

**DEPARTMENT OF HOMELAND  
SECURITY**

**U.S. Customs and Border Protection**

**DEPARTMENT OF THE TREASURY**

**19 CFR Part 12**

[CBP Dec. 17–15]

RIN 1515–AE27

**Removing the Prohibition on the  
Importation of Jadeite or Rubies Mined  
or Extracted From Burma, and Articles  
of Jewelry Containing Jadeite or  
Rubies Mined or Extracted From  
Burma**

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security; Department of Treasury.

**ACTION:** Final rule.

**SUMMARY:** This document amends the U.S. Customs and Border Protection (CBP) regulations to remove the provision relating to the prohibition on the importation of jadeite or rubies mined or extracted from Burma, and articles of jewelry containing jadeite or rubies mined or extracted from Burma. This reflects the termination of all Burmese sanctions by Executive Order 13742, of October 7, 2016.

**DATES:** This final rule is effective on October 30, 2017.

**FOR FURTHER INFORMATION CONTACT:** Daniel Collier, Partner Government Agency Branch, Trade Policy and Programs, Office of Trade, (202) 863–6225, [Daniel.Collier@cbp.dhs.gov](mailto:Daniel.Collier@cbp.dhs.gov); or William Scopa, Branch Chief, Partner Government Agency Branch, Trade Policy and Programs, Office of Trade, (202) 863–6554, [William.R.Scopa@cbp.dhs.gov](mailto:William.R.Scopa@cbp.dhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

On July 28, 2003, the President signed into law the Burmese Freedom and Democracy Act of 2003 (Pub. L. 108–61) (the “BFDA”) to sanction the military junta then ruling Burma. Among other provisions, the BFDA required the imposition, subject to annual renewal, of a ban on the importation into the United States of any article that is a product of Burma. To implement the BFDA, the President issued Executive Order (“E.O.”) 13310 (68 FR 44853, July 30, 2003), which prohibited, among other things, the importation into the United States of any article that is a product of Burma.

On July 29, 2008, the President signed into law the Tom Lantos Block Burmese JADE (Junta’s Anti-Democratic Efforts)

Act of 2008 (Pub. L. 110–286) (the “JADE Act”), which, among other things, amended the BFDA to require a prohibition on the importation into the United States of jadeite or rubies mined or extracted from Burma and articles of jewelry containing such jadeite or rubies. Section 12.151 of the CBP regulations (Title 19, Code of Federal Regulations (“CFR”) section 12.151) reflects this prohibition on the importation of jadeite or rubies mined or extracted from Burma and articles of jewelry containing such jadeite or rubies.

The BFDA, as amended by the JADE Act, required annual renewal, which did not occur in 2013. As a result, the prohibition on the importation of jadeite or rubies mined or extracted from Burma and articles of jewelry containing jadeite or rubies mined or extracted from Burma expired on July 28, 2013. On August 6, 2013, the President signed E.O. 13651, titled “Prohibiting Certain Imports of Burmese Jadeite and Rubies” (78 FR 48793), which revoked the sections of E.O. 13310 imposing a prohibition on the importation into the United States of any article that is a product of Burma. As a result, there was no longer a general ban on importing into the United States any article that is a product of Burma; however, the specific ban of jadeite and rubies mined or extracted from Burma as well as articles of jewelry containing jadeite or rubies mined or extracted from Burma was reinstated by E.O. 13651. Consequently, on August 23, 2016, CBP published a final rule in the **Federal Register** (81 FR 57456) amending the CBP regulations to update the relevant provisions to reflect the import prohibitions set forth in E.O. 13651.

**II. Termination of the Burmese Sanctions**

On October 7, 2016, the President signed E.O. 13742, titled “Termination of Emergency With Respect to the Actions and Policies of the Government of Burma” (81 FR 70593), which revoked, among others, E.O. 13310 and 13651. The President found that the situation that gave rise to the declaration of a national emergency with respect to the actions and policies of the Government of Burma has been significantly altered by Burma’s substantial advances in promoting democracy, including historic elections that resulted in the formation of a democratically elected, civilian-led government; the release of many political prisoners; and greater enjoyment of human rights and fundamental freedoms, including freedom of expression and freedom of

association and peaceful assembly. As a result, President Obama revoked all the Burmese sanctions. This was accomplished by revoking, among others, E.O. 13651, which prohibited the importation of any jadeite or rubies mined or extracted from Burma as well as any articles of jewelry containing jadeite or rubies mined or extracted from Burma. As of October 7, 2016, CBP is no longer enforcing this import prohibition. To reflect this, CBP is removing the relevant provision, 19 CFR 12.151, from the CBP regulations.

**III. Statutory and Regulatory Requirements**

*A. Inapplicability of Public Notice and Delayed Effective Date Requirements*

Under section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553), rulemaking generally requires prior notice and comment, and a 30-day delayed effective date, subject to specified exceptions. This document amends the regulations to remove 19 CFR 12.151 to reflect Executive Order 13742 of October 7, 2016, which terminated the import prohibitions on Burmese articles. Since this document removes a regulation that is no longer applicable or enforced by CBP in light of the Executive Order, CBP has determined it is a nondiscretionary action and that, pursuant to the provisions of 5 U.S.C. 553(b)(B), prior public notice and comment procedures on this regulation are impracticable, unnecessary, and contrary to the public interest and that there is good cause for this rule to become effective immediately upon publication. For these reasons, pursuant to the provision of 5 U.S.C. 553(d)(3), CBP finds that there is good cause for dispensing with a delayed effective date.

*B. Executive Orders 13563 and 12866: Regulatory Planning and Review*

Executive Orders 13563 and 12866 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 (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule is not a “significant regulatory action,” under section 3(f) of Executive Order 12866. Accordingly, the Office of Management and Budget has not reviewed this regulation.

### C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement and Fairness Act of 1996, requires an agency to prepare and make available to the public a regulatory flexibility analysis that describes the effect of a proposed rule on small entities (*i.e.*, small businesses, small organizations, and small governmental jurisdictions) when the agency is required to publish a general notice of proposed rulemaking for a rule. As a notice of proposed rulemaking is not necessary for this rule, CBP is not required to prepare a regulatory flexibility analysis for this rule.

### D. Signing Authority

This regulation is being issued in accordance with 19 CFR 0.1(a)(1) pertaining to the Secretary of the Treasury's authority (or that of his delegate) to approve regulations related to certain customs revenue functions.

### List of Subjects in 19 CFR Part 12

Customs duties and inspection, Reporting and recordkeeping requirements.

### Amendments to the Regulations

For the reasons set forth in the preamble, part 12 of title 19 of the Code of Federal Regulations (19 CFR part 12) is amended as set forth below.

### PART 12—SPECIAL CLASSES OF MERCHANDISE

■ 1. The general authority citation for part 12 continues to read as follows:

**Authority:** 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States (HTSUS)), 1624.

\* \* \* \* \*

■ 2. The specific authority citation for § 12.151 is removed.

#### § 12.151 [Removed and Reserved]

■ 3. Remove and reserve § 12.151.

Dated: October 25, 2017.

**Kevin K. McAleenan,**

*Acting Commissioner, U.S. Customs and Border Protection.*

Approved:

**Timothy E. Skud,**

*Deputy Assistant Secretary of the Treasury.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 862

[Docket No. FDA-2017-N-5685]

#### Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of the Acute Kidney Injury Test System

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA or we) is classifying the acute kidney injury test system into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the acute kidney injury test system's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

**DATES:** This order is effective October 30, 2017. The classification was applicable on September 5, 2014.

**FOR FURTHER INFORMATION CONTACT:** Seth Olson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4561, Silver Spring, MD 20993-0002, 301-796-4364, [Jeremy.Olson@fda.hhs.gov](mailto:Jeremy.Olson@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Upon request, FDA has classified the acute kidney injury test system as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device

(see 21 U.S.C. 360c(f)(1)). We refer to these devices as "postamendments devices" because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act to a predicate device that does not require premarket approval (see 21 U.S.C. 360c(i)). We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act and part 807 (21 U.S.C. 360(k) and 21 CFR part 807, respectively).

FDA may also classify a device through "De Novo" classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105-115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112-144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA