

**DEPARTMENT OF HOMELAND SECURITY****U.S. Customs and Border Protection****DEPARTMENT OF THE TREASURY****19 CFR Parts 12 and 163**

[USCBP–2008–0111; CBP Dec. 10–04]

RIN 1505–AC06

**Prohibitions and Conditions for Importation of Burmese and Non-Burmese Covered Articles of Jadeite, Rubies, and Articles of Jewelry Containing Jadeite or Rubies****AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security; Department of the Treasury.**ACTION:** Final rule.

**SUMMARY:** This document adopts as a final rule, interim amendments to title 19 of the Code of Federal Regulations (“19 CFR”) which were published in the **Federal Register** on January 16, 2009, as CBP Dec. 09–01 to implement the prohibitions and conditions for importation of Burmese and non-Burmese covered articles of jadeite, rubies, and articles of jewelry containing jadeite or rubies.

**DATES:** Final rule effective April 22, 2010.

**FOR FURTHER INFORMATION CONTACT:**

Cathy Saucedo, Director, Import Safety and Interagency requirements Division, Office of International Trade (202) 863–6556, or Brenda Brockman Smith, Executive Director, Trade Policy and Programs, Office of International Trade (202) 863–6406.

**SUPPLEMENTARY INFORMATION:****Background**

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”). Section 6 of the JADE Act amends the Burmese Freedom and Democracy Act of 2003 (Pub. L. 108–61) (as so amended, the “BFDA”) by adding a new section 3A that prohibits the importation of jadeite and rubies mined or extracted from Burma, and articles of jewelry containing jadeite or rubies mined or extracted from Burma (Burmese covered articles). Section 3A of the JADE Act also regulates the importation of jadeite and rubies mined or extracted from a country other than Burma, and articles of jewelry containing jadeite or rubies mined or extracted from a country other than Burma (non-Burmese covered articles). Presidential Proclamation 8294 of

September 26, 2008, implements the prohibitions and conditions of the JADE Act. (See Annex of Presidential Proclamation 8294 for Additional U.S. Note 4 to Chapter 71, Harmonized Tariff Schedule of the United States (“HTSUS”).)

On January 16, 2009, U.S. Customs and Border Protection (“CBP”) published CBP Dec. 09–01 in the **Federal Register** (74 FR 2844), setting forth interim amendments to implement certain provisions of the JADE Act and Presidential Proclamation 8294 by prohibiting the importation of “Burmese covered articles” (jadeite, rubies, and articles of jewelry containing jadeite or rubies, mined or extracted from Burma), and by setting forth conditions for the importation of “non-Burmese covered articles” (jadeite, rubies, and articles of jewelry containing jadeite or rubies, mined or extracted from a country other than Burma).

Although the interim regulations were promulgated without prior public notice and comment procedures and took effect on January 16, 2009, CBP Dec. 09–01 provided for the submission of public comments that would be considered before adopting the interim regulations as a final rule. The prescribed public comment period closed on March 17, 2009.

**Discussion of Comment Received in Response to CBP Dec. 09–01**

One commenter responded to the solicitation of comments on the interim regulations set forth in CBP Dec. 09–01. The commenter stated that the interim final rule provided “an excellent platform that offers both very workable and realistic means to uphold the law as written and to support the spirit of the law drafted by U.S. Congress.” The commenter offered a few suggestions. A description of the commenter’s suggestions and CBP’s analysis are set forth below.

**Comment**

The commenter recommended that in order to support the importer certification under Additional U.S. Note 4(a), Chapter 71, HTSUS, importers be required, at their sole expense, to confirm the veracity of their certification of non-Burmese covered articles by conducting random spot checks utilizing lab testing by an independent gemological laboratory accredited by CBP. The commenter also recommends requiring the importer to maintain records showing a history of the auditing process for a period of at least five years, and to make such records available to CBP upon request.

**CBP’s Response**

Requiring an importer to conduct lab testing on the merchandise to be imported goes beyond the explicit statutory requirements and the importer certification requirement of 19 CFR 12.151(d). Additional U.S. Note 4(a), Chapter 71, HTSUS, provides that the presentation of an entry for any good under heading 7103, 7113, or 7116 is deemed to be a certification by the importer that any jadeite or rubies contained in such good were not mined in or extracted from Burma. As such, the presentation of an entry serves as the importer certification. If an importer elects to test the imported gems to bolster the information provided by the exporter, the results of the testing will serve to reflect upon the importer’s level of reasonable care used and will be objective evidence that the goods were not mined in or extracted from Burma. CBP concurs with the commenter regarding retaining the 5-year record retention period in the final rule as set forth in § 12.151(e) as well as the requirement in § 12.151(f) that the importer must provide, upon CBP’s request, all documentation to support the importer and exporter certifications.

**Comment**

The commenter recommended that only government-validated certificates of origin from the country in which the jadeite or rubies are mined or extracted be accepted as verifiable evidence, and that protocols related to the issuance of the exporter’s government-validated certification guaranteeing non-Burmese origin should require random spot testing by an independent gemological laboratory accredited by CBP to verify non-Burmese origin.

**CBP’s Response**

The commenter’s recommendations with respect to foreign government certification and validation of exporter certificates cannot be enforced by CBP because no international arrangement, similar to the Kimberley Process Certification Scheme for conflict diamonds, currently exists for jadeite or rubies from Burma.

**Comment**

The commenter recommended that as a condition for export with the intent of re-importation into the United States, CBP should require that any Burmese covered article be detailed in such a way so as to ensure the same article is the one considered for re-importation to prevent circumvention of the JADE sanctions. Further, the commenter recommended that for the re-importation of non-Burmese covered

articles, the original country of origin certificate be required, including a statement detailing any transformation that may have occurred.

#### *CBP's Response*

On CBP Form 4457, Certificate of Registration for Personal Effects Taken Abroad, CBP collects information from the owner in advance of departure concerning articles that will be re-imported into the United States. In addition, on CBP Form 4455, Certificate of Registration, CBP collects information about articles that are exported from the United States via a carrier for alteration, repairs, use abroad, replacement, or processing that will be re-imported into the United States and that may be subject to duty for the cost or value of the alteration, repair, or processing. Completion of this form is mandatory. Although CBP cannot ensure that the item being re-imported is the actual item that was exported unless the article has permanent identifying information such as etched or engraved serial numbers, CBP will endeavor to use the information contained on these forms to prevent the circumvention of the JADE sanctions when a covered article is exported with the intention of re-importation. As is the case with all CBP forms, the importer is responsible for the truthfulness of the information submitted on the form.

#### *Comment*

The commenter asserts that there is a risk that the personal-use exemption will be used as a means to circumvent the prohibitions and conditions for the importation of non-Burmese covered articles. The commenter recommended increased scrutiny be placed on individuals claiming a personal-use exemption and that random spot-testing be conducted to verify the imported goods are in fact non-Burmese covered articles.

#### *CBP's Response*

CBP appreciates the commenter's concerns and the underlying rationale. Any Burmese covered articles or non-Burmese covered articles that are imported into the United States in violation of any prohibition of the JADE Act are subject to all applicable seizure and forfeiture laws to the same extent as any other violation of the customs laws.

#### *Comment*

The commenter stated that the reliance on a "paper-only" system of verifiable controls without built-in safeguards such as random spot lab testing to verify authenticity and

accuracy of documentation is susceptible to the risk for fraud.

#### *CBP's Response*

CBP acknowledges that until there is an international certification scheme in place, the authenticity and accuracy of documentation in the required "system of verifiable controls" is susceptible to fraud. CBP will enforce the JADE Act through the use of an importer's and exporter's certification and the other applicable customs laws.

#### *Comment*

The commenter recommended that importers should be required to provide a written warranty to each buyer or ultimate consignee of non-Burmese covered articles, affirming that an established system of verified controls from the mine to the supplier is in place and that officially validated certification has accompanied the articles at all stages.

#### *CBP's Response*

The commenter's suggestion that the importer issue a written warranty to the ultimate consumer goes beyond what is required by the JADE Act. Accordingly, CBP cannot prescribe in this final rule such entry requirements that are not mandated by the Act.

#### **Conclusion**

As indicated in the above discussion, CBP is unable to adopt the commenter's suggestions given the current statutory scheme. Accordingly, the interim rule published as CBP Dec. 09-01 is being adopted as a final rule.

#### **Executive Order 12866**

CBP has determined that this document does not meet the criteria for a "significant regulatory action" as specified in Executive Order 12866 of September 30, 1993 (58 FR 51735, October 1993).

#### **Regulatory Flexibility Act**

CBP Dec. 09-01 was issued as an interim rule rather than a notice of proposed rulemaking because CBP had determined that, pursuant to the provisions of 5 U.S.C. 553(b)(B) of the Administrative Procedure Act, prior public notice and comment procedures on the interim regulations were impracticable and contrary to public interest, and that there was good cause for the rule to become effective immediately upon publication since the JADE Act is already in effect. Because no notice of proposed rulemaking was required, the provisions of the Regulatory Flexibility Act, as amended (5 U.S.C. 601 *et seq.*), do not apply to

this rulemaking. Accordingly, this final rule is not subject to the regulatory analysis requirements or other requirements of 5 U.S.C. 603 and 604.

#### **Paperwork Reduction Act**

The collections of information in this final rule have previously been reviewed and approved by the Office of Management and Budget in accordance with the requirements of the Paperwork Reduction Act (44 U.S.C. 3507) under control number 1651-0133.

The collections of information in these regulations are contained in § 12.151(d) (19 CFR 12.151(d)). This information is used by CBP to fulfill its information collection obligations under section 3A(c)(1) of the BFDA, as amended, and Additional U.S. Note 4, Chapter 71, HTSUS, required in connection with entry of non-Burmese covered articles. The likely respondents are business organizations, including importers and brokers.

The estimated average annual burden associated with the collection of information in this final rule is 0.2 hours per respondent or record keeper. Under the Paperwork Reduction Act, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number.

#### **Signing Authority**

This document is being issued in accordance with § 0.1(a)(1) of the CBP regulations (19 CFR 0.1(a)(1)) pertaining to the authority of the Secretary of the Treasury (or his/her delegate) to approve regulations related to certain customs revenue functions.

#### **List of Subjects**

##### *19 CFR Part 12*

Customs duties and inspection, Economic sanctions, Entry of merchandise, Foreign assets control, Imports, Licensing, Prohibited merchandise, Reporting and recordkeeping requirements, Restricted merchandise, Sanctions.

##### *19 CFR Part 163*

Administrative practice and procedure, Customs duties and inspection, Exports, Imports, Penalties, Reporting and recordkeeping requirements.

#### **Amendments to the CBP Regulations**

■ Accordingly, the interim rule amending parts 12 and 163 of the CBP regulations (19 CFR parts 12 and 163), which was published at 74 FR 2844 on January 16, 2009, is adopted as a final rule.

Approved: March 10, 2010.

**Timothy E. Skud,**

*Deputy Assistant Secretary of the Treasury.*

**David V. Aguilar,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 3

[Docket No. FDA-2010-N-0010]

#### Product Jurisdiction; Change of Address and Telephone Number; Technical Amendment

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

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is amending its regulations to reflect a change in the address and telephone number for the Office of Combination Products (OCP). This action is editorial in nature and is intended to improve the accuracy of the agency's regulations.

**DATES:** Effective Date: April 19, 2010.

**FOR FURTHER INFORMATION CONTACT:** John Barlow Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5130, Silver Spring, MD 20993-0002, 301-796-8930. To confirm that this change of address and telephone number has occurred, please see our Web site at [www.fda.gov/CombinationProducts/default.htm](http://www.fda.gov/CombinationProducts/default.htm).

**SUPPLEMENTARY INFORMATION:** FDA is amending its regulations in 21 CFR part 3 to reflect a change in the address and telephone number for OCP. Publication of this document constitutes final action on this change under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedures are unnecessary because FDA is merely updating nonsubstantive content.

#### List of Subjects in 21 CFR Part 3

Administrative practice and procedure, Biologics, Combination products, Drugs, 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 3 is amended as follows:

## PART 3—PRODUCT JURISDICTION

■ 1. The authority citation for 21 CFR part 3 continues to read as follows:

**Authority:** 21 U.S.C. 321, 351, 353, 355, 360, 360c-360f, 360h-360j, 360gg-360ss, 360bbb-2, 371(a), 379e, 381, 394; 42 U.S.C. 216, 262, 264.

### § 3.6 [Amended]

■ 2. Section 3.6 is amended by removing “(HFG-3), Food and Drug Administration, 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855, 301-427-1934” and by adding in its place “Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5129, Silver Spring, MD 20993-0002, 301-796-8930.”.

Dated: March 17, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1308

[Docket No. DEA-329F]

**RIN 1117-AB23**

#### Schedules of Controlled Substances; Table of Excluded Nonnarcotic Products: Nasal Decongestant Inhalers Manufactured by Classic Pharmaceuticals, LLC

**AGENCY:** Drug Enforcement Administration (DEA), Department of Justice.

**ACTION:** Final rule.

**SUMMARY:** Under this Final Rule, the Drug Enforcement Administration (DEA) is updating the Table of Excluded Nonnarcotic Products found in 21 CFR 1308.22 to include the Nasal Decongestant Inhaler/Vapor Inhaler (containing 50 mg Levmetamfetamine) manufactured by Classic Pharmaceuticals, LLC and marketed under various private labels (to include the “Premier Value” and “Kroger” labels). This nonnarcotic drug product, which may be lawfully sold over the counter without a prescription under the Federal Food, Drug, and Cosmetic Act, is excluded from provisions of the Controlled Substances Act (CSA) pursuant to 21 U.S.C. 811(g)(1).

**DATES:** This rulemaking shall become effective on March 23, 2010.

**FOR FURTHER INFORMATION CONTACT:** Christine A. Sannerud, PhD, Chief, Drug

and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152; telephone: (202) 307-7183.

**SUPPLEMENTARY INFORMATION:** On August 28, 2009, the DEA published an interim rule with request for comments [74 FR 44281]. This interim rule updated the Table of Excluded Nonnarcotic Products found in 21 CFR 1308.22 to include the Nasal Decongestant Inhaler/Vapor Inhaler (containing 50 mg Levmetamfetamine) manufactured by Classic Pharmaceuticals, LLC and marketed under various private labels (to include the “Premier Value” and “Kroger” labels). This nonnarcotic drug product, which may be lawfully sold over the counter without a prescription under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*), is excluded from provisions of the Controlled Substances Act (CSA) pursuant to 21 U.S.C. 811(g)(1).

### Comments Received

DEA did not receive any comments to its interim rule published August 28, 2009, regarding this exemption. Therefore, DEA is issuing this rulemaking to finalize the interim rule without change.

### Background

The CSA, specifically 21 U.S.C. 811(g)(1), states that the Attorney General shall by regulation exclude any nonnarcotic drug which contains a controlled substance from the application of the CSA, if such drug may, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*), be lawfully sold over the counter without a prescription. This authority has been delegated to the Administrator of DEA and redelegated to the Deputy Assistant Administrator of the Office of Diversion Control pursuant to 28 CFR 0.100 and title 28, part 0, appendix to subpart R, 7(g), respectively.

Such exclusions apply only to nonnarcotic products and are only granted following suitable application to the DEA per the provisions of 21 CFR 1308.21. The current Table of Excluded Nonnarcotic Products found in 21 CFR 1308.22 lists those products that have been granted excluded status.

Pursuant to the application process of 21 CFR 1308.21, DEA received application for exclusion from Classic Pharmaceuticals, LLC, the manufacturer of a Nasal Decongestant Inhaler/Vapor Inhaler which contains the schedule II controlled substance Levmetamfetamine. This inhaler is sold over the counter under various private labels (such as the “Premier Value” label