

### III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

### IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

### List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 876 is amended as follows:

#### PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

■ 1. The authority citation for part 876 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 876.4330 to subpart E to read as follows:

#### § 876.4330 Endoscopic pancreatic debridement device.

(a) *Identification.* An endoscopic pancreatic debridement device is inserted via an endoscope and placed through a cystogastrostomy fistula into the pancreatic cavity. It is intended for removal of necrotic tissue from a walled off pancreatic necrosis (WOPN) cavity.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including evaluation of debridement of walled off pancreatic necrosis and all adverse events.

(2) The patient-contacting components of the device must be demonstrated to be biocompatible.

(3) Performance data must demonstrate the sterility of the patient-contacting components of the device.

(4) The patient-contacting components of the device must be demonstrated to be non-pyrogenic.

(5) Performance testing must support the shelf life of device components provided sterile by demonstrating continued sterility, package integrity, and device functionality over the labeled shelf life.

(6) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Testing of rotational speeds and vacuum pressure;

(ii) Functional testing including testing with all device components and the ability to torque the device; and

(iii) Functional testing in a relevant tissue model to demonstrate the ability to resect and remove tissue.

(7) Performance data must demonstrate the electromagnetic compatibility (EMC) and electrical safety of the device.

(8) Software verification, validation, and hazard analysis must be performed.

(9) Training must be provided so that upon completion of the training program, the user can resect and remove tissue of interest while preserving non-target tissue.

(10) Labeling must include the following:

(i) A summary of the clinical performance testing conducted with the device;

(ii) Instructions for use, including the creation of a conduit for passage of endoscope and device into a walled off pancreatic necrotic cavity;

(iii) Unless clinical performance data demonstrates that it can be removed or modified, a boxed warning stating that the device should not be used in patients with known or suspected pancreatic cancer;

(iv) The recommended training for safe use of the device; and

(v) A shelf life for any sterile components.

Dated: September 4, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF THE TREASURY

### Office of Foreign Assets Control

#### 31 CFR Part 591

#### Publication of Venezuela Sanctions Regulations Web General License 5P

**AGENCY:** Office of Foreign Assets Control, Treasury.

**ACTION:** Publication of web general license.

**SUMMARY:** The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing one general license (GL) issued pursuant to the Venezuela Sanctions Regulations: GL 5P, which was previously made available on OFAC's website.

**DATES:** GL 5P was issued on August 12, 2024. See **SUPPLEMENTARY INFORMATION** for additional relevant dates.

**FOR FURTHER INFORMATION CONTACT:** OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Compliance, 202–622–2490.

#### SUPPLEMENTARY INFORMATION:

##### Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: <https://ofac.treasury.gov>.

##### Background

On August 12, 2024, OFAC issued GL 5P to authorize certain transactions otherwise prohibited by the Venezuela Sanctions Regulations (VSR), 31 CFR part 591. GL 5P was made available on OFAC's website (<https://ofac.treasury.gov>) when it was issued. GL 5P supersedes GL 5O, which was issued on April 15, 2024. The text of GL 5P is provided below.

#### OFFICE OF FOREIGN ASSETS CONTROL

#### Venezuela Sanctions Regulations

#### 31 CFR Part 591

#### GENERAL LICENSE NO. 5P

#### Authorizing Certain Transactions Related to the Petróleos de Venezuela, S.A. 2020 8.5 Percent Bond on or After November 12, 2024

(a) Except as provided in paragraph (b) of this general license, on or after

November 12, 2024, all transactions related to, the provision of financing for, and other dealings in the *Petróleos de Venezuela, S.A. 2020 8.5 Percent Bond* that would be prohibited by subsection l(a)(iii) of Executive Order (E.O.) 13835 of May 21, 2018, as amended by E.O. 13857 of January 25, 2019, and incorporated into the *Venezuela Sanctions Regulations*, 31 CFR part 591 (the VSR), are authorized.

(b) This general license does not authorize any transactions or activities otherwise prohibited by the VSR, or any other part of 31 CFR chapter V.

(c) Effective August 12, 2024, General License No. 5O, dated April 15, 2024, is replaced and superseded in its entirety by this General License No. 5P.

Lisa M. Palluconi,

*Acting Director Office of Foreign Assets Control.*

Dated: August 12, 2024.

**Lisa M. Palluconi,**

*Acting Director, Office of Foreign Assets Control.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG–2024–0741]

RIN 1625–AA00

#### Safety Zone; Missouri River Mile Markers 19–20 Florissant, MO

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone for the Missouri River at mile markers (MM) 19 through 20. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by a power line wire crossing near Florissant, MO. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Sector Upper Mississippi River.

**DATES:** For the purposes of enforcement, actual notice will be used from September 5, 2024, until September 9, 2024. This rule is effective without actual notice from September 9, 2024 through September 20, 2024.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2024–

0741 in the search box and click “Search.” Next, in the Document Type column, select “Supporting & Related Material.”

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this rule, call or email MST1 Benjamin Conger, Sector Upper Mississippi River Waterways Management Division, U.S. Coast Guard; telephone 314–269–2573, email [Benjamin.D.Conger@uscg.mil](mailto:Benjamin.D.Conger@uscg.mil).

#### SUPPLEMENTARY INFORMATION:

##### I. Table of Abbreviations

CFR Code of Federal Regulations  
DHS Department of Homeland Security  
FR Federal Register  
MM Mile marker  
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 under authority in 5 U.S.C. 553(b)(B). This statutory provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” The Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because of potential hazards created by the power line crossing over the Missouri River that need to be addressed. As such, the Coast Guard lacks sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule. It is impracticable to publish an NPRM because we must establish this safety zone by September 5, 2024.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because immediate action is needed to respond to the potential safety hazards associated with the power line crossing starting September 5, 2024.

##### III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Sector Upper Mississippi (COTP) has determined that potential hazards associated with the power line crossing starting September 5, 2024, will be a safety concern for anyone operating in or transiting the Missouri River from or between MM 19–20. This rule is needed to protect

personnel, vessels, and the marine environment in the navigable waters within the safety zone while the power line crossing is being conducted.

##### IV. Discussion of the Rule

This rule establishes a safety zone during a power line crossing project over the Missouri River on September 5, 2024 through September 20, 2024. The safety zone will cover all navigable waters from MM 19–20. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while the power line crosses the Missouri River. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative via VHF–FM channel 16, or through USCG Sector Upper Mississippi River at 314–269–2332. Persons and vessels permitted to enter the safety zone must comply with all lawful orders or directions issued by the COTP or designated representative. The COTP or a designated representative will inform the public of the effective period for the safety zone as well as any changes in the dates and times of enforcement, as well as reductions in the size of the safety zone as conditions improve, through Local Notice to Mariners (LNMs), Broadcast Notices to Mariners (BNMs), and/or Safety Marine Information Broadcast (SMIB), as appropriate.

##### V. Regulatory Analyses

We developed this 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 rule 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, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on a safety zone located on the Missouri River between MM 19–20 near Florissant, MO. The safety zone will be active only while work associated with the power line crossing is being