

### 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-1978-N-0018 (formerly Docket No. FDA-1978-N-0038) for “Sunscreen Drug Products for Over-the-Counter Human Use.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

#### FOR FURTHER INFORMATION CONTACT:

Kristen Hardin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5443, Silver Spring, MD 20993, 240-402-4246.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of February 26, 2019, FDA published a proposed rule with a 90-day comment period to request comments on the Agency’s proposals relating to the regulation of OTC sunscreen monograph products. These proposals described the conditions under which the Agency proposes that OTC sunscreen monograph products are generally recognized as safe and effective and not misbranded. Comments on these proposals will inform FDA’s rulemaking to establish regulations putting into effect a final monograph for nonprescription, OTC sunscreen drug products. FDA also indicated in the proposed rule that the Agency would consider requests to defer further rulemaking with respect to specific sunscreen active ingredients to allow the submission of new safety and/or effectiveness data to the record if such requests were submitted to the docket within the initial 90-day comment period. Elsewhere in this issue of the **Federal Register**, the Agency is publishing a correction to the proposed rule to clarify illegible graphics of equations.

The Agency has received a request for a 60- to 90-day extension of the comment period for the proposed rule. This request conveyed concern that the current 90-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule.

FDA has considered the request and is extending the comment period for the proposed rule for 30 days, until June 27, 2019. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues. We note that this 30-day extension applies both to comments and to requests for the Agency to defer further rulemaking with respect to specific sunscreen active ingredients.

Dated: April 12, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 100

[Docket Number USCG-2019-0150]

RIN 1625-AA08

### Special Local Regulation; Kailua Bay, Ironman World Championship, Kailua-Kona, Hawaii

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard is proposing to establish a recurring special local regulation for certain waters of Kailua Bay, Hawaii. This action is necessary to provide for the safety of life on these navigable waters located at Kailua-Kona, HI, during the swim portion of the Ironman World Championship Triathlon and practice swim held on consecutive Saturdays annually in October. This proposed rulemaking would prohibit persons and vessels from being in the regulated area each day of the event unless authorized by the Captain of the Port Honolulu. We invite your comments on this proposed rulemaking.

**DATES:** Comments and related material must be received by the Coast Guard on or before May 20, 2019.

**ADDRESSES:** You may submit comments identified by docket number USCG-2019-0150 using the Federal eRulemaking Portal at <https://www.regulations.gov>. See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this proposed rulemaking, call or email Chief Jason Olney, Waterways Management Division, U.S. Coast Guard Sector Honolulu; telephone (808) 522-8265, email [jason.r.olney@uscg.mil](mailto:jason.r.olney@uscg.mil).

#### SUPPLEMENTARY INFORMATION:

##### I. Table of Abbreviations

CFR Code of Federal Regulations  
COTP Captain of the Port  
DHS Department of Homeland Security  
FR Federal Register

NPRM Notice of proposed rulemaking  
 § Section  
 SLR Special Local Regulation  
 U.S.C. United States Code

## II. Background, Purpose, and Legal Basis

The Ironman World Championship Triathlon is held annually on the first two Saturdays in October and consists of two swim events, the race itself, and a practice swim held the week before. This event is a world famous triathlon with participants coming from around the world to compete. The event occurs within the ocean waters of Kailua Bay, HI. Each swim event consists of 2,500 participants swimming a 2.4 mile (4,224 yard) marked race course located in navigable shallow ocean waters. Each year, an increasing number of spectator pleasure craft are drawn to support and view the Ironman swim event. Spectator vessels and other vessel traffic pose a significant safety hazard due to the limited maneuverability of swim participants and vessels navigating in close proximity to the designated area.

The purpose of this rulemaking is to protect event participants, spectators, and transiting vessels on navigable waters of Kailua Bay before, during, and after the scheduled event held annually. The Captain of the Port (COTP) Honolulu has determined that potential hazards associated with the swimmers are a safety concern for anyone intending to operate near the event area.

The Coast Guard proposes this rulemaking under authority in 46 U.S.C. 70041 which authorizes the Coast Guard to establish and define special local regulations.

## III. Discussion of Proposed Rule

The COTP Honolulu proposes to establish a recurring special local regulation to be enforced from 5 a.m. to 11 a.m., on the first two Saturdays in October annually. For both the race itself and the practice swim event, six hours are required for all participants to complete the swim course.

The regulated area would cover all navigable waters of Kailua Bay within 100 yards adjacent to the 2.4 mile (4,224 yards) swim course, starting at the shoreline northeast of Kailua Pier at 19°38.341' N, 155°59.782' W; thence southeast to 19°37.416' N, 155°59.444' W; thence southwest to 19°37.397' N, 155°59.500' W; thence northwest to 19°38.150' N, 155°59.760' W, thence north and back to Kailua Pier at 19°38.398' N, 155°59.816' W, and returning along the pier to the originating point on the shoreline at 19°38.341' N, 155°59.782' W.

This proposed rule provides additional information about areas with the regulated area and the restrictions that apply to mariners. These areas include a "Course Area", and "Buffer Area". The duration of the rule and size of the regulated area are intended to ensure the safety of life on these navigable waters before, during, and after the event, scheduled from 5 a.m. until 11 a.m. on the first two Saturdays in October annually. The COTP and Coast Guard Patrol Commander (PATCOM) would have authority to forbid and control the movement of all vessels and persons, including event participants, in the regulated area. When hailed or signaled by an official patrol, a vessel or person in the regulated area would be required to immediately comply with the directions given by the COTP or PATCOM. If a person or vessel fails to follow such directions, the Coast Guard may expel them from the area, issue them a citation for failure to comply, or both. Except for Ironman participants and vessels already identified as part of the event safety or security, a vessel or person would be required to get permission from the COTP or PATCOM before entering the regulated area while the rule is being enforced. Vessel operators could request permission to enter and transit through the regulated area by contacting the PATCOM on VHF-FM channel 16. Vessel traffic would be able to safely transit the regulated area once the PATCOM deems it safe to do so. A person or vessel not registered with the event sponsor as a participant or assigned as official patrols would be considered a spectator. Official Patrols are any vessel assigned or approved by the Commander, Coast Guard Sector Honolulu, with a commissioned, warrant, or petty officer on board.

If permission is granted by the COTP or PATCOM, a person or vessel would be allowed to enter the regulated area or pass directly through the regulated area as instructed. Vessels would be required to operate at a safe speed while within the regulated area. Official patrol vessels will assist with the safety of the event and ensure spectator vessels remain outside the regulated area. The designated swim area will remain closed until races have concluded and the regulated area is deemed safe for normal operations.

The regulatory text we are proposing appears at the end of this document.

## IV. Regulatory Analyses

We developed this proposed 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 protestors.

### 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 NPRM has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, the NPRM 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 size, location, duration, event history, time of day and time of year of the regulated area which would impact a small designated area of Kailua Bay. Accordingly, this NPRM has not been reviewed by the Office of Management and Budget.

The Coast Guard would promulgate a Notice of Enforcement and issue a Local Notice to Mariners each year. In addition, the Coast Guard will issue a Broadcast Notice to Mariners with information pertaining to the regulated area via VHF-FM marine channel 16 about the status of the regulated area. Moreover, the rule would allow vessels to seek permission to enter the regulated area, transit around the race area, and vessel traffic would be able to safely transit the regulated area once the COTP of Honolulu's PATCOM deems it safe to do so.

### B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 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 certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the regulated area may be small entities, this proposed rule would not have a significant economic impact on vessel

owners or operators for the reasons stated in section IV.A above.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

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 proposed 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** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

#### C. Collection of Information

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

#### D. Federalism and Indian Tribal Governments

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 proposed 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 proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would 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. If you believe this proposed rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

#### 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 proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

#### F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves implementation of regulations within 33 CFR 100 applicable to organized marine events on the navigable waters of the United States that could negatively impact the safety of waterway users. Normally such actions are categorically excluded from further review under paragraph L61 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed 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.

#### V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment

applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at <http://www.regulations.gov>. If your material cannot be submitted using <http://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to <https://www.regulations.gov> and will include any personal information you have provided. For more about privacy and the docket, visit <https://www.regulations.gov/privacyNotice>.

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at <https://www.regulations.gov> and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

#### List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 100 as follows:

#### PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

**Authority:** 46 U.S.C. 70041; 33 CFR 1.05–1.

■ 2. Add § 100.1402 to read as follows:

**§ 100.1402 Special Local Regulation; Kailua Bay, Ironman World Championship, Kailua-Kona, Hawaii.**

(a) *Definitions.* As used in this section:

*Buffer area* is a neutral 100-yard area that surrounds the perimeter of the course area's navigable waters as described by this section. The purpose of a buffer area is to minimize potential collision conflicts with marine event participants and spectator vessels or nearby transiting vessels. This area provides separation between a course area and spectator viewing areas.

*Captain of the Port (COTP) Honolulu* means the Commander, U.S. Coast Guard Sector Honolulu or any Coast Guard commissioned, warrant or petty officer who has been authorized by the COTP to act on his behalf.

*Coast Guard Patrol Commander (PATCOM)* means a commissioned, warrant, or petty officer of the U.S. Coast Guard who has been designated as PATCOM by the Commander, Coast Guard Sector Honolulu.

*Course area* is an area described by a line bound by coordinates provided in latitude and longitude that outlines the boundary of the event swim area within the overall regulated area defined by this section.

*Enforcement vessels* are designated vessels authorized by the COTP Honolulu, the event PATCOM, or COTP Honolulu's designated representatives to support the safety and security of the marine event.

*Official Patrol* means any vessel assigned or approved by Commander, Coast Guard Sector Honolulu with a commissioned, warrant, or petty officer on board.

*Participant* means any persons registered with the event sponsor as participating in the Ironman Triathlon or practice swim.

*Regulated area* is the combined course area and buffer area.

*Spectators* are all persons and vessels not registered with the sponsor as participants, support vessels, or enforcement vessels.

(b) *Location*. All coordinates reference Datum NAD 1983.

(1) *Regulated area*. All navigable waters within Kailua Bay and encompasses the course area and surrounding 100-yard buffer area. This course area and 100-yard buffer area extends from the surface of the water to the ocean floor.

(2) *Course area*. The 2.24 mile (4,224 yards) swim course is a temporary marked swim course within the regulated area located in Kailua Bay.

(3) *Buffer area*. All navigable waters 100 yards outside of the perimeter of the course area, described in paragraph (c)(4) of this section.

(c) *Special local regulations*: (1) The COTP Honolulu or PATCOM may forbid and control the movement of all vessels and persons, including event participants, in the regulated area. When hailed or signaled by an official patrol, a vessel or person in the regulated area shall immediately comply with the directions given by the patrol. Failure to do so may result in the Coast Guard expelling the person or vessel from the area, issuing a citation for failure to comply, or both. The COTP Honolulu or PATCOM may terminate the event at any time the COTP Honolulu or PATCOM believes it necessary to do so for the protection of life.

(2) Except for participants and safety support vessels, a person or vessel within the regulated area at the start of enforcement of this section must immediately depart the regulated area.

(3) Support and enforcement vessels consist of any local law enforcement and sponsor provided vessels assigned or approved by the COTP Honolulu, the event PATCOM, or COTP Honolulu designated representatives, to patrol the regulated area.

(4) The regulated area consists of all navigable waters starting at the shoreline northeast of Kailua Pier at 19°38.341' N, 155°59.782' W; thence southeast to 19°37.416' N, 155°59.444' W; thence southwest to 19°37.397' N, 155°59.500' W; thence northwest to 19°38.150' N, 155°59.760' W, thence north and back to Kailua Pier at 19°38.398' N, 155°59.816' W, and returning along the pier to the originating point on the shoreline at 19°38.341' N, 155°59.782' W.

(5) Spectators shall not enter into, anchor, block, loiter, or impede the transit of participants or support/enforcement vessels in the regulated area during the enforcement of this regulation, unless cleared for entry by the COTP Honolulu, the event PATCOM, or the COTP's designated representatives.

(6) Persons desiring to transit the regulated area identified may contact the COTP Honolulu in advance at the Sector Honolulu Command Center telephone number (808) 842-2600 and (808) 842-2601 or immediately prior to or during the event to the COTP Honolulu's PATCOM or designated representative on VHF-FM marine channel 16 (156.8 Mhz) to seek permission to transit or remain in the area. If permission is granted, all persons and vessels must comply with the instructions of the COTP Honolulu, the event PATCOM or the COTP's designated representative and proceed at the minimum speed necessary to maintain a safe course while in the area.

(7) If enforcement of the regulated area is no longer necessary, the COTP Honolulu, event Patrol Commander, or COTP designated representative will inform the public through radio broadcasts that the regulated area is no longer being enforced.

(d) *Enforcement officials*. The Coast Guard may be assisted with event patrol and enforcement of the regulated area by other Federal, State, and local agencies.

(e) *Enforcement period*. The marine event and special local regulation will be enforced from 5 a.m. to 11 a.m. on the first two Saturdays in October annually. The Coast Guard will publish

a notice in the Fourteen Coast Guard District Local Notice to Mariners, a Notice of the Enforcement in the **Federal Register**, and issue a marine information broadcast on VHF-FM marine band radio on channel 16 announcing specific event date and times.

Dated: April 12, 2019.

**M.C. Long,**

*Captain, U.S. Coast Guard, Captain of the Port Honolulu.*

[FR Doc. 2019-07777 Filed 4-17-19; 8:45 am]

**BILLING CODE 9110-04-P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA-R06-OAR-2018-0706; FRL-9991-79-Region 6]

### Air Plan Approval; New Mexico; Infrastructure for the 2015 Ozone National Ambient Air Quality Standards and Repeal of State Regulations for Total Suspended Particulate

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to approve State Implementation Plan (SIP) infrastructure certifications from the State of New Mexico and Albuquerque-Bernalillo County to address Clean Air Act (CAA or Act) section 110(a)(1) and (2) requirements for the 2015 ozone (O<sub>3</sub>) National Ambient Air Quality Standards (NAAQS). The submittals address how the existing SIP provides for the implementation, maintenance, and enforcement of the 2015 O<sub>3</sub> NAAQS (infrastructure SIP or i-SIP). The i-SIP ensures that the New Mexico SIP is adequate to meet the state's responsibilities under the CAA for this NAAQS. The EPA is also proposing to approve a SIP revision for the repeal of the New Mexico Ambient Air Quality Standards (NMAAQs) for total suspended particulate (TSP) in the New Mexico regulations incorporated into the SIP.

**DATES:** Written comments must be received on or before May 20, 2019.

**ADDRESSES:** Submit your comments, identified by Docket No. EPA-R06-OAR-2018-0706, at <https://www.regulations.gov> or via email to [ruan-lei.karolina@epa.gov](mailto:ruan-lei.karolina@epa.gov). Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from