DEPARTMENT OF HOMELAND SECURITY

U.S. CUSTOMS AND BORDER PROTECTION

NOTICE OF ISSUANCE OF FINAL DETERMINATION

CONCERNING PONSTEL® (MEFENAMIC ACID) CAPSULES

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

ACTION: Notice of final determination.

SUMMARY: This document provides notice that U.S. Customs and Border Protection (''CBP'') has issued a final determination concerning the country of origin of Ponstel® (mefenamic acid) capsules. Based upon the facts presented, CBP has concluded in the final determination that India is the country of origin of the Ponstel (mefenamic acid) capsules for purposes of U.S. Government procurement.

DATE: The final determination was issued on December 26, 2012. A copy of the final determination is attached. Any party-at-interest, as defined in 19 C.F.R. § 177.22(d), may seek judicial review of this final determination on or before [insert 30 days from date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Heather K. Pinnock, Valuation and Special Programs Branch: (202) 325-0034.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on December 26, 2012, pursuant to subpart B of part 177, Customs and Border Protection Regulations (19 C.F.R. Part 177, subpart B), CBP issued a final determination concerning the country of origin of Ponstel (mefenamic acid) capsules, which may be offered to the U.S. Government under an undesignated government procurement contract. This final determination, in HQ

H233356, was issued at the request of West-Ward Pharmaceutical Corp., under procedures set forth at 19 C.F.R. Part 177, subpart B, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511–18). In the final determination CBP concluded that, based upon the facts presented, mefenamic acid from India, blended with excipients and packaged into dosage form in the United States, was not substantially transformed in the United States, such that India is the country of origin of the finished Ponstel (mefenamic acid) capsules for purposes of U.S. Government procurement.

Section 177.29, CBP Regulations (19 C.F.R. § 177.29), provides that a notice of final determination shall be published in the *Federal Register* within 60 days of the date the final determination is issued. Section 177.30, CBP Regulations (19 C.F.R. § 177.30), provides that any party-at-interest, as defined in 19 C.F.R. § 177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the *Federal Register*.

DATED: January 3, 2013

Jeremy Baskin
Acting Executive Director
Regulations and Rulings
Office of International Trade

Attachment

HQ H233356

December 26, 2012

MAR-2 OT:RR:CTF:VS H233356HkP

CATEGORY: Origin

Ms. Susan Todd
Senior Manager, Regulatory Affairs
West-Ward Pharmaceutical Corp.
435 Industrial Way West
Eatontown, NJ 07724

RE: Government Procurement; Trade Agreements Act; Country of Origin of Ponstel® (mefenamic acid) Capsules; Substantial Transformation

Dear Ms. Todd:

This is in response to your letter, dated August 21, 2012, requesting a final determination on behalf of West-Ward Pharmaceutical Corp. ("West-Ward") pursuant to subpart B of part 177 of the U.S. Customs and Border Protection ("CBP") Regulations (19 C.F.R. Part 177). Under these regulations, which implement Title III of the Trade Agreements Act of 1979 ("TAA"), as amended (19 U.S.C. § 2511 et seq.), CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain "Buy American" restrictions in U.S. law or practice for products offered for sale to the U.S. Government.

This final determination concerns the country of origin of Ponstel (mefenamic acid) capsules. As a U.S. importer, West-Ward is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

FACTS:

West-Ward imports mefenamic acid powder in bulk form from India, where it is manufactured. Mefenamic acid is the active pharmaceutical ingredient ("API") in the pharmaceutical product Ponstel. Ponstel is indicated for the relief of mild to moderate pain caused by primary dysmenorrhea and is approved by the U.S. Food and Drug Administration, NDA no. 015034.

After importation, West-Ward combines the API, mefenamic acid, with inactive ingredients and processes it into dosage form. The inactive ingredients are lactose monohydrate, D&C Yellow No. 10, FD&C Yellow No. 6, gelatin, titanium dioxide, and food-grade inks. The mefenamic acid is added to a tumbler and blended. Lactose monohydrate, a diluent, is then added to the tumbler and blended with the API. The blend is transferred to an encapsulating machine and used to fill capsules purchased from a U.S. supplier. The capsules are packed into bottles of 30 capsules each, which are packaged and shipped to the U.S.-holder of the New Drug Application for Ponstel.

ISSUE:

What is the country of origin of Ponstel (mefenamic acid) capsules for purposes of U.S. Government procurement?

LAW AND ANALYSIS:

Pursuant to Subpart B of Part 177, 19 CFR § 177.21 et seq., which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 et seq.), CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain "Buy American" restrictions in U.S. law or practice for products offered for sale to the U.S. Government.

Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B):

> An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

See also 19 C.F.R. § 177.22(a).

A substantial transformation occurs when an article emerges from a process with a new name, character and use different from that possessed by the article prior to processing. A substantial transformation will not result from a minor manufacturing or combining process that leaves the identity of the article intact. SeeUnited States v. Gibson-Thomsen Co., 27 C.C.P.A. 267 (1940); and,National Juice Products Association v. United States, 628 F. Supp. 978 (Ct. Int'l Trade 1986).

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, CBP has generally held that the processing of pharmaceutical products from bulk form into measured doses does not result in a substantial transformation of the product. See e.g., Headquarters Ruling Letter ("HQ") 561975, dated April 3, 2002; HQ 561544, dated May 1, 2000; and, HQ 735146, dated November 15, 1993.

For instance, in HQ 561975, the anesthetic drug sevoflurane imported into the U.S. in bulk form and processed into dosage form by extensive testing operations, followed by filtering and packaging into bottles, was found not to have undergone a substantial transformation in the U.S. There was no change in name (the product was identified as sevoflurane in both its bulk and processed form). The sevoflurane retained its chemical and physical properties after the U.S. processing. Lastly, because the imported bulk sevoflurane had a predetermined medicinal use as an inhalable anesthetic drug, the processing in the United States resulted in no change in the product's use.

Likewise, in HQ 561544, the testing, filtering and sterile packaging of Geneticin Sulfate bulk powder, to create Geneticin Selective Antibiotic, was not found to have

substantially transformed the antibiotic substance because the processing only involved the removal of impurities from the bulk chemical and the placement of the chemical into smaller packaging.

In HQ 735146, 100 percent pure acetaminophen imported from China was blended with excipients in the United States, granulated and sold to pharmaceutical companies to process into tablets for retail sale under private labels. U.S. Customs (now CBP) found that the process in the United States did not substantially transform the imported product because the product was referred to as acetaminophen both before importation and after U.S. processing, as imported the acetaminophen was used for medicinal purposes and continued to be so used after U.S. processing, and the granulating process minimally affected the chemical and physical properties of the acetaminophen.

In this case, the mefenamic acid imported from India is blended with excipients and packaged into dosage form in the United States. Based on the rulings above, we find that this process does not substantially transform the mefenamic acid because its chemical character remains the same. As such, we find that the country of origin of the Ponstel (mefenamic acid) capsules is India, where the mefanamic acid was manufactured.

HOLDING:

Based on the facts in this case, the blending and packaging operations performed in the United States do not substantially transform the mefenamic acid imported from India. Therefore, the country of origin of the Ponstel® (mefenamic acid) capsules is India for purposes of U.S. Government procurement.

Notice of this final determination will be given in the Federal Register, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R. § 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-

interest may, within 30 days of publication of the Federal Register Notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Jeremy Baskin
Acting Executive Director
Regulations and Rulings
Office of International Trade

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