the CBP Regulations). This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours. This document is published to obtain comments from the public and affected agencies. This information collection was previously published in the Federal Register (77 FR 64533) on October 22, 2012, allowing for a 60-day comment period. Two comments were received. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

DATES: Written comments should be received on or before February 7, 2013.

ADDRESSES: Interested persons are invited to submit written comments on this information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for U.S. Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to oira_submission@omb.eop.gov or faxed to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 799 9th Street NW., 5th Floor, Washington, DC 20229–1177, at 202–325–0265.

SUPPLEMENTARY INFORMATION: CBP invites the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act (Pub. L. 104–13). Your comments should address one of the following four points:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency/component estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collections of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological techniques or other forms of information.

Title: Regulations Relating to Recordation and Enforcement of Trademark and Copyrights (Part 133 of the CBP Regulations).

OMB Number: 1651–0123.

Abstract: In accordance with 19 CFR part 133, trademark and trade name owners and those claiming copyright protection may submit information to CBP to enable CBP officers to identify violating articles at the borders. Parties seeking to have merchandise excluded from entry must provide proof to CBP of the validity of the rights they seek to protect. The information collected by CBP is used to identify infringing goods at the borders and determine if such goods infringe on intellectual property rights for which federal law provides import protection. Respondents may submit their information to CBP electronically at https://apps.cbp.gov/e-recordings/, or they may submit their information on paper in accordance with 19 CFR 133.2 and 133.3 for trademarks, or 19 CFR 133.32 and 133.33 for copyrights.

Current Actions: This submission is being made to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Businesses and Individuals.

Estimated Number of Respondents: 2,000.

Estimated Time per Respondent: 2 hours.

Estimated Total Annual Burden Hours: 4,000.


Tracey Denning,
Agency Clearance Officer, U.S. Customs and Border Protection.

[FR Doc. 2013–00144 Filed 1–7–13; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determination Concerning Ponstel® (Mefenamic Acid) Capsules


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.

DATES: 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 CFR 177.22(d), may seek judicial review of this final determination on or before February 7, 2013.

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 CFR 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 CFR 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 CFR 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 CFR 177.30), provides that any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the Federal Register.


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

Attachment

HQ H233356

December 26, 2012

MAR-2 OT:RR:CTF:VS H233356HHP
CATEGORICAL: 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 Agreement 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
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 in 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,
In determining whether a substantial
transformation occurs in the manufacture of
chemical products such as pharmaceuticals,
CBP has considered 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
chemical products such as pharmaceuticals,
transformation occurs in the manufacture 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 pre-determined 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 an inhalable form for
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
governmental purposes and continued to be
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 mefenamic 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. § 177.30. 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 Baxtin,
Acting Executive Director, Regulations and
Rulings, Office of International Trade.
[FR Doc. 2013–00140 Filed 1–7–13; 8:45 am]
BILLING CODE: 9990–57–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

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