

neither an environmental assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act of 1995

FDA concludes that this final order contains no new collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) is not required. This final order refers to previously approved FDA collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR parts 801 and 809, regarding labeling, have been approved under OMB control number 0910–0485; and the collections of information in part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073.

List of Subjects in 21 CFR Parts 884, 888, and 890

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 884, 888, and 890 are amended as follows:

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

- 1. The authority citation for part 884 continues to read as follows:

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

- 2. In § 884.6120, revise paragraph (b) to read as follows:

§ 884.6120 Assisted reproduction accessories.

* * * * *

(b) *Classification.* Class II (special controls) (design specifications, labeling requirements, and clinical testing). The device, when it is a simple embryo incubator with only temperature, gas, and humidity control; a syringe pump; a collection tube warmer; a dish/plate/microscope stage warmer; a controlled-rate cryopreservation freezer; or an assisted reproduction laminar flow workstation is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

- 3. In § 884.6180, revise paragraph (b) to read as follows:

§ 884.6180 Reproductive media and supplements.

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(b) *Classification.* Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization validation, design specifications, labeling requirements, biocompatibility testing, and clinical testing). The device, when it is phosphate-buffered saline used for washing, and short-term handling and manipulation of gametes and embryos; culture oil used as an overlay for culture media containing gametes and embryos; and water for assisted reproduction applications, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

PART 888—ORTHOPEDIC DEVICES

- 4. The authority citation for part 888 continues to read as follows:

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

- 5. Amend § 888.4505 by revising paragraph (b) introductory text to read as follows:

§ 888.4505 Orthopedic surgical instrumentation designed for osteochondral implants with press-fit fixation.

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(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 888.9. The special controls for this device are:

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PART 890—PHYSICAL MEDICINE DEVICES

- 6. The authority citation for part 890 continues to read as follows:

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

- 7. In § 890.5360, revise paragraph (b) to read as follows:

§ 890.5360 Measuring exercise equipment.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is a measuring exerciser or an interactive rehabilitation exercise device for prescription use only, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 890.9.

- 8. Amend § 890.5670 by revising paragraph (b) introductory text to read as follows:

§ 890.5670 Internal therapeutic massager.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is for prescription use only with a quantitative feedback mechanism and a disposable covering, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 890.9. The special controls for this device are:

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Dated: July 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15256 Filed 7–21–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF STATE

22 CFR Part 126

[Public Notice 10969]

RIN 1400–AE97

International Traffic in Arms Regulations: Amendment of Central African Republic

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State is amending the International Traffic in Arms Regulations (ITAR) to reflect recently adopted United Nations Security Council Resolutions (UNSCRs) concerning the Central African Republic.

DATES: The rule is effective on July 22, 2020.

FOR FURTHER INFORMATION CONTACT: Ms. Engda Wubneh, Foreign Affairs Officer, Office of Defense Trade Controls Policy, U.S. Department of State, telephone (202) 663–1809, or email DDTCResponseTeam@state.gov. ATTN: Regulatory Change, ITAR Section 126.1 Central African Republic Update 2020.

SUPPLEMENTARY INFORMATION: On September 12, 2019, the United Nations Security Council (UNSC) adopted resolution 2488, which adjusted the arms embargo on the Central African Republic (CAR) to allow additional exceptions to the embargo and committed to further review of the sanctions regime within four months. On January 31, 2020, four months later, the UNSC adopted resolution 2507 renewing that arms embargo until July 31, 2020 and providing additional exceptions to those adopted by resolution 2488. The UNSC initially imposed an arms embargo on the country with certain enumerated exceptions in 2013. The CAR government has made progress since,

including the signing of a peace agreement between the CAR government and fourteen armed groups on February 6, 2019. These resolutions are intended to support the CAR government as it works to implement the peace agreement and extend state control over the entire territory of the country. The Department of State is amending ITAR § 126.1(u) to implement the changes to the embargo. Further, in accordance with ITAR § 129.7, no broker, as described in ITAR § 129.2, may engage in or make a proposal to engage in brokering activities subject to the ITAR that involve the Central African Republic without first obtaining the approval of the Directorate of Defense Trade Controls. Lastly, this rule revises the authority citation to Part 126 by removing reference to E.O. 12918, 59 FR 28205. Rwanda, was removed from ITAR § 126.1 in 2008, and this non-substantive edit reflects the current defense trade posture toward Rwanda.

Regulatory Analysis and Notices

Administrative Procedure Act

The Department of State is of the opinion that controlling the import and export of defense articles and services is a foreign affairs function of the United States Government and that rules implementing this function are exempt from sections 553 (rulemaking) and 554 (adjudications) of the Administrative Procedure Act. Since this rule is exempt from 5 U.S.C. 553, the provisions of § 553(d) do not apply to this rulemaking. Therefore, this rule is effective upon publication. The Department also finds that, given the national security issues surrounding U.S. policy towards the aforementioned country, there is good cause for the effective date of this rule to be the date of publication, as provided by 5 U.S.C. 553(d)(3).

Regulatory Flexibility Act

Since this rule is exempt from the provisions of 5 U.S.C. 553, there is no requirement for an analysis under the Regulatory Flexibility Act.

Unfunded Mandates Reform Act of 1995

This rulemaking does not involve a mandate that will result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

The Department does not believe this rulemaking is a major rule within the definition of 5 U.S.C. 804.

Executive Orders 12372 and 13132

This rulemaking will not have substantial direct effects 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. Therefore, in accordance with Executive Order 13132, the Department has determined that this rulemaking does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this rulemaking.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributed impacts, and equity). These executive orders stress the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Because the scope of this rule implements a governmental policy limiting defense trade with a country the Department believes costs associated with this rule will be minimal. The Department also finds that any costs of this rulemaking do not outweigh the foreign policy benefits, as described in the preamble. This rule has been designated non-significant by the Office of Information and Regulatory Affairs under Executive Order 12866 Sec. 3(d)(2).

Executive Order 12988

The Department of State reviewed this rulemaking in light of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13175

The Department of State determined that this rulemaking will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not preempt tribal law. Accordingly, the

requirements of Executive Order 13175 do not apply to this rulemaking.

Executive Order 13771

This rule is not subject to the requirements of Executive Order 13771 because it is issued with respect to a foreign affairs function of the United States.

Paperwork Reduction Act

This rule does not impose any new reporting or recordkeeping requirements subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

List of Subjects in 22 CFR Part 126

Arms and munitions, Exports.

Accordingly, for the reasons set forth above, Title 22, Chapter I, Subchapter M, part 126 is amended as follows:

PART 126—GENERAL POLICIES AND PROVISIONS

- 1. The authority citation for part 126 is revised to read as follows:

Authority: 22 U.S.C. 2752, 2778, 2780, 2791, and 2797; 22 U.S.C. 2651a; 22 U.S.C. 287c; Sec. 1225, Pub. L. 108–375; Sec. 7089, Pub. L. 111–117; Pub. L. 111–266; Sections 7045 and 7046, Pub. L. 112–74; E.O. 13637, 78 FR 16129.

- 2. Amend § 126.1 by revising paragraph (u) to read as follows:

§ 126.1 Prohibited exports, imports, and sales to or from certain countries.

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(u) *Central African Republic.* It is the policy of the United States to deny licenses or other approvals for exports and imports of defense articles and defense services destined for or originating in the Central African Republic, except that a license or other approval may be issued, on a case-by-case basis, for:

(1) Defense articles intended solely for the support of or use by the UN Multidimensional Integrated Stabilization Mission in the Central African Republic (MINUSCA) and the European Union training missions deployed to the Central African Republic; French forces within the provisions of their bilateral agreement with the Central African Republic and the limits of their capacities and areas of deployment, and other Member States' forces providing training and assistance as notified in advance to the Committee of the Security Council concerning the Central African Republic;

(2) Non-lethal equipment and the provision of assistance, including operational and non-operational training to the Central African Republic

security forces, including state civilian law enforcement institutions, intended solely for the support of or use in the Central African Republic process of security sector reform, in coordination with MINUSCA, and as notified in advance to the Committee of the Security Council concerning the Central African Republic;

(3) Supplies brought into the Central African Republic by Chadian or Sudanese forces solely for their use in international patrols of the tripartite force to enhance security in the common border areas, in cooperation with MINUSCA, as approved in advance by the Committee of the Security Council concerning the Central African Republic;

(4) Non-lethal military equipment and related technical assistance or training intended solely for humanitarian and protective use, as notified in advance to the Committee of the Security Council concerning the Central African Republic;

(5) Personal protective equipment temporarily exported to the Central African Republic by United Nations personnel, representatives of the media, and humanitarian and developmental workers and associated personnel, for their personal use only;

(6) Small arms and related equipment intended solely for use in international patrols providing security in the Sangha River Tri-national Protected Area and by armed wildlife rangers of the Chinko Project and the Bamingui-Bangoran National Park to defend against poaching, smuggling of ivory and arms, and other activities contrary to the laws of the Central African Republic or its international legal obligations, as notified in advance to the Committee of the Security Council concerning the Central African Republic;

(7) Defense articles with a caliber of 14.5mm or less, and ammunition and components specially designed for such weapons, and defense articles that are unarmed ground military vehicles and ground military vehicles mounted with weapons with a caliber of 14.5mm or less, to the Central African Republic security forces, including state civilian law enforcement institutions, and intended solely for the support of or use in the Central African Republic security sector reform process, as notified in advance to the Committee of the Security Council concerning the Central African Republic;

(8) Defense articles and any related lethal equipment that are not listed in (u)(7) to the Central African Republic security forces, including state civilian law enforcement institutions, and

intended solely for the support of or use in the Central African Republic process of security sector reform, as approved in advance by the Committee of the Security Council concerning the Central African Republic; or

(9) Other sales or supply of defense articles and related materiel, or provision of assistance or personnel, as approved in advance by the Committee of the Security Council concerning the Central African Republic.

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Zachary A. Parker,

*Director, Office of Directives Management,
U.S. Department of State.*

[FR Doc. 2020-13511 Filed 7-21-20; 8:45 am]

BILLING CODE 4710-25-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG-2020-0438]

Special Local Regulation; Olympia Harbor Days Tug Boat Races, Budd Inlet, WA

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce Special Local Regulations for the Olympia Harbor Days Tug Boat Races, Budd, Inlet, WA, from 11 a.m. until 4 p.m. on September 6, 2020. This action is necessary to limit vessel movement within the specified race area immediately prior to, during, and immediately after racing activity in order to ensure the safety of participants, spectators, and the maritime public. Entry into, transit through, mooring, or anchoring within the specified race area is prohibited unless authorized by the Captain of the Port Puget Sound or Designated Representatives.

DATES: The regulations in 33 CFR 100.1309 will be enforced from 11 a.m. until 4 p.m. on September 6, 2020.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email CWO2 William E. Martinez, Sector Puget Sound Waterways Management Division, U.S. Coast Guard; telephone 206-217-6051, email SectorPugetSoundWWM@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce Special Local Regulations for Olympia Harbor Days

Tug Boat Races, Budd Inlet, WA in 33 CFR 100.1309(a), which encompasses approximately 2 nautical miles of the navigable waters in Budd Inlet south of Big Tykle Cove to west of Priest Point.

Under the provisions of 33 CFR 100.1309, the regulated area shall be closed immediately prior to, during, and immediately after the event to all persons and vessels not participating in the event and authorized by the event sponsor. This action is necessary to ensure the safety of participants, spectators, and the maritime public. Entry into, transit through, mooring, or anchoring within the specified race area is prohibited unless authorized by the Captain of the Port Puget Sound or Designated Representatives. All persons or vessels who desire to enter the race area while it is enforced must obtain permission from the on-scene patrol craft on VHF-FM channel 13.

In addition to this notice of enforcement in the **Federal Register**, the Coast Guard will provide notification of this enforcement period via the Local Notice to Mariners. If the Captain of the Port determines that the regulated area need not be enforced for the full duration stated in this notice, she may use a Broadcast Notice to Mariners to grant general permission to enter the regulated area.

Dated: July 14, 2020.

L.A. Sturgis,

Captain, U.S. Coast Guard, Captain of the Port Puget Sound.

[FR Doc. 2020-15705 Filed 7-21-20; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2020-0433]

RIN 1625-AA00

Safety Zone; West Side of Moran Bay St. Ignace, MI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters within a 560-foot radius of a recurring fireworks display. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards associated with the fireworks display. Entry of vessels or persons into this zone is prohibited unless specifically