

Lists of Subjects in 14 CFR 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ACE KS E5 Ellsworth, KS [Establish]

Ellsworth Municipal Airport, KS
(Lat. 38°45'02" N, long. 98°13'49" W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Ellsworth Municipal Airport.

Issued in Fort Worth, Texas, on October 7, 2022.

Martin A. Skinner,

*Acting Manager, Operations Support Group,
ATO Central Service Center.*

[FR Doc. 2022–22291 Filed 10–20–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 216**

[Docket No. FDA–2015–N–0030]

Extension of the Period Before the Food and Drug Administration Intends To Begin Enforcing the Statutory 5 Percent Limit on Out-of-State Distribution of Compounded Human Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; extension of period before enforcement.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is

extending the period before FDA intends to begin enforcing the statutory 5 percent limit on distribution of compounded human drug products out of the State in which they are compounded in States that have not entered into a standard memorandum of understanding (MOU) with FDA addressing certain distributions of compounded human drug products. FDA is extending the period, which was scheduled to end on October 27, 2022, until the effective date of a final rule regarding certain distributions of compounded human drug products and publication of an updated standard MOU.

DATES: FDA is extending the period before FDA intends to begin enforcing the statutory 5 percent limit on distribution of compounded human drug products out of the State in which they are compounded in States that have not entered into a standard MOU with FDA as of October 21, 2022.

FOR FURTHER INFORMATION CONTACT: Dominic Markwordt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5104, Silver Spring, MD 20993–0002, 301–796–9349.

SUPPLEMENTARY INFORMATION: Section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a) describes the conditions that must be satisfied for drug products compounded by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, to be exempt from the following sections of the FD&C Act: (1) section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice (CGMP) requirements), (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use), and (3) section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications).

One of the conditions to qualify for the exemptions listed in section 503A of the FD&C Act is that: (1) the drug product is compounded in a State that has entered into an MOU with the FDA that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State or (2) if the drug product is compounded in a State that has not entered into such an MOU, the licensed pharmacist, pharmacy, or physician does not distribute, or cause

to be distributed, compounded drug products out of the State in which they are compounded in quantities that exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician (statutory 5 percent limit) (see section 503A(b)(3)(B)(i) and (ii) of the FD&C Act).

In the **Federal Register** of October 27, 2020 (85 FR 68074), FDA announced the availability of a standard MOU describing the responsibilities of a State Board of Pharmacy or other appropriate State agency that chooses to sign the standard MOU in investigating and responding to complaints related to drug products compounded in such State and distributed outside such State and in addressing the interstate distribution of inordinate amounts of compounded human drug products.

In the October 27, 2020, **Federal Register** notice, FDA stated that it was providing a 365-day period that was scheduled to end on October 27, 2021, for States to decide whether to sign the standard MOU before FDA intended to begin enforcing the statutory 5 percent limit in States that do not sign the standard MOU. Soon after announcing the availability of the standard MOU, FDA was sued by several compounding pharmacies regarding the standard MOU in the U.S. District Court for the District of Columbia (*Wellness Pharmacy, Inc. v. Becerra* (D.D.C. Sep. 21, 2021)).

In the **Federal Register** of August 9, 2021 (86 FR 43550), FDA extended the period to October 27, 2022, before FDA intends to begin enforcing the statutory 5 percent limit in States that do not sign the standard MOU.

On September 21, 2021, the Court remanded the standard MOU to FDA to either certify that it will not have a significant economic effect on small businesses or prepare a regulatory flexibility analysis. To undertake this analysis more fully and ensure a robust framework for these important public health protections, FDA intends to engage in notice-and-comment rulemaking regarding certain distributions of compounded human drug products under section 503A of the FD&C Act. FDA considers the standard MOU published in October 2020 to be suspended. This means that during the rulemaking process, FDA will not enter into new agreements with States based on the October 2020 standard MOU. FDA does not expect States that have signed the October 2020 standard MOU to carry out the activities described in the MOU. The October 2020 standard MOU will be updated based on the content of a final rule, and FDA intends to announce a new opportunity for all

States to consider and sign the updated standard MOU.

FDA is now extending the period before FDA intends to begin enforcing the statutory 5 percent limit in States that have not entered into a standard MOU with FDA until the effective date of a final rule regarding certain distributions of compounded human drug products under section 503A of the FD&C Act and publication of an updated standard MOU.¹

Dated: October 17, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-22876 Filed 10-20-22; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG-2022-0870]

Special Local Regulations Northern California and Lake Tahoe Area Annual Marine Events; Sacramento Ironman Swim, Sacramento, CA

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the special local regulations for the annual Sacramento Ironman Triathlon marine event on October 23, 2022, to provide for the safety of life on navigable waterways in the Sacramento River during this event. Our regulation for marine events in Northern California identifies the regulated area for this event. During the enforcement period, unauthorized persons or vessels are prohibited from entering into, transiting through, or loitering or anchoring in the regulated area, unless authorized by the designated Patrol Commander (PATCOM) or other Federal, State, or local law enforcement agencies on scene to assist the Coast Guard in enforcing the regulated area.

DATES: The regulations in 33 CFR 100.1103 will be enforced for the location listed in Table 1 to § 100.1103, Item number 5 from 6 a.m. to 10 a.m. on October 23, 2022.

¹ The Office of the Federal Register has published this document under the category "Rules and Regulations" pursuant to 1 CFR 5.9(b). We note that the categorization as such for purposes of publication in the **Federal Register** does not affect the legal content or intent of the document. See, 1 CFR 5.1(c).

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email Lieutenant Anthony I. Solares, Sector San Francisco Waterways Management, U.S. Coast Guard; telephone 415-399-3585, email SFWaterways@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulations in 33 CFR 100.1103, Table 1 to § 100.1103, Item number 5 for the Sacramento Ironman Swim regulated area from 6 a.m. to 10 a.m. on October 23, 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 Northern California, § 100.1103, specifies the location of the regulated area for the Sacramento Ironman Swim which encompasses portions of the American River and Sacramento River. During the enforcement period, the regulated area will be in effect in the navigable waters of the American River and Sacramento River from Township 9 Park to North of Tower Bridge.

During the enforcement period, under the provisions of 33 CFR 100.1103(b), if you are the operator of a vessel in the regulated area you must comply with directions from the Patrol Commander (PATCOM) or any other Official Patrol, defined as a Federal, State, or local law enforcement agency on scene to assist the Coast Guard in enforcing the regulated area. During the enforcement period, if you are the operator of a vessel that participates in the marine event within the regulated area, you must follow the route established by the marine event sponsor, and comply with directions from the Patrol Commander or other Official Patrol. The PATCOM or Official Patrol may, upon request, allow the transit of commercial vessels through regulated areas when it is safe to do so.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via Local Notice to Mariners. If the Captain of the Port determines that the regulated area need not be enforced for the full duration stated in this notification, a Broadcast Notice to Mariners may be used to grant general permission to enter the regulated area.

Dated: October 17, 2022.

Jordan M. Balduenza,

Captain, U.S. Coast Guard, Alternate Captain of the Port, San Francisco.

[FR Doc. 2022-22950 Filed 10-20-22; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2022-0853]

RIN 1625-AA11

Safety Zone; Oil Pipeline Repairs, San Pedro Bay, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the oil pipeline repair operations in the vicinity of a damaged pipeline, off the coast of Orange County and near San Pedro Bay, CA. The safety zone is necessary to reduce significant hazards to vessels, the harbor, and the public during ongoing pipeline repair. Entry of persons or vessels into this temporary safety zone is prohibited unless specifically authorized by the Captain of the Port Sector Los Angeles—Long Beach, or his designated representative.

DATES: This rule is effective without actual notice from October 21, 2022 through December 24, 2022. For the purposes of enforcement, actual notice will be used from October 10, 2022, until October 21, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2022-0853 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LCDR Maria Wiener, Waterways Management, U.S. Coast Guard Sector Los Angeles—Long Beach; telephone (310) 357-1603, email Maria.C.Wiener@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision