33781) now codified primarily at 21 CFR 101.9 and 101.36). With respect to our enforcement discretion policy pertaining to "calories from fat" declarations, this part of the guidance is immediately effective because we have determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)). The guidance announced in this notice finalizes the draft guidance dated November 2017.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. 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. 3501–3520). The collections of information in § 101.11(b)(2), (c)(3), and (d) have been approved under OMB control number 0910–0783.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either https://www.fda.gov/FoodGuidances or https://www.regulations.gov. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: May 3, 2018.

Leslie Kux,

Associate Commissioner for Policy. [FR Doc. 2018–09725 Filed 5–7–18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 147

[Docket Number USCG-2017-0446] RIN 1625-AA00

Safety Zone; Appomattox FPS, Mississippi Canyon 437, Outer Continental Shelf on the Gulf of Mexico

AGENCY: Coast Guard, DHS. **ACTION:** Final rule.

SUMMARY: The Coast Guard is establishing a permanent safety zone extending 500 meters around the Appomattox Floating Production System (FPS) facility located in Mississippi Canyon Block 437 on the Outer Continental Shelf (OCS) in the Gulf of Mexico. This action is necessary to protect the facility from all vessels operating outside the normal shipping channels and fairways that are not

providing services to or working with the facility. Only vessels measuring less than 100 feet in length overall and not engaged in towing, attending vessels as defined in 33 CFR 147.20, or those vessels specifically authorized by the Eighth Coast Guard District Commander or a designated representative are permitted to enter or remain in the safety zone.

DATES: This rule is effective on May 8, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to http://www.regulations.gov, type USCG-2017-0446 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 Ms. Laura Knoll, U.S. Coast Guard, District Eight Waterways Management Branch; telephone 504–671–2139, Laura.B.Knoll@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FPS Floating production system
FR Federal Register
NPRM Notice of proposed rulemaking
OCS Outer Continental Shelf
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

Shell Exploration and Production Co. requested that the Coast Guard establish an Outer Continental Shelf (OCS) safety zone extending 500 meters from each point on the Appomattox Floating Production System (FPS) facility structure's outermost edge. In response to Shell Exploration and Production Co.'s request and on the basis of the District Commander's safety analysis, on March 20, 2018, the Coast Guard published a notice of proposed rulemaking (NPRM) titled Safety Zone; Appomattox FPS, Mississippi Canyon 437, Outer Continental Shelf on the Gulf of Mexico (83 FR 12144). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to establishing the 500-meter safety zone. During the comment period that ended on April 19, 2018, we received no comments.

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 contrary to the public interest because immediate action is needed to respond to the potential safety concerns and hazards that could occur within 500 meters of the facility.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under the authority provided in 14 U.S.C. 85, 43 U.S.C. 1333, and Department of Homeland Security Delegation No. 0170.1(90), and Title 33, CFR 147.1, 147.5, and 147.10. The District Commander determined that placing a safety zone around the facility will significantly reduce the threat of allisions, oil spills, and releases of natural gas, and thereby protect the safety of life, property, and living marine resources. The purpose of this rule is to protect the facility from all vessels operating outside the normal shipping channels and fairways that are not providing services to or working with the facility.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published on March 20, 2018. This regulatory text of this final rule contains one technical amendment. In the NPRM, we indicated that permission to enter the safety zone may be obtained from the District Commander or a designated representative in the discussion of the proposed rule but not the regulatory text. This final rule corrects the regulatory text to indicate that permission to enter the safety zone may be obtained from the District Commander or a designated representative.

This rule establishes a safety zone on the OCS in the deepwater area of the Gulf of Mexico at Mississippi Canyon Block 437. The area for the safety zone is 500 meters (1640.4 feet) from each point on the facility, which is located at 28°34′25.47″ N 87°56′03.11″ W. Only vessels measuring less than 100 feet in length overall and not engaged in towing, attending vessels as defined in 33 CFR 147.20, or those vessels specifically authorized by the Eighth Coast Guard District Commander or a designated representative are permitted to enter or remain in the safety zone.

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. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated as a "significant regulatory action," under Executive Order 12866. Accordingly, this rule 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 safety zone's location and its distance from both land and safety fairways. This rule is not a significant regulatory action due to the location of the Appomattox FPS on the Outer Continental Shelf, and its distance from both land and safety fairways. Vessels traversing waters near the proposed safety zone are able to safely travel around the zone using alternate routes. Exceptions to this rule also include vessels measuring less than 100 feet in length overall and not engaged in towing and attending vessels as defined in 33 CFR 147.20. In addition, the Eighth Coast Guard District Commander or a designated representative will consider requests to enter or transit through the safety zone on a case-by-case basis.

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 received no comments from the Small Business Administration on this rulemaking. 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.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

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 section.

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.

C. 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).

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 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 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. If you believe this 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 rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this 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 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 establishing a safety zone around an offshore deepwater facility. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01, A Record of Environmental Consideration supporting this determination is available in the docket where indicated under ADDRESSES.

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.

List of Subjects in 33 CFR Part 147

Continental shelf, Marine safety, Navigation (water).

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 147 as follows:

PART 147—SAFETY ZONES

■ 1. The authority citation for part 147 continues to read as follows:

Authority: 14 U.S.C. 85; 43 U.S.C. 1333; and Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 147.869 to read as follows:

§ 147.869 Safety Zone; Appomattox FPS Facility, Outer Continental Shelf on the Gulf of Mexico.

(a) Description. The Appomattox Floating Production System (FPS) system is in the deepwater area of the Gulf of Mexico at Mississippi Canyon Block 437. The facility is located at 28°34′25.47″ N 87°56′03.11″ W (NAD 83), and the area within 500 meters (1640.4 feet) from each point on the facility structure's outer edge is a safety zone.

(b) Regulation. No vessel may enter or remain in this safety zone except the following:

- (1) An attending vessel, as defined by 33 CFR 147.20;
- (2) A vessel under 100 feet in length overall not engaged in towing; or
- (3) A vessel authorized by the Eighth Coast Guard District Commander or a designated representative.

Dated: May 2, 2018.

Paul F. Thomas.

Rear Admiral, U.S. Coast Guard, Commander, Eighth Coast Guard District.

[FR Doc. 2018-09789 Filed 5-7-18; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900-AP23

Special Monthly Compensation for Veterans With Traumatic Brain Injury

AGENCY: Department of Veterans Affairs. **ACTION:** Final rule.

SUMMARY: The Department of Veterans Affairs (VA) amends its adjudication regulations to add an additional compensation benefit for veterans with residuals of traumatic brain injury (TBI). This final rule incorporates in regulations a benefit authorized by the enactment of the Veterans' Benefits Act of 2010. The Veterans' Benefits Act authorizes special monthly compensation (SMC) for veterans with TBI who are in need of aid and attendance, and in the absence of such aid and attendance, would require hospitalization, nursing home care, or other residential institutional care.

DATES: *Effective Date:* This final rule is effective June 7, 2018.

Applicability Date: The provisions of this final rule shall apply to all applications for benefits received by VA on or after October 1, 2011, or that were pending before VA, the United States Court of Appeals for Veterans Claims, or the United States Court of Appeals for the Federal Circuit on October 1, 2011.

FOR FURTHER INFORMATION CONTACT:

Roselyn Tyson, Regulations Staff (211D), Compensation Service, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461–9700. (This is not a toll-free telephone number.)

SUPPLEMENTARY INFORMATION: On December 21, 2016, VA published in the Federal Register (81 FR 93649) a proposed rule to amend 38 CFR 3.350 and 3.352 to add SMC for veterans with residuals of TBI. As explained in the proposed rule, section 601 of the Veterans' Benefits Act of 2010, Public Law 111-275 (the Veterans' Benefits Act) authorized SMC for veterans who, as the result of service-connected disability, are in need of regular aid and attendance for the residuals of TBI, and in the absence of such regular aid and attendance, would require hospitalization, nursing home care, or other residential institutional care. Effective October 1, 2011, section 601 authorized an additional monetary allowance for veterans with residuals of TBI who require this higher level of care but would not otherwise qualify for the benefit under 38 U.S.C. 1114(r)(2).

To date, VA has relied on non-regulatory guidance to implement section 601 of the Veterans' Benefits Act. By issuing this final rule, VA updates its adjudication regulations to reflect the authorization provided by section 601.

Response to Public Comments

As noted above, VA published the proposed rule in the Federal Register (81 FR 93649) on December 21, 2016. VA provided a 60-day public comment period, which ended on February 21, 2017, and received two comments. VA responds to all comments as follows. For the reasons set forth in the proposed rule and below, VA adopts the proposed rule as final, without changes.

Both commenters expressed support for the rulemaking, noting that SMC should be awarded for TBI. VA appreciates the time and effort expended by these commenters in reviewing the proposed rule and in submitting comments, as well as their support for this rulemaking.

One commenter stated that this rulemaking should restrict the use of SMC payments to treatment for TBI. The commenter noted that application for SMC funds should be made on a yearly basis and the funds should be applied specifically for medical care of the TBI. VA notes that it has no authority to direct how payments are used once awarded to a veteran; VA only has legal authority to determine benefit eligibility and entitlement.

The same commenter stated that application of SMC should be limited to claims where TBI that was incurred in the line of duty and was not a result of self-inflicted injury, and the veteran

applying for the benefit was not dishonorably discharged. This commenter also appears to suggest that posttraumatic stress disorder (PTSD) be included in the definition of a TBI and provided examples of individuals who may have benefited from this approach.

While any injury outside the line of duty would not be service connected, we note that the occurrence of such an injury is interpreted very broadly. See Holton v. Shinseki, 557 F.3d 1362, 1366-67 (Fed. Cir. 2009) (explaining that an injury or disease will be deemed to have been incurred in the line of duty if it occurred at almost any time during a veteran's active service—even during authorized leave). With regard to the commenter's statement that selfinflicted injuries should not be the basis for service-connected TBI for SMC, we note that self-inflicted injuries generally would not be covered to the extent they constituted willful misconduct. Whether or not a given self-injury rises to the level of willful misconduct is a case specific factual determination that is separate from the level of compensation at stake, which is what is affected by this rule. See 38 CFR 3.301. While the commenter also expressed that SMC based on service-connected TBI should not be available to individuals with a dishonorable discharge, VA statutes and regulations preclude veteran status and benefits for individuals with a dishonorable discharge. 38 U.S.C. 101(2); 38 CFR 3.12(a). Finally, in response to the commenter's last assertion that VA should define whether PTSD "is included under the definition of [TBI]," we note that PTSD is already a disability available for VA service connection and rating as a mental disorder under 38 CFR 4.130, Diagnostic Code 9411. Therefore, VA already compensates veterans for service-connected PTSD, including with PTSD that is somehow causally related to TBI.

In any case, the general eligibility criteria for SMC and the definition of TBI are outside the scope of this rulemaking. Therefore, VA makes no change based on these comments.

The second commenter stated that veterans with TBI should have always qualified for maximum monthly relief. VA notes that SMC is authorized by statute, and prior to the enactment of the Veterans' Benefits Act, VA lacked the statutory authority to provide the level of SMC contemplated in the Act for TBI. The commenter also noted the length of time it took to authorize and implement SMC for TBI. As noted above, VA has to date relied on non-regulatory guidance to implement the statutory authorization for SMC for TBI.