SUPPLEMENT NO. 4 TO PART 744—ENTITY LIST—Continued

Country	Entity	License requirement	License review policy	Federal Register citation
	Veteran Avia LLC, a.k.a., the following one alias: —Veteran Airline. Sharjah SAIF Zone, Sharjah, U.A.E.; *and* Y2–307, Saif Zone, Sharjah International Airport, P.O. Box 122598, Sharjah, U.A.E. (See also addresses under Armenia, Greece, India, Pakistan, and U.K.).	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	79 FR [INSERT FR PAGE NUMBER] 09/18/14.
	* * *	* * *	* * *	* * *
UNITED KINGDOM	* * *	* * *	* * *	* * *
	Veteran Avia LLC, a.k.a., the following one alias: —Veteran Airline. 1 Beckett Place, South Hamptonshire, London, U.K. (See also addresses under Armenia, Greece, India, Pakistan, and U.A.E.).	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	79 FR [INSERT FR PAGE NUMBER] 09/18/14.
	* * *	* * *	* * *	* * *

Dated: September 15, 2014.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2014–22277 Filed 9–17–14; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2014–N–1251]

Medical Devices; Immunology and Microbiology Devices; Classification of Tryptase Test System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying tryptase test system devices into class II (special controls). The Agency is classifying the device into class II (special controls) because special controls, in addition to general controls, will provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective October 20, 2014. The classification was applicable February 15, 2012.

FOR FURTHER INFORMATION CONTACT: Elizabeth Stafford, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5608, Silver Spring, MD 20993–0002, 301–796–6184.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of ''low-moderate risk'' or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on January 3, 2012, classifying the ImmunoCAP Tryptase into class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On January 12, 2013, Phadia U.S., Inc. submitted a request for de novo classification of the ImmunoCAP Tryptase under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II.

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request for de novo classification in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

The device is assigned the generic name tryptase test system, and it is identified as a device that aids in the diagnosis of systemic mastocytosis. It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of patients with a suspicion of systemic mastocytosis in conjunction with other clinical and laboratory findings.

FDA has identified the following risks to health associated with this type of device and the measures required to mitigate these risks in Table 1:

TABLE 1—IDENTIFIED RISKS TO HEALTH AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
False negative result	Device description containing the information specified in the special control guideline. Analytical performance validation. Software. Clinical performance evaluation. Labeling.
False positive result	Device description containing the information specified in the special control guideline. Analytical performance validation. Software. Clinical performance evaluation. Labeling.
Inappropriate use	Labeling.

FDA believes that the measures set forth in the special controls guideline entitled ''Class II Special Controls Guideline: Tryptase Test System as an Aid in the Diagnosis of Systemic Mastocytosis'' are necessary, in addition to general controls, to mitigate the risks to health described in table 1.

Therefore, on February 15, 2012, FDA issued an order to the petitioner classifying tryptase test system devices into class II. FDA is codifying this device type by adding § 866.5760.

Following the effective date of this final classification order, any firm submitting a 510(k) premarket notification for this device type will need to comply with the special controls.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this type of device is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the tryptase test system they intend to market.

II. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of 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.

III. Paperwork Reduction Act of 1995

This final administrative order establishes special controls that refer to previously approved collections of information found in other 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 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 have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, 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 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 866 continues to read as follows:

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

■ 2. Add § 866.5760 to subpart F to read as follows:

§ 866.5760 Tryptase test system.

(a) *Identification.* A tryptase test system is a device that aids in the diagnosis of systemic mastocytosis. It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of patients with a suspicion of systemic mastocytosis in conjunction with other clinical and laboratory findings.

(b) *Classification.* Class II (special controls). The special control is FDA's guideline entitled ''Class II Special Controls Guideline: Tryptase Test System as an Aid in the Diagnosis of Systemic Mastocytosis.'' For availability of the document, see § 866.1(e).

Dated: September 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–22254 Filed 9–17–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2014–0610]

RIN 1625–AA00

Safety Zone; International Jet Sports Boating Association World Finals; Lake Havasu City, AZ

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone within the navigable waters of the Colorado River in Lake Havasu, AZ in support of the International Jet Sports Boating Association (IJSBA) World Finals. This safety zone is necessary to ensure the safety of participants, crew, spectators, participating vessels, and other vessels and users of the waterway. Unauthorized persons and vessels are prohibited from entering into, transiting through, or anchoring within this safety zone unless authorized by the Captain of the Port, or their designated representative.

DATES: This rule is effective from 6:30 a.m. to 6:30 p.m. on October 4, 2014 through October 12, 2014.

ADDRESSES: Documents mentioned in this preamble are part of docket [USCG–2014–0610]. 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 Petty Officer Giacomo Terrizzi, Waterways Management, U.S. Coast Guard Sector San Diego, Coast Guard; telephone 619–278–7656, email *d11marineeventssandiego@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Cheryl Collins, 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
TFR Temporary Final Rule
IJSBA International Jet Sports Boating Association

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 an NPRM would be impracticable. Logistical details did not present the Coast Guard enough time to draft, publish, and receive public comment on an NPRM. As such, the event would occur before the rulemaking process was complete. Immediate action is needed to help protect the safety of the participants, crew, spectators, and participating vessels from other vessels during the duration of this event.

Under 5 U.S.C. 553(d)(3), for the same reasons mentioned above, the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Any delay in the effective date of this rule would be contrary to the public interest, because immediate action is necessary to protect the safety of the participants from the dangers associated with other vessels transiting this area while the race occurs.

B. Basis and Purpose

The legal basis and authorities for this rule are found in 33 U.S.C. 1231, 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Public Law 107–295, 116 Stat. 2064; and Department of Homeland Security Delegation No. 0170.1, which collectively authorize the Coast Guard to propose, establish, and define regulatory safety zones.

IJSBA is sponsoring the IJSBA World Finals, which will involve approximately 800 personal water craft, 5 to 13 feet in length. The safety zone will encompass an area in the vicinity of the Crazy Horse Campgrounds. This temporary safety zone is necessary to provide for the safety of the participants, crew, spectators, sponsor vessels, other vessels, and users of the waterway, specifically in minimizing vessel wakes by transiting vessels in the vicinity of the racing area. Unnecessary wakes can disrupt the personal water craft and could cause injury or damage to the participants.

C. Discussion of the Final Rule

The Coast Guard is establishing a safety zone that will be enforced from 6:30 a.m. to 6:30 p.m. on October 4, 2014 through October 12, 2014. The effect of the temporary safety zone will be to restrict navigation in the vicinity of the race site until the conclusion of the races. The limits of the safety zone will encompass the waters of Lake Havasu, AZ in the area of Crazy Horse Campgrounds encompassed by the following positions:

34°28.32′ N, 114°21.71′ W
34°28.43′ N, 114°21.81′ W
34°28.55′ N, 114°21.56′ W
34°28.49′ N, 114°21.33′ W

The safety zone is necessary to provide for the safety of the crew, spectators, participants, and other vessels and users of the waterway. Persons and vessels will be prohibited from entering into, transiting through, or anchoring within this safety zone unless authorized by the Captain of the Port, or his designated representative, during the proposed times. Before the effective period, the Coast Guard will publish a local notice to mariners (LNM). Also, the event sponsor through Lake Havasu City has extensively advertised the marine event with the public.

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