IX. Environmental Considerations

The Commission's regulations provide a categorical exclusion for the Commission's rules from any requirement to prepare an environmental assessment or an environmental impact statement because they ''have little or no potential for affecting the human environment.'' 16 CFR 1021.5(c)(2). This rule falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required.

X. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that where a ''consumer product safety standard under [the Consumer Product Safety Act (CPSA)]'' is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a requirement dealing with the same risk of injury, unless the state requirement is identical to the federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption in certain circumstances.

Section 1404(a) of the VGBA specifies that a rule issued under section 1404(b) of the VGBA shall be treated as a consumer product safety standard under the CPSA, thus, implying that the preemptive effect of section 26(a) of the CPSA would apply. Therefore, this rule will invoke the preemptive effect of section 26(a) of the CPSA when it becomes effective.

List of Subjects in 16 CFR Part 1450

Consumer protection, Incorporation by reference, Infants and children, Law enforcement.

For the reasons stated above, the Commission amends part 1450 of title 16 of the Code of the Federal Regulations as follows:

PART 1450—VIRGINIA GRAEME BAKER POOL AND SPA SAFETY ACT REGULATIONS

■ 1. The authority citation for part 1450 continues to read as follows:

Authority: 15 U.S.C. 2051–2089, 86 Stat. 1207; 15 U.S.C. 8001–8008, 121 Stat. 1794.

■ 2. Revise § 1450.3 to read as follows:

§ 1450.3 Incorporation by reference.

(a) Except as provided in paragraph (b) of this section, each swimming pool or spa drain cover manufactured, distributed, or entered into commerce in the United States shall conform to the entrapment protection standards of ANSI/APSP/ICC–16 2017, American National Standard for *Suction Outlet Fitting Assemblies (SOFA) for Use in Pools, Spas and Hot Tubs,* approved on August 18, 2017. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from the Pool & Hot Tub Alliance (formerly known as the Association of Pool & Spa Professionals), 2111 Eisenhower Avenue, Alexandria, Virginia 22314; *http://www.apsp.org,* telephone 703–838–0083. You may inspect a copy at the Division of the Secretariat, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301–504–7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *https://www.archives.gov/federal-regster/cfr/ibr-locations.html.*

(b) The CPSC standard does not require compliance with the following provisions:

(1) Section 1.1.3 of ANSI/APSP/ICC–16 2017.

(2) Sections 1.3.3.1 through 1.3.3.2 of ANSP/APSP/ICC–16 2017.

(3) Section 3.2.4 of ANSI/APSP/ICC–16 2017.

(4) Section 3.5.1 of ANSI/APSP/ICC–16 2017.

(5) Sections 3.6.1 through 3.6.4.3 of ANSI/APSP/ICC–16 2017.

(6) Section 3.7 of ANSI/APSP/ICC–16 2017.

(7) Section 9.4 of ANSI/APSP/ICC–16 2017.

Abioye E. Mosheim,

Acting Secretary, Consumer Product Safety Commission.

[FR Doc. 2019–10845 Filed 5–23–19; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 216

[Docket No. FDA–2019–D–2011]

Section 503A Bulks List Final Rule Questions and Answers; Guidance for Industry; Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a guidance for industry entitled ''Section 503A Bulks List Final Rule Questions and Answers—Small Entity Compliance Guide.'' The small entity compliance guide (SECG) is intended to help small entities comply with the final rule establishing the list of bulk drug substances that can be used in accordance with certain compounding provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: The announcement of the guidance is published in the **Federal Register** on May 24, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

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.*

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://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 *msupdxwwm@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: