

■ 4. Amend § 129.9 by revising paragraphs (a)(3) and (b)(3) to read as follows:

**§ 129.9 Contents of operations specifications.**

(a) \* \* \*

(3) The certificate number and validity of the foreign air carrier's air operator certificate issued by the State of the Operator or a Regional Safety Oversight Organization on behalf of the State of the Operator;

\* \* \* \* \*

(b) \* \* \*

(3) In the case of a foreign air carrier, the certificate number and validity of the foreign air carrier's Air Operator Certificate issued by the State of the Operator or a Regional Safety Oversight Organization on behalf of the State of the Operator;

\* \* \* \* \*

Issued under authority provided by 49 U.S.C. 106(f) and 44701(a) in Washington, DC.

**Robert M. Ruiz,**

*Deputy Executive Director, Flight Standards Service.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 201, 500, 501, 510, 514, and 516

[Docket No. FDA-2023-N-5160]

RIN 0910-A143

#### Labeling Requirements for Approved or Conditionally Approved New Animal Drugs; Extension of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is extending the comment period for the proposed rule entitled "Labeling Requirements for Approved or Conditionally Approved New Animal Drugs" published in the **Federal Register** of March 12, 2024, by 60 days. The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

**DATES:** FDA is extending the comment period on the proposed rule published March 12, 2024 (89 FR 18262), by 60

days. Either electronic or written comments must be submitted by August 9, 2024.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 9, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

#### 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-2023-N-5160 for "Labeling Requirements for Approved or Conditionally Approved New Animal Drugs." 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, 240-402-7500.

- **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.govinfo.gov/content/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, 240-402-7500.

#### FOR FURTHER INFORMATION CONTACT:

*With regard to the proposed rule:* Suzanne Sechen, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0814, [Suzanne.Sechen@fda.hhs.gov](mailto:Suzanne.Sechen@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of March 12, 2024 (89 FR 18262), FDA published a proposed rule entitled "Labeling Requirements for Approved or Conditionally Approved New Animal Drugs" with a 90-day

period for submission of public comments.

The Agency has received a request for an extension of the comment period for the proposed rule. The request conveyed concern that the current 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 60 days, until August 9, 2024. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

Dated: May 17, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024-11229 Filed 5-21-24; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG-2024-0023]

RIN 1625-AA11

#### Safety Zone; Sea Otter Point, Port of Valdez, AK

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard is proposing to amend its regulations titled, Safety Zone; City of Valdez July 4th Fireworks, Port Valdez; Valdez, AK. The City of Valdez has changed the annual firework displays from July 4th to December 31st each year. It is therefore necessary to amend the CFR to reflect the correct date of the fireworks display. We invite your comments on this proposed rulemaking.

**DATES:** Comments and related material must be received by the Coast Guard on or before June 21, 2024.

**ADDRESSES:** You may submit comments identified by docket number USCG-2024-0023 using the Federal Decision-Making 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. This notice of proposed rulemaking with its plain-language, 100-word-or-less proposed rule summary will be available in this same docket.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rulemaking, call or email LTJG Abigail Ferrara, Waterways Management Division, U.S. Coast Guard; 907-835-7209, email [Abigail.C.Ferrara@uscg.mil](mailto:Abigail.C.Ferrara@uscg.mil).

#### SUPPLEMENTARY INFORMATION:

##### I. Table of Abbreviations

CFR Code of Federal Regulations  
COTP Captain of the Port Prince William Sound  
DHS Department of Homeland Security  
FR Federal Register  
NPRM Notice of proposed rulemaking  
§ Section  
U.S.C. United States Code

##### II. Background, Purpose, and Legal Basis

The Coast Guard began issuing temporary final rules establishing safety zones during the Valdez July 4th fireworks display beginning in 2014. The Coast Guard received no comments or concerns from the public when the temporary safety zones were in place. Due to the repeating nature of the event, on February 28, 2017, the Coast Guard published a notice of proposed rulemaking (NPRM) titled Safety Zone; City of Valdez July 4th Fireworks, Port Valdez; Valdez, AK (82 FR 12076). There we stated why we issued the NPRM and invited comments on our proposed regulatory action related to this fireworks display. Since then, the City of Valdez has changed the firework display from July 4th to December 31st. The Coast Guard again began issuing temporary final rules annually for the new date. Again, due to the repeating nature of the event, we are issuing this NPRM to change the date and time to reflect the correct event details.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters within a 200-yard radius of the firework display before, during, and after the scheduled event. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70034.

##### III. Discussion of Proposed Rule

The COTP is proposing to amend 33 CFR part 165.1713, titled Safety Zone; City of Valdez July 4th Fireworks, Port Valdez; Valdez, AK to reflect the actual date of the fireworks display of December 31st. The time of the safety zone would change to 7:30 p.m. to 9:00 p.m. The safety zone would still encompass all navigable waters of Port Valdez within a 200-yard radius from a position of 61°07'22" N and 146°21'13" W. No vessel or person would be permitted to enter the safety zone without obtaining permission from the

COTP or a designated representative. 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. This NPRM has not been designated a "significant regulatory action," under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on extremely limited vessel traffic in the winter months, as well as the size, location, time of day, and duration of the safety zone. Furthermore, vessels may request authorization to transit through the safety zone with the permission of the COTP, Prince William Sound, Alaska. The Coast Guard will still issue a Broadcast Notice to Mariners via VHF-FM marine channel 16 about the zone.

##### 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 safety zone may be small entities, for the reasons stated in section IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it,