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. *See United 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.

[FR Doc. 2013–00140 Filed 1–7–13; 8:45 am]

BILLING CODE;P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Quarterly IRS Interest Rates Used in Calculating Interest on Overdue Accounts and Refunds on Customs Duties

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

ACTION: General notice.

SUMMARY: This notice advises the public of the quarterly Internal Revenue Service interest rates used to calculate interest on overdue accounts (underpayments) and refunds (overpayments) of customs duties. For the calendar quarter beginning January 1, 2013, the interest rates for

overpayments will be 2 percent for corporations and 3 percent for non-corporations, and the interest rate for underpayments will be 3 percent for both corporations and non-corporations. This notice is published for the convenience of the importing public and U.S. Customs and Border Protection personnel.

DATES: *Effective Date:* January 1, 2013.

FOR FURTHER INFORMATION CONTACT: Ron Wyman, Revenue Division, Collection and Refunds Branch, 6650 Telecom Drive, Suite #100, Indianapolis, Indiana 46278; telephone (317) 614–4516.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to 19 U.S.C. 1505 and Treasury Decision 85–93, published in the **Federal Register** on May 29, 1985 (50 FR 21832), the interest rate paid on applicable overpayments or underpayments of customs duties must be in accordance with the Internal Revenue Code rate established under 26 U.S.C. 6621 and 6622. Section 6621 was amended (at paragraph (a)(1)(B) by the Internal Revenue Service Restructuring and Reform Act of 1998, Public Law 105–206, 112 Stat. 685) to provide different interest rates applicable to overpayments: one for corporations and one for non-corporations.

The interest rates are based on the Federal short-term rate and determined by the Internal Revenue Service (IRS) on behalf of the Secretary of the Treasury on a quarterly basis. The rates effective for a quarter are determined during the first-month period of the previous quarter.

In Revenue Ruling 2012–32, the IRS determined the rates of interest for the calendar quarter beginning January 1, 2013, and ending on March 31, 2013. The interest rate paid to the Treasury for underpayments will be the Federal short-term rate (1%) plus two percentage points (2%) for a total of three percent (3%) for both corporations and non-corporations. For corporate overpayments, the rate is the Federal short-term rate (1%) plus one percentage point (1%) for a total of two percent (2%). For overpayments made by non-corporations, the rate is the Federal short-term rate (1%) plus two percentage points (2%) for a total of three percent (3%). These interest rates are subject to change for the calendar quarter beginning April 1, 2013, and ending June 30, 2013.

For the convenience of the importing public and U.S. Customs and Border Protection personnel the following list of IRS interest rates used, covering the period from before July of 1974 to date, to calculate interest on overdue accounts and refunds of customs duties, is published in summary format.

Beginning date	Ending date	*Under-payments (percent)*	Over-payments (percent)	Corporate overpayments (Eff. 1–1–99) (percent)
070174	063075	6	6	.....
070175	013176	9	9	.....
020176	013178	7	7	.....
020178	013180	6	6	.....
020180	013182	12	12	.....
020182	123182	20	20	.....
010183	063083	16	16	.....
070183	123184	11	11	.....
010185	063085	13	13	.....
070185	123185	11	11	.....
010186	063086	10	10	.....
070186	123186	9	9	.....
010187	093087	9	8	.....
100187	123187	10	9	.....
010188	033188	11	10	.....
040188	093088	10	9	.....
100188	033189	11	10	.....
040189	093089	12	11	.....
100189	033191	11	10	.....
040191	123191	10	9	.....
010192	033192	9	8	.....
040192	093092	8	7	.....
100192	063094	7	6	.....
070194	093094	8	7	.....
100194	033195	9	8	.....
040195	063095	10	9	.....
070195	033196	9	8	.....
040196	063096	8	7	.....
070196	033198	9	8	.....
040198	123198	8	7	.....
010199	033199	7	7	6
040199	033100	8	8	7
040100	033101	9	9	8
040101	063001	8	8	7
070101	123101	7	7	6
010102	123102	6	6	5
010103	093003	5	5	4
100103	033104	4	4	3
040104	063004	5	5	4
070104	093004	4	4	3
100104	033105	5	5	4
040105	093005	6	6	5
100105	063006	7	7	6
070106	123107	8	8	7
010108	033108	7	7	6

Beginning date	Ending date	*Under-payments (percent)*	Over-payments (percent)	Corporate overpayments (Eff. 1–1–99) (percent)
040108	063008	6	6	5
070108	093008	5	5	4
100108	123108	6	6	5
010109	033109	5	5	4
040109	123110	4	4	3
010111	033111	3	3	2
040111	093011	4	4	3
100111	033113	3	3	2

Dated: January 2, 2013.

Thomas S. Winkowski,

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

[FR Doc. 2013–00146 Filed 1–7–13; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5667–N–01]

Supportive Housing for the Elderly; Advance Notice of Senior Preservation Rental Assistance Contracts Award Process

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, (HUD).

ACTION: Notice.

SUMMARY: The Section 202 Supportive Housing for the Elderly Act of 2010, signed into law in January 2011, authorizes HUD to provide Senior Preservation Rental Assistance Contracts (SPRACs) with 20-year terms to prevent displacement of elderly residents of certain projects assisted under HUD's Section 202 Supportive Housing for the Elderly program in the case of refinancing or recapitalization and to further preserve and maintain affordability of Section 202 Direct Loan projects. In Fiscal Year (FY) 2012, $16 million was made available for SPRAC funding. This notice advises of HUD's intent to award SPRACs through the proposed application process described in this notice. HUD is soliciting comments on the proposed process for awarding SPRACs and the associated criteria for establishing eligibility to apply for a SPRAC.

DATES: *Comment Due Date: March 11, 2013.*

ADDRESSES: Interested persons are invited to submit comments regarding this notice to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500. Communications must refer to the above docket number and title. There are two methods for submitting public comments. All submissions must refer to the above docket number and title.

1. Submission of Comments by Mail. Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500.

2. Electronic Submission of Comments. Interested persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the notice.

No Facsimile Comments. Facsimile (FAX) comments are not acceptable.

Public Inspection of Public Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an appointment to review the public comments must be scheduled in advance by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay Service at 800–877–8339. Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Margaret Salazar, Deputy Director of the Office of Affordable Housing Development, Office of Multifamily Housing Programs, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 6112, Washington, DC 20410; telephone number 202–708–2495 (this is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

The Section 202 Supportive Housing for the Elderly Act of 2010 (Pub. L. 111–372, approved January 4, 2011) (Section 202 of 2010 Act) authorizes HUD to provide SPRACs with 20-year terms to prevent displacement of elderly residents of certain projects assisted under HUD's Section 202 Supportive Housing for the Elderly program (Section 202 program) in the case of refinancing or recapitalization and to further preserve and maintain affordability of Section 202 Direct Loan projects. General authority for a Section 202 Direct Loan is provided by Section 811 of the American Homeownership and Economic Opportunity (AHEO) Act of 2000, as amended by the Section 202 of 2010 Act (12 U.S.C. 1701q note). Pursuant to this authority, SPRAC assistance may be provided to Section 202 properties with original interest rates of 6 percent or less (financed prior to 1974), when the property is refinanced to make capital repairs and the owner does not anticipate debt service savings from the refinance. In FY 2012, $16 million was made available for SPRAC funding.

II. This Notice—Solicitation of Comment

This notice advises of HUD's intent to award SPRACs through the proposed application process described in this notice. HUD is soliciting comments on