manner of a domestic futures account, the appropriate ''type of account'' is ambiguous. One can distinguish between a ''foreign future'' which is characterized by the place in which it is executed, and a ''foreign futures account'' which may be characterized by the calculation of the applicable segregation requirements. A ''futures account'' is also characterized by the calculation of the applicable segregation requirement. If the Commission grants Section 4d relief to permit funds supporting foreign futures to be deposited in a ''futures account'' calculated pursuant to Section 4d and Commission Regulation 1.20, then it would appear apposite to treat claims on those funds as belonging to the futures account class of accounts.

Second, where a customer account contains both foreign futures contracts and domestic futures contracts, with those positions margined on a portfolio basis, such that the same property margins, guarantees, or secures both types of contracts in one account, the appropriate allocation of claims on the collateral between ''futures contracts'' and ''foreign futures contracts'' is, again, ambiguous.

As the Commission noted in the proposing release for Commission Regulation 190.01,

> ''The allocation provisions are intended to prefer customers for which segregation is undertaken over * * * customers holding accounts of a class for which segregation is not required * * * The reason for identifying classes of customer accounts is to permit the implementation of the principle of pro rata distribution so that the differing segregation requirements with respect to different classes of accounts benefit customer claimants based on the class of account for which they were imposed.'' 46 FR 57535, 57536 (November 24, 1981).

Thus, the Commission intended the customers who contribute to a segregated pool to benefit from that pool. Later in that release the Commission explained that the distinction in treatment between account classes sprang from the contrast in segregation requirements:

> all property segregated on behalf of a particular class would be allocated to the class on behalf of which it is segregated. This approach is consistent with the fact that differing segregation requirements exist for different classes of accounts. Obviously, much of the benefit of segregation would be lost if property segregated on behalf of a particular account class could be allocated to pay the claims of customers of a different account for which less stringent segregation provisions were in effect. 46 FR at 57554.

Again, the Commission contemplated that customers would benefit from the stringency of the segregation regime to which their funds were subject. To the extent that, subject to a Commission order, customer margin supporting non-domestic trades is subject to the full stringency of segregation under Commission Regulation 1.20 rather than the less stringent Commission Regulation 30.7 secured amount calculation, it is consistent with the Commission's intentions in adopting the Part 190 scheme that the property in the accounts of these customers be treated as futures accounts. Conversely, it would be inconsistent with the Commission's intentions to deny customers who had contributed property that was, in accordance with Commission Orders, deposited into accounts segregated pursuant to Commission Regulation 1.20, any participation in those accounts based on those contributions.

Thus, the Commission intended that the customers who contribute to a segregated pool benefit from that pool. If customers do not contribute to a pool, they should not benefit from that pool. The Commission's intent to tie distribution of funds to the contribution of those funds, and the ambiguity of how to allocate claims on collateral that supports both futures and foreign futures positions placed in domestic segregation, both support the interpretation that, in the event of an insolvency, collateral supporting foreign futures placed in domestic segregation pursuant to Commission Order should be treated as in a futures account, not a foreign futures account, for purposes of Part 190. Thus, in a situation where by Commission order or direction, customers are required or allowed to contribute to a Commission Regulation 1.20 segregated account, those customers also should benefit from the distribution of that account proportionately to their contributions in the event of an insolvency. Such claims should be treated as encompassed within the futures account class as opposed to the foreign futures account class or an other account class.

* * * * *

Issued in Washington, DC, on October 21, 2004, by the Commodity Futures Trading Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 04–26386 Filed 11–29–04; 8:45 am]

BILLING CODE 6351–01–M

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

DEPARTMENT OF THE TREASURY

19 CFR Parts 10 and 163

[CBP Dec. 04–40]

RIN 1505–AB42

Preferential Treatment of Brassieres Under the Caribbean Basin Economic Recovery Act

AGENCY: Customs and Border Protection, Department of Homeland Security.

ACTION: Final rule.

SUMMARY: This document adopts as a final rule amendments to the Customs and Border Protection (CBP) Regulations to implement the standards for preferential treatment for brassieres imported from Caribbean Basin countries. This rule was initially published as an interim regulation in the **Federal Register** on October 4, 2001, as T.D. 01–74, and later amended by T.D. 03–29 published in the **Federal Register** on September 30, 2003.

T.D. 01–74 set forth interim amendments to the CBP Regulations to implement those provisions within the United States-Caribbean Basin Trade Partnership Act (CBTPA) which established the standards for preferential treatment for brassieres imported from CBTPA beneficiary countries. T.D. 03–29 amended the brassieres provision set forth in T.D. 01–74 to reflect the amendments to section 213(b) of the Caribbean Basin Economic Recovery Act (the CBERA) that were made by section 3107 of the Trade Act of 2002. T.D. 03–29 also included a number of other changes to the CBERA implementing regulations for brassieres to clarify a number of issues that arose after their original publication.

EFFECTIVE DATES: Final rule effective on December 30, 2004.

FOR FURTHER INFORMATION CONTACT:

Operational issues: Robert Abels, Office of Field Operations ((202) 344–1959).

Legal issues: Cynthia Reese, Office of Regulations and Rulings ((202) 572–8790).

SUPPLEMENTARY INFORMATION:

Background

Textile and Apparel Articles Under the Caribbean Basin Economic Recovery Act

The Caribbean Basin Economic Recovery Act (the CBERA, also referred

to as the Caribbean Basin Initiative, or CBI, statute codified at 19 U.S.C. 2701–2707) instituted a duty preference program that applies to exports of goods from those Caribbean Basin countries that have been designated by the President as program beneficiaries. On May 18, 2000, the President signed into law the Trade and Development Act of 2000, Pub. L. 106–200, 114 Stat. 251, which included as Title II the United States-Caribbean Basin Trade Partnership Act, or CBTPA. The CBTPA provisions included section 211 which amended section 213(b) of the CBERA (19 U.S.C. 2703(b)) in order to, among other things, provide in new paragraph (2) for the preferential treatment of certain textile and apparel articles, specified in subparagraph (A), that had previously been excluded from the CBI duty-free program. The preferential treatment for those textile and apparel articles under paragraph (2)(A) of section 213(b) involves not only duty-free treatment but also entry in the United States free of quantitative restrictions, limitations, or consultation levels for all qualifying goods. Paragraph (2)(A) of the statute includes, in clause (iv), a specific provision covering brassieres from designated CBTPA beneficiary countries.

On October 2, 2000, the President signed Proclamation 7351 to implement the provisions of the CBTPA. This Proclamation, which was published in the **Federal Register** (65 FR 59329) on October 4, 2000, modified the Harmonized Tariff Schedule of the United States (HTSUS) by, among other things, the addition of a new Subchapter XX to Chapter 98 to address the majority of the textile and apparel provisions of the CBTPA. Within that Subchapter XX, the brassieres provision of paragraph (2)(A)(iv) of the CBTPA statute is dealt with in U.S. Note 2(d) and in subheading 9820.11.15.

On October 5, 2000, the U.S. Customs Service (now U.S. Customs and Border Protection (CBP)) published in the **Federal Register** (65 FR 59650) T.D. 00–68 to amend the Customs and Border Protection (CBP) Regulations on an interim basis in order to set forth basic legal requirements and procedures that apply for purposes of obtaining preferential treatment of textile and apparel articles pursuant to the provisions added to section 213(b) by the CBTPA. Those interim regulations, consisting of §§ 10.221 through 10.227 of the CBP Regulations (19 CFR 10.221 through 10.227), include, in paragraph (a) of § 10.223, a list of the various groups of articles that are eligible for preferential treatment under the statute. Paragraph (a)(6) of § 10.223 specifically addressed the basic CBTPA brassieres provision of subclause (I) of paragraph (2)(A)(iv) of the statute and subheading 9820.11.15 of the HTSUS. The regulatory texts set forth in T.D. 00–68 did not address subclauses (II) and (III) of paragraph (2)(A)(iv) of the statute and U.S. Note 2(d) of Subchapter XX, Chapter 98, HTSUS, because under the terms of the statute those provisions applied only to articles entered on or after October 1, 2001.

On October 4, 2001, CBP (as legacy Customs) published in the **Federal Register** (66 FR 50534) T.D. 01–74 to amend the CBP Regulations on an interim basis in order to implement the terms of subclauses (II) and (III) of paragraph (2)(A)(iv) of the statute and U.S. Note 2(d) of Subchapter XX, Chapter 98, HTSUS. Those regulatory amendments involved primarily the addition of a new § 10.228 which set forth specific rules for the application of the minimum 75 and 85 percent U.S. fabric component content requirements under subclauses (II) and (III) that took effect for purposes of preferential treatment of brassieres described in subclause (I) starting on October 1, 2001.

T.D. 01–74 also amended the introductory text in § 10.222 to account for the newly created § 10.228. In addition, T.D. 01–74 amended paragraph (a)(7) of § 10.223 to exclude brassieres from the apparel articles that are constructed of fabrics or yarns that are considered to be in ''short supply'' for purposes of Annex 401 of the NAFTA. We note that while T.D. 01–74 amended paragraph (a)(6) of § 10.223 by adding a proviso at the end to indicate that the requirements of new § 10.228 also must be satisfied, paragraph (a)(6) was later amended in its entirety by T.D. 03–12, published in the **Federal Register** (68 FR 13827) on March 21, 2003.

T.D. 01–74 also amended the Appendix to Part 163 of the CBP Regulation (19 CFR 163), which sets forth a list of entry records (that is, records that are required by statute or regulation for the entry of merchandise—the ''(a)(1)(A)'' list), by adding a listing that covers the CBTPA declaration of compliance for brassieres.

Trade Act of 2002 Amendments

On August 6, 2002, the President signed into law the Trade Act of 2002 (the ''Act''), Pub. L. 107–210, 116 Stat. 933. Section 3107(a) of the Act made a number of changes to the textile and apparel provisions of paragraph (2)(A) of section 213(b) of the CBERA. The amendments made by section 3107(a) of the Act included a revision of the brassieres provisions of paragraph (2)(A)(iv) of the statute which involved the following textual changes: (1) Subclause (I) was amended by the addition of exception language regarding articles covered by certain other clauses under paragraph (2)(A); and (2) subclauses (II) and (III) were amended by replacing each reference to ''fabric components'' with ''fabrics,'' by adding exclusion language regarding findings and trimmings after each reference to fabric(s), and by adding various references to articles that are ''entered'' and that are ''eligible'' under clause (iv). The principal effects of the language changes within subclauses (II) and (III) were: (1) Adoption of a cost or value percentage standard based on a comparison between U.S. fabric and all fabric (rather than based on a comparison between U.S. fabric components and all fabric) contained in the articles; and (2) removal of the requirement that the articles must be both produced and entered in the same year. The amended paragraph (2)(A)(iv) text now reads as follows:

(iv) Certain Other Apparel Articles.—(I) General Rule.—Subject to subclause (II), any apparel article classifiable under subheading 6212.10 of the HTS, except for articles entered under clause (i), (ii), (iii), (v), or (vi), if the article is both cut and sewn or otherwise assembled in the United States, or one or more CBTPA beneficiary countries, or both.

(II) Limitation.—During the 1-year period beginning on October 1, 2001, and during each of the 6 succeeding 1-year periods, apparel articles described in subclause (I) of a producer or an entity controlling production shall be eligible for preferential treatment under subparagraph (B) only if the aggregate cost of fabrics (exclusive of all findings and trimmings) formed in the United States that are used in the production of all such articles of that producer or entity that are entered and eligible under this clause during the preceding 1-year period is at least 75 percent of the aggregate declared customs value of the fabric (exclusive of all findings and trimmings) contained in all such articles of that producer or entity that are entered and eligible under this clause during the preceding 1-year period.

(III) Development of Procedure to Ensure Compliance.—The United States Customs Service shall develop and implement methods and procedures to ensure ongoing compliance with the requirement set forth in subclause (II). If the Customs Service finds that a producer or an entity controlling production has not satisfied such requirement in a 1-year period, then apparel articles described in subclause (I) of that producer or entity shall be ineligible for preferential treatment under subparagraph (B) during any succeeding 1-year period until the aggregate cost of fabrics (exclusive of all findings and trimmings) formed in the United States that are used in the production of such articles of that producer or entity

entered during the preceding 1-year period is at least 85 percent of the aggregate declared customs value of the fabric (exclusive of all findings and trimmings) contained in all such articles of that producer or entity that are entered and eligible under this clause during the preceding 1-year period.

On November 13, 2002, the President signed Proclamation 7626 (published in the **Federal Register** at 67 FR 69459 on November 18, 2002) which included, among other things, modifications to the HTSUS to implement the changes to section 213(b)(2)(A) of the CBERA made by section 3107(a) of the Act. Those modifications included an amendment of U.S. Note 2(d) to Subchapter XX, Chapter 98, HTSUS, to reflect the changes to subclauses (II) and (III) of paragraph (2)(A)(iv) of the statute discussed above. The Proclamation further provided that this amendment of U.S. Note 2(d) was effective with respect to goods entered, or withdrawn from warehouse for consumption, on or after October 1, 2002.

Interim Regulatory Amendments in T.D. 03–29

As a consequence of the statutory amendments described above and as a result of the modifications to the HTSUS made by Proclamation 7626, the interim regulatory provisions published in T.D. 01–74 no longer fully reflected the current standards that apply for purposes of preferential treatment of brassieres under the CBERA. In this regard, the effect of the statutory changes required changes throughout the text of interim § 10.228. Moreover, following publication of T.D. 01–74, some other issues came to the attention of CBP that warranted additional changes to the interim § 10.228 text.

Accordingly, in T.D. 03–29, CBP set forth an interim rule document revising interim § 10.228 in its entirety to reflect the amendments to the statute and to clarify or otherwise improve the previously published text. T.D. 03–29 was limited to the text of interim § 10.228 and therefore did not address the change that the Act made to paragraph (2)(A)(iv)(I) of the statute; that provision was reflected in § 10.223(a)(6) within the interim CBTPA regulations published in T.D. 00–68, and later amended by T.D. 03–12, published in the **Federal Register** on March 21, 2003. That change is discussed in a separate final rule document that addresses the other statutory changes to the CBERA made by the Act.

The interim regulatory changes to § 10.228 contained in T.D. 03–29 are restated below.

Amendments To Reflect the Statutory Changes

The changes to § 10.228 as set forth in T.D. 03–29 in response to the changes made to paragraph (2)(A)(iv) of the statute by section 3107(a) of the Act were as follows:

1. The definition of ''fabric components formed in the United States'' in paragraph (a)(3) was replaced by a definition of ''fabrics formed in the United States'' to reflect the fact that subclauses (II) and (III) of the statute no longer refer to fabric ''components.'' Similarly, the definition of ''cost'' in paragraph (a)(4) and the definition of ''declared customs value'' in paragraph (a)(5) were modified to refer simply to ''fabrics.''

2. The following changes were made to paragraph (b) which concerns the 75/85 percent U.S. fabric content requirements for preferential treatment in subclauses (II) and (III) of the statute:

a. In the introductory text of paragraph (b)(1), reference was made to the year that begins on ''October 1, 2002'' (rather than ''October 1, 2001'') to reflect the applicable effective date set forth in Proclamation 7626.

b. Throughout the paragraph (b) texts, all references to U.S.-formed ''fabric components'' were replaced by references to U.S.-formed ''fabric,'' the words ''produced and'' were removed from the expression ''produced and entered,'' and the parenthetical reference ''(exclusive of all findings and trimmings)'' has been added as appropriate after references to ''fabrics'' and ''fabric.'' These changes simply conform the regulatory text to the wording changes in the statute.

c. Paragraph (b)(1)(i), which concerns the 75 percent requirement of subclause (II) of the statute, was changed to refer to articles that are ''entered as articles described in § 10.223(a)(6),'' and paragraph (b)(1)(ii), which concerns the 85 percent requirement of subclause (III) of the statute, was changed to refer to articles that ''conform to the production standards set forth in § 10.223(a)(6).'' These wording changes are in response to the statutory wording changes regarding articles that are ''entered'' and that are ''eligible'' under clause (iv). The differences in wording in the two regulatory texts were necessary in order to enable the 85 percent standard to operate. As explained in T.D. 03–29, CBP notes that if the universe of articles that are looked at for purposes of assessing compliance with the 85 percent standard is the same as that used for purposes of the 75 percent standard (that is, articles that were entered under the HTSUS subheading that applies to articles described in paragraph (2)(A)(iv)(I) of the statute and § 10.223(a)(6)), it would be impossible in the first year following the statutory changes (that is, starting on October 1, 2002) for a new producer or entity to enter the program, or for a producer or entity that failed to meet the 75 percent standard in the previous year to reenter the program. This is because application of the 85 percent standard presupposes a failure to have met the 75 percent standard in the preceding year. This would mean that there could not be any entries in the next year under the HTSUS subheading that applies to articles described in paragraph (2)(A)(iv)(I) of the statute and § 10.223(a)(6) against which compliance with the 85 percent standard can be determined. The wording used in paragraph (b)(1)(ii) of the regulatory text (which is also reflected in the general statement of the paragraph (b)(1) introductory text and in the general rule in paragraph (b)(2)(i)(A)), by referring to articles that meet the U.S./Caribbean cutting and assembly production requirement (regardless of the HTSUS subheading under which they are entered), is intended to avoid this anomalous result.

d. In the general rules of application set forth in paragraph (b)(2)(i), two new subparagraphs (C) and (D) were added to clarify the application of the different regulatory language for the 75 and 85 percent standards discussed at point c. above, and former subparagraph (D) was removed because it concerned the year of production which is no longer relevant under the amended statutory text.

e. Also in paragraph (b)(2)(i), former subparagraph (C) was redesignated as subparagraph (E) and the text was modified, and a new subparagraph (L) was added, primarily to reflect that the findings and trimmings referred to in the context of brassieres are not limited to foreign findings and trimmings.

f. Also in paragraph (b)(2)(i), former subparagraph (E) was redesignated as subparagraph (G) and the text, which concerns a new producer or new entity controlling production, was revised to incorporate the new wording (''entered as articles described in § 10.223(a)(6)'') of paragraph (b)(1)(i) and to clarify what CBP believes is a necessary conclusion under the statutory text, that is, that in the described context the producer or entity must first meet the 85 (rather than the 75) percent standard.

g. In paragraph (b)(2)(ii), a new Example 2 and a new Example 3 were added to cover new subparagraphs (C) and (D) of paragraph (b)(2)(i), and Examples 2 through 6 consequently

were redesignated as Examples 4 through 8.

h. Also in paragraph (b)(2)(ii), redesignated Example 6 was revised in order to replace the former ''produced and entered'' in the same year scenario with a factual pattern addressing the 75 versus 85 percent standard and entry in different years.

i. Also in paragraph (b)(2)(ii), redesignated Example 7 was revised in order to reflect that the 85 percent standard (rather than the 75 percent standard) applies to a new producer or entity controlling production, as stated in redesignated and revised subparagraph (G) of paragraph (b)(2)(i).

3. In paragraph (c)(3)(i), the text of the declaration of compliance was modified by removing each reference to ''components'' and by removing the words ''produced and'' before the word ''entered'' in blocks 4 and 6, in each case to reflect changes in statutory language.

4. Finally, in paragraph (d)(1)(v), the next to last sentence was modified to state that the inventory records must indicate that the required production occurred (rather than ''identify the date of'' production), and the last sentence was modified to refer to purchases made during the ''accounting period'' (rather than ''year''), because the year of production is not relevant under the amended statute.

Other Amendments

In addition to the changes described above that result from the changes made to the statute by section 3107(a) of the Act, CBP also included a number of other changes in the revised text of § 10.228 set forth in T.D. 03–29. These additional changes, which were intended to clarify or otherwise improve the previous interim regulatory texts, were as follows:

1. The definition of ''cost'' in paragraph (a)(4) and the definition of ''declared customs value'' in paragraph (a)(5) were revised for purposes of clarity, in particular in order to include rules covering cases in which there is no price based on an exportation to a CBTPA beneficiary country.

2. The definition of ''year'' in paragraph (a)(6) was reworded for purposes of clarity.

3. In Example 1 under paragraph (b)(2)(ii), the words ''in the first year'' were added to the scenario in the first sentence to clarify that the year in question is one during which the 75 percent standard must be met.

4. In Example 5 under paragraph (b)(2)(ii), the references to foreign origin straps were replaced by references to ''strips and labels'' to ensure that the example is clearly directed to findings and trimmings and not to materials that are considered to be components of brassieres.

5. In paragraph (c)(3)(i), the text of the declaration of compliance was modified by replacing the words ''all articles'' with ''brassieres'' in blocks 4 through 6 and by simplifying the wording within block 6.

6. Finally, in paragraph (c)(3)(ii), the subparagraph (E) instruction for completion of block 6 was removed in light of the simplification of the block 6 text, and former subparagraph (F) consequently was redesignated as (E).

CBP is now publishing one document that adopts, as a final rule, the § 10.228 provisions contained in T.D. 03–29 and the other regulatory changes pertaining to brassieres under the CBTPA that were published in T.D. 01–74. This final rule document also summarizes and responds to the public comments previously submitted on the changes to §§ 10.222 and 10.223(a)(7) published in T.D. 01–74 and addresses the comments submitted on the revised § 10.228 text set forth in T.D. 03–29. Because CBP significantly modified § 10.228 in T.D. 03–29, CBP did not consider or address any public comments previously submitted on the text of § 10.228 as published in T.D. 01–74 that were addressed by statutory changes.

Discussion of Comments in Response to T.D. 01–74

A total of 8 commenters responded to the solicitation of public comments in the October 4, 2001, interim rule document referred to above. The comments submitted are summarized and responded to below. To the extent that the comments received regarding § 10.228 were not addressed by the changes made in T.D. 03–29, CBP has responded.

We note that after T.D. 01–74 amended § 10.223(a)(6), T.D. 03–12 again amended § 10.223(a)(6). Therefore, the change to § 10.223(a)(6) and the comments submitted regarding that change are discussed in a separate final rule document that addresses the other statutory changes to the CBERA made by the Trade Act of 2002.

Exclusion of Brassieres From Short Supply Provision

Six commenters disagree with the amendment to § 10.223(a)(7), which excludes brassieres conforming to the description set forth in § 10.223(a)(6) from receiving preferential treatment under the CBTPA short supply provision found in revised § 213(b)(2)(A)(v)(I) of the CBERA (and § 10.223(a)(7)). The specific points made by the commenters on this issue are set forth below.

Comment: There is nothing in the CBTPA or its legislative history to support CBP's interpretation in regard to this issue. While Congress did create a separate provision for brassieres in the CBTPA, with a minimum United States fabric content requirement, there is no evidence that Congress also meant to disqualify brassieres made of fabrics that have already been determined to be in short supply in the U.S., such as silk, from CBTPA eligibility. CBP's interpretation has the absurd consequence of precluding a CBTPA producer or entity that make only silk brassieres from receiving CBTPA treatment even though no silk is made in the United States. Congress intended that the short supply provision be applied equally to all garments.

CBP's Response: As stated in the preamble of the interim regulations, § 10.223(a)(7) provides for apparel articles constructed of fabrics or yarns which for purposes of Annex 401 of the NAFTA are deemed to be in ''short supply.'' There is no list of ''short supply'' fabrics or yarns for purposes of NAFTA. The determination of these ''short supply'' fabrics or yarns is based upon the various provisions of NAFTA and whether, under NAFTA, for the particular apparel article at issue, certain fabrics or yarns are explicitly permitted to be sourced from outside the NAFTA parties for use in the production of an ''originating'' good by omission of the fabrics or yarns from the list of excluded materials in the rule of origin for the particular apparel article. If sourcing of certain fabrics or yarns outside the NAFTA parties is allowed, then those fabrics or yarns are deemed to be in ''short supply'' for that apparel article.

In the case of brassieres under NAFTA, no restrictions or limitations apply regarding fabrics or yarns. Fabrics and yarns may be sourced from anywhere. The only requirement under Annex 401 is that articles classified in subheading 6212.10, HTSUS, must be ''both cut (or knit to shape) and sewn or otherwise assembled in the territory of one or more of the NAFTA parties.'' CBP does not agree with the presumption that since no restrictions exist, then all fabrics or yarns must be in ''short supply.'' If that presumption were true, § 10.223(a)(6) would be rendered meaningless. Accordingly, CBP concludes that the amendment to § 10.223(a)(7) of clarifying language to exclude articles described in § 10.223(a)(6) is appropriate.

Comment: If CBP insists that the CBTPA brassiere provision is *sui*

generis, standing alone, and must be read divorced from the rest of the statute, CBP should make clear that the separate CBTPA provisions relating to ''findings and trimmings,'' *de minimis*, and elastomeric yarn also do not apply to brassieres classified in subheading 6212.10, HTSUS.

CBP's Response: CBP disagrees with the assertion that the CBTPA provisions relating to ''findings and trimmings,'' *de minimis*, and elastomeric yarn do not apply to brassieres classified in subheading 6212.10, HTSUS. These provisions of the CBTPA clearly do apply to the provision of the CBTPA specific to brassieres, as well as the other various provisions described in paragraph (b)(2)(A) of amended section 213. These special rules refer to eligibility for ''preferential treatment under this paragraph.'' The paragraph referred to in these contexts is paragraph (b)(2) of amended section 213, and since the brassiere provision is part of paragraph (b)(2), there is no doubt these ''special rules'' are applicable to goods described in that provision.

Comment: CBTPA provisions that exempt, exclude or deem products ineligible for preferential treatment do so by identifying the product by HTS [HTSUS] number. Had Congress wanted to exclude brassieres of subheading 6212.10, HTSUS, from receiving duty-free treatment under the short supply provision found in § 213(b)(2)(A)(v)(I) of the CBERA, they would have included a specific provision to that effect. An example of a specific limitation in a CBTPA provision is the ''findings and trimmings'' provision where by explicit reference it is stated that elastic strips are findings and trimmings if ''less than one inch in width and used in the production of brassieres.'' In fact, the reference to brassieres in the ''findings and trimmings'' provision confirms that Congress intended for brassieres to be entitled to preference through a variety of CBTPA provisions.

CBP's Response: This comment has been addressed, in part, in the above responses. In addition, however, it is CBP's view that although the ''current short supply'' provision in the CBTPA does not encompass brassieres based upon the application of the ''short supply'' provisions in Annex 401 of the NAFTA, the language in § 211(b)(2)(A)(v), as written, would allow for the designation of new or additional fabrics or yarns as in ''short supply'' for apparel articles including brassieres. If, as suggested by the commenter, Congress had included language in § 211(b)(2)(A)(v)(I) to exclude brassieres of subheading 6212.10, HTSUS, then brassieres would be excluded from possible application of 211(b)(2)(A)(v)(II), thus precluding the designation of new or additional fabrics or yarns as in ''short supply'' for brassiereres.

Comment: The CBTPA and the Africa Growth and Opportunity Act (AGOA) are both part of the Trade and Development Act of 2000. While the CBTPA includes both short supply and brassiere provisions, the AGOA contains short supply provisions but no separate brassiere provision. CBP's instructions to the ports dated September 14, 2001 (TBT–00–023–01) state that the AGOA short supply provisions do not apply to brassieres. This instruction seems to contradict CBP's logic that the presence of the separate CBTPA brassiere provision confirms Congressional intent that the § 10.223(a)(7) short supply provision does not apply to brassieres of subheading 6212.10, HTSUS. CBP's logic is also called into question by the exclusion of brassieres of subheading 6212.10, HTSUS, only from the § 10.223(a)(7) provision. If the presence of the specific brassiere provision in the CBTPA were construed to exclude brassieres from one CBTPA preference provision, it follows that brassieres should be excluded from the other CBTPA preference provisions (including the § 10.223(a)(8) short supply provision) as well.

CBP's Response: CBP's rationale for clarifying that § 10.223(a)(7) does not include brassieres of subheading 6212.10, HTSUS, is based upon the application of the current ''short supply'' provisions in Annex 401 of the NAFTA and the methodology necessary to determine fabrics and yarns deemed to be in ''short supply'' for purposes of NAFTA. In order to qualify for preferential treatment under NAFTA, brassieres need only be cut (or knit to shape) and sewn or otherwise assembled in the territory of one or more of the NAFTA parties. There is no requirement provided for the sourcing of fabrics or yarns used in the production of qualifying brassieres, thus allowing fabrics or yarns to be sourced from anywhere. As it would be nonsensical to view the rule as establishing all fabrics and yarns to be ''short supply'' for brassieres under NAFTA, CBP interprets the rule as not designating any fabrics or yarns as ''short supply'' for brassieres. Based on that rationale, the instructions to the ports dated September 14, 2001 (TBT–00–023–01) stating that the AGOA ''short supply'' provision did not apply to brassieres was appropriate. The reference by CBP in the interim regulations document to § 10.223(a)(6) as support for CBP's view that § 10.223(a)(7) does not include brassieres of subheading 6212.10, HTSUS, was simply, as stated, additional support for the view adopted by CBP. As a result of the amendments to the CBTPA brassiere provision in the Trade Act of 2002, reliance on § 10.223(a)(6) as support for CBP's view would now seem misplaced. However, it was not the basis for that view.

The primary reason that CBP has concluded that the current ''short supply'' provision of the CBTPA does not include brassieres is based upon the manner in which ''short supply'' yarns and fabrics are determined under the NAFTA as has already been explained above.

Comment: The fact that the short supply provision of § 213(b)(2)(A)(v)(I) comes directly after the CBTPA brassieres provision suggests that, contrary to CBP's reasoning, Congress intended the short supply provision to apply to brassieres of subheading 6212.10, HTSUS.

CBP's Response: CBP does not believe that the order of the statutory provisions in question is persuasive, and CBP disagrees with the conclusion of the commenter for the reasons set forth earlier in this comment discussion.

Comment: In support of its interpretation regarding this issue, CBP notes that the NAFTA Annex 401 rule for subheading 6212.10, HTSUS, includes no designation of fabrics or yarns in short supply. This is a misreading of the application of Annex 401 to the CBTPA short supply provision. Congress was using the Annex 401 language as the easiest way of capturing those fabrics and yarns that are already designated as short supply under NAFTA, and not as a re-creation of the basic rule of origin under NAFTA.

CBP's Response: Annex 401 of the NAFTA does not contain a convenient list of ''short supply'' fabrics and yarns. Additionally, for certain apparel, annex 401 specifies distinct fabrics by technical descriptions. The only means by which CBP is able to determine the ''short supply'' fabrics and yarns currently allowed under the NAFTA and thus allowed under the CBTPA is by reviewing the specific rules contained in annex 401.

Declaration of Compliance

Comment: One commenter recommends that § 10.228(c)(1) provide that the declaration of compliance be submitted to CBP no later than 30 days prior to the beginning of the next year (October 1st) to afford CBP sufficient time to evaluate the declaration, assign a distinct and unique identifier, and

notify the ports of the identifier. The 10-day time frame currently specified in this regulation is unrealistic.

CBP's Response: CBP does not agree that it is necessary to make any change in the specified time frame for filing the Declaration of Compliance. CBP notes that the requirement is for submission at least 10 calendar days prior to the date of the first shipment. The reference to the first shipment was intended to accommodate goods shipped after a year has already begun, and the change suggested by this commenter would remove this flexibility. CBP is still of the opinion that the 10-day period is the appropriate minimum period needed for processing the Declaration of Compliance and giving notice of the distinct and unique identifier to the producer or entity controlling production and to the importer. However, CBP would not object to submissions made well in advance of that 10-day period. It is noted that the regulatory text merely sets forth a minimum period and therefore does not preclude earlier submissions.

Comment: Four commenters disagree with the general rule set forth in § 10.228(b)(2)(i)(G), providing that a declaration of compliance prepared by a producer or by an entity must cover all production of that producer or all production that the entity controls. The commenters allege that requiring a declaration to cover all of a producer's production presents confidentiality problems in situations such as presented in Example 6 under § 10.228(b)(2)(ii) where an entity controls a portion of a producer's production but the producer also operates independently by producing for several U.S. importers. The commenters maintain that the entity may be reluctant or may even refuse to provide the producer with the fabric cost and value information needed for the producer to file its declaration of compliance. According to these commenters, the statute does not require that production be reported twice, as it would be in this example. The commenters suggest that the regulations should provide some method through which confidentiality for cost information can be maintained by the producer or entity that has this information but still allow each party to file a declaration based only on that part of the information for which it is directly responsible.

CBP's Response: In the case of the producer, the Declaration of Compliance must include all the production of the producer that meets the description of 19 CFR 10.223(a)(6) and is entered in the United States. In the case of an entity controlling production, the Declaration of Compliance must include all the production that meets the description of § 10.223(a)(6) and is entered in the United States. These requirements reflect the wording of the statute as regards who must bear the burden of meeting the 75 or 85 percent standard. The regulatory provisions are intended to encompass all possible production scenarios that could arise under the statutory framework and therefore include circumstances in which there is an overlap as regards information reported by an entity and information reported by a producer. Since the suggestion of these commenters would lead to a result that is incompatible with the wording of the statute, it cannot be adopted.

With regard to the issue of confidentiality, CBP recognizes that there may be legitimate commercial concerns regarding the information that must be disclosed between producers and entities controlling production in order to demonstrate compliance with the statutory requirements. However, CBP believes that confidentiality issues in this context are a private commercial matter which must be addressed by the private parties directly affected, as part of the process of weighing the advantages and disadvantages of participating in this statutory preferential tariff program. CBP further believes that it would be inadvisable to address those concerns in the manner suggested by these commenters because it would result in a reporting requirement that would not allow CBP to effectively verify compliance with the statutory requirements.

Certificate of Origin

Comment: Four commenters argue that a Certificate of Origin under § 10.224 should not be required for brassieres entered duty-free under subheading 9820.11.15, HTSUS. The commenters state that, because CBTPA eligibility for brassieres is dictated only by the validity of the information on the Declaration of Compliance, a Certificate of Origin should be unnecessary when the declaration identifier number is on the entry.

CBP's Response: Paragraph (b)(4)(A)(i) of amended section 213 provides that ''[a]ny importer that claims preferential treatment under paragraph (2) or (3) shall comply with customs procedures similar in all material respects to the requirements of Article 502(1) of the NAFTA * * *.'' Article 502(1)(a) of the NAFTA obligates each NAFTA Party to require an importer that claims preferential tariff treatment to make a written declaration based on a valid Certificate of Origin. Paragraph (b)(4)(A)(ii) of amended section 213 sets forth certain conditions that must be met in order for a CBTPA beneficiary country's merchandise ''to qualify for the preferential treatment under paragraph (2) or (3) and for a Certificate of Origin to be valid with respect to any article for which such treatment is claimed.'' CBP interprets the references in paragraph (b)(4)(A)(i) to NAFTA Article 502(10) and in paragraph (b)(4)(A)(ii) to a Certificate of Origin to mean that Congress intended to require Certificates of Origin for claims of CBTPA preferential treatment, including for brassieres. The commenters seem to be suggesting that, for brassieres alone, the declaration of compliance should replace the Certificate of Origin.

Furthermore, as a practical matter, the Declaration of Compliance cannot effectively replace the CBTPA Textile Certificate of Origin provided for under § 10.224 because the latter document contains information elements that are not set forth on, or that are useful in verifying information provided on, the Declaration of Compliance.

Recordkeeping and Verification Requirements

Comment: Five commenters allege that the recordkeeping and verification requirements set forth in § 10.228(d) are too onerous, do not conform to the way most companies maintain their records and are not authorized by the CBTPA. The commenters contend that a company should not have to create new accounting records to satisfy this regulatory provision; they note in this regard that many companies do not keep cash disbursement, purchase journals or record the date of production. According to these commenters, so long as the producer or the entity is able to establish that the 75 or 85 percent standard is met in any given year using generally accepted accounting principles, the statutory requirement should be satisfied.

CBP's Response: With regard to the assertion that the § 10.228(d) recordkeeping requirements (such as the cash disbursement or purchase journal) do not conform to the way most companies keep their records, CBP notes that the regulatory text does not mandate the maintenance of specific types of records. Rather, the regulatory text states in this regard that the audit trail documents must consist of a cash disbursement or purchase journal ''or equivalent records'' to establish the purchase of the fabric or component. Therefore, if a company does not maintain a cash disbursement or purchase journal, alternative records

that reflect the purchase of the fabric or component would be acceptable.

The recordkeeping and verification requirements were included in § 10.228 so that the trade community would know what CBP would expect to see when verifying a claim for preferential treatment of brassieres under the CBTPA. These requirements are implicitly authorized by the CBTPA because they are directed to the specific statutory standards that apply in the case of brassieres under the CBTPA and because they are promulgated by the government agency that is charged with responsibility for enforcing those statutory standards. The basic point to remember is that CBP must be able to verify that the requirements of the statute have been met, even if this means that a producer must create certain records that were not maintained prior to the CBTPA (such as records regarding the date of production, which are germane to the year-to-year standard established by the statute). There would be no objection to the use of generally accepted accounting principles (GAAP) to establish that the 75 or 85 percent standard is met, provided that the use of GAAP yields a result that is verifiable and that accurately reflects the applicable CBTPA statutory standards.

Finally, as regards the complaint that the recordkeeping and verification requirements are too onerous, CBP would simply note that a decision whether to enter into transactions under a duty-preference program may require the consideration of a variety of factors, including whether the benefits outweigh the business costs that must be incurred in order to comply with the requirements of the program.

Comments in Response to T.D. 03–29

One comment was received in response to the notice of solicitation of comments on the interim regulations implementing the Preferential Treatment of Brassieres Under the Caribbean Basin Economic Recovery Act (68 FR 56166) which appeared in the **Federal Register** on September 30, 2003. The comment addressed two concerns with regard to the implementing regulations.

Comment: The first concern expressed by the commenter is with regard to the clarity of the regulations as to the entry requirement for brassieres entered into the United States in a prior year which are considered in the calculation to determine whether the U.S. fabric content requirement set forth by Congress has been met in order for imported brassieres to qualify for preferential treatment in a subsequent year. The commenter is concerned that the language of the regulations as drafted suggests that brassieres considered in the fabric content calculation must be produced in the same year in which they are entered. The regulations contain examples of the application of the provisions set forth in the regulations and the commenter acknowledges that Example 6, which illustrates that brassieres may be produced in one year and entered in a different year, is consistent with changes in the brassiere provision enacted by Congress in the Trade Act of 2002. However, the commenter seeks further clarification and suggests the addition of the phrase ''without regard to the year in which the articles were produced'' after the phrase ''within the same year'' in § 10.228(b)(2)(i)(A).

CBP's Response: CBP disagrees with the need for further clarification as suggested by the commenter. The language at issue in § 10.228(b)(2)(i)(A) clearly addresses the manner of production of the brassieres in question and then specifies that the brassieres must all be entered in the same year. Example 6 serves to further clarify that the production of the brassieres under consideration need not occur in the same year as the entry of the brassieres. However, all brassieres considered in determining whether brassieres in a subsequent year will qualify for preferential treatment must be entered in the same program year.

Comment: The commenter's second concern is that the regulations need to be clarified as to the relationship between § 10.223(a)(6), the provision specific to brassieres, and other provisions of the CBTPA. Specifically, the commenter requests that CBP clarify the regulations to provide that brassieres entered under 19 U.S.C. 2703(b)(2)(A)(i), (ii), (iii), (v), or (vi), which are described in § 10.223(a)(1), (2), (3), (4), (7), (8) or (9) of the CBP Regulations, are not to be considered in the fabric content calculation to determine the eligibility of brassieres for preferential treatment in a subsequent year. The commenter suggests as an example that brassieres may be entered under the provision for apparel made of regionally produced knit fabric, § 10.223(a)(4), or under either short supply provision, § 10.223(a)(7) or § 10.223(a)(8), and brassieres so entered would not be considered in calculating the fabric content to determine if the requisite percentage of U.S. fabric had been used to allow for subsequent year preferential treatment.

CBP's Response: CBP disagrees with the commenter. First, CBP cannot agree with the commenter that brassieres entered under other provisions of the CBTPA will not be considered for determining eligibility for preferential treatment under § 10.223(a)(6). CBP agrees with this assertion of the commenter only to the extent that it applies to determining whether the 75 percent threshold U.S. fabric content requirement has been met. With regard to cases when the 75 percent requirement has not been met and a producer or entity controlling production must meet the stricter 85 percent U.S. fabric content requirement, or in the case of a new producer or entity controlling production which did not enter brassieres in the first year of the program and must therefore meet the stricter 85 percent U.S. fabric content requirement, if CBP does not consider brassieres entered under other provisions of the CBTPA, that is, provisions other than § 10.223(a)(6), a producer or entity controlling production would never be able to meet the 85 percent U.S. fabric content requirement.

Secondly, CBP rejects the commenter's suggestion that brassieres currently may be entered under all of the provisions associated with the statutory paragraphs identified in 19 U.S.C. 2703(b)(2)(A)(i), (ii), (iii), (v), or (vi). Section 10.223(a)(9) of the CBP Regulations is associated with 19 U.S.C. 2703(b)(2)(A)(vi) and provides for handloomed, hand-made and folklore articles. At this time, this provision does not include brassieres as eligible for entry under that provision. Therefore, brassieres may not be entered under § 10.223(a)(9). Likewise, § 10.223(a)(7) and (8), the provisions which allow for apparel articles produced from fabrics or yarns determined to be in short supply, do not currently include brassieres as eligible for entry under those provisions.

Additional Change to the Regulations

While CBP has not adopted any changes identified and discussed above in connection with the public comments, CBP has amended blocks 4–6 of the declaration of compliance for brassieres by adding exclusion language regarding findings and trimmings after each reference to fabric(s) as provided for in section 3107(a) of the Act. Additionally, wherever the term ''Customs'' appears in the CBP Regulations affected by this final rule (*i.e.* 19 CFR 10.228), it is replaced with the term ''CBP.''

Conclusion

After analysis of the comments and further review and consideration of the matter, CBP is adopting as a final rule the interim rule set forth in T.D. 01–74

amending § 10.222, paragraph (a)(7) of § 10.223, and the Appendix to Part 163 of the CBP Regulations which was published in the **Federal Register** at 66 FR 50534 on October 4, 2001. CBP is also adopting as a final rule, with the changes discussed above, the interim rule set forth in T.D. 03–29 amending § 10.228 of Part 10 of the CBP Regulations which was published in the **Federal Register** at 68 FR 56166 on September 30, 2003.

It is noted that while T.D. 01–74 amended § 10.223(a)(6), T.D. 03–12 published in the **Federal Register** at 68 FR 59649 on March 21, 2003, set forth additional changes to § 10.223(a)(6). Therefore, as the changes to § 10.223(a)(6) set forth in T.D. 01–74 were further amended, those changes will be finalized in a separate final rule document that addresses the other statutory changes to the CBERA made by the Act.

Executive Order 12866

This document does not meet the criteria for a ''significant regulatory action'' as specified in E.O. 12866. This rule is limited in scope and affects only a small segment of the trade community. Moreover, it sets forth the technical requirements for a statutorily mandated trade benefits program.

Regulatory Flexibility Act

As set forth in the preamble, the regulations to implement the standards for preferential treatment for brassieres imported from Caribbean Basin countries were previously published as interim regulations. Those interim regulations provided trade benefits to the importing public, implemented direct statutory mandates, and were necessary to carry out the preferential treatment and United States tariff changes proclaimed by the President under the Caribbean Basin Economic Recovery Act. Pursuant to the provisions of 5 U.S.C. 553(b)(B), CBP issued the regulations as interim rules because it had determined that prior public notice and comment procedures on these regulations were unnecessary and contrary to the public interest. For these reasons, pursuant to the provisions of 5 U.S.C. 553(d)(1) and (3), CBP also found that there was good cause for dispensing with a delayed effective date. Because no notice of proposed rulemaking was required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply. Accordingly, this final rule is not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 and 604.

Paperwork Reduction Act

The collection of information contained in this interim rule has previously been reviewed and approved by the Office of Management and Budget (OMB) in accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) under OMB control number 1651–0083.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

Signing Authority

This regulation is being issued in accordance with 19 CFR 0.1(a)(1).

List of Subjects

19 CFR Part 10

Assembly, Bonds, Caribbean Basin Initiative, Customs duties and inspection, Exports, Imports, Preference programs, Reporting and recordkeeping requirements, Trade agreements.

19 CFR Part 163

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

Amendments to the Regulations

■ For the reasons stated in the preamble, Part 10 and Part 163 (19 CFR Part 10 and 19 CFR Part 163) are amended to read as follows:

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

■ 1. The authority citation for Part 10 continues to read in part as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 23, Harmonized Tariff Schedule of the United States (HTSUS)), 1321, 1481, 1484, 1498, 1508, 1623, 1624, 3314;

* * * * *

Sections 10.221 through 10.228 and §§ 10.231 through 10.237 also issued under 19 U.S.C. 2701 *et seq.*

■ 2. The introductory text in § 10.222 is republished to read as follows:

§ 10.222 Definitions.

When used in §§ 10.221 through 10.228, the following terms have the meanings indicated:

* * * * *

■ 3. In § 10.223, paragraph (a)(7) is republished to read as follows:

§ 10.223 Articles eligible for preferential treatment

* * * * *

(a) * * *

(7) Apparel articles, other than articles described in paragraph (a)(6) of this section, that are both cut (or knit-to-shape) and sewn or otherwise assembled in one or more CBTPA beneficiary countries, from fabrics or yarn that is not formed in the United States or in one or more CBTPA beneficiary countries, to the extent that apparel articles of those fabrics or yarn would be eligible for preferential treatment, without regard to the source of the fabrics or yarn, under Annex 401 of the NAFTA;

* * * * *

■ 4. Section 10.228 is revised to read as follows:

§ 10.228 Additional requirements for preferential treatment of brassieres.

(a) *Definitions.* When used in this section, the following terms have the meanings indicated:

(1) *Producer.* ''Producer'' means an individual, corporation, partnership, association, or other entity or group that exercises direct, daily operational control over the production process in a CBTPA beneficiary country.

(2) *Entity controlling production.* ''Entity controlling production'' means an individual, corporation, partnership, association, or other entity or group that is not a producer and that controls the production process in a CBTPA beneficiary country through a contractual relationship or other indirect means.

(3) *Fabrics formed in the United States.* ''Fabrics formed in the United States'' means fabrics that were produced by a weaving, knitting, needling, tufting, felting, entangling or other fabric-making process performed in the United States.

(4) *Cost.* ''Cost'' when used with reference to fabrics formed in the United States means:

(i) The price of the fabrics when last purchased, f.o.b. port of exportation, as set out in the invoice or other commercial documents, or, if the price is other than f.o.b. port of exportation:

(A) The price as set out in the invoice or other commercial documents adjusted to arrive at an f.o.b. port of exportation price; or

(B) If no exportation to a CBTPA beneficiary country is involved, the price as set out in the invoice or other commercial documents, less the freight, insurance, packing, and other costs incurred in transporting the fabrics to the place of production if included in that price; or

(ii) If the price cannot be determined under paragraph (a)(4)(i) of this section or if CBP finds that price to be

unreasonable, all reasonable expenses incurred in the growth, production, manufacture, or other processing of the fabrics, including the cost or value of materials (which includes the cost of non-recoverable scrap generated in forming the fabrics) and general expenses, plus a reasonable amount for profit, and the freight, insurance, packing, and other costs, if any, incurred in transporting the fabrics to the port of exportation.

(5) *Declared customs value.* ''Declared customs value'' when used with reference to fabric contained in an article means the sum of:

(i) The cost of fabrics formed in the United States that the producer or entity controlling production can verify; and

(ii) The cost of all other fabric contained in the article, exclusive of all findings and trimmings, determined as follows:

(A) In the case of fabric purchased by the producer or entity controlling production, the f.o.b. port of exportation price of the fabric as set out in the invoice or other commercial documents, or, if the price is other than f.o.b. port of exportation:

(*1*) The price as set out in the invoice or other commercial documents adjusted to arrive at an f.o.b. port of exportation price, plus expenses for embroidering and dyeing, printing, and finishing operations applied to the fabric if not included in that price; or

(*2*) If no exportation to a CBTPA beneficiary country is involved, the price as set out in the invoice or other commercial documents, plus expenses for embroidering and dyeing, printing, and finishing operations applied to the fabric if not included in that price, but less the freight, insurance, packing, and other costs incurred in transporting the fabric to the place of production if included in that price;

(B) In the case of fabric for which the cost cannot be determined under paragraph (a)(5)(ii)(A) of this section or if CBP finds that cost to be unreasonable, all reasonable expenses incurred in the growth, production, or manufacture of the fabric, including the cost or value of materials (which includes the cost of non-recoverable scrap generated in the growth, production, or manufacture of the fabric), general expenses and embroidering and dyeing, printing, and finishing expenses, plus a reasonable amount for profit, and the freight, insurance, packing, and other costs, if any, incurred in transporting the fabric to the port of exportation;

(C) In the case of fabric components purchased by the producer or entity controlling production, the f.o.b. port of exportation price of those fabric components as set out in the invoice or other commercial documents, less the cost or value of any non-textile materials, and less expenses for cutting or other processing to create the fabric components other than knitting to shape, that the producer or entity controlling production can verify, or, if the price is other than f.o.b. port of exportation:

(*1*) The price as set out in the invoice or other commercial documents adjusted to arrive at an f.o.b. port of exportation price, less the cost or value of any non-textile materials, and less expenses for cutting or other processing to create the fabric components other than knitting to shape, that the producer or entity controlling production can verify; or

(*2*) If no exportation to a CBTPA beneficiary country is involved, the price as set out in the invoice or other commercial documents, less the cost or value of any non-textile materials, and less expenses for cutting or other processing to create the fabric components other than knitting to shape, that the producer or entity controlling production can verify, and less the freight, insurance, packing, and other costs incurred in transporting the fabric components to the place of production if included in that price; and

(D) In the case of fabric components for which a fabric cost cannot be determined under paragraph (a)(5)(ii)(C) of this section or if CBP finds that cost to be unreasonable: all reasonable expenses incurred in the growth, production, or manufacture of the fabric components, including the cost or value of materials (which does not include the cost of recoverable scrap generated in the growth, production, or manufacture of the fabric components) and general expenses, but excluding the cost or value of any non-textile materials, and excluding expenses for cutting or other processing to create the fabric components other than knitting to shape, that the producer or entity controlling production can verify, plus a reasonable amount for profit, and the freight, insurance, packing, and other costs, if any, incurred in transporting the fabric components to the port of exportation.

(6) *Year.* ''Year'' means a 12-month period beginning on October 1 and ending on September 30 but does not include any 12-month period that began prior to October 1, 2000.

(7) *Entered.* ''Entered'' means entered, or withdrawn from warehouse for consumption, in the customs territory of the United States.

(b) *Limitations on preferential treatment*—(1) *General.* During the year that begins on October 1, 2002, and during any subsequent year, articles of a producer or an entity controlling production that conform to the production standards set forth in § 10.223(a)(6) will be eligible for preferential treatment only if:

(i) The aggregate cost of fabrics (exclusive of all findings and trimmings) formed in the United States that were used in the production of all of those articles of that producer or that entity controlling production that are entered as articles described in § 10.223(a)(6) during the immediately preceding year was at least 75 percent of the aggregate declared customs value of the fabric (exclusive of all findings and trimmings) contained in all of those articles of that producer or that entity controlling production that are entered as articles described in § 10.223(a)(6) during that year; or

(ii) In a case in which the 75 percent requirement set forth in paragraph (b)(1)(i) of this section was not met during a year and therefore those articles of that producer or that entity controlling production were not eligible for preferential treatment during the following year, the aggregate cost of fabrics (exclusive of all findings and trimmings) formed in the United States that were used in the production of all of those articles of that producer or that entity controlling production that conform to the production standards set forth in § 10.223(a)(6) and that were entered during the immediately preceding year was at least 85 percent of the aggregate declared customs value of the fabric (exclusive of all findings and trimmings) contained in all of those articles of that producer or that entity controlling production that conform to the production standards set forth in § 10.223(a)(6) and that were entered during that year; and

(iii) In conjunction with the filing of the claim for preferential treatment under § 10.225, the importer records on the entry summary or warehouse withdrawal for consumption (CBP Form 7501, column 34), or its electronic equivalent, the distinct and unique identifier assigned by CBP to the applicable documentation prescribed under paragraph (c) of this section.

(2) *Rules of application*—(i) *General.* For purposes of paragraphs (b)(1)(i) and (b)(1)(ii) of this section and for purposes of preparing and filing the documentation prescribed in paragraph (c) of this section, the following rules will apply:

(A) The articles in question must have been produced in the manner specified

in § 10.223(a)(6) and the articles in question must be entered within the same year;

(B) Articles that are exported to countries other than the United States and are never entered are not to be considered in determining compliance with the 75 or 85 percent standard specified in paragraph (b)(1)(i) or paragraph (b)(1)(ii) of this section;

(C) Articles that are entered under an HTSUS subheading other than the HTSUS subheading which pertains to articles described in § 10.223(a)(6) are not to be considered in determining compliance with the 75 percent standard specified in paragraph (b)(1)(i) of this section;

(D) For purposes of determining compliance with the 85 percent standard specified in paragraph (b)(1)(ii) of this section, all articles that conform to the production standards set forth in § 10.223(a)(6) must be considered, regardless of the HTSUS subheading under which they were entered;

(E) Fabric components and fabrics that constitute findings or trimmings are not to be considered in determining compliance with the 75 or 85 percent standard specified in paragraph (b)(1)(i) or paragraph (b)(1)(ii) of this section;

(F) Beginning October 1, 2002, in order for articles to be eligible for preferential treatment in a given year, a producer of, or entity controlling production of, those articles must have met the 75 percent standard specified in paragraph (b)(1)(i) of this section during the immediately preceding year. If articles of a producer or entity controlling production fail to meet the 75 percent standard specified in paragraph (b)(1)(i) of this section during a year, articles of that producer or entity controlling production:

(*1*) Will not be eligible for preferential treatment during the following year;

(*2*) Will remain ineligible for preferential treatment until the year that follows a year in which articles of that producer or entity controlling production met the 85 percent standard specified in paragraph (b)(1)(ii) of this section; and

(*3*) After the 85 percent standard specified in paragraph (b)(1)(ii) of this section has been met, will again be subject to the 75 percent standard specified in paragraph (b)(1)(i) of this section during the following year for purposes of determining eligibility for preferential treatment in the next year.

(G) A new producer or new entity controlling production, that is, a producer or entity controlling production which did not produce or control production of articles that were entered as articles described in § 10.223(a)(6) during the immediately preceding year, must first establish compliance with the 85 percent standard specified in paragraph (b)(1)(ii) of this section as a prerequisite to preparation of the declaration of compliance referred to in paragraph (c) of this section;

(H) A declaration of compliance prepared by a producer or by an entity controlling production must cover all production of that producer or all production that the entity controls for the year in question;

(I) A producer is not required to prepare a declaration of compliance if all of its production is covered by a declaration of compliance prepared by an entity controlling production;

(J) In the case of a producer, the 75 or 85 percent standard specified in paragraph (b)(1)(i) or paragraph (b)(1)(ii) of this section and the declaration of compliance procedure under paragraph (c) of this section apply to all articles of that producer for the year in question, even if some but not all of that production is also covered by a declaration of compliance prepared by an entity controlling production;

(K) The U.S. importer does not have to be the producer or the entity controlling production who prepared the declaration of compliance; and

(L) The exclusion references regarding findings and trimmings in paragraph (b)(1)(i) and paragraph (b)(1)(ii) of this section apply to all findings and trimmings, whether or not they are of foreign origin.

(ii) *Examples.* The following examples will illustrate application of the principles set forth in paragraph (b)(2)(i) of this section.

Example 1. A CBTPA beneficiary country producer of articles that meet the production standards specified in § 10.223(a)(6) in the first year sends 50 percent of that production to CBTPA region markets and the other 50 percent to the U.S. market; the cost of the fabrics formed in the United States equals 100 percent of the value of all of the fabric in the articles sent to the CBTPA region and 60 percent of the value of all of the fabric in the articles sent to the United States. Although the cost of fabrics formed in the United States is more than 75 percent of the value of all of the fabric used in all of the articles produced, this producer could not prepare a valid declaration of compliance because the articles sent to the United States did not meet the minimum 75 percent standard.

Example 2. A producer sends to the United States in the first year three shipments of articles that meet the description in § 10.223(a)(6); one of those shipments is entered under the HTSUS subheading that covers articles described in § 10.223(a)(6), the second shipment is entered under the HTSUS subheading that covers articles described in § 10.223(a)(12), and the third shipment is entered under subheading 9802.00.80, HTSUS. In determining whether the minimum 75 percent standard has been met in the first year for purposes of entry of articles under the HTSUS subheading that covers articles described in § 10.223(a)(6) during the following (that is, second) year, consideration must be restricted to the articles in the first shipment and therefore must not include the articles in the second and third shipments.

Example 3. A producer in the second year begins production of articles that conform to the production standards specified in § 10.223(a)(6); some of those articles are entered in that year under HTSUS subheading 6212.10 and others under HTSUS subheading 9802.00.80 but none are entered in that year under the HTSUS subheading which pertains to articles described in § 10.223(a)(6) because the 75 percent standard had not been met in the preceding (that is, first) year. In this case the 85 percent standard applies, and all of the articles that were entered under the various HTSUS provisions in the second year must be taken into account in determining whether that 85 percent standard has been met. If the 85 percent was met in the aggregate for all of the articles entered in the second year, in the next (that is, third) year articles of that producer may receive preferential treatment under the HTSUS subheading which pertains to articles described in § 10.223(a)(6).

Example 4. An entity controlling production of articles that meet the description in § 10.223(a)(6) buys for the U.S., Canadian and Mexican markets; the articles in each case are first sent to the United States where they are entered for consumption and then placed in a commercial warehouse from which they are shipped to various stores in the United States, Canada and Mexico. Notwithstanding the fact that some of the articles ultimately ended up in Canada or Mexico, a declaration of compliance prepared by the entity controlling production must cover all of the articles rather than only those that remained in the United States because all of those articles had been entered for consumption.

Example 5. Fabric is cut and sewn in the United States with other U.S. materials to form cups which are joined together to form brassiere front subassemblies in the United States, and those front subassemblies are then placed in a warehouse in the United States where they are held until the following year; during that following year all of the front subassemblies are shipped to a CBTPA beneficiary country where they are assembled with elastic strips and labels produced in an Asian country and other fabrics, components or materials produced in the CBTPA beneficiary country to form articles that meet the production standards specified in § 10.223(a)(6) and that are then shipped to the United States and entered during that same year. In determining whether the entered articles meet the minimum 75 or 85 percent standard, the fabric in the elastic strips and labels is to be disregarded entirely because the strips and labels constitute findings or trimmings for purposes of this section, and all of the fabric

in the front subassemblies is countable because it was all formed in the United States and used in the production of articles that were entered in the same year.

Example 6. A CBTPA beneficiary country producer's entire production of articles that meet the description in § 10.223(a)(6) is sent to a U.S. importer in two separate shipments, one in February and the other in June of the same calendar year; the articles shipped in February do not meet the minimum 75 percent standard, the articles shipped in June exceed the 85 percent standard, and the articles in the two shipments, taken together, do meet the 75 percent standard; the articles covered by the February shipment are entered for consumption on March 1 of that calendar year, and the articles covered by the June shipment are placed in a CBP bonded warehouse upon arrival and are subsequently withdrawn from warehouse for consumption on November 1 of that calendar year. The CBTPA beneficiary country producer may not prepare a valid declaration of compliance covering the articles in the first shipment because those articles did not meet the minimum 75 percent standard and because those articles cannot be included with the articles of the second shipment on the same declaration of compliance since they were entered in a different year. However, the CBTPA beneficiary country producer may prepare a valid declaration of compliance covering the articles in the second shipment because those articles did meet the requisite 85 percent standard which would apply for purposes of entry of articles in the following year.

Example 7. A producer in the second year begins production of articles exclusively for the U.S. market that meet the production standards specified in § 10.223(a)(6), but the entered articles do not meet the requisite 85 percent standard until the third year; the entered articles fail to meet the 75 percent standard in the fourth year; and the entered articles do not attain the 85 percent standard until the sixth year. The producer's articles may not receive preferential treatment during the second year because there was no production (and thus there were no entered articles) in the immediately preceding (that is, first) year on which to assess compliance with the 75 percent standard. The producer's articles also may not receive preferential treatment during the third year because the 85 percent standard was not met in the immediately preceding (that is, second) year. However, the producer's articles are eligible for preferential treatment during the fourth year based on compliance with the 85 percent standard in the immediately preceding (that is, third) year. The producer's articles may not receive preferential treatment during the fifth year because the 75 percent standard was not met in the immediately preceding (that is, fourth) year. The producer's articles may not receive preferential treatment during the sixth year because the 85 percent standard has become applicable and was not met in the immediately preceding (that is, fifth) year. The producer's articles are eligible for preferential treatment during the seventh year because the 85 percent standard was met in the immediately preceding (that is, sixth) year, and during that seventh year the 75 percent standard is applicable for purposes of determining whether the producer's articles are eligible for preferential treatment in the following (that is, eighth) year.

Example 8. An entity controlling production (Entity A) uses five CBTPA beneficiary country producers (Producers 1–5), all of which produce only articles that meet the description in § 10.223(a)(6); Producers 1–4 send all of their production to the United States and Producer 5 sends 10 percent of its production to the United States and the rest to Europe; Producers 1–3 and Producer 5 produce only pursuant to contracts with Entity A, but Producer 4 also operates independently of Entity A by producing for several U.S. importers, one of which is an entity controlling production (Entity B) that also controls all of the production of articles of one other producer (Producer 6) which sends all of its production to the United States. A declaration of compliance prepared by Entity A must cover all of the articles of Producers 1–3 and the 10 percent of articles of Producer 5 that are sent to the United States and that portion of the articles of Producer 4 that are produced pursuant to the contract with Entity A, because Entity A controls the production of those articles. There is no need for Producers 1–3 and Producer 5 to prepare a declaration of compliance because they have no production that is not covered by a declaration of compliance prepared by an entity controlling production. A declaration of compliance prepared by Producer 4 would cover all of its production, that is, articles produced for Entity A, articles produced for Entity B, and articles produced independently for other U.S. importers; a declaration of compliance prepared by Entity B must cover that portion of the production of Producer 4 that it controls as well as all of the production of Producer 6 because Entity B also controls all of the production of Producer 6. Producer 6 would not prepare a declaration of compliance because all of its production is covered by the declaration of compliance prepared by Entity B.

(c) *Documentation*—(1) *Initial declaration of compliance.* In order for an importer to comply with the requirement set forth in paragraph (b)(1)(iii) of this section, the producer or the entity controlling production must have filed with CBP, in accordance with paragraph (c)(4) of this section, a declaration of compliance with the applicable 75 or 85 percent requirement prescribed in paragraph (b)(1)(i) or (b)(1)(ii) of this section. After filing of the declaration of compliance has been completed, CBP will advise the producer or the entity controlling production of the distinct and unique identifier assigned to that declaration. The producer or the entity controlling production will then be responsible for advising each appropriate U.S. importer of that distinct and unique identifier for purposes of recording that identifier on the entry summary or warehouse withdrawal. In order to provide sufficient time for advising the U.S. importer of that distinct and unique identifier prior to the arrival of the articles in the United States, the producer or the entity controlling production should file the declaration of compliance with CBP at least 10 calendar days prior to the date of the first shipment of the articles to the United States.

(2) *Amended declaration of compliance.* If the information on the declaration of compliance referred to in paragraph (c)(1) of this section is based on an estimate because final year-end information was not available at that time and the final data differs from the estimate, or if the producer or the entity controlling production has reason to believe for any other reason that the declaration of compliance that was filed contained erroneous information, within 30 calendar days after the final year-end information becomes available or within 30 calendar days after the date of discovery of the error:

(i) The producer or the entity controlling production must file with the CBP office identified in paragraph (c)(4) of this section an amended declaration of compliance containing that final year-end information or other corrected information; or

(ii) If that final year-end information or other corrected information demonstrates noncompliance with the applicable 75 or 85 percent requirement, the producer or the entity controlling production must in writing advise both the CBP office identified in paragraph (c)(4) of this section and each appropriate U.S. importer of that fact.

(3) *Form and preparation of declaration of compliance*—(i) *Form.* The declaration of compliance referred to in paragraph (c)(1) of this section may be printed and reproduced locally and must be in the following format:

CARIBBEAN BASIN TRADE PARTNERSHIP ACT DECLARATION OF COMPLIANCE FOR BRASSIERES

[19 CFR 10.223(a)(6) and 10.228]

1. Year beginning date: October 1, ____.
   Year ending date: September 30, ____.

Official U.S. Customs and Border Protection Use Only
Assigned number: _____
Assignment date: _____

2. Identity of preparer (producer or entity controlling production):
   Full name and address:

Telephone number: _____
Facsimile number: _____
Importer identification number: _____

3. If the preparer is an entity controlling production, provide the following for each producer:
   Full name and address:

Telephone number: _____
Facsimile number: _____

4. Aggregate cost of fabrics (exclusive of all findings and trimmings) formed in the United States that were used in the production of brassieres that were entered during the year: _____

5. Aggregate declared customs value of the fabric (exclusive of all findings and trimmings) contained in brassieres that were entered during the year: _____

6. I declare that the aggregate cost of fabric (exclusive of all findings and trimmings) formed in the United States was at least 75 percent (or 85 percent, if applicable under 19 CFR 10.228(b)(1)(ii)) of the aggregate declared customs value of the fabric contained in brassieres entered during the year.

7. Authorized signature:

8. Name and title (print or type):

_____
Date:

(ii) *Preparation.* The following rules will apply for purposes of completing the declaration of compliance set forth in paragraph (c)(3)(i) of this section:

(A) In block 1, fill in the year commencing October 1 and ending September 30 of the calendar year during which the applicable 75 or 85 percent standard specified in paragraph (b)(1)(i) or paragraph (b)(1)(ii) of this section was met;

(B) Block 2 should state the legal name and address (including country) of the preparer and should also include the preparer's importer identification number (see § 24.5 of this chapter), if the preparer has one;

(C) Block 3 should state the legal name and address (including country) of the CBTPA beneficiary country producer if that producer is not already identified in block 2. If there is more than one producer, attach a list stating the legal name and address (including country) of all additional producers;

(D) Blocks 4 and 5 apply only to articles that were entered during the year identified in block 1; and

(E) In block 7, the signature must be that of an authorized officer, employee, agent or other person having knowledge of the relevant facts and the date must be the date on which the declaration of compliance was completed and signed.

(4) *Filing of declaration of compliance.* The declaration of compliance referred to in paragraph (c)(1) of this section:

(i) Must be completed either in the English language or in the language of the country in which the articles covered by the declaration were produced. If the declaration is completed in a language other than English, the producer or the entity controlling production must provide to CBP upon request a written English translation of the declaration; and

(ii) Must be filed with the New York Strategic Trade Center, Customs and Border Protection, 1 Penn Plaza, New York, New York 10119.

(d) *Verification of declaration of compliance*—(1) *Verification procedure.* A declaration of compliance filed under this section will be subject to whatever verification CBP deems necessary. In the event that CBP for any reason is prevented from verifying the statements made on a declaration of compliance, CBP may deny any claim for preferential treatment made under § 10.225 that is based on that declaration. A verification of a declaration of compliance may involve, but need not be limited to, a review of:

(i) All records required to be made, kept, and made available to CBP by the importer, the producer, the entity controlling production, or any other person under part 163 of this chapter;

(ii) Documentation and other information regarding all articles that meet the production standards specified in § 10.223(a)(6) that were exported to the United States and that were entered during the year in question, whether or not a claim for preferential treatment was made under § 10.225. Those records and other information include, but are not limited to, work orders and other production records, purchase orders, invoices, bills of lading and other shipping documents;

(iii) Evidence to document the cost of fabrics formed in the United States that were used in the production of the articles in question, such as purchase orders, invoices, bills of lading and other shipping documents, and customs import and clearance documents, work orders and other production records, and inventory control records;

(iv) Evidence to document the cost or value of all fabric other than fabrics formed in the United States that were used in the production of the articles in question, such as purchase orders, invoices, bills of lading and other shipping documents, and customs import and clearance documents, work orders and other production records, and inventory control records; and

(v) Accounting books and documents to verify the records and information referred to in paragraphs (d)(1)(ii) through (d)(1)(iv) of this section. The verification of purchase orders, invoices and bills of lading will be accomplished through the review of a distinct audit trail. The audit trail documents must consist of a cash disbursement or purchase journal or equivalent records to establish the purchase of the fabric. The headings in each of these journals or other records must contain the date, vendor name, and amount paid for the fabric. The verification of production records and work orders will be accomplished through analysis of the inventory records of the producer or entity controlling production. The inventory records must reflect the production of the finished article which must be referenced to the original purchase order or lot number covering the fabric used in production. In the inventory production records, the inventory should show the opening balance of the inventory plus the purchases made during the accounting

period and the inventory closing balance.

(2) *Notice of determination*. If, based on a verification of a declaration of compliance filed under this section, CBP determines that the applicable 75 or 85 percent standard specified in paragraph (b)(1)(i) or paragraph (b)(1)(ii) of this section was not met, CBP will publish a notice of that determination in the **Federal Register**.

PART 163—RECORDKEEPING

■ 5. 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.

■ 6. In the Appendix to Part 163 the listing under section IV of ''§ 10.228 CBTPA Declaration of Compliance for brassieres'' is republished.

* * * * *

Approved: November 23, 2004.

Robert C. Bonner,

Commissioner of Customs and Border Protection.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 04–26359 Filed 11–29–04; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 522

New Animal Drugs; Meloxicam

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 two supplemental new animal drug applications (NADAs) filed by Boehringer Ingelheim Vetmedica, Inc. The first supplemental NADA provides for use of meloxicam injectable solution in cats for control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy, and castration when administered prior to surgery. It also provides revised dosage labeling for this product in dogs. The other supplemental NADA provides revised dosage labeling for use of meloxicam oral suspension in dogs.

DATES: This rule is effective November 30, 2004.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540, e-mail: *melanie.berson@fda.gov*.

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Hwy., St. Joseph, MO 64506–2002, filed a supplement to NADA 141–219 that provides for use of METACAM (meloxicam) Solution for Injection in cats for control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy, and castration when administered prior to surgery, and also revises dosage information for use of this product in dogs. Boehringer Ingelheim Vetmedica, Inc., also filed a supplement to NADA 141–213 that provides revised dosage information for use of METACAM (meloxicam) Oral Suspension in dogs. The supplemental NADAs are approved as of October 28, 2004, and the regulations are amended in 21 CFR 520.1350 and 522.1367 to reflect the approval. The basis of approval is discussed in the freedom of information summaries.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of safety and effectiveness data and information submitted to support approval of these applications 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)(iii) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(iii)), the supplemental approval of meloxicam injectable solution for use in cats qualifies for 3 years of marketing exclusivity beginning October 28, 2004.

The agency has determined under 21 CFR 25.33(d)(5) that these actions are of a type that do 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 Parts 520 and 522

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 parts 520 and 522 are 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. Section 520.1350 is amended by revising paragraph (c)(1) to read as follows:

§ 520.1350 Meloxicam.

* * * * *

(c) * * *

(1) *Amount.* Administer orally as a single dose at 0.09 mg per pound (mg/lb) body weight (0.2 mg per kilogram (mg/kg)) on the first day of treatment. For all treatment after day 1, administer 0.045 mg/lb (0.1 mg/kg) body weight once daily.

* * * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 4. Section 522.1367 is amended by revising paragraph (c) to read as follows:

§ 522.1367 Meloxicam.

* * * * *

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 0.09 mg per pound (mg/lb) body weight (0.2 mg per kilogram (mg/kg)) by intravenous or subcutaneous injection on the first day of treatment. For treatment after day 1, administer meloxicam suspension orally at 0.045 mg/lb (0.1 mg/kg) body weight once daily as in § 520.1350(c) of this chapter.

(ii) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* Administer 0.14 mg/lb (0.3 mg/kg) body weight as a single, one-time subcutaneous injection.

(ii) *Indications for use.* For the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy, and castration when administered prior to surgery.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.