcement of regulation.

**SUMMARY:** The Coast Guard will enforce special local regulations at eight locations in the Sector Columbia River Captain of the Port zone during the dates and times noted in this document. This action is necessary to prevent injury and to protect life and property of the maritime public from the hazards associated with special marine events. These regulations prohibit persons and vessels from entry into, transit through, mooring, anchoring, or loitering within the regulated area unless authorized by the Captain of the Port, Sector Columbia River or their designated representative.

**DATES:** The regulations in 33 CFR 100.1302 will be enforced for the eight regulated areas identified in the **SUPPLEMENTARY INFORMATION** section below for the dates and times specified in this document.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this notice of enforcement, call or email LCDR Dixon Whitley, Waterways Management Division, Marine Safety Unit Portland, Coast Guard; telephone 503–240–9319, email [msupdxwmm@uscg.mil](mailto:msupdxwmm@uscg.mil).

**SUPPLEMENTARY INFORMATION:** The Coast Guard will enforce special local regulations established in 33 CFR 100.1302 for the following eight events during the hours specified on the dates and at the locations listed in the following Table:

TABLE—DATES AND TIMES OF ENFORCEMENT OF 33 CFR 100.1302 SPECIAL LOCAL REGULATIONS AT VARIOUS LOCATIONS IN THE SECTOR COLUMBIA RIVER CAPTAIN OF THE PORT ZONE IN 2019

No.	Date	Event	Sponsor	Location
1 .....	May 31, 2019, 9 a.m. to 5 p.m.	Spring Testing Hydroplane races.	Tri-Cities Water Follies Association.	Kennewick, WA. Regulated area includes all navigable waters within the Columbia River in the vicinity of Columbia Park, commencing at the Interstate 395 Bridge and continuing up river approximately 2.0 miles and terminating at the northern end of Wade Island.
2 .....	June 8, 2019– June 9, 2019, 7 a.m. to 4 p.m.	Rose Fest Drag-on Boat Races.	Portland-Kaohsiung Sister Association.	Portland, OR. Regulated area includes all waters of the Willamette River shore to shore, bordered on the north by the Hawthorne Bridge, and on the south by the Marquam Bridge.
3 .....	June 28, 2019– June 30, 2019, 8 a.m. to 7 p.m.	Richland Regatta Hydroplane races.	Northwest Power Boat Association.	Richland, WA. Regulated area includes all navigable waters of the Columbia River in the vicinity of Howard Amon Park, between River Miles 337 and 338.
4 .....	July 13, 2019, 11 a.m. to 7 p.m.	The Big Float, group inner-tube float.	Human Access Project.	Portland, OR. Regulated area includes all navigable waters of the Willamette River, in Portland, Oregon, enclosed by the Hawthorne Bridge, the Marquam Bridge, and west of a line beginning at the Hawthorne Bridge at approximate location 45°30'50" N; 122°40'21" W, and running south to the Marquam Bridge at approximate location 45°30'27" N; 122°40'11" W.
5 .....	July 26, 2019– July 28, 2019, 6 a.m. to 6 p.m.	Kennewick Hydroplane Races.	Tri-Cities Water Follies Association.	Kennewick, WA. Regulated area includes all navigable waters within the Columbia River in the vicinity of Columbia Park, commencing at the Interstate 395 Bridge and continuing up river approximately 2.0 miles and terminating at the northern end of Wade Island.
6 .....	August 10, 2019, 11 a.m. to 1 p.m.	Swim the Snake	Blue Mountain Resource Conservation and Development.	Perry, WA. Regulated area includes all navigable waters, bank-to-bank of the Snake River, 500 yards upstream and 500 yards downstream from the Washington State Highway 261 Bridge at the approximate position of 46°35'23" N; 118°13'10" W.
7 .....	September 7, 2019, 9 a.m. to 10:30 a.m.	Columbia Crossing Swim.	3 Rivers Road Runners.	Pasco, WA. Regulated area includes all navigable waters, bank-to-bank of the Columbia River in Pasco, Washington, between river mile 332 and river mile 335.
8 .....	September 7, 2019– September 8, 2019, 8 a.m. to 6 p.m.	Portland Dragon Boat Races.	DragonSports USA.	Portland, OR. Regulated area includes the western side of the Willamette River extending from Tom McCall Waterfront Park between the Hawthorne and Marquam Bridges, Portland, OR: Line one starting at 45–30'49" N/122–40'24" W then heading east to 45–30'49" N/122–40'22" W then heading south to 45–30'29" N/122–40'08" W then heading west to 45–30'26" N/122–40'14" W then heading north ending at 45–30'49"N/122–40'24" W.

All coordinates are listed in reference Datum NAD 1983.

The special requirements listed in 33 CFR 100.1302 apply to the activation and enforcement of these special local regulations. All vessel operators who desire to enter the designated zone must obtain permission from the Captain of the Port or their Designated Representative. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

In addition to this notice of enforcement in the **Federal Register**, the Coast Guard will provide notification of this enforcement period via the Local Notice to Mariners and marine information broadcasts.

Dated: May 20, 2019.

**J.C. Smith,**  
*Captain, U.S. Coast Guard, Captain of the Port Columbia River.*

[FR Doc. 2019–10890 Filed 5–23–19; 8:45 am]

**BILLING CODE 9110–04–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket No. USCG–2019–0288]

#### Safety Zones; Annual Events in the Captain of the Port Buffalo Zone

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of enforcement of regulation.

**SUMMARY:** The Coast Guard will enforce certain safety zones located in federal regulations for Annual Events in the Captain of the Port Buffalo. This action is necessary and intended to protect the safety of life and property on navigable waters prior to, during, and immediately after these events. During each enforcement period, no person or vessel may enter the respective safety zone without the permission of the Captain of the Port Buffalo.

**DATES:** The regulations in 33 CFR 165.939(b)(1), as listed in Table 165.939,

will be enforced from 6:15 a.m. through 10:45 a.m. on July 21, 2019.

The regulations in 33 CFR 165.939(b)(4), as listed in Table 165.939, will be enforced from 9:15 p.m. through 10:15 p.m. on July 4, 2019.

The regulations in 33 CFR 165.939(b)(6), as listed in Table 165.939, will be enforced from 8:45 p.m. through 11:45 p.m. on July 27, 2019.

The regulations in 33 CFR 165.939(b)(12), as listed in Table 165.939, will be enforced from 6:45 a.m. through 10:45 a.m. on July 13, 2019.

The regulations in 33 CFR 165.939(d)(2), as listed in Table 165.939, will be enforced daily from 9 a.m. through 6 p.m. August 30, 2019 through September 2, 2019.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this notice of enforcement, call or email LT Ryan Junod, Chief of Waterways Management, U.S. Coast Guard Marine Safety Unit Cleveland; telephone (216) 937–0124, email [ryan.s.junod@uscg.mil](mailto:ryan.s.junod@uscg.mil).

**SUPPLEMENTARY INFORMATION:** The Coast Guard will enforce the Safety Zones; Annual Events in the Captain of the Port