

1. DEN130046: De Novo Request per 513(f)(2) from Somna Therapeutics, LLC, dated November 11, 2013.

#### List of Subjects in 21 CFR Part 874

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 874 is amended as follows:

#### PART 874—EAR, NOSE, AND THROAT DEVICES

- 1. The authority citation for 21 CFR part 874 continues to read as follows:

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

- 2. Add § 874.5900 to subpart F to read as follows:

##### § 874.5900 External upper esophageal sphincter compression device.

(a) *Identification.* An external upper esophageal sphincter compression device is a prescription device used to apply external pressure on the cricoid cartilage for the purpose of reducing the symptoms of laryngopharyngeal reflux disease.

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

(1) The patient contacting components must be demonstrated to be biocompatible.

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

(i) Mechanical integrity testing (*e.g.*, tensile strength testing, fatigue testing) and

(ii) Shelf life testing.

(3) The technical specifications must include pressure measurement accuracy to characterize device performance.

(4) Clinical performance testing must document any adverse events observed during clinical use, and demonstrate that the device performs as intended under anticipated conditions of use.

(5) Labeling must include the following:

(i) Appropriate warnings and precautions,

(ii) A detailed summary of the clinical testing pertinent to use of the device including a detailed summary of the device-related complications or adverse events,

(iii) Detailed instructions on how to fit the device to the patient, and

(iv) Instructions for reprocessing of any reusable components.

(6) Patient labeling must be provided and must include:

- (i) Relevant warnings, precautions, and adverse effects/complications,  
 (ii) Information on how to correctly wear the device,  
 (iii) The potential risks and benefits associated with the use of the device,  
 (iv) Alternative treatments, and  
 (v) Reprocessing instructions.

Dated: July 30, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–19074 Filed 8–3–15; 8:45 am]

**BILLING CODE 4164–01–P**

#### DEPARTMENT OF HOMELAND SECURITY

##### Coast Guard

##### 33 CFR Part 165

[Docket Number USCG–2015–0543]

RIN 1625–AA00; 1625–AA11

##### Safety Zones and Regulated Navigation Area; Shell Arctic Drilling/Exploration Vessel and Associated Voluntary First Amendment Area, Portland, OR

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing temporary safety zones around Royal Dutch Shell's (Shell) contracted vessel FENNICA, which is participating in Shell's planned Arctic oil drilling and exploration operations, while it is located in the U.S. Territorial and Internal Waters of the Sector Columbia River Captain of the Port Zone. In addition, the Coast Guard is establishing a regulated navigation area to designate a Voluntary First Amendment Area for individuals that desire to exercise their First Amendment free speech rights with regards to Shell's operations. The safety zones and regulated navigation area created by this rule are necessary to ensure the mutual safety of all waterways users including the FENNICA and those individuals that desire to exercise their First Amendment rights.

**DATES:** This rule is effective without actual notice from August 4, 2015 until August 22, 2015. For the purposes of enforcement, actual notice will be used from July 22, 2015 until August 4, 2015.

**ADDRESSES:** Documents mentioned in this preamble are part of docket USCG–2015–0543 to view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type the docket

number in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or email Lieutenant Commander Laura Springer, Waterways Management Division, Coast Guard Marine Safety Unit Portland; telephone (503) 240–2594, email [Laura.M.Springer@uscg.mil](mailto:Laura.M.Springer@uscg.mil). If you have questions on viewing or submitting material to the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone (202) 366–9826.

#### SUPPLEMENTARY INFORMATION:

##### Table of Acronyms

DHS Department of Homeland Security  
 FR Federal Register  
 NPRM Notice of Proposed Rulemaking

#### A. Regulatory History and Information

The Coast Guard is issuing this temporary final 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 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." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because publishing an NPRM would be impracticable since the regulation is immediately necessary to help ensure the safety of all waterway users including the Shell contracted vessel FENNICA and those individuals that desire to exercise their First Amendment rights regarding Shell's activities and holding a notice and comment period at this time would delay regulatory implementation beyond the arrival of the FENNICA and expected start of First Amendment activities regarding Shell's operations, thereby increasing the safety risk to all waterways users.

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**. For reasons identical to those described above, delaying the effective

date until 30 days after publication would be impracticable since the regulation is immediately necessary to help ensure the safety of all waterway users.

### B. Basis and Purpose

The legal basis for this rule is the Coast Guard's authority to establish limited access areas: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05-1, 6.04-1, 6.04-6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

Shell is planning Arctic oil drilling and exploration operations for the summer of 2015. One of the Shell contracted vessels related to these operations, FENNICA, has been damaged and will be returning to Portland, Oregon for repairs. Over the last several months there has been significant waterborne First Amendment activity related to Shell's operations, particularly in the Puget Sound region, and the Coast Guard believes there will be similar activity in the greater Portland area related to FENNICA's presence there. The First Amendment activity previously observed includes unauthorized boardings of Shell contracted vessels and the formation of a "kayak flotilla" designed to protest as well as attempt to block Shell contracted vessels from departing for the Arctic.

Draft restrictions, vessel maneuvering characteristics, and geographic/environmental conditions may constrain the ability of large commercial vessels such as FENNICA to maneuver in close quarters with other vessels, particularly small craft piloted by recreational operators. Intentional close-in interaction of these vessels will create an increased risk of collision, grounding, or personal injury for all parties. Furthermore, while moored, at anchor, and in drydock the FENNICA will have ongoing operations occurring onboard, some of which could pose a safety risk to other maritime traffic. The myriad of potential safety risks to all parties and the port itself is best addressed by mandating a minimum zone of separation. For these reasons, the Coast Guard believes that a safety zone around the FENNICA is necessary to ensure the safety of all waterways users.

Additionally, the Coast Guard believes that given the nature of the First Amendment activity expected and the likely type of vessels used by individuals desiring to express their First Amendment rights, namely kayaks and other small vessels, a regulated navigation area designating a Voluntary First Amendment Area is necessary to

ensure the safety of those vessels and persons. The regulated navigation area encompassing the Voluntary First Amendment Area would do so by establishing it as a "no wake" area, which is particularly important for small boats such as kayaks, to better enable persons and vessels to congregate and exercise their First Amendment rights safely and without interference from or interfering with other maritime traffic.

### C. Discussion of the Final Rule

In this rule, the Coast Guard is establishing safety zones around the FENNICA, a Shell contracted vessel involved in the company's Arctic oil drilling and exploration operations, and a regulated navigation area for a Voluntary Free Speech Area that will allow individuals a meaningful opportunity to be heard in exercising their First Amendment rights while not compromising the safety of maritime traffic or the individuals exercising their First Amendment rights.

The safety zones are established in subsection (a) of this temporary regulation. Per subsection (a)(1)(i), while transiting, the safety zone around FENNICA will encompass all waters within a rectangle measuring 500 yards in front and 100 yards to the port, starboard, and astern of that vessel and any other vessel actively engaged in towing or escorting it. Per subsection (a)(1)(ii), while moored, anchored, or in drydock, the safety zone around FENNICA will encompass all waters within 100 yards of the vessel in all directions. Persons and/or vessels that desire to enter these safety zones must request permission to do so from the Captain of the Port, Columbia River by contacting the Coast Guard Sector Columbia River Command Center at 866-284-6958 or 503-861-6211, or the on-scene Law Enforcement patrol craft, if any, via VHF-FM CH 16.

The Coast Guard is also establishing a regulated navigation area to ensure the safety of individuals that desire to exercise their First Amendment rights related to Shell's activities in subsection (b) of this regulation. The Voluntary First Amendment Area is being established in an area where we believe individuals will be able to effectively communicate their message, without posing an undue risk to maritime safety, after analyzing maritime traffic patterns and other environmental factors. The regulated navigation area encompassing the Voluntary First Amendment Area will ensure the safety of small boats by establishing it as a "no wake" area for persons and/or vessels to congregate and exercise their First Amendment

rights safely and without interference from or interfering with other maritime traffic. The "no wake" provisions will ensure all interactions between vessels within the area occur at a low rate of speed, thereby reducing risk of collision and personal injury. Likewise, the designation of a Voluntary First Amendment Area will help to ensure that a large congregation of vessels does not impede or endanger other commercial and recreational users who are not associated with Shell's arctic drilling and exploration operations or the associated First Amendment activity.

These provisions are particularly vital given the expected presence of a "kayak flotilla" described above. Persons or vessels desiring to exercise their First Amendment rights to free speech regarding Shell's Arctic drilling and exploration operations may enter the regulated navigation area at any time. All other persons or vessels are advised to avoid the regulated navigation area. When inside the regulated navigation area, all vessels must proceed at "no wake" speed and with due regard for all other persons and/or vessels inside the regulated navigation area.

### D. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on these statutes and executive orders.

#### 1. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders. This rule is not a significant regulatory action as the safety zones and regulated navigation area are limited in both size and duration and any person and/or vessel needing to transit through the safety zones or regulated navigation area may be allowed to do so in accordance with the regulatory provisions.

#### 2. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 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 rule will not have a significant economic impact on a substantial number of small entities. This rule will affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit the affected waterways when the safety zones and regulated navigation area are in effect. The safety zones and regulated navigation area will not have a significant economic impact on a substantial number of small entities, however, because the safety zones and regulated navigation area are limited in both size and duration and any person and/or vessel needing to transit through the safety zones or regulated navigation area may be allowed to do so in accordance with the regulatory provisions.

### 3. Assistance for Small Entities

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 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**, above.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

### 4. Collection of Information

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

### 5. Federalism

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 rule under that Order and determined that this rule does not have implications for federalism.

### 6. First Amendment Activities

The Coast Guard respects the First Amendment rights of all individuals. This regulation establishes a regulated navigation area to create a Voluntary First Amendment Area so that persons and vessels can congregate and exercise their First Amendment free speech rights safely and without interference from or interfering with other maritime traffic. Of particular note, large vessels operating in restricted waters cannot maneuver freely, nor can they stop immediately. As such, any First Amendment activity taking place in immediate proximity to such vessels can quickly result in extremis. The Voluntary First Amendment Area has been located to allow individuals a meaningful opportunity to be heard. Individuals that desire to exercise their First Amendment rights are asked to utilize the designated area to the extent possible, however, its use is voluntary. Individuals that desire to exercise their First Amendment rights outside the designated area are requested to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate their activities so that their message can be heard, without jeopardizing the safety or security of people, places, or vessels.

### 7. 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 rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

### 8. Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

### 9. Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

### 10. Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

### 11. Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does 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.

### 12. Energy Effects

This action is not a “significant energy action” under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

### 13. Technical Standards

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

### 14. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have determined 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 rule involves the establishment of temporary safety zones and a regulated navigation area to deal with an emergency situation that is one week or longer in duration. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**.

**List of Subjects in 33 CFR Part 165**

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

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

**PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS**

- 1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

- 2. Add § 165.T13–292 to read as follows:

**§ 165.T13–292 Safety Zones and Regulated Navigation Area; Shell Arctic Drilling/Exploration Vessel and Associated Voluntary First Amendment Area, Portland, OR.**

(a) *Safety Zones*—(1) *Location*. The following areas are designated as safety zones:

(i) All waters within a rectangle measuring 500 yards in front and 100 yards to the port, starboard, and astern of the vessel FENNICA and any other vessel actively engaged in towing or escorting it while transiting within the U.S. Territorial or Internal Waters of the Sector Columbia River Captain of the Port Zone as defined in 33 CFR 3.65–15.

(ii) All waters within 100 yards of the vessel FENNICA while moored, anchored, or in drydock within the U.S. Territorial or Internal Waters of the Sector Columbia River Captain of the Port Zone as defined in 33 CFR 3.65–15.

(2) *Regulations*. In accordance with the general regulations in 33 CFR part 165 Subpart C, no persons or vessels may enter these safety zones unless authorized by the Captain of the Port, Columbia River or his designated representative. To request permission to enter one of these safety zones contact the Coast Guard Sector Columbia River Command Center at 866–284–6958 or 503–861–6211, or the on-scene Law Enforcement patrol craft, if any, via VHF–FM CH 16. If permission for entry into one of these safety zones is granted, vessels must proceed at a minimum speed for safe navigation.

(b) *Regulated Navigation Area*—(1) *Location*. The following area is designated as a regulated navigation area: All waters of Swan Island Basin south east from a line connecting the following points: 45°34′04″ N, 122°42′57″ W and 45°34′00″ N, 122°43′03″ W.

(2) *Regulations*. In accordance with the general regulations in 33 CFR part 165 Subpart B, persons or vessels desiring to exercise their First Amendment right to free speech regarding Royal Dutch Shell's Arctic drilling and exploration operations may enter the regulated navigation area at any time. All other persons or vessels are advised to avoid the regulated navigation area. When inside the regulated navigation area, all vessels must proceed at no wake speed and with due regard for all other persons and/or vessels inside the regulated navigation area.

(c) *Dates*. This rule will be enforced from July 22, 2015 through August 22, 2015.

Dated: July 22, 2015.

**D.L. Cottrell,**

*Captain, U.S. Coast Guard, Acting Commander, Thirteenth Coast Guard District.*

[FR Doc. 2015–19120 Filed 8–3–15; 8:45 am]

**BILLING CODE 9110–04–P**

**DEPARTMENT OF VETERANS AFFAIRS****38 CFR Part 17****RIN 2900–AP21****Vet Centers**

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Interim final rule.

**SUMMARY:** The Department of Veterans Affairs (VA) is amending its medical regulation that governs Vet Center services. The National Defense Authorization Act for Fiscal Year 2013 (the 2013 Act) requires Vet Centers to provide readjustment counseling services to broader groups of veterans, members of the Armed Forces, including a member of a reserve component of the Armed Forces, and family members of such veterans and members. This interim final rule amends regulatory criteria to conform to the 2013 Act, to include new and revised definitions.

**DATES:** *Effective date:* This rule is effective on August 4, 2015.

*Comment date:* Comments must be received by VA on or before October 5, 2015.

**ADDRESSES:** Written comments may be submitted through [www.Regulations.gov](http://www.Regulations.gov); by mail or hand-delivery to Director, Regulation Policy and Management (02REG), Department of Veterans Affairs, 810 Vermont Avenue NW., Room 1068, Washington, DC 20420; or by fax to (202) 273–9026. Comments should indicate that they are

submitted in response to “RIN 2900–AP21—Vet Centers.” Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1068, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at [www.Regulations.gov](http://www.Regulations.gov).

**FOR FURTHER INFORMATION CONTACT:**

Michael Fisher, Readjustment Counseling Service (10RCS), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420; (202) 461–6525. (This is not a toll-free number.)

**SUPPLEMENTARY INFORMATION:**

On September 17, 2013, VA promulgated 38 CFR 17.2000, which implemented VA's authority to provide readjustment counseling services through Vet Centers based on 38 U.S.C. 1712A, as amended by the Caregivers and Veterans Omnibus Health Services Act of 2010 (the 2010 Act), Public Law 111–163, sec. 304, 401(a) and (b). The 2010 Act amended section 1712A to require VA to provide readjustment counseling services to certain servicemembers and veterans who served on active duty in specific theaters of combat operations, or in certain areas in which hostilities occurred. The 2010 Act also mandated that VA provide readjustment counseling to veterans and servicemembers of Operation Enduring Freedom and Operation Iraqi Freedom, and the family members of such veterans and servicemembers after the veterans and servicemembers return from deployment. Although not expressly stated in the 2010 Act, VA also considered veterans, servicemembers, and the family members of such veterans and servicemembers who participated in Operation New Dawn as eligible for readjustment counseling. In promulgating § 17.2000, VA implemented the mandates in the 2010 Act, as well as interpreted section 1712A to permit VA to provide readjustment counseling to family members of all veterans that were themselves eligible for readjustment counseling. See 77 FR 14707 and 78 FR 57067. The term “servicemembers” as used in § 17.2000 means a member of the Armed Forces, including a member of a reserve component of the Armed Forces. We note, however, that the terms servicemembers and member of the Armed Forces, including a member