operating under part 121 of 14 CFR, you have met the requirements of this AD when you modify your continuous airworthiness air carrier maintenance program as specified in paragraph (f) of this AD. You do not need to record each piece-part inspection as compliance to this AD, but you must maintain records of those inspections according to the regulations governing your operation. For air carriers operating under part 121, you may use either the system established to comply with section 121.369 or an alternative accepted by your principal maintenance inspector if that alternative:

- (i) Includes a method for preserving and retrieving the records of the inspections resulting from this AD;
- (ii) Meets the requirements of section 121.369(c); and
- (iii) Maintains the records either indefinitely or until the work is repeated.
- (2) These record keeping requirements apply only to the records used to document the mandatory inspections required as a result of revising the ALS of the manufacturer's ICA as specified in paragraph (f) of this AD. These record keeping requirements do not alter or amend the record keeping requirements for any other AD or regulatory requirement.

#### (j) Related Information

For more information about this AD, contact Ian Dargin, Aerospace Engineer, Engine & Propeller Directorate, FAA, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7178; fax: 781–238–7199; email: ian.dargin@faa.gov.

# **(k) Material Incorporated by Reference**None.

Issued in Burlington, Massachusetts, on February 22, 2012.

#### Peter A. White,

Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2012–6504 Filed 3–16–12; 8:45 am]

BILLING CODE 4910-13-P

## DEPARTMENT OF HOMELAND SECURITY

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

#### **DEPARTMENT OF THE TREASURY**

19 CFR Parts 10, 24, 162, 163, and 178 [USCBP-2012-0007; CBP Dec. 12-03] RIN 1515-AD86

# United States-Korea Free Trade Agreement

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security; Department of the Treasury. **ACTION:** Interim regulations; solicitation of comments.

**SUMMARY:** This rule amends the Customs and Border Protection (CBP) regulations

on an interim basis to implement the preferential tariff treatment and other customs-related provisions of the United States-Korea Free Trade Agreement.

**DATES:** Effective March 15, 2012; comments must be received by May 18, 2012.

**ADDRESSES:** You may submit comments, identified by docket number, by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments via docket number USCBP-2012-007.
- Mail: Trade and Commercial Regulations Branch, Regulations and Rulings, Office of International Trade, U.S. Customs and Border Protection, 799 9th Street NW., 5th Floor, Washington, DC 20229–1179.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to <a href="http://www.regulations.gov">http://www.regulations.gov</a>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Public Participation" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to http:// www.regulations.gov. Submitted comments may also be inspected during regular business days between the hours of 9 a.m. and 4:30 p.m. at the Trade and Commercial Regulations Branch, Regulations and Rulings, Office of International Trade, U.S. Customs and Border Protection, 799 9th Street NW., 5th Floor, Washington, DC. Arrangements to inspect submitted comments should be made in advance by calling Mr. Joseph Clark at (202) 325-0118.

#### FOR FURTHER INFORMATION CONTACT:

Textile Operational Aspects: Nancy Mondich, Trade Policy and Programs, Office of International Trade, (202) 863– 6524.

Other Operational Aspects: Katrina Chang, Trade Policy and Programs, Office of International Trade, (202) 863–6532.

Legal Aspects: Yuliya A. Gulis, Regulations and Rulings, Office of International Trade, (202) 325–0042.

#### SUPPLEMENTARY INFORMATION:

#### **Public Participation**

Interested persons are invited to participate in this rulemaking by submitting written data, views, or

arguments on all aspects of the interim rule. U.S. Customs and Border Protection (CBP) also invites comments that relate to the economic, environmental, or federalism effects that might result from this interim rule. Comments that will provide the most assistance to CBP in developing these regulations will reference a specific portion of the interim rule, explain the reason for any recommended change, and include data, information, or authority that support such recommended change. See ADDRESSES above for information on how to submit comments.

#### Background

On June 30, 2007, the United States and the Republic of Korea (hereinafter "Korea") signed the United States-Korea Free Trade Agreement (hereinafter "UKFTA" or the "Agreement"). On December 3, 2010, the United States and Korea concluded new agreements, reflected in letters signed on February 10, 2011 that provide new market access and level the playing field for U.S. auto manufacturers and workers. The stated objectives of the UKFTA include: Strengthening close economic relations between the United States and Korea; creating an expanded and secure market for goods and services in the United States and Korea and a stable and predictable environment for investment, thus enhancing the competitiveness of U.S. and Korean firms in global markets; raising living standards, promoting economic growth and stability; creating new employment opportunities, and improving the general welfare by liberalizing and expanding trade and investment between the United States and Korea; establishing clear and mutually advantageous rules governing the two countries' trade and investment and reducing or eliminating the barriers to trade and investment between the United States and Korea; not according foreign investors greater substantive rights with respect to investment protections than domestic investors under domestic law where, as in the United States, protections of investor rights under domestic law equal or exceed those set forth in this Agreement; contributing to the harmonious development and expansion of world trade by removing obstacles to trade through the creation of a free trade area and avoiding new barriers to trade or investment between the territories of the United States and Korea that could reduce the benefits of this Agreement; strengthening the development and enforcement of labor and environmental laws and policies, promoting basic workers' rights and

sustainable development, and implementing this Agreement in a manner consistent with environmental protection and conservation; observing the Parties' respective rights and obligations under the Marrakesh Agreement Establishing the World Trade Organization and other multilateral, regional, and bilateral agreements and arrangements to which they are both parties; and furthering the economic leadership of the United States and Korea in the Asia Pacific region, in particular by seeking to reduce barriers to trade and investment in the region.

The provisions of the FTA were approved by the United States with the enactment on October 21, 2011, of the United States-Korea Free Trade Agreement Implementation Act (the "Act"), Public Law 112–41, 125 Stat. 428 (19 U.S.C. 3805, note). Sections 103(b) and 208 of the Act require that regulations be prescribed as necessary to implement the provisions of the LIKFTA

On March 6, 2012, the President signed Proclamation 8783 to implement the provisions of the UKFTA for the United States. The Proclamation, which was published in the Federal Register on March 9, 2012 (77 FR 14265) modified the Harmonized Tariff Schedule of the United States ("HTSUS") as set forth in Annexes I and II of Publication No. 4308 of the U.S. International Trade Commission entitled "Modifications to the Harmonized Tariff Schedule of the United States to Implement the United States-Korea Free Trade Agreement". The modifications to the HTSUS included the addition of new General Note 33, incorporating the relevant UKFTA rules of origin as set forth in the Act, and the insertion throughout the HTSUS of the preferential duty rates applicable to individual products under the UKFTA where the special program indicator "KR" appears in parenthesis in the "Special" rate of duty subcolumn. The modifications to the HTSUS also included a new Subchapter XX to Chapter 99 to provide for temporary tariff-rate quotas and applicable safeguards implemented by the UKFTA.

U.S. Customs and Border Protection ("CBP") is responsible for administering the provisions of the UKFTA and the Act that relate to the importation of goods into the United States from Korea.

#### **Customs-Related UKFTA Provisions**

Those customs-related UKFTA provisions which require implementation through regulation as called for in § 208 of the Act include certain tariff and non-tariff provisions within Chapter One (Initial Provisions

and Definitions), Chapter Two (National Treatment and Market Access for Goods), Chapter Four (Textiles and Apparel), Chapter Six (Rules of Origin and Origin Procedures), and Chapter Seven (Customs Administration and Trade Facilitation).

Certain general definitions set forth in Chapter One of the UKFTA and §§ 3 and 202(n) of the Act have been incorporated into the UKFTA implementing regulations. These regulations also implement Article 2.6 (Goods Re-entered after Repair or Alteration) of the UKFTA.

Chapter Four of the FTA sets forth provisions relating to trade in textile and apparel goods between Korea and the United States. The provisions within Chapter Four that require regulatory action by CBP include Article 4.2 (Rules of Origin and Related Matters), Article 4.3 (Customs Cooperation for Textile or Apparel Goods), and Article 4.5 (Definitions).

Chapter Six of the UKFTA sets forth the rules for determining whether an imported good is an originating good of the United States or Korea and, as such, is therefore eligible for preferential tariff (duty-free or reduced duty) treatment under the UKFTA as specified in the Agreement and the HTSUS. The basic rules of origin in Section A of Chapter Six are set forth in General Note 33, HTSUS.

Under Article 6.1 of Chapter Six and § 202(b) of the Act, originating goods may be grouped in three broad categories: (1) Goods that are wholly obtained or produced entirely in the territory of one or both of the Parties; (2) goods that are produced entirely in the territory of one or both of the Parties and that satisfy the product-specific rules of origin in UKFTA Annex 6-A (Specific Rules of Origin; change in tariff classification requirement and/or regional value content requirement) or Annex 4-A (Specific Rules of Origin for Textile or Apparel Goods) and all other applicable requirements of Chapter Six; and (3) goods that are produced entirely in the territory of one or both of the Parties exclusively from originating materials. Article 6.2 and § 202(c) of the Act set forth the methods for calculating the regional value content of a good. Articles 6.3 and 6.4 as well as § 202(d) of the Act set forth the rules for determining the value of materials for purposes of calculating the regional value content of a good. Article 6.5 and § 202(e) of the Act provide that production that takes place in the territory of one or both of the Parties may be accumulated such that, provided other requirements are met, the resulting good is considered originating.

Article 6.6 and § 202(f) of the Act provide the de minimis criterion. The remaining Articles within Section A of Chapter Six consist of additional subrules, applicable to the originating good concept, involving fungible goods and materials, accessories, spare parts, and tools, sets of goods, packaging materials and containers for retail sale, packing materials and containers for shipment, indirect materials, transit and transshipment, and consultation and modifications. All Articles within Section A are reflected in the UKFTA implementing regulations, except for Article 6.14 (Consultation and Modifications).

Section B of Chapter Six sets forth procedures that apply under the UKFTA in regard to claims for preferential tariff treatment. Specifically, Section B includes provisions concerning claims for preferential tariff treatment, waiver of certification or other information, recordkeeping requirements, verification of preference claims, obligations relating to importations and exportations, common guidelines, and definitions of terms used within the context of the rules of origin. All Articles within Section B, except for Article 6.21 (Common Guidelines) are reflected in these implementing regulations.

Chapter Seven sets forth operational provisions related to customs administration and trade facilitation under the UKFTA. Article 7.9, concerning the general application of penalties to UKFTA transactions, is the only provision within Chapter Seven that is reflected in the UKFTA implementing regulations.

# Placement of CBP Implementing Regulations

In order to provide transparency and facilitate their use, the majority of the UKFTA implementing regulations set forth in this document have been included within Subpart R in Part 10 of the CBP regulations (19 CFR part 10). However, in those cases in which UKFTA implementation is more appropriate in the context of an existing regulatory provision, the UKFTA regulatory text has been incorporated in an existing Part within the CBP regulations. In addition, this document sets forth several cross-references and other consequential changes to existing regulatory provisions to clarify the relationship between those existing provisions and the new UKFTA implementing regulations. The regulatory changes are discussed below in the order in which they appear in this document.

#### **Discussion of Amendments**

Part 10

Section 10.31(f) concerns temporary importations under bond. It is amended by adding references to certain goods originating in Korea for which, like goods originating in Canada, Mexico, Singapore, Chile, Morocco, El Salvador, Guatemala, Honduras, Nicaragua, the Dominican Republic, Costa Rica, Bahrain, Oman, or Peru, no bond or other security will be required when imported temporarily for prescribed uses. The provisions of UKFTA Article 2.5 (Temporary Admission of Goods) are already reflected in existing temporary importation bond or other provisions contained in Part 10 of the CBP regulations and in Chapter 98 of the HTSUS.

#### Part 10, Subpart R

#### **General Provisions**

Section 10.1001 outlines the scope of Subpart R, Part 10 of the CBP regulations. This section also clarifies that, except where the context otherwise requires, the requirements contained in Subpart R, Part 10 are in addition to general administrative and enforcement provisions set forth elsewhere in the CBP regulations. Thus, for example, the specific merchandise entry requirements contained in Subpart R, Part 10 are in addition to the basic entry requirements contained in Parts 141–143 of the CBP regulations.

Section 10.1002 sets forth definitions of common terms used in multiple contexts or places within Subpart R, Part 10. Although the majority of the definitions in this section are based on definitions contained in Articles 1.4 and 6.22 as well as Annexes 4–A and 6–A of the UKFTA, and § 3 of the Act, other definitions have also been included to clarify the application of the regulatory texts. Additional definitions that apply in a more limited Subpart R, Part 10 context are set forth elsewhere with the substantive provisions to which they relate.

#### Import Requirements

Section 10.1003 sets forth the procedure for claiming UKFTA preferential tariff treatment at the time of entry and, as provided in UKFTA Article 6.15.1, states that an importer may make a claim for UKFTA preferential tariff treatment based on a certification by the importer, exporter, or producer or the importer's knowledge that the good is an originating good. Section 10.1003 also provides, consistent with UKFTA Article 6.19.4(e), that when an importer has

reason to believe that a claim is based on inaccurate information, the importer must correct the claim and pay any duties that may be due.

Section 10.1004, which is based on UKFTA Articles 6.15 and 6.19.4, requires a U.S. importer, upon request, to submit a copy of the certification of the importer, exporter, or producer if the certification forms the basis for the claim. Section 10.1004 specifies the information that must be included on the certification, sets forth the circumstances under which the certification may be prepared by the exporter or producer of the good, and provides that the certification may be used either for a single importation or for multiple importations of identical goods.

Section 10.1005 sets forth certain importer obligations regarding the truthfulness of information and documents submitted in support of a claim for preferential tariff treatment. Section 10.1006, which is based on UKFTA Article 6.16, provides that the certification is not required for certain non-commercial or low-value importations.

Section 10.1007 implements UKFTA Article 6.17 and § 206 of the Act concerning the maintenance of relevant records regarding the imported good.

Section 10.1008, which reflects UKFTA Article 6.19.2 and § 204(b) of the Act, authorizes the denial of UKFTA tariff benefits if the importer fails to comply with any of the requirements under Subpart R, Part 10, CBP regulations.

#### **Export Requirements**

Section 10.1009, which implements UKFTA Articles 6.20.1 and 6.17.1, sets forth certain obligations of a person who completes and issues a certification for a good exported from the United States to Korea. Paragraphs (a) and (b) of § 10.1009, reflecting UKFTA Article 6.20.1, require a person who completes such a certification to provide a copy of the certification to CBP upon request and to give prompt notification of any errors in the certification to every person to whom the certification was given. Paragraph (c) of § 10.1009 reflects Article 6.17.1, concerning the recordkeeping requirements that apply to a person who completes and issues a certification for a good exported from the United States to Korea.

#### Post-Importation Duty Refund Claims

Sections 10.1010 through 10.1012 implement UKFTA Article 6.19.5 and section 205 of the Act, which allow an importer who did not claim UKFTA tariff benefits on a qualifying good at the

time of importation to apply for a refund of any excess duties at any time within one year after the date of importation. Such a claim may be made even if liquidation of the entry would otherwise be considered final under other provisions of law.

#### Rules of Origin

Sections 10.1013 through 10.1025 provide the implementing regulations regarding the rules of origin provisions of General Note 33, HTSUS, Article 4.2 and Chapter Six of the UKFTA, and § 202 of the Act.

#### **Definitions**

Section 10.1013 sets forth terms that are defined for purposes of the rules of origin as found in § 202(n) of the Act.

#### General Rules of Origin

Section 10.1014 sets forth the basic rules of origin established in Article 6.1 of the UKFTA, § 202(b) of the Act, and General Note 33(b), HTSUS. The provisions of § 10.1014 apply both to the determination of the status of an imported good as an originating good for purposes of preferential tariff treatment and to the determination of the status of a material as an originating material used in a good which is subject to a determination under General Note 33, HTSUS. Section 10.1014(a)(1), reflecting § 202(b)(1) of the Act, specifies those goods that are originating goods because they are wholly obtained or produced entirely in the territory of one or both of the Parties.

Section 10.1014(a)(2), reflecting § 202(b)(2) of the Act, provides that goods that have been produced entirely in the territory of one or both of the Parties from non-originating materials each of which undergoes an applicable change in tariff classification and satisfies any applicable regional value content or other requirement set forth in General Note 33, HTSUS, are originating goods. Essential to the rules in § 10.1014(a)(2) are the specific rules of General Note 33(o), HTSUS, which are incorporated by reference.

Section 10.1014(a)(3), reflecting § 202(b)(3) of the Act, provides that goods that have been produced entirely in the territory of one or both of the Parties exclusively from originating materials are originating goods.

#### Value Content

Section 10.1015 reflects UKFTA Article 6.2 and § 202(c) of the Act concerning the basic rules that apply for purposes of determining whether an imported good satisfies a minimum regional value content ("RVC") requirement. Section 10.1016, reflecting UKFTA Articles 6.3 and 6.4 as well as § 202(d) of the Act, sets forth the rules for determining the value of a material for purposes of calculating the regional value content of a good as well as for purposes of applying the *de minimis* rules.

#### Accumulation

Section 10.1017, which is derived from UKFTA Article 6.5 and § 202(e) of the Act, sets forth the rule by which originating materials from the territory of a Party that are used in the production of a good in the territory of the other Party will be considered to originate in the territory of that other country. In addition, this section also establishes that a good that is produced by one or more producers in the territory of one or both of the Parties is an originating good if the good satisfies all of the applicable requirements of the rules of origin of the UKFTA.

#### De Minimis

Section 10.1018, as provided for in UKFTA Article 6.6 and § 202(f) of the Act, sets forth *de minimis* rules for goods that may be considered to qualify as originating goods even though they fail to qualify as originating goods under the rules specified in § 10.1014. There are a number of exceptions to the *de minimis* rule set forth in UKFTA Annex 6–B (Exceptions to Article 6.6) as well as a separate rule for textile and apparel goods.

#### Fungible Goods and Materials

Section 10.1019, as provided for in UKFTA Article 6.7 and § 202(g) of the Act, sets forth the rules by which "fungible" goods or materials may be claimed as originating.

Accessories, Spare Parts, or Tools

Section 10.1020, as set forth in UKFTA Article 6.8 and § 202(h) of the Act, specifies the conditions under which a good's standard accessories, spare parts, or tools are: (1) Treated as originating goods; and (2) disregarded in determining whether all non-originating materials undergo an applicable change in tariff classification under General Note 33(o), HTSUS.

Goods Classifiable as Goods Put Up in Sets

Section 10.1021, which is based on UKFTA Articles 4.2.8 and 6.9 as well as § 202(m) of the Act, provides that, notwithstanding the specific rules of General Note 33(o), HTSUS, goods classifiable as goods put up in sets for retail sale as provided for in General Rule of Interpretation 3, HTSUS, will not qualify as originating goods unless:

(1) Each of the goods in the set is an originating good; or (2) the total value of the non-originating goods in the set does not exceed 15 percent of the adjusted value of the set, or 10 percent of the adjusted value of the set in the case of textile or apparel goods.

Packaging Materials and Packing Materials

Sections 10.1022 and 10.1023, which are derived from UKFTA Articles 6.10 and 6.11, as well as §§ 202(i) and (j) of the Act, respectively, provide that retail packaging materials and packing materials for shipment are to be disregarded with respect to their actual origin in determining whether non-originating materials undergo an applicable change in tariff classification under General Note 33(o), HTSUS. These sections also set forth the treatment of packaging and packing materials for purposes of the regional value content requirement of the note.

#### **Indirect Materials**

Section 10.1024, as set forth in UKFTA Article 6.12 and § 202(k) of the Act, provides that indirect materials, as defined in § 10.1002(n) (General definitions), are disregarded for the purpose of determining whether a good is originating.

#### Transit and Transshipment

Section 10.1025, which is derived from UKFTA Article 6.13 and § 202(l) of the Act, sets forth the rule that an originating good loses its originating status and is treated as a non-originating good if, subsequent to production in the territory of one or both of the Parties that qualifies the good as originating, the good: (1) Undergoes production outside the territories of the Parties, other than certain specified minor operations; or (2) does not remain under the control of customs authorities in the territory of a non-Party.

#### Origin Verifications and Determinations

Section 10.1026 implements UKFTA Article 6.18 which concerns the conduct of verifications to determine whether imported goods are originating goods entitled to UKFTA preferential tariff treatment. This section also governs the conduct of verifications directed to producers of materials that are used in the production of a good for which UKFTA preferential duty treatment is claimed.

Section 10.1027, which reflects UKFTA Article 4.3, sets forth the verification and enforcement procedures specifically relating to trade in textile and apparel goods.

Section 10.1028 provides the procedures that apply when preferential tariff treatment is denied on the basis of an origin verification conducted under Subpart R of Part 10.

Section 10.1029 implements UKFTA Article 6.18.6 and § 204(b) of the Act, concerning the denial of preferential tariff treatment in situations in which there is a pattern of conduct by an importer, exporter, or producer of false or unsupported FTA preference claims.

#### Penalties

Section 10.1030 concerns the general application of penalties to UKFTA transactions and is based on UKFTA Article 7.9.

Section 10.1031 reflects UKFTA Article 6.19.3 and § 204(a)(1) of the Act with regard to an exception to the application of penalties in the case of an importer who promptly and voluntarily makes a corrected claim and pays any duties owing.

Section 10.1032 implements UKFTA Article 6.20.2 and § 204(a)(2) of the Act, concerning an exception to the application of penalties in the case of a U.S. exporter or producer who promptly and voluntarily provides notification of the making of an incorrect certification with respect to a good exported to Korea

Section 10.1033 sets forth the circumstances under which the making of a corrected claim or certification by an importer or the providing of notification of an incorrect certification by a U.S. exporter or producer will be considered to have been done "promptly and voluntarily." Corrected claims or certifications that fail to meet these requirements are not excepted from penalties, although the U.S. importer, exporter, or producer making the corrected claim or certification may, depending on the circumstances, qualify for a reduced penalty as a prior disclosure under 19 U.S.C. 1592(c)(4). Section 10.1033 also specifies the content of the statement that must accompany each corrected claim or certification, including any certifications and records demonstrating that a good is an originating good.

Goods Returned After Repair or Alteration

Section 10.1034 implements UKFTA Article 2.6 regarding duty-free treatment for goods re-entered after repair or alteration in Korea.

#### Other Amendments

Part 21

An amendment is made to § 24.23(c), which concerns the merchandise

processing fee, to implement § 203 of the Act, providing that the merchandise processing fee is not applicable to goods that qualify as originating goods under the UKFTA.

#### Part 162

Part 162 contains regulations regarding the inspection and examination of, among other things, imported merchandise. A cross-reference is added to § 162.0, which is the scope section of the part, to refer readers to the additional UKFTA records maintenance and examination provisions contained in Subpart R, Part 10, CBP regulations.

#### Part 163

A conforming amendment is made to § 163.1 to include the maintenance of any documentation, as required by § 206 of the Act, that the importer may have in support of a claim for preference under the UKFTA as an activity for which records must be maintained. Also, the list of records and information required for the entry of merchandise appearing in the Appendix to Part 163 (commonly known as the (a)(1)(A) list) is also amended to add the records that the importer may have in support of a UKFTA claim for preferential tariff treatment.

#### Part 178

Part 178 sets forth the control numbers assigned to information collections of CBP by the Office of Management and Budget, pursuant to the Paperwork Reduction Act of 1995, Public Law 104–13. The list contained in § 178.2 is amended to add the information collections used by CBP to determine eligibility for preferential tariff treatment under the UKFTA and the Act.

# Inapplicability of Notice and Delayed Effective Date Requirements

Under the Administrative Procedure Act ("APA") (5 U.S.C. 553), agencies generally are required to publish a notice of proposed rulemaking in the **Federal Register** that solicits public comment on the proposed regulatory amendments, consider public comments in deciding on the content of the final amendments, and publish the final amendments at least 30 days prior to their effective date. However, section 553(a)(1) of the APA provides that the standard prior notice and comment procedures do not apply to an agency rulemaking to the extent that it involves a foreign affairs function of the United States. CBP has determined that these interim regulations involve a foreign affairs function of the United States

because they implement preferential tariff treatment and related provisions of the FTA. Therefore, the rulemaking requirements under the APA do not apply and this interim rule will be effective upon publication. However, CBP is soliciting comments in this interim rule and will consider all comments received before issuing a final rule.

# **Executive Order 12866 and Regulatory Flexibility Act**

This document is not subject to the provisions of Executive Order 12866 of September 30, 1993 (58 FR 51735, October 4, 1993), because it pertains to a foreign affairs function of the United States and implements an international agreement, as described above, and therefore is specifically exempted by section 3(d)(2) of Executive Order 12866. Because a notice of proposed rulemaking is not required under section 553(b) of the APA for the reasons described above, the provisions of the Regulatory Flexibility Act, as amended (5 U.S.C. 601 et seq.), do not apply to this rulemaking. Accordingly, this interim rule is not subject to the regulatory analysis requirements or other requirements of 5 U.S.C. 603 and

#### **Paperwork Reduction Act**

The collections of information contained in these regulations are under the review of the Office of Management and Budget in accordance with the requirements of the Paperwork Reduction Act (44 U.S.C. 3507) under control number 1651-0117, which covers many of the free trade agreements requirements that CBP administers. The addition of the UKFTA requirements will result in an increase in the number of respondents and burden hours for this information collection. Under the Paperwork Reduction Act, an agency may not conduct or sponsor, and an individual is not required to respond to, a collection of information unless it displays a valid OMB control number.

The collections of information in these regulations are in §§ 10.1003 and 10.1004. This information is required in connection with claims for preferential tariff treatment under the UKFTA and the Act and will be used by CBP to determine eligibility for tariff preference under the UKFTA and the Act. The likely respondents are business organizations including importers, exporters and manufacturers.

Estimated total annual reporting burden: 40,000 hours.

Estimated number of respondents: 200,000.

Estimated annual frequency of responses per respondent: 1.

Estimated average annual burden per response: .2 hours.

Comments concerning the collections of information and the accuracy of the estimated annual burden, and suggestions for reducing that burden, should be directed to the Office of Management and Budget, Attention: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503. A copy should also be sent to the Trade and Commercial Regulations Branch, Regulations and Rulings, Office of International Trade, U.S. Customs and Border Protection, 799 9th Street NW., 5th Floor, Washington, DC 20229-1179.

#### **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 10

Alterations, Bonds, Customs duties and inspection, Exports, Imports, Preference programs, Repairs, Reporting and recordkeeping requirements, Trade agreements.

#### 19 CFR Part 24

Accounting, Customs duties and inspection, Financial and accounting procedures, Reporting and recordkeeping requirements, Trade agreements, User fees.

#### 19 CFR Part 162

Administrative practice and procedure, Customs duties and inspection, Penalties, Trade agreements.

#### 19 CFR Part 163

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

#### 19 CFR Part 178

Administrative practice and procedure, Exports, Imports, Reporting and recordkeeping requirements.

#### Amendments to the Regulations

Accordingly, Chapter I of Title 19, Code of Federal Regulations (19 CFR chapter I), is amended as set forth below.

# PART 10—ARTICLES CONDITIONALLY FREE, SUBJECT TO A REDUCED RATE. ETC.

■ 1. The general authority citation for Part 10 continues to read, and the specific authority for Subpart R is added, to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1321, 1481, 1484, 1498, 1508, 1623, 1624, 3314;

\* \* \* \* \*

Sections 10.1001 through 10.1034 also issued under 19 U.S.C. 1202 (General Note 33, HTSUS), 19 U.S.C. 1520(d), and Pub. L. 112–41, 125 Stat. 428 (19 U.S.C. 3805 note).

■ 2. In § 10.31, paragraph (f), the last sentence is revised to read as follows:

#### §10.31 Entry; bond.

\* \* \* \* \*

- (f) \* \* \* In addition, notwithstanding any other provision of this paragraph, in the case of professional equipment necessary for carrying out the business activity, trade or profession of a business person, equipment for the press or for sound or television broadcasting, cinematographic equipment, articles imported for sports purposes and articles intended for display or demonstration, if brought into the United States by a resident of Canada, Mexico, Singapore, Chile, Morocco, El Salvador, Guatemala, Honduras, Nicaragua, the Dominican Republic, Costa Rica, Bahrain, Oman, Peru, or the Republic of Korea and entered under Chapter 98, Subchapter XIII, HTSUS, no bond or other security will be required if the entered article is a good originating, within the meaning of General Note 12, 25, 26, 27, 29, 30, 31, 32, and 33, HTSUS, in the country of which the importer is a resident.
- 3. Add subpart R to read as follows:

# Subpart R—United States-Korea Free Trade Agreement

Sec.

#### **General Provisions**

10.1001 Scope.

10.1002 General definitions.

#### **Import Requirements**

10.1003 Filing of claim for preferential tariff treatment upon importation.

10.1004 Certification.

10.1005 Importer obligations.

10.1006 Certification not required.

10.1007 Maintenance of records.

10.1008 Effect of noncompliance; failure to provide documentation regarding transshipment.

#### **Export Requirements**

10.1009 Certification for goods exported to Korea.

#### **Post-Importation Duty Refund Claims**

10.1010 Right to make post-importation claim and refund duties.

10.1011 Filing procedures.10.1012 CBP processing procedures.

#### **Rules of Origin**

10.1013 Definitions.

10.1014 Originating goods.

10.1015 Regional value content.

10.1016 Value of materials.

10.1017 Accumulation.

10.1018 De minimis.

10.1019 Fungible goods and materials.

10.1020 Accessories, spare parts, or tools.

10.1021 Goods classifiable as goods put up in sets.

10.1022 Retail packaging materials and containers.

10.1023 Packing materials and containers for shipment.

10.1024 Indirect materials.

10.1025 Transit and transshipment.

#### **Origin Verifications and Determinations**

10.1026 Verification and justification of claim for preferential tariff treatment.

10.1027 Special rule for verifications in Korea of U.S. imports of textile and apparel goods.

10.1028 Issuance of negative origin determinations.

10.1029 Repeated false or unsupported preference claims.

#### **Penalties**

10.1030 General.

10.1031 Corrected claim or certification by importers.

10.1032 Corrected certification by U.S. exporters or producers.

10.1033 Framework for correcting claims or certifications.

#### Goods Returned After Repair or Alteration

10.1034 Goods re-entered after repair or alteration in Korea.

# Subpart R—United States-Korea Free Trade Agreement

#### **General Provisions**

#### §10.1001 Scope.

This subpart implements the duty preference and related customs provisions applicable to imported and exported goods under the United States-Korea Free Trade Agreement (the UKFTA) signed on June 30, 2007, and under the United States-Korea Free Trade Agreement Implementation Act (the Act; Pub. L. 112-41, 125 Stat. 428 (19 U.S.C. 3805 note)). Except as otherwise specified in this subpart, the procedures and other requirements set forth in this subpart are in addition to the customs procedures and requirements of general application contained elsewhere in this chapter. Additional provisions implementing certain aspects of the UKFTA and the Act are contained in parts 24, 162, and 163 of this chapter.

#### § 10.1002 General definitions.

As used in this subpart, the following terms will have the meanings indicated unless either the context in which they are used requires a different meaning or a different definition is prescribed for a particular section of this subpart:

(a) Claim for preferential tariff treatment. "Claim for preferential tariff treatment" means a claim that a good is entitled to the duty rate applicable under the UKFTA to an originating good and to an exemption from the merchandise processing fee;

(b) Claim of origin. "Claim of origin" means a claim that a textile or apparel good is an originating good or satisfies the non-preferential rules of origin of a Porty:

(c) Customs duty. "Customs duty" includes any customs or import duty and a charge of any kind imposed in connection with the importation of a good, including any form of surtax or surcharge in connection with such importation, such as an adjustment tariff imposed pursuant to Article 69 of Korea's Customs Act, but does not include any:

(1) Charge equivalent to an internal tax imposed consistently with Article III:2 of GATT 1994, in respect of like, directly competitive, or substitutable goods of the Party, or in respect of goods from which the imported good has been manufactured or produced in whole or in part;

(2) Antidumping or countervailing duty that is applied pursuant to a

Party's law; or

(3) Fee or other charge in connection with importation commensurate with the cost of services rendered.

- (d) Customs Valuation Agreement. "Customs Valuation Agreement" means the Agreement on Implementation of Article VII of the General Agreement on Tariffs and Trade 1994, contained in Annex 1A to the WTO Agreement;
- (e) Days. "Days" means calendar days;
- (f) Enterprise. "Enterprise" means any entity constituted or organized under applicable law, whether or not for profit, and whether privately or governmentally-owned or controlled, including any corporation, trust, partnership, sole proprietorship, joint venture, association, or similar organization;
- (g) Enterprise of a Party. "Enterprise of a Party" means an enterprise constituted or organized under a Party's law:
- (h) GATT 1994. "GATT 1994" means the General Agreement on Tariffs and Trade 1994, contained in Annex 1A to the WTO Agreement;

(i) Goods of a Party. "Goods of a Party" means domestic products as these are understood in GATT 1994 or such goods as the Parties may agree, and includes originating goods of that Party;

(j) Harmonized System. "Harmonized System" means the Harmonized Commodity Description and Coding System, including its General Rules of Interpretation, Section Notes, and Chapter Notes, as adopted and implemented by the Parties in their respective tariff laws;

(k) *Heading*. "*Heading*" means the first four digits in the tariff classification number under the Harmonized System;

(1) HTSUS. "HTSUS" means the Harmonized Tariff Schedule of the United States as promulgated by the U.S. International Trade Commission;

(m) Identical goods. "Identical goods" means goods that are the same in all respects relevant to the rule of origin that qualifies the goods as originating;

(n) Indirect material. "Indirect material" means a good used in the production, testing, or inspection of a good but not physically incorporated into the good, or a good used in the maintenance of buildings or the operation of equipment associated with the production of a good, including:

(1) Fuel and energy;

(2) Tools, dies, and molds;(3) Spare parts and materials used in the maintenance of equipment or

(4) Lubricants, greases, compounding materials, and other materials used in production or used to operate

equipment or buildings;

buildings:

(5) Gloves, glasses, footwear, clothing, safety equipment, and supplies;

(6) Equipment, devices, and supplies used for testing or inspecting the good;

(7) Catalysts and solvents; and (8) Any other goods that are not incorporated into the other good but the use of which in the production of the other good can reasonably be demonstrated to be a part of that production;

(o) Korea. "Korea" means the

Republic of Korea.

- (p) Originating. "Originating" means qualifying for preferential tariff treatment under the rules of origin set out in Chapter Four (Textiles and Apparel) or Chapter Six (Rules of Origin and Origin Procedures) of the UKFTA and General Note 33, HTSUS;
- (q) Party. "Party" means the United States or the Republic of Korea;

(r) *Person.* "*Person*" means a natural person or an enterprise;

- (s) Person of a Party. "Person of a Party" means a national or an enterprise of a Party;
- (t) Preferential tariff treatment. "Preferential tariff treatment" means the

- duty rate applicable under the UKFTA to an originating good, and an exemption from the merchandise processing fee;
- (u) Subheading. "Subheading" means the first six digits in the tariff classification number under the Harmonized System;
- (v) Textile or apparel good. "Textile or apparel good" means a good listed in the Annex to the Agreement on Textiles and Clothing (commonly referred to as "the ATC");
  - (w) Territory. "Territory" means:
- (1) With respect to Korea, the land, maritime, and air space over which Korea exercises sovereignty, and those maritime areas, including the seabed and subsoil adjacent to and beyond the outer limit of the territorial seas over which it may exercise sovereign rights or jurisdiction in accordance with international law and its domestic law; and
  - (2) With respect to the United States,
- (i) The customs territory of the United States, which includes the 50 states, the District of Columbia, and Puerto Rico;
- (ii) The foreign trade zones located in the United States and Puerto Rico; and
- (iii) Any areas beyond the territorial seas of the United States within which, in accordance with international law and its domestic law, the United States may exercise sovereign rights with respect to the seabed and subsoil and their natural resources;
- (x) WTO. "WTO" means the World Trade Organization; and
- (y) WTO Agreement. "WTO Agreement" means the Marrakesh Agreement Establishing the World Trade Organization of April 15, 1994.

#### **Import Requirements**

### § 10.1003 Filing of claim for preferential tariff treatment upon importation.

- (a) Basis of claim. An importer may make a claim for UKFTA preferential tariff treatment, including an exemption from the merchandise processing fee, based on either:
- (1) A written or electronic certification, as specified in § 10.1004 of this subpart, that is prepared by the importer, exporter, or producer of the good; or

(2) The importer's knowledge that the good is an originating good, including reasonable reliance on information in the importer's possession that the good is an originating good.

(b) Making a claim. The claim is made by including on the entry summary, or equivalent documentation, the letters "KR" as a prefix to the subheading of the HTSUS under which each qualifying good is classified, or by the method

specified for equivalent reporting via an authorized electronic data interchange system.

(c) Corrected claim. If, after making the claim specified in paragraph (b) of this section, the importer has reason to believe that the claim is based on inaccurate information or is otherwise invalid, the importer must, within 30 calendar days after the date of discovery of the error, correct the claim and pay any duties that may be due. The importer must submit a statement either in writing or via an authorized electronic data interchange system to the CBP office where the original claim was filed specifying the correction (see §§ 10.1031 and 10.1033 of this subpart).

#### §10.1004 Certification.

(a) General. An importer who makes a claim pursuant to § 10.1003(b) of this subpart based on a certification by the importer, exporter, or producer that the good is originating must submit, at the request of the port director, a copy of the certification. The certification:

(1) Need not be in a prescribed format but must be in writing or must be transmitted electronically pursuant to any electronic means authorized by CBP

for that purpose;

- (2) Must be in the possession of the importer at the time the claim for preferential tariff treatment is made if the certification forms the basis for the claim:
- (3) Must include the following information:
- (i) The legal name, address, telephone, and email address (if any) of the importer of record of the good (if known), the exporter of the good (if different from the producer), and the producer of the good (if known);

(ii) The legal name, address, telephone, and email address (if any) of the responsible official or authorized agent of the importer, exporter, or producer signing the certification (if different from the information required by paragraph (a)(3)(i) of this section);

(iii) A description of the good for which preferential tariff treatment is claimed, which must be sufficiently detailed to relate it to the invoice and

the HS nomenclature;

(iv) The HTSUS tariff classification, to six or more digits, as necessary for the specific change in tariff classification rule for the good set forth in General Note 33(o), HTSUS; and

(v) The applicable rule of origin set forth in General Note 33, HTSUS, under which the good qualifies as an originating good;

(vi) Date of certification;

(vii) In case of a blanket certification issued with respect to the multiple

shipments of identical goods within any period specified in the written or electronic certification, not exceeding 12 months from the date of certification, the period that the certification covers; and

(4) Must include a statement, in substantially the following form:

#### "I certify that:

The information on this document is true and accurate and I assume the responsibility for proving such representations. I understand that I am liable for any false statements or material omissions made on or in connection with this document:

I agree to maintain and present upon request, documentation necessary to support these representations;

The goods comply with all requirements for preferential tariff treatment specified for those goods in the United States-Korea Free Trade Agreement; and This document consists of pages,

including all attachments."

- (b) Responsible official or agent. The certification provided for in paragraph (a) of this section must be signed and dated by a responsible official of the importer, exporter, or producer, or by the importer's, exporter's, or producer's authorized agent having knowledge of the relevant facts.
- (c) Language. The certification provided for in paragraph (a) of this section must be completed in either the English or Korean language. In the latter case, the port director may require the importer to submit an English translation of the certification.
- (d) Certification by the exporter or producer. (1) A certification may be prepared by the exporter or producer of the good on the basis of:
- (i) The exporter's or producer's knowledge that the good is originating; or
- (ii) In the case of an exporter, reasonable reliance on the producer's written or electronic certification that the good is originating.
- (2) The port director may not require an exporter or producer to provide a written or electronic certification to another person.
- (e) Applicability of certification. The certification provided for in paragraph (a) of this section may be applicable to:
- (1) A single shipment of a good into the United States; or
- (2) Multiple shipments of identical goods into the United States that occur within a specified blanket period, not exceeding 12 months, set out in the certification.
- (f) Validity of certification. A certification that is properly completed, signed, and dated in accordance with the requirements of this section will be accepted as valid for four years

following the date on which it was issued.

#### §10.1005 Importer obligations.

- (a) *General*. An importer who makes a claim for preferential tariff treatment under § 10.1003(b) of this subpart:
- (1) Will be deemed to have certified that the good is eligible for preferential tariff treatment under the UKFTA;
- (2) Is responsible for the truthfulness of the claim and of all the information and data contained in the certification provided for in § 10.1004 of this subpart; and
- (3) Is responsible for submitting any supporting documents requested by CBP, and for the truthfulness of the information contained in those documents. When a certification prepared by an exporter or producer forms the basis of a claim for preferential tariff treatment, and CBP requests the submission of supporting documents, the importer will provide to CBP, or arrange for the direct submission by the exporter or producer of, all information relied on by the exporter or producer in preparing the certification.
- (b) Information provided by exporter or producer. The fact that the importer has made a claim or submitted a certification based on information provided by an exporter or producer will not relieve the importer of the responsibility referred to in paragraph (a) of this section.
- (c) Exemption from penalties. An importer will not be subject to civil or administrative penalties under 19 U.S.C. 1592 for making an incorrect claim for preferential tariff treatment or submitting an incorrect certification, provided that the importer promptly and voluntarily corrects the claim or certification and pays any duty owing (see §§ 10.1031 and 10.1033 of this subpart).

#### § 10.1006 Certification not required.

- (a) *General*. Except as otherwise provided in paragraph (b) of this section, an importer will not be required to submit a copy of a certification under § 10.1004 of this subpart for:
- (1) A non-commercial importation of a good; or
- (2) A commercial importation for which the value of the originating goods does not exceed U.S. \$2,500.
- (b) Exception. If the port director determines that an importation described in paragraph (a) of this section is part of a series of importations carried out or planned for the purpose of evading compliance with the certification requirements of § 10.1004 of this subpart, the port director will

notify the importer that for that importation the importer must submit to CBP a copy of the certification. The importer must submit such a copy within 30 days from the date of the notice. Failure to timely submit a copy of the certification will result in denial of the claim for preferential tariff treatment.

#### § 10.1007 Maintenance of records.

- (a) General. An importer claiming preferential tariff treatment for a good (based on either the importer's certification or its knowledge, or on the certification issued by the exporter or producer) imported into the United States under § 10.1003(b) of this subpart must maintain for a minimum of five years from the date of importation of the good, all records and documents that the importer has demonstrating that the good qualifies for preferential tariff treatment under the UKFTA. These records are in addition to any other records that the importer is required to prepare, maintain, or make available to CBP under part 163 of this chapter.
- (b) Method of maintenance. The records and documents referred to in paragraph (a) of this section must be maintained by importers as provided in § 163.5 of this chapter.

# §10.1008 Effect of noncompliance; failure to provide documentation regarding transshipment.

- (a) General. If the importer fails to comply with any requirement under this subpart, including submission of a complete certification prepared in accordance with § 10. 1004 of this subpart, when requested, the port director may deny preferential tariff treatment to the imported good.
- (b) Failure to provide documentation regarding transshipment. Where the requirements for preferential tariff treatment set forth elsewhere in this subpart are met, the port director nevertheless may deny preferential tariff treatment to an originating good if the good is shipped through or transshipped in a country other than a Party to the UKFTA, and the importer of the good does not provide, at the request of the port director, evidence demonstrating to the satisfaction of the port director that the conditions set forth in § 10.1025(a) of this subpart were met.

#### **Export Requirements**

### § 10.1009 Certification for goods exported to Korea.

(a) Submission of certification to CBP. Any person who completes and issues a certification for a good exported from the United States to Korea must provide

a copy of the certification (written or electronic) to CBP upon request.

- (b) Notification of errors in certification. Any person who completes and issues a certification for a good exported from the United States to Korea and who has reason to believe that the certification contains or is based on incorrect information must promptly notify every person to whom the certification was provided of any change that could affect the accuracy or validity of the certification. Notification of an incorrect certification must also be given either in writing or via an authorized electronic data interchange system to CBP specifying the correction (see §§ 10.1032 and 10.1033 of this subpart).
- (c) Maintenance of records—(1) General. Any person who completes and issues a certification for a good exported from the United States to Korea must maintain, for a period of at least five years after the date the certification was issued, all records and supporting documents relating to the origin of a good for which the certification was issued, including the certification or copies thereof and records and documents associated with:
- (i) The purchase, cost, and value of, and payment for, the good;
- (ii) The purchase, cost, and value of, and payment for, all materials, including indirect materials, used in the production of the good; and
- (iii) The production of the good in the form in which the good was exported.
- (2) Method of maintenance. The records referred to in paragraph (c) of this section must be maintained as provided in § 163.5 of this chapter.
- (3) Availability of records. For purposes of determining compliance with the provisions of this part, the records required to be maintained under this section must be stored and made available for examination and inspection by the port director or other appropriate CBP officer in the same manner as provided in Part 163 of this chapter.

#### **Post-Importation Duty Refund Claims**

### § 10.1010 Right to make post-importation claim and refund duties.

Notwithstanding any other available remedy, where a good would have qualified as an originating good when it was imported into the United States but no claim for preferential tariff treatment was made, the importer of that good may file a claim for a refund of any excess duties at any time within one year after the date of importation of the good in accordance with the procedures set forth in § 10.1011 of this subpart.

Subject to the provisions of § 10.1008 of this subpart, CBP may refund any excess duties by liquidation or reliquidation of the entry covering the good in accordance with § 10.1012(c) of this subpart.

#### §10.1011 Filing procedures.

- (a) *Place of filing.* A post-importation claim for a refund must be filed with the director of the port at which the entry covering the good was filed.
- (b) *Contents of claim.* A postimportation claim for a refund must be filed by presentation of the following:
- (1) A written or electronic declaration or statement stating that the good was an originating good at the time of importation and setting forth the number and date of the entry or entries covering the good;
- (2) A copy of a written or electronic certification prepared in accordance with § 10.1004 of this subpart if a certification forms the basis for the claim, or other information demonstrating that the good qualifies for preferential tariff treatment;
- (3) A written statement indicating whether the importer of the good provided a copy of the entry summary or equivalent documentation to any other person. If such documentation was so provided, the statement must identify each recipient by name, CBP identification number, and address and must specify the date on which the documentation was provided; and
- (4) A written statement indicating whether or not any person has filed a protest relating to the good under any provision of law; and if any such protest has been filed, the statement must identify the protest by number and date.

#### §10.1012 CBP processing procedures.

- (a) Status determination. After receipt of a post-importation claim made pursuant to § 10.1011 of this subpart, the port director will determine whether the entry covering the good has been liquidated and, if liquidation has taken place, whether the liquidation has become final.
- (b) Pending protest or judicial review. If the port director determines that any protest relating to the good has not been finally decided, the port director will suspend action on the claim filed under § 10.1011 of this subpart until the decision on the protest becomes final. If a summons involving the tariff classification or dutiability of the good is filed in the Court of International Trade, the port director will suspend action on the claim filed under § 10.1011 of this subpart until judicial review has been completed.

- (c) Allowance of claim. (1) Unliquidated entry. If the port director determines that a claim for a refund filed under § 10.1011 of this subpart should be allowed and the entry covering the good has not been liquidated, the port director will take into account the claim for refund in connection with the liquidation of the entry.
- (2) Liquidated entry. If the port director determines that a claim for a refund filed under § 10.1011 of this subpart should be allowed and the entry covering the good has been liquidated, whether or not the liquidation has become final, the entry must be reliquidated in order to effect a refund of duties under this section. If the entry is otherwise to be reliquidated based on administrative review of a protest or as a result of judicial review, the port director will reliquidate the entry taking into account the claim for refund under § 10.1011 of this subpart.
- (d) Denial of claim. (1) General. The port director may deny a claim for a refund filed under § 10.1011 of this subpart if the claim was not filed timely, if the importer has not complied with the requirements of § 10.1008 and 10.1011 of this subpart, or if, following an origin verification under § 10.1026 of this subpart, the port director determines either that the imported good was not an originating good at the time of importation or that a basis exists upon which preferential tariff treatment may be denied under § 10.1026 of this subpart.
- (2) Unliquidated entry. If the port director determines that a claim for a refund filed under this subpart should be denied and the entry covering the good has not been liquidated, the port director will deny the claim in connection with the liquidation of the entry, and notice of the denial and the reason for the denial will be provided to the importer in writing or via an authorized electronic data interchange system.
- (3) Liquidated entry. If the port director determines that a claim for a refund filed under this subpart should be denied and the entry covering the good has been liquidated, whether or not the liquidation has become final, the claim may be denied without reliquidation of the entry. If the entry is otherwise to be reliquidated based on administrative review of a protest or as a result of judicial review, such reliquidation may include denial of the claim filed under this subpart. In either case, the port director will provide notice of the denial and the reason for the denial to the importer in writing or

via an authorized electronic data interchange system.

#### **Rules of Origin**

#### § 10.1013 Definitions.

For purposes of §§ 10.1013 through 10.1025:

- (a) Adjusted value. "Adjusted value" means the value determined in accordance with Articles 1 through 8, Article 15, and the corresponding interpretative notes of the Customs Valuation Agreement, adjusted, if necessary, to exclude:
- (1) Any costs, charges, or expenses incurred for transportation, insurance and related services incident to the international shipment of the good from the country of exportation to the place of importation; and

(2) The value of packing materials and containers for shipment as defined in paragraph (m) of this section;

- (b) Class of motor vehicles. "Class of motor vehicles" means any one of the following categories of motor vehicles:
- Motor vehicles classified under subheading 8701.20, HTSUS, motor vehicles for the transport of 16 or more persons classified under subheading 8702.10 or 8702.90, HTSUS, and motor vehicles classified under subheading 8704.10, 8704.22, 8704.23, 8704.32, or 8704.90, or heading 87.05 or 87.06,
- (2) Motor vehicles classified under subheading 8701.10 or subheading 8701.30 through 8701.90, HTSUS;
- (3) Motor vehicles for the transport of 15 or fewer persons classified under subheading 8702.10 or 8702.90, HTSUS and motor vehicles classified under subheading 8704.21 or 8704.31, HTSUS;
- (4) Motor vehicles classified under subheading 8703.21 through 8703.90,
- (c) Exporter. "Exporter" means a person who exports goods from the territory of a Party;
- (d) Fungible goods or materials. "Fungible goods or materials" means goods or materials that are interchangeable with another good or material for commercial purposes and the properties of which are essentially identical to such other good or material;
- (e) Generally Accepted Accounting Principles. "Generally Accepted Accounting Principles" means the recognized consensus or substantial authoritative support in the territory of a Party, with respect to the recording of revenues, expenses, costs, assets, and liabilities, the disclosure of information, and the preparation of financial statements. These principles may encompass broad guidelines of general

application as well as detailed standards, practices, and procedures; (f) Good. "Good" means any

- merchandise, product, article, or material:
- (g) Goods wholly obtained or produced entirely in the territory of one or more of the Parties. "Goods wholly obtained or produced entirely in the territory of one or both of the Parties"
- (1) Plants and plant products grown, and harvested or gathered, in the territory of one or both of the Parties:
- (2) Live animals born and raised in the territory of one or both of the Parties:
- (3) Goods obtained in the territory of one or both of the Parties from live
- (4) Goods obtained from hunting, trapping, fishing, or aquaculture conducted in the territory of one or both of the Parties;
- (5) Minerals and other natural resources not included in paragraphs (g)(1) through (g)(4) extracted or taken from the territory of one or both of the Parties;
- (6) Fish, shellfish, and other marine life taken from the sea, seabed, or subsoil outside the territory of the Parties by:
- (i) A vessel that is registered or recorded with Korea and flying the flag of Korea; or
- (ii) A vessel that is documented under the laws of the United States;
- (7) Goods produced on board factory ships from the goods referred to in paragraph (g)(6), if such factory ship:

(i) Is registered or recorded with Korea and flies the flag of Korea; or

(ii) Is a vessel that is documented under the laws of the United States;

(8) Goods taken by a Party or a person of a Party from the seabed or subsoil outside the territory of one or both of the Parties, provided that Party has rights to exploit such seabed or subsoil;

(9) Goods taken from outer space, provided they are obtained by a Party or a person of a Party and not processed in the territory of a non-Party;

(10) Waste and scrap derived from: (i) Manufacturing or processing operations in the territory of one or both

of the Parties: or

(ii) Used goods collected in the territory of one or both of the Parties, provided such goods are fit only for the recovery of raw materials;

(11) Recovered goods derived in the territory of one or both of the Parties from used goods, and used in the territory of one or both of the Parties in the production of remanufactured goods; and

(12) Goods produced in the territory of one or both of the Parties exclusively

from goods referred to in paragraphs (g)(1) through (g)(10) of this section, or from their derivatives, at any stage of production;

(h) Material. "Material" means a good that is used in the production of another good, including a part or an ingredient; (i) Model line. "Model line" means a

group of motor vehicles having the same

platform or model name; (j) Net cost. "Net cost" means total cost minus sales promotion, marketing, and after-sales service costs, royalties, shipping and packing costs, and nonallowable interest costs that are included in the total cost:

(k) Non-allowable interest costs. "Non-allowable interest costs" means interest costs incurred by a producer that exceed 700 basis points above the applicable official interest rate on debt obligations of comparable maturities issued by the central level of government of the Party in which the producer is located;

(1) Non-originating good or non-originating material. "Non-originating good" or "non-originating material" means a good or material, as the case may be, that does not qualify as originating under General Note 33,

HTSUS, or this subpart;

(m) Packing materials and containers for shipment. "Packing materials and containers for shipment" means the goods used to protect a good during its transportation to the United States and does not include the packaging materials and containers in which a good is packaged for retail sale;

(n) Producer. "Producer" means a person who engages in the production of a good in the territory of a Party;

(o) Production. "Production" means growing, mining, harvesting, fishing, breeding, raising, trapping, hunting, manufacturing, processing, assembling, or disassembling a good;

(p) Reasonably allocate. "Reasonably allocate" means to apportion in a manner that would be appropriate under Generally Accepted Accounting

Principles;

(q) Reasonable suspicion of unlawful activity. "Reasonable suspicion of unlawful activity" means a suspicion based on relevant factual information obtained from public or private sources comprising one or more of the following:

(1) Historical evidence of noncompliance with laws or regulations governing importations by an importer

or exporter;

(2) Historical evidence of noncompliance with laws or regulations governing importations by a manufacturer, producer, or other person involved in the movement of goods from the territory of one Party to the territory of the other Party;

- (3) Historical evidence that some or all of the persons involved in the movement from the territory of one Party to the territory of the other Party of goods within a specific product sector have not complied with a Party's laws and regulations governing importations; or
- (4) Other information that the requesting Party and the Party from whom the information is requested agree is sufficient in the context of a particular request;
- (r) Recovered goods. "Recovered goods" means materials in the form of individual parts that are the result of:

(1) The disassembly of used goods into individual parts; and

- (2) The cleaning, inspecting, testing, or other processing that is necessary to improve such individual parts to sound working condition;
- (s) Remanufactured goods. "Remanufactured goods" means goods classified in Chapter 84, 85, 87, or 90, or under heading 9402, HTSUS, that:
- (1) Are entirely or partially comprised of recovered goods as defined in § 10.1013(r) and,
- (2) Have a similar life expectancy and enjoy a factory warranty similar to such new goods;
- (t) Royalties. "Royalties" means payments of any kind, including payments under technical assistance agreements or similar agreements, made as consideration for the use of, or right to use, any copyright, literary, artistic, or scientific work, patent, trademark, design, model, plan, secret formula or process, excluding those payments under technical assistance agreements or similar agreements that can be related to specific services such as:

(1) Personnel training, without regard

to where performed; and

- (2) If performed in the territory of one or both of the Parties, engineering, tooling, die-setting, software design and similar computer services;
- (u) Sales promotion, marketing, and after-sales service costs. "Sales promotion, marketing, and after-sales service costs" means the following costs related to sales promotion, marketing, and after-sales service:
- (1) Sales and marketing promotion; media advertising; advertising and market research; promotional and demonstration materials; exhibits; sales conferences, trade shows and conventions; banners; marketing displays; free samples; sales, marketing, and after-sales service literature (product brochures, catalogs, technical literature, price lists, service manuals, sales aid information); establishment

and protection of logos and trademarks; sponsorships; wholesale and retail restocking charges; entertainment;

- (2) Sales and marketing incentives; consumer, retailer or wholesaler rebates; merchandise incentives:
- (3) Salaries and wages, sales commissions, bonuses, benefits (for example, medical, insurance, pension), traveling and living expenses, membership and professional fees, for sales promotion, marketing, and aftersales service personnel:
- (4) Recruiting and training of sales promotion, marketing, and after-sales service personnel, and after-sales training of customers' employees, where such costs are identified separately for sales promotion, marketing, and after-sales service of goods on the financial statements or cost accounts of the producer;

(5) Product liability insurance;

- (6) Office supplies for sales promotion, marketing, and after-sales service of goods, where such costs are identified separately for sales promotion, marketing, and after-sales service of goods on the financial statements or cost accounts of the producer;
- (7) Telephone, mail and other communications, where such costs are identified separately for sales promotion, marketing, and after-sales service of goods on the financial statements or cost accounts of the producer;

(8) Rent and depreciation of sales promotion, marketing, and after-sales service offices and distribution centers;

- (9) Property insurance premiums, taxes, cost of utilities, and repair and maintenance of sales promotion, marketing, and after-sales service offices and distribution centers, where such costs are identified separately for sales promotion, marketing, and after-sales service of goods on the financial statements or cost accounts of the producer; and
- (10) Payments by the producer to other persons for warranty repairs;
- (v) Self-produced material. "Self-produced material" means an originating material that is produced by a producer of a good and used in the production of that good;

(w) Shipping and packing costs. "Shipping and packing costs" means the costs incurred in packing a good for shipment and shipping the good from the point of direct shipment to the buyer, excluding the costs of preparing and packaging the good for retail sale;

(x) Total cost. "Total cost" means all product costs, period costs, and other costs for a good incurred in the territory of one or both of the Parties. Product

- costs are costs that are associated with the production of a good and include the value of materials, direct labor costs, and direct overhead. Period costs are costs, other than product costs, that are expensed in the period in which they are incurred, such as selling expenses and general and administrative expenses. Other costs are all costs recorded on the books of the producer that are not product costs or period costs, such as interest. Total cost does not include profits that are earned by the producer, regardless of whether they are retained by the producer or paid out to other persons as dividends, or taxes paid on those profits, including capital gains taxes;
- (y) *Used.* "*Used*" means utilized or consumed in the production of goods; and
- (z) Value. "Value" means the value of a good or material for purposes of calculating customs duties or for purposes of applying this subpart.

#### § 10.1014 Originating goods.

Except as otherwise provided in this subpart and General Note 33(n), HTSUS, a good imported into the customs territory of the United States will be considered an originating good under the UKFTA only if:

- (a) The good is wholly obtained or produced entirely in the territory of one or both of the Parties;
- (b) The good is produced entirely in the territory of one or both of the Parties and:
- (1) Each non-originating material used in the production of the good undergoes an applicable change in tariff classification specified in General Note 33(o), HTSUS, and the good satisfies all other applicable requirements of General Note 33, HTSUS; or
- (2) The good otherwise satisfies any applicable regional value content or other requirements specified in General Note 33(o), HTSUS, and satisfies all other applicable requirements of General Note 33, HTSUS; or
- (c) The good is produced entirely in the territory of one or both of the Parties exclusively from originating materials.

#### § 10.1015 Regional value content.

(a) General. Except for goods to which paragraph (d) of this section applies, where General Note 33, HTSUS, sets forth a rule that specifies a regional value content test for a good, the regional value content of such good must be calculated by the importer, exporter, or producer of the good on the basis of the build-down method described in paragraph (b) of this section or the build-up method

described in paragraph (c) of this

(b) Build-down method. Under the build-down method, the regional value content must be calculated on the basis of the formula RVC = ((AV - VNM)/AV)  $\times$  100, where RVC is the regional value content, expressed as a percentage; AV is the adjusted value of the good; and VNM is the value of nonoriginating materials, other than indirect materials, that are acquired and used by the producer in the production of the good, but does not include the value of a material that is self-produced.

(c) Build-up method. Under the buildup method, the regional value content must be calculated on the basis of the formula RVC =  $(VOM/AV) \times 100$ , where RVC is the regional value content, expressed as a percentage; AV is the adjusted value of the good; and VOM is the value of originating materials, other than indirect materials, that are acquired or self-produced and used by the producer in the production of the

good.

(d) Special rule for certain automotive goods. (1) General. Where General Note 33, HTSUS, sets forth a rule that specifies a regional value content test for an automotive good provided for in any of subheadings 8407.31 through 8407.34 (engines), subheading 8408.20 (diesel engine for vehicles), heading 8409 (parts of engines), headings 8701 through 8705 (motor vehicles), and headings 8706 (chassis), 8707 (bodies), and 8708 (motor vehicle parts), HTSUS, the regional value content of such good may be calculated by the importer, exporter, or producer of the good on the basis of the net cost method described

in paragraph (d)(2) of this section.

(2) Net cost method. Under the net cost method, the regional value content is calculated on the basis of the formula  $RVC = ((NC - VNM)/NC) \times 100$ , where RVC is the regional value content, expressed as a percentage; NC is the net cost of the good; and VNM is the value of non-originating materials, other than indirect materials, that are acquired and used by the producer in the production of the good, but does not include the value of a material that is self-produced. Consistent with the provisions set out in Generally Accepted Accounting Principles, applicable in the territory of the Party where the good is produced, the net cost of the good must be determined by:

(i) Calculating the total cost incurred with respect to all goods produced by the producer of the automotive good, subtracting any sales promotion, marketing, and after-sales service costs, royalties, shipping and packing costs, and non-allowable interest costs that are included in the total cost of all such goods, and then reasonably allocating the resulting net cost of those goods to

the automotive good;

(ii) Calculating the total cost incurred with respect to all goods produced by the producer of the automotive good, reasonably allocating the total cost to the automotive good, and then subtracting any sales promotion, marketing, and after-sales service costs, royalties, shipping and packing costs, and non-allowable interest costs that are included in the portion of the total cost allocated to the automotive good; or

(iii) Reasonably allocating each cost that forms part of the total costs incurred with respect to the automotive good so that the aggregate of these costs does not include any sales promotion, marketing, and after-sales service costs, royalties, shipping and packing costs, or

non-allowable interest costs.

(3) Motor vehicles. (i) General. For purposes of calculating the regional value content under the net cost method for an automotive good that is a motor vehicle provided for in any of headings 8701 through 8705, an importer, exporter, or producer may average the amounts calculated under the formula set forth in paragraph (d)(2) of this section over the producer's fiscal year using any one of the categories described in paragraph (d)(3)(ii) of this section either on the basis of all motor vehicles in the category or those motor vehicles in the category that are exported to the territory of one or both Parties.

(ii) Categories. The categories referred to in paragraph (d)(3)(i) of this section

are as follows:

(A) The same model line of motor vehicles, in the same class of vehicles, produced in the same plant in the territory of a Party, as the motor vehicle for which the regional value content is being calculated;

(B) The same class of motor vehicles, and produced in the same plant in the territory of a Party, as the motor vehicle for which the regional value content is

being calculated; and

(C) The same model line of motor vehicles produced in the territory of a Party as the motor vehicle for which the regional value content is being calculated.

(4) Other automotive goods. (i) *General.* For purposes of calculating the regional value content under the net cost method for automotive goods provided for in any of subheadings 8407.31 through 8407.34, subheading 8408.20, heading 8409, 8706, 8707, or 8708, HTSUS, that are produced in the same plant, an importer, exporter, or producer may:

- (A) Average the amounts calculated under the formula set forth in paragraph (d)(2) of this section over any of the following: the fiscal year, or any quarter or month, of the motor vehicle producer to whom the automotive good is sold, or the fiscal year, or any quarter or month, of the producer of the automotive good, provided the goods were produced during the fiscal year, quarter, or month that is the basis for the calculation;
- (B) Determine the average referred to in paragraph (d)(4)(i)(A) of this section separately for such goods sold to one or more motor vehicle producers; or
- (C) Make a separate determination under paragraph (d)(4)(i)(A) or (B) of this section for automotive goods that are exported to the territory of Korea or the United States.
- (ii) Duration of use. A person selecting an averaging period of one month or quarter under paragraph (d)(4)(i)(A) of this section must continue to use that method for that category of automotive goods throughout the fiscal

#### § 10.1016 Value of materials.

- (a) Calculating the value of materials. Except as provided in § 10.1024 of this subpart, for purposes of calculating the regional value content of a good under General Note 33 HTSUS, and for purposes of applying the de minimis (see § 10.1018 of this subpart) provisions of General Note 33, HTSUS, the value of a material is:
- (1) In the case of a material imported by the producer of the good, the adjusted value of the material;
- (2) In the case of a material acquired by the producer in the territory where the good is produced, the value, determined in accordance with Articles 1 through 8, Article 15, and the corresponding interpretative notes of the Customs Valuation Agreement, of the material, i.e., in the same manner as for imported goods, with reasonable modifications to the provisions of the Customs Valuation Agreement as may be required due to the absence of an importation by the producer (including, but not limited to, treating a domestic purchase by the producer as if it were a sale for export to the country of importation); or
- (3) In the case of a self-produced material, the sum of:
- (i) All the costs incurred in the production of the material, including general expenses; and
- (ii) An amount for profit equivalent to the profit added in the normal course of trade.
- (b) Examples. The following examples illustrate application of the principles

set forth in paragraph (a)(2) of this section:

Example 1. A producer in Korea purchases material x from an unrelated seller in Korea for \$100. Under the provisions of Article 1 of the Customs Valuation Agreement, transaction value is the price actually paid or payable for the goods when sold for export to the country of importation adjusted in accordance with the provisions of Article 8. In order to apply Article 1 to this domestic purchase by the producer, such purchase is treated as if it were a sale for export to the country of importation. Therefore, for purposes of determining the adjusted value of material x, Article 1 transaction value is the price actually paid or payable for the goods when sold to the producer in Korea (\$100), adjusted in accordance with the provisions of Article 8. In this example, it is irrelevant whether material x was initially imported into Korea by the seller (or by anyone else). So long as the producer acquired material x in Korea, it is intended that the value of material x will be determined on the basis of the price actually paid or payable by the producer adjusted in accordance with the provisions of Article 8.

Example 2. Same facts as in Example 1, except that the sale between the seller and the producer is subject to certain restrictions that preclude the application of Article 1. Under Article 2 of the Customs Valuation Agreement, the value is the transaction value of identical goods sold for export to the same country of importation and exported at or about the same time as the goods being valued. In order to permit the application of Article 2 to the domestic acquisition by the producer, it should be modified so that the value is the transaction value of identical goods sold within Korea at or about the same time the goods were sold to the producer in Korea. Thus, if the seller of material x also sold an identical material to another buyer in Korea without restrictions, that other sale would be used to determine the adjusted. value of material x.

- (c) Permissible additions to, and deductions from, the value of materials. (1) Additions to originating materials. For originating materials, the following expenses, if not included under paragraph (a) of this section, may be added to the value of the originating material:
- (i) The costs of freight ("cost of freight" includes the costs of all types of freight, including in-land freight incurred within a Party's territory, regardless of the mode of transportation), insurance, packing, and all other costs incurred in transporting the material within a Party's territory or between the Parties to the location of the producer;
- (ii) Duties, taxes, and customs brokerage fees on the material paid in the territory of one or both of the Parties, other than duties and taxes that are waived, refunded, refundable, or otherwise recoverable, including credit against duty or tax paid or payable; and

- (iii) The cost of waste and spoilage resulting from the use of the material in the production of the good, less the value of renewable scrap or byproducts.
- (2) Deductions from non-originating materials. For non-originating materials, if included under paragraph (a) of this section, the following expenses may be deducted from the value of the non-originating material:
- (i) The costs of freight ("cost of freight" includes the costs of all types of freight, including in-land freight incurred within a Party's territory, regardless of the mode of transportation), insurance, packing, and all other costs incurred in transporting the material within a Party's territory or between the territories of the Parties to the location of the producer;
- (ii) Duties, taxes, and customs brokerage fees on the material paid in the territory of one or both of the Parties, other than duties and taxes that are waived, refunded, refundable, or otherwise recoverable, including credit against duty or tax paid or payable;
- (iii) The cost of waste and spoilage resulting from the use of the material in the production of the good, less the value of renewable scrap or by-products; and
- (iv) The cost of originating materials used in the production of the non-originating material in the territory of a Party.
- (d) Accounting method. Any cost or value referenced in General Note 33, HTSUS, and this subpart, must be recorded and maintained in accordance with the Generally Accepted Accounting Principles applicable in the territory of the Party in which the good is produced.

#### §10.1017 Accumulation.

- (a) Originating goods or materials from the territory of one Party, incorporated into a good in the territory of the other Party will be considered to originate in the territory of that other Party.
- (b) A good that is produced in the territory of one or both of the Parties by one or more producers is an originating good if the good satisfies the requirements of § 10.1014 of this subpart and all other applicable requirements of General Note 33, HTSUS.

#### § 10.1018 De minimis.

(a) General. Except as provided in paragraphs (b) and (c) of this section, a good that does not undergo a change in tariff classification pursuant to General Note 33, HTSUS, is an originating good if:

- (1) The value of all non-originating materials used in the production of the good that do not undergo the applicable change in tariff classification does not exceed 10 percent of the adjusted value of the good;
- (2) The value of the non-originating materials described in paragraph (a)(1) of this section is included in the value of non-originating materials for any applicable regional value content requirement for the good under General Note 33, HTSUS; and
- (3) The good meets all other applicable requirements of General Note 33, HTSUS.
- (b) *Exceptions*. Paragraph (a) of this section does not apply to:
- (1) A non-originating material provided for in Chapter 3, HTSUS, that is used in the production of a good classified in that Chapter;
- (2) A non-originating material provided for in Chapter 4, HTSUS, or a non-originating dairy preparation containing over 10 percent by weight of milk solids classified under subheadings 1901.90 or 2106.90, HTSUS, that is used in the production of a good provided for in Chapter 4, HTSUS:
- (3) A non-originating material provided for in Chapter 4, HTSUS, or a non-originating dairy preparation containing over 10 percent by weight of milk solids provided for in subheading 1901.90, HTSUS, which is used in the production of the following goods:
- (i) Infant preparations containing over 10 percent by weight of milk solids provided for in subheading 1901.10, HTSUS:
- (ii) Mixes and doughs, containing over 25 percent by weight of butterfat, not put up for retail sale, provided for in subheading 1901.20, HTSUS;
- (iii) Dairy preparations containing over 10 percent by weight of milk solids provided for in subheading 1901.90 or 2106.90, HTSUS;
- (iv) Goods provided for in heading 2105, HTSUS;
- (v) Beverages containing milk provided for in subheading 2202.90, HTSUS; or
- (vi) Animal feeds containing over 10 percent by weight of milk solids provided for in subheading 2309.90, HTSUS;
- (4) A non-originating material provided for in Chapter 7, HTSUS that is used in the production of a good classified under the following subheadings: 0703.10, 0703.20, 0709.59, 0709.60, 0710.21 through 0710.80, 0711.90, 0712.20, 0712.39 through 0713.10 or 0714.20, HTSUS;
- (5) A non-originating material provided for in heading 1006, HTSUS,

or a non-originating rice product classified in Chapter 11, HTSUS that is used in the production of a good provided for under the headings 1006, 1102, 1103, 1104, HTSUS, or subheadings 1901.20 or 1901.90, HTSUS:

- (6) A non-originating material provided for in heading 0805, HTSUS or subheadings 2009.11 through 2009.39, HTSUS, that is used in the production of a good provided for under subheadings 2009.11 through 2009.39, HTSUS, or in fruit or vegetable juice of any single fruit or vegetable, fortified with minerals or vitamins, concentrated or unconcentrated, provided for under subheadings 2106.90 or 2202.90, HTSUS;
- (7) Non-originating peaches, pears, or apricots provided for in Chapters 8 or 20, HTSUS, that are used in the production of a good classified under heading 2008, HTSUS;

(8) A non-originating material provided for in Chapter 15, HTSUS, that is used in the production of a good classified under headings 1501 through 1508, 1512, 1514, or 1515, HTSUS;

(9) A non-originating material provided for in heading 1701, HTSUS, that is used in the production of a good provided for in any of headings 1701 through 1703, HTSUS;

(10) A non-originating material provided for in Chapter 17, HTSUS, that is used in the production of a good provided for in subheading 1806.10, HTSUS: or

(11) Except as provided in paragraphs (b)(1) through (10) of this section and General Note 33, HTSUS, a non-originating material used in the production of a good provided for in any of Chapters 1 through 24, HTSUS, unless the non-originating material is provided for in a different subheading than the good for which origin is being determined under this subpart.

(c) Textile and apparel goods. (1) General. Except as provided in paragraph (c)(2) of this section, a textile or apparel good that is not an originating good because certain fibers or yarns used in the production of the component of the good that determines the tariff classification of the good do not undergo an applicable change in tariff classification set out in General Note 33, HTSUS, will nevertheless be considered to be an originating good if the total weight of all such fibers or yarns in that component is not more than 7 percent of the total weight of that component.

(2) Exception for goods containing elastomeric yarns. A textile or apparel good containing elastomeric yarns in the component of the good that determines

the tariff classification of the good will be considered an originating good only if such yarns are wholly formed and finished in the territory of a Party.

(3) For purposes of this section, "wholly formed or finished" means when used in reference to fabrics, all production processes and finishing operations necessary to produce a finished fabric ready for use without further processing. These processes and operations include formation processes, such as weaving, knitting, needling, tufting, felting, entangling, or other such processes, and finishing operations, including bleaching, dyeing, and printing. When used in reference to yarns, "wholly formed or finished" means all production processes and finishing operations, beginning with the extrusion of filaments, strips, film, or sheet, and including drawing to fully orient a filament or slitting a film or sheer into strip, or the spinning of all fibers into yarn, or both, and ending with a finished yarn or plied yarn.

#### § 10.1019 Fungible goods and materials.

- (a) General. A person claiming that a fungible good or material is an originating good may base the claim either on the physical segregation of each fungible good or material or by using an inventory management method with respect to the fungible good or material. For purposes of this section, the term "inventory management method" means:
  - (1) Averaging;
  - (2) "Last-in, first-out;"
  - (3) "First-in, first-out;" or
- (4) Any other method that is recognized in the Generally Accepted Accounting Principles of the Party in which the production is performed or otherwise accepted by that country.
- (b) Duration of use. A person selecting an inventory management method under paragraph (a) of this section for a particular fungible good or material must continue to use that method for that fungible good or material throughout the fiscal year of that person.

### § 10.1020 Accessories, spare parts, or tools.

(a) General. Accessories, spare parts, or tools that are delivered with a good and that form part of the good's standard accessories, spare parts, or tools will be treated as originating goods if the good is an originating good, and will be disregarded in determining whether all the non-originating materials used in the production of the good undergo an applicable change in tariff classification specified in General Note 33, HTSUS, provided that:

- (1) The accessories, spare parts, or tools are classified with, and not invoiced separately from, the good; and
- (2) The quantities and value of the accessories, spare parts, or tools are customary for the good.
- (b) Regional value content. If the good is subject to a regional value content requirement, the value of the accessories, spare parts, or tools is taken into account as originating or non-originating materials, as the case may be, in calculating the regional value content of the good under § 10.1015 of this subpart.

### § 10.1021 Goods classifiable as goods put up in sets.

Notwithstanding the specific rules set forth in General Note 33, HTSUS, goods classifiable as goods put up in sets for retail sale as provided for in General Rule of Interpretation 3, HTSUS, will not be considered to be originating goods unless:

- (a) Each of the goods in the set is an originating good; or
- (b) The total value of the nonoriginating goods in the set does not exceed:
- (1) In the case of textile or apparel goods, 10 percent of the adjusted value of the set; or
- (2) In the case of a good other than a textile or apparel good, 15 percent of the adjusted value of the set.

### § 10.1022 Retail packaging materials and containers.

- (a) Effect on tariff shift rule. Packaging materials and containers in which a good is packaged for retail sale, if classified with the good for which preferential tariff treatment under the UKFTA is claimed, will be disregarded in determining whether all non-originating materials used in the production of the good undergo the applicable change in tariff classification set out in General Note 33, HTSUS.
- (b) Effect on regional value content calculation. If the good is subject to a regional value content requirement, the value of such packaging materials and containers will be taken into account as originating or non-originating materials, as the case may be, in calculating the regional value content of the good.

Example 1. Korean Producer A of good C imports 100 non-originating blister packages to be used as retail packaging for good C. As provided in  $\S$  10.1016(a)(1) of this subpart, the value of the blister packages is their adjusted value, which in this case is \$10. Good C has a regional value content requirement. The United States importer of good C decides to use the build-down method, RVC =  $((AV - VNM)/AV) \times 100$  (see  $\S$  10.1015(b) of this subpart), in determining whether good C satisfies the regional value

content requirement. In applying this method, the non-originating blister packages are taken into account as non-originating. As such, their \$10 adjusted value is included in the VNM, value of non-originating materials,

Example 2. Same facts as in Example 1, except that the blister packages are originating. In this case, the adjusted value of the originating blister packages would not be included as part of the VNM of good C under the build-down method. However, if the U.S. importer had used the build-up method, RVC  $= (VOM/AV) \times 100 (see § 10.1015(c) of this$ subpart), the adjusted value of the blister packaging would be included as part of the VOM, value of originating materials.

#### § 10.1023 Packing materials and containers for shipment.

(a) Effect on tariff shift rule. Packing materials and containers for shipment, as defined in § 10.1013(m) of this subpart, are to be disregarded in determining whether the nonoriginating materials used in the production of the good undergo an applicable change in tariff classification set out in General Note 33, HTSUS. Accordingly, such materials and containers are not required to undergo the applicable change in tariff classification even if they are non-

(b) Effect on regional value content calculation. Packing materials and containers for shipment, as defined in § 10.1013(m) of this subpart, are to be disregarded in determining the regional value content of a good imported into the United States. Accordingly, in applying the build-down, build-up, or net cost method for determining the regional value content of a good imported into the United States, the value of such packing materials and containers for shipment (whether originating or non-originating) is disregarded and not included in AV, adjusted value, VNM, value of nonoriginating materials, VOM, value of originating materials, or NC, net cost of a good.

Example. Korean producer A produces good C. Producer A ships good C to the United States in a shipping container that it purchased from Company B in Korea. The shipping container is originating. The value of the shipping container determined under § 10.1016(a)(2) of this subpart is \$3. Good C is subject to a regional value content requirement. The transaction value of good C is \$100, which includes the \$3 shipping container. The U.S. importer decides to use the build-up method,  $\hat{RVC} = (VOM/AV) \times$ 100 (see § 10.1015(c) of this subpart), in determining whether good C satisfies the regional value content requirement. In determining the AV, adjusted value, of good C imported into the U.S., paragraph (b) of this section and the definition of AV require a \$3 deduction for the value of the shipping

container. Therefore, the AV is \$97 (\$100-\$3). In addition, the value of the shipping container is disregarded and not included in the VOM, value of originating materials.

#### § 10.1024 Indirect materials.

An indirect material, as defined in § 10.1002(n) of this subpart, will be disregarded for the purpose of determining whether a good is originating.

Example. Korean Producer A produces good C using non-originating material B. Producer A imports non-originating rubber gloves for use by workers in the production of good C. Good C is subject to a tariff shift requirement. As provided in § 10.1014(b)(1) of this subpart and General Note 33, each of the non-originating materials in good C must undergo the specified change in tariff classification in order for good C to be considered originating. Although nonoriginating material B must undergo the applicable tariff shift in order for good C to be considered originating, the rubber gloves do not because they are indirect materials and are disregarded for purposes of determining whether the good is originating.

#### § 10.1025 Transit and transshipment.

(a) General. A good that has undergone production necessary to qualify as an originating good under § 10.1014 of this subpart will not be considered an originating good if, subsequent to that production, the good:

(1) Undergoes further production or any other operation outside the territories of the Parties, other than unloading, reloading, or any other operation necessary to preserve the good in good condition or to transport the good to the territory of a Party; or

(2) Does not remain under the control of customs authorities in the territory of a non-Party.

(b) Documentary evidence. An importer making a claim that a good is originating may be required to demonstrate, to CBP's satisfaction, that the conditions and requirements set forth in paragraph (a) of this section were met. An importer may demonstrate compliance with this section by submitting documentary evidence. Such evidence may include, but is not limited to, bills of lading, airway bills, packing lists, commercial invoices, receiving and inventory records, and customs entry and exit documents.

#### Origin Verifications and **Determinations**

#### § 10.1026 Verification and justification of claim for preferential tariff treatment.

(a) Verification. A claim for preferential tariff treatment made under § 10.1003(b) or § 10.1011 of this subpart, including any statements or other information submitted to CBP in

support of the claim, will be subject to such verification as the port director deems necessary. In the event that the port director is provided with insufficient information to verify or substantiate the claim, the port director finds a pattern of conduct, indicating that an importer, exporter, or producer has provided false or unsupported declarations or certifications, or the exporter or producer fails to consent to a verification visit, the port director may deny the claim for preferential treatment. A verification of a claim for preferential tariff treatment under UKFTA for goods imported into the United States may be conducted by means of one or more of the following:

(1) Written requests for information from the importer, exporter, or

producer;

(2) Written questionnaires to the importer, exporter, or producer;

- (3) Visits to the premises of the exporter or producer in the territory of Korea, to review the records of the type referred to in § 10.1009(c)(1) of this subpart or to observe the facilities used in the production of the good, in accordance with the framework that the Parties develop for conducting verifications; and
- (4) Such other procedures to which the Parties may agree.
- (b) Applicable accounting principles. When conducting a verification of origin to which Generally Accepted Accounting Principles may be relevant, CBP will apply and accept the Generally Accepted Accounting Principles applicable in the country of production.

#### § 10.1027 Special rule for verifications in Korea of U.S. imports of textile and apparel goods.

- (a) Procedures to determine whether a claim of origin is accurate. (1) General. For the purpose of determining that a claim of origin for a textile or apparel good is accurate, CBP may request that the government of the Republic of Korea conduct a verification, regardless of whether a claim is made for preferential tariff treatment.
- (2) Actions during a verification. While a verification under this paragraph is being conducted, CBP, if directed by the President, may take appropriate action, which may include suspending the liquidation of the entry of the textile or apparel good for which a claim for preferential tariff treatment or a claim of origin has been made.

(3) Actions following a verification. If on completion of a verification under this paragraph, CBP makes a negative determination, or if CBP is unable to determine that a claim of origin for a textile or apparel good is accurate

within 12 months after its request for a verification, CBP, if directed by the President, may take appropriate action, which may include:

(i) Denying the application of preferential tariff treatment to the textile or apparel good for which a claim for preferential tariff treatment has been made that is the subject of a verification if CBP determines that the enterprise has provided insufficient or incorrect information to support the claim; and

(ii) Denying entry to the textile or apparel good for which a claim for preferential tariff treatment or a claim of origin has been made that is the subject of a verification, if CBP determines that the enterprise has provided insufficient or incorrect information to support the claim.

(b) Procedures to determine compliance with applicable customs laws and regulations of the United States. (1) General. For purposes of enabling CBP to determine that an exporter or producer is complying with applicable customs laws, regulations, and procedures regarding trade in textile and apparel goods, CBP may request that the government of the Republic of Korea conduct a verification, if CBP has a reasonable suspicion of unlawful activity relating to trade in textile or apparel goods by a person of Korea.

(2) Actions during a verification. While a verification under this paragraph is being conducted, CBP, if directed by the President, may take appropriate action, which may include suspending the liquidation of the entry of any textile or apparel good exported or produced by the enterprise subject to

the verification.

(3) Actions following a verification. If on completion of a verification under this paragraph, CBP makes a negative determination, or if CBP is unable to determine that the person is complying with applicable customs measures affecting trade in textile or apparel goods within 12 months after its request for a verification, CBP, if directed by the President, may take appropriate action, which may include:

(i) Denying the application of preferential tariff treatment to any textile or apparel good exported or produced by the enterprise subject to the verification if CBP determines that the enterprise has provided insufficient or incorrect information with respect to its obligations under the applicable customs laws, regulations, and procedures regarding trade in textile and apparel goods; and

(ii) Denying entry to any textile or apparel good exported or produced by the enterprise subject to the verification, if CBP determines that the enterprise has provided insufficient or incorrect information with respect to its obligations under the applicable customs laws, regulations, and procedures regarding trade in textile and apparel goods.

(c) Denial of permission to conduct a verification. If an enterprise does not consent to a verification under this section, CBP may deny preferential tariff treatment or deny entry to similar goods exported or produced by the enterprise that would have been the subject of the

verification

(d) Action by U.S. officials in conducting a verification abroad. U.S. officials may undertake or assist in a verification under this section by conducting visits in the territory of Korea, along with the competent authorities of Korea, to the premises of an exporter, producer, or any other enterprise involved in the movement of textile or apparel goods from Korea to the United States.

(e) Continuation of appropriate action. Before taking any action under paragraph (a) or (b), CBP will notify the government of the Republic of Korea. CBP may continue to take appropriate action under paragraph (a) or (b) of this section until it receives information sufficient to enable it to make the determination described in paragraphs (a) and (b) of this section. CBP may make public the identity of a person that CBP has determined to be engaged in circumvention as provided under this section or that has failed to demonstrate that it produces, or is capable of producing, textile or apparel goods.

### § 10.1028 Issuance of negative origin determinations.

If, as a result of an origin verification initiated under this subpart, CBP determines that a claim for preferential tariff treatment under this subpart should be denied, it will issue a determination in writing or via an authorized electronic data interchange system to the importer that sets forth the following:

(a) A description of the good that was the subject of the verification together with the identifying numbers and dates of the import documents pertaining to the good;

(b) A statement setting forth the findings of fact made in connection with the verification and upon which the determination is based; and

(c) With specific reference to the rules applicable to originating goods as set forth in General Note 33, HTSUS, and in §§ 10.1013 through 10.1025 of this subpart, the legal basis for the determination.

### § 10.1029 Repeated false or unsupported preference claims.

Where verification or other information reveals a pattern of conduct by an importer, exporter, or producer of false or unsupported representations that goods qualify under the UKFTA rules of origin set forth in General Note 33, HTSUS, CBP may suspend preferential tariff treatment under the UKFTA to entries of identical goods covered by subsequent statements, declarations, or certifications by that importer, exporter, or producer until CBP determines that representations of that person are in conformity with General Note 33, HTSUS.

#### **Penalties**

#### §10.1030 General.

Except as otherwise provided in this subpart, all criminal, civil, or administrative penalties which may be imposed on U.S. importers, exporters, and producers for violations of the customs and related U.S. laws and regulations will also apply to U.S. importers, exporters, and producers for violations of the U.S. laws and regulations relating to the UKFTA.

# $\S\,10.1031$ Corrected claim or certification by importers.

An importer who makes a corrected claim under § 10.1003(c) of this subpart will not be subject to civil or administrative penalties under 19 U.S.C. 1592 for having made an incorrect claim or having submitted an incorrect certification, provided that the corrected claim is promptly and voluntarily made.

### § 10.1032 Corrected certification by U.S. exporters or producers.

Civil or administrative penalties provided for under 19 U.S.C. 1592 will not be imposed on an exporter or producer in the United States who promptly and voluntarily provides written notification pursuant to § 10.1009(b) with respect to the making of an incorrect certification.

### § 10.1033 Framework for correcting claims or certifications.

(a) "Promptly and voluntarily" defined. Except as provided for in paragraph (b) of this section, for purposes of this subpart, the making of a corrected claim or certification by an importer or the providing of written notification of an incorrect certification by an exporter or producer in the United States will be deemed to have been done promptly and voluntarily if:

(1)(i) Done before the commencement of a formal investigation, within the meaning of § 162.74(g) of this chapter;

or

- (ii) Done before any of the events specified in § 162.74(i) of this chapter have occurred; or
- (iii) Done within 30 days after the importer, exporter, or producer initially becomes aware that the claim or certification is incorrect; and
- (2) Accompanied by a statement setting forth the information specified in paragraph (c) of this section; and
- (3) In the case of a corrected claim or certification by an importer, accompanied or followed by a tender of any actual loss of duties and merchandise processing fees, if applicable, in accordance with paragraph (d) of this section.
- (b) Exception in cases involving fraud or subsequent incorrect claims. (1) Fraud. Notwithstanding paragraph (a) of this section, a person who acted fraudulently in making an incorrect claim or certification may not make a voluntary correction of that claim or certification. For purposes of this paragraph, the term "fraud" will have the meaning set forth in paragraph (C)(3) of appendix B to part 171 of this chapter.
- (2) Subsequent incorrect claims. An importer who makes one or more incorrect claims after becoming aware that a claim involving the same merchandise and circumstances is invalid may not make a voluntary correction of the subsequent claims pursuant to paragraph (a) of this section.
- (c) Statement. For purposes of this subpart, each corrected claim or certification must be accompanied by a statement, submitted in writing or via an authorized electronic data interchange system, which:
- (1) Identifies the class or kind of good to which the incorrect claim or certification relates:
- (2) In the case of a corrected claim or certification by an importer, identifies each affected import transaction, including each port of importation and the approximate date of each importation;
- (3) Specifies the nature of the incorrect statements or omissions regarding the claim or certification; and
- (4) Sets forth, to the best of the person's knowledge, the true and accurate information or data which should have been covered by or provided in the claim or certification, and states that the person will provide any additional information or data which is unknown at the time of making the corrected claim or certification within 30 days or within any extension of that 30-day period as CBP may permit in order for the person to obtain the information or data.

(d) Tender of actual loss of duties. A U.S. importer who makes a corrected claim must tender any actual loss of duties at the time of making the corrected claim, or within 30 days thereafter, or within any extension of that 30-day period as CBP may allow in order for the importer to obtain the information or data necessary to calculate the duties owed.

### Goods Returned After Repair or Alteration

### § 10.1034 Goods re-entered after repair or alteration in Korea.

- (a) General. This section sets forth the rules which apply for purposes of obtaining duty-free treatment on goods returned after repair or alteration in Korea as provided for in subheadings 9802.00.40 and 9802.00.50, HTSUS. Goods returned after having been repaired or altered in Korea, regardless of whether the repair or alteration could be performed in the United States or has increased the value of the good and regardless of their origin, are eligible for duty-free treatment, provided that the requirements of this section are met. For purposes of this section, "repairs or alterations" means restoration, addition, renovation, re-dyeing, cleaning, resterilizing, or other treatment that does not destroy the essential characteristics of, or create a new or commercially different good from, the good exported from the United States.
- (b) Goods not eligible for duty-free treatment after repair or alteration. The duty-free treatment referred to in paragraph (a) of this section will not apply to goods which, in their condition as exported from the United States to Korea, are incomplete for their intended use and for which the processing operation performed in Korea constitutes an operation that is performed as a matter of course in the preparation or manufacture of finished goods.
- (c) Documentation. The provisions of § 10.8(a), (b), and (c) of this part, relating to the documentary requirements for goods entered under subheading 9802.00.40 or 9802.00.50, HTSUS, will apply in connection with the entry of goods which are returned from Korea after having been exported for repairs or alterations and which are claimed to be duty free.

# PART 24—CUSTOMS FINANCIAL AND ACCOUNTING PROCEDURE

■ 4. The general authority citation for part 24 and specific authority for § 24.23 continue to read as follows:

**Authority:** 5 U.S.C. 301; 19 U.S.C. 58a–58c, 66, 1202 (General Note 3(i), Harmonized

Tariff Schedule of the United States), 1505, 1520, 1624; 26 U.S.C. 4461, 4462; 31 U.S.C. 9701; Public Law 107–296, 116 Stat. 2135 (6 U.S.C. 1 et seq.).

Section 24.23 also issued under 19 U.S.C. 3332;

■ 5. Section 24.23 is amended by adding paragraph (c)(12) to read as follows:

#### § 24.23 Fees for processing merchandise.

\* \* \* \* \* \* (C) \* \* \*

(12) The ad valorem fee, surcharge, and specific fees provided under paragraphs (b)(1) and (b)(2)(i) of this section will not apply to goods that qualify as originating goods under § 203 of the United States-Korea Free Trade Agreement (see also General Note 33, HTSUS) that are entered, or withdrawn from warehouse for consumption, on or after March 15, 2012.

# PART 162—INSPECTION, SEARCH, AND SEIZURE

■ 6. The authority citation for part 162 continues to read in part as follows:

**Authority:** 5 U.S.C. 301; 19 U.S.C. 66, 1592, 1593a, 1624.

■ 7. Section 162.0 is amended by revising the last sentence to read as follows:

#### § 162.0 Scope.

\* \* \* Additional provisions concerning records maintenance and examination applicable to U.S. importers, exporters and producers under the U.S.-Chile Free Trade Agreement, the U.S.-Singapore Free Trade Agreement, the Dominican Republic-Central America-U.S. Free Trade Agreement, the U.S.-Morocco Free Trade Agreement, the U.S.- Peru Trade Promotion Agreement, and the U.S.-Korea Free Trade Agreement are contained in Part 10, Subparts H, I, J, M, Q, and R of this chapter, respectively.

#### PART 163—RECORDKEEPING

■ 8. The authority citation for part 163 continues to read as follows:

**Authority:** 5 U.S.C. 301; 19 U.S.C. 66, 1484, 1508, 1509, 1510, 1624.

■ 9. Section 163.1 is amended by redesignating paragraph (a)(2)(xiv) as (a)(2)(xv) and adding a new paragraph (a)(2)(xiv) to read as follows:

#### § 163.1 Definitions.

\* \* \* \* (a) \* \* \* (2) \* \* \*

(xiv) The maintenance of any documentation that the importer may

have in support of a claim for preferential tariff treatment under the United States-Korea Free Trade Agreement (UKFTA), including a UKFTA importer's certification.

\* \* \* \* \*

■ 10. The appendix to part 163 is amended by adding a new listing under section IV in numerical order to read as follows:

#### Appendix to Part 163—Interim (a)(1)(A) List

\* \* \* \* \* IV. \* \* \*

§ 10.1005 UKFTA records that the importer may have in support of a UKFTA claim for preferential tariff treatment, including an importer's certification.

\* \* \* \* \*

# PART 178—APPROVAL OF INFORMATION COLLECTION REQUIREMENTS

■ 11. The authority citation for part 178 continues to read as follows:

**Authority:** 5 U.S.C. 301; 19 U.S.C. 1624; 44 U.S.C. 3501 *et seq.* 

■ 12. Section 178.2 is amended by adding new listings for "§§ 10.1003 and 10.1004" to the table in numerical order to read as follows:

§ 178.2 Listing of OMB control numbers.

19 CFR Section		Description			OMB Control No.	
* §§ 10.1003 and 10.100	* )4	Claim for preferential	* tariff treatment unde	* r the US-Korea Free	*	* 1651–0117
*	*	Trade Agreement.  *	*	*	*	*

\_ .....

David V. Aguilar,

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

Approved: March 14, 2012.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury. [FR Doc. 2012–6554 Filed 3–15–12; 8:45 am]

BILLING CODE 9111-14-P

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Food and Drug Administration

21 CFR Part 520

[Docket No. FDA-2011-N-0003]

# Oral Dosage Form New Animal Drugs; Pergolide

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

**ACTION:** Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an original new animal drug application (NADA) filed by Boehringer Ingelheim Vetmedica, Inc. The NADA provides for the veterinary prescription use of pergolide mesylate tablets in horses for the control of clinical signs associated with Pituitary Pars Intermedia Dysfunction (Equine Cushing's Disease).

**DATES:** This rule is effective March 19, 2012.

#### FOR FURTHER INFORMATION CONTACT:

Amy L. Omer, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8336, email: amy.omer@fda.hhs.gov.

#### SUPPLEMENTARY INFORMATION:

Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506–2002, filed NADA 141–331 for the veterinary prescription use in horses of PRASCEND (pergolide mesylate) Tablets for the control of clinical signs associated with Pituitary Pars Intermedia Dysfunction (Equine Cushing's Disease). The NADA is approved as of September 7, 2011, and 21 CFR part 520 is amended to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning on the date of approval.

The Agency has determined under 21 CFR 25.33 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.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because

it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

#### List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

# PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Add § 520.1705 to read as follows:

#### § 520.1705 Pergolide.

- (a) Specifications. Each tablet contains 1 milligram (mg) pergolide mesylate.
- (b) *Sponsor*. See No. 000010 in § 510.600(c) of this chapter.
- (c) Conditions of use in horses—(1) Amount. Administer orally at a starting dose of 2 micrograms/kilograms ( $\mu$ /kg) once daily. Dosage may be adjusted to effect, not to exceed 4  $\mu$ g/kg daily.
- (2) *Indications for use.* For the control of clinical signs associated with Pituitary Pars Intermedia Dysfunction (Equine Cushing's Disease).
- (3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.