

regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action as defined under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule generally increases flexibility for safety testing and would result in the reduction of certain regulatory burdens and does not add any new regulatory responsibilities, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

This final rule amends the biologics regulations by removing the GST requirements for biological products found in §§ 610.11, 610.11a and 680.3(b). FDA is finalizing this action because the current codified GST regulations are duplicative of requirements that are also specified in biologics licenses, or are no longer necessary or appropriate to help ensure the safety, purity, and potency of licensed biological products. The removal of the GST regulations for biological products, however, would not remove GST requirements specified in individual BLAs. All manufacturers that currently conduct a GST are already required, as part of the standards specified in their BLAs, to perform the GST and would thus continue to be required to perform the GST unless the BLA were revised to eliminate or modify the test through a supplement in accordance with § 601.12. Because this rule would impose no additional regulatory burdens, this regulation is not anticipated to result in any compliance costs and the economic impact is expected to be minimal.

### VIII. The Paperwork Reduction Act of 1995

This final rule refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The collections of information in § 601.12 have been approved under OMB control number 0910–0338. Therefore, FDA tentatively concludes that the requirements in this document are not subject to review by OMB because they do not constitute a “new collection of information” under the PRA.

### IX. Environmental Impact

The Agency has determined under 21 CFR 25.30(h) 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.

### X. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that would 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. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

### List of Subjects

#### 21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

#### 21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

#### 21 CFR Part 680

Biologics, Blood, Reporting and recordkeeping requirements.

Therefore under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 601, 610, and 680 are amended as follows:

### PART 601—LICENSING

■ 1. The authority citation for 21 CFR part 601 continues to read as follows:

**Authority:** 15 U.S.C. 1451–1561; 21 U.S.C. 321, 351, 352, 353, 355, 356b, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263, 264; sec 122, Pub. L. 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

#### § 601.2 [Amended]

■ 2. Section 601.2 is amended in paragraph (c)(1) by removing “610.11,”.

#### § 601.22 [Amended]

■ 3. Section 601.22 is amended in the third sentence by removing “610.11,”.

### PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

■ 4. The authority citation for 21 CFR part 610 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

#### § 610.11 [Removed and Reserved]

■ 5. Remove and reserve § 610.11.

#### § 610.11a [Removed and Reserved]

■ 6. Remove and reserve § 610.11a.

### PART 680—ADDITIONAL STANDARDS FOR MISCELLANEOUS PRODUCTS

■ 7. The authority citation for 21 CFR part 680 continues to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

#### § 680.3 [Amended]

■ 8. In § 680.3, remove and reserve paragraph (b).

Dated: June 26, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–16366 Filed 7–1–15; 8:45 am]

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### DEPARTMENT OF STATE

#### 22 CFR Part 121

[Public Notice: 8996]

RIN 1400–AD74

### Temporary Modification of Category XI of the United States Munitions List

**AGENCY:** Department of State.

**ACTION:** Final rule; notice of temporary modification.

**SUMMARY:** The Department of State, pursuant to its regulations and in the

interest of the security of the United States, temporarily modifies Category XI of the United States Munitions List (USML).

**DATES:** Amending instructions 1 and 2 are effective July 2, 2015. Amending instruction No. 3 is effective December 29, 2015.

**FOR FURTHER INFORMATION CONTACT:** Mr. C. Edward Peartree, Director, Office of Defense Trade Controls Policy, Department of State, telephone (202) 663-2792; email [DDTCResponseTeam@state.gov](mailto:DDTCResponseTeam@state.gov). ATTN: Temporary Modification of Category XI.

**SUPPLEMENTARY INFORMATION:** On July 1, 2014, the Department published a final rule revising Category XI of the USML, 79 FR 37535, effective December 30, 2014. This final rule, consistent with the two prior proposed rules for USML Category XI (78 FR 45017, July 25, 2013 and 77 FR 70958, November 28, 2012), revised paragraph (b) of Category XI to clarify the extent of the control and maintain the existing scope of control on items described in paragraph (b) and the directly related software described in paragraph (d). The Department has determined that exporters may read the revised control language to exclude certain intelligence analytics software that has been and remains controlled on the USML. Therefore, the Deputy Assistant Secretary of State for Defense Trade Controls determined that it is in the interest of the security of the United States to temporarily revise USML Category XI paragraph (b), pursuant to the provisions of 22 CFR 126.2, while a long term solution is developed. The Department will publish any permanent revision to USML Category XI paragraph (b) addressing this issue as a proposed rule for public comment.

This temporary revision clarifies that the scope of control in existence prior to December 30, 2014 for USML paragraph (b) and directly related software in paragraph (d) remains the same. This clarification is achieved by reinserting the words “analyze and produce information from” and by adding software to the description of items controlled. In effect, this rule modifies USML Category XI paragraph (b) until December 29, 2015.

### Regulatory Findings

#### *Administrative Procedure Act*

The Department is publishing this rule as a final rule based upon good cause, and its determination that delaying the effect of this rule during a period of public comment would be impractical, unnecessary and contrary to public interest. 5 U.S.C. 553(b)(3)(B).

In addition, the Department 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 (APA).

#### *Regulatory Flexibility Act*

Since the Department is of the opinion that 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 under the criteria of 5 U.S.C. 804.

#### *Executive Orders 12372 and 13132*

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*

The Department believes that benefits of the rulemaking outweigh any costs, which are estimated to be insignificant. It is the Department's position that this rulemaking is not a significant rule under the criteria of Executive Order 12866, and is consistent with the provisions of Executive Order 13563.

#### *Executive Order 12988*

The Department of State has reviewed this rulemaking in light of sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

#### *Executive Order 13175*

The Department of State has 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.

#### *Paperwork Reduction Act*

This rulemaking does not impose or revise any information collections subject to 44 U.S.C. Chapter 35.

#### List of Subjects in 22 CFR Part 121

Arms and munitions, Classified information, Exports.

For reasons stated in the preamble, the State Department amends 22 CFR part 121 as follows:

### PART 121—THE UNITED STATES MUNITIONS LIST

■ 1. The authority citation for part 121 continues to read as follows:

**Authority:** Secs. 2, 38, and 71, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2797); 22 U.S.C. 2651a; Pub. L. 105–261, 112 Stat. 1920; Section 1261, Pub. L. 112–239; E.O. 13637, 78 FR 16129.

■ 2. In § 121.1, under Category XI, revise paragraph (b), effective July 2, 2015 to read as follows:

#### § 121.1 The United States Munitions List.

\* \* \* \* \*

#### Category XI—Military Electronics

\* \* \* \* \*

\*(b) Electronic systems, equipment or software, not elsewhere enumerated in this sub-chapter, specially designed for intelligence purposes that collect, survey, monitor, or exploit, or analyze and produce information from, the electromagnetic spectrum (regardless of transmission medium), or for counteracting such activities.

\* \* \* \* \*

■ 3. In § 121.1, under Category XI, revise paragraph (b), effective December 29, 2015, to read as follows:

#### § 121.1 The United States Munitions List.

\* \* \* \* \*

#### Category XI—Military Electronics

\* \* \* \* \*

\*(b) Electronic systems or equipment, not elsewhere enumerated in this sub-chapter, specially designed for intelligence purposes that collect, survey, monitor, or exploit the electromagnetic spectrum (regardless of

transmission medium), or for counteracting such activities.

\* \* \* \* \*

**Kenneth B. Handelman,**

*Deputy Assistant Secretary for Defense Trade Controls, Bureau of Political-Military Affairs, U.S. Department of State.*

[FR Doc. 2015-16489 Filed 7-1-15; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG-2015-0504]

RIN 1625-AA00

#### **Safety Zone; Alexandria Bay Chamber of Commerce Fireworks Display; Saint Lawrence River, Heart Island, Alexandria Bay, NY**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone on the Saint Lawrence River, Heart Island, Alexandria Bay, NY. This safety zone is intended to restrict vessels from a portion of the Saint Lawrence River during the Alexandria Bay Chamber of Commerce fireworks display. This temporary safety zone is necessary to protect mariners and vessels from the navigational hazards associated with a fireworks display.

**DATES:** This rule is effective on July 5, 2015 from 9:15 p.m. until 10 p.m.

**ADDRESSES:** Documents mentioned in this preamble are part of docket [USCG-2015-0504]. 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 LTJG Amanda Garcia, Chief of Waterways Management, U.S. Coast Guard Sector Buffalo; telephone 716-843-9343, email [SectorBuffaloMarineSafety@uscg.mil](mailto:SectorBuffaloMarineSafety@uscg.mil). If you have questions on viewing the

docket, call Ms. Cheryl Collins, Program Manager, Docket Operations, telephone 202-366-9826 or 1-800-647-5527.

#### **SUPPLEMENTARY INFORMATION:**

##### **Table of Acronyms**

DHS Department of Homeland Security  
FR Federal Register  
NPRM Notice of Proposed Rulemaking  
TFR Temporary Final Rule

#### **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 doing so would be impracticable and contrary to the public interest. The final details for this event were not known to the Coast Guard until there was insufficient time remaining before the event to publish an NPRM. Thus, delaying the effective date of this rule to wait for a comment period to run would be impracticable and contrary to the public interest because it would inhibit the Coast Guard's ability to protect spectators and vessels from the hazards associated with a maritime fireworks display. Therefore, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this temporary rule effective less than 30 days after publication in the **Federal Register**. For the same reasons discussed above, waiting for a 30 day notice period to run would be impracticable.

#### **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 establish and define regulatory safety zones.

Between 9:15 p.m. and 10 p.m. on July 5, 2015, a fireworks display will be held on the shoreline of the Saint Lawrence River on Heart Island in Alexandria Bay, NY. It is anticipated that numerous vessels will be in the immediate vicinity of the launch point.

The Captain of the Port Buffalo has determined that such a launch proximate to a gathering of watercraft pose a significant risk to public safety and property. Such hazards include premature and accidental detonations, dangerous projectiles, and falling or burning debris.

#### **C. Discussion of the Final Rule**

With the aforementioned hazards in mind, the Captain of the Port Buffalo has determined that this temporary safety zone is necessary to ensure the safety of spectators and vessels during the Alexandria Bay Chamber of Commerce fireworks display. This zone will be enforced from 9:15 p.m. until 10 p.m. on July 5, 2015. This zone will encompass all waters of the Saint Lawrence River, Heart Island, Alexandria Bay, NY within an 800-foot radius of position 44°20'38.5" N and 075°55'19.1" W (NAD 83).

Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Buffalo or his designated on-scene representative. The Captain of the Port or his designated on-scene representative may be contacted via VHF Channel 16.

#### **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.

We conclude that this rule is not a significant regulatory action because we anticipate that it will have minimal impact on the economy, will not interfere with other agencies, will not adversely alter the budget of any grant or loan recipients, and will not raise any novel legal or policy issues. The safety zone created by this rule will be relatively small and enforced for a relatively short time. Also, the safety zone is designed to minimize its impact on navigable waters. Furthermore, the safety zone has been designed to allow