

**§ 720.8 Confidentiality of statements.**

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(e) If, after receiving all of the data that are necessary to make a determination about whether the identity of an ingredient is a trade secret, FDA tentatively decides to deny the request, the Agency will inform the person requesting trade secrecy of its tentative determination in writing. FDA will set forth the grounds upon which it relied in making this tentative determination. The petitioner may submit, within 60 days from the date of receipt of the written notice of the tentative denial, additional relevant information and arguments and request that the Agency reconsider its decision in light of both the additional material and the information that it originally submitted.

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(g) A final determination that an ingredient is not a trade secret within the meaning of § 20.61 of this chapter constitutes final Agency action that is subject to judicial review under 5 U.S.C. Chapter 7. If suit is brought within 30 calendar days after such a determination, FDA will not disclose the records involved or require that the disputed ingredient or ingredients be disclosed in labeling until the matter is finally determined in the courts. If suit is not brought within 30 calendar days after a final determination that an ingredient is not a trade secret within the meaning of § 20.61 of this chapter, the records involved will be available for public disclosure in accordance with part 20 of this chapter.

Dated: August 31, 2022.

**Robert M. Califf,***Commissioner of Food and Drugs.*

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**DEPARTMENT OF HOMELAND SECURITY****Coast Guard****33 CFR Part 100**

[Docket No. USCG–2022–0628]

**Special Local Regulations; Marine Events Within the Seventh Coast Guard District****AGENCY:** Coast Guard, Department of Homeland Security (DHS).**ACTION:** Notification of enforcement of regulation.**SUMMARY:** The Captain of the Port (COTP) Savannah, Georgia will enforce a special local regulation for the

Ironman Triathlon in Augusta, Georgia, on September 25, 2022, to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the Seventh Coast Guard District identifies the regulated area for this event in Augusta, GA. 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 100.701 will be enforced for the location identified in Section (d), Item 3 of Table 1 to § 100.701, from 6:30 a.m. until 10:30 a.m., on September 25, 2022.**FOR FURTHER INFORMATION CONTACT:** If you have questions about this notification of enforcement, contact Coast Guard Marine Safety Unit Savannah, Office of Waterways Management, by calling or emailing MSTC Ashley Schad, telephone 912–652–4353 ext 242, or email [Ashley.M.Schad@uscg.mil](mailto:Ashley.M.Schad@uscg.mil).**SUPPLEMENTARY INFORMATION:** The Coast Guard will enforce a special local regulation in 33 CFR 100.701, Table 1 to § 100.701, Section (d), Item 3, for the Ironman Triathlon, from 6:30 a.m. to 10:30 a.m., on September 25, 2022.

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 Seventh Coast Guard District, 33 CFR 100.701, specifies the location of the regulated area for the Ironman Triathlon which encompasses portions of the Savannah River and its branches. During the enforcement periods, as reflected in 33 CFR 100.701(c), if you are the operator of a vessel in the regulated area you must comply with directions from the Patrol Commander. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

In addition to this notification 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.

**K.A. Broyles,***Commander, U.S. Coast Guard, Captain of the Port Savannah.*

[FR Doc. 2022–19741 Filed 9–12–22; 8:45 am]

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**DEPARTMENT OF HOMELAND SECURITY****Coast Guard****33 CFR Part 100**

[Docket No. USCG–2022–0653]

**Special Local Regulation; Marine Events Within the Eleventh Coast Guard District—San Diego Bayfair****AGENCY:** Coast Guard, Department of Homeland Security (DHS).**ACTION:** Notification of enforcement of regulation.**SUMMARY:** The Coast Guard will enforce the special local regulation on the waters of Mission Bay, CA, during the San Diego Bayfair on September 16, 2022, through September 18, 2022. This special local regulation is necessary to provide for the safety of the participants, crew, sponsor vessels of the event, and general users of the waterway. During the enforcement period, persons and vessels are prohibited from entering into, transiting through, or anchoring within this regulated area unless authorized by the Captain of the Port, or his designated representative.**DATES:** The regulations in 33 CFR 100.1101 for the location listed in Item 9 in table 1 to § 100.1101 will be enforced from 6 a.m. until 6 p.m., each day from September 16, 2022, through September 18, 2022.**FOR FURTHER INFORMATION CONTACT:** If you have questions about this notification of enforcement, call or email Lieutenant Junior Grade Shera Kim, Waterways Management, U.S. Coast Guard Sector San Diego, CA; telephone (619) 278–7656, email [MarineEventsSD@uscg.mil](mailto:MarineEventsSD@uscg.mil).**SUPPLEMENTARY INFORMATION:** The Coast Guard will enforce the special local regulations in 33 CFR 100.1101 for the location identified in Item 9 in table 1 to § 100.1101, from 6 a.m. until 6 p.m., each day from September 16, 2022, through September 18, 2022, for the San Diego Bayfair in Mission Bay, CA. This action is being taken to provide for the safety of life on the navigable waterways during the event. Our regulation for recurring marine events in the San Diego Captain of the Port Zone, § 100.1101, Item No. 9 in table 1 to § 100.1101 specifies the location of the regulated area for the San Diego Bayfair, which encompasses portions of Mission Bay. Under the provisions of § 100.1101, persons and vessels are prohibited from entering into, transiting through, or anchoring within this regulated area