DEPARTMENT OF HOMELAND SECURITY

U.S. CUSTOMS AND BORDER PROTECTION

NOTICE OF ISSUANCE OF FINAL DETERMINATION

CONCERNING RYBIX® (TRAMADOL HYDROCHLORIDE) TABLETS

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 Rybix® (tramadol hydrochloride) tablets. Based upon the facts presented, CBP has concluded in the final determination that India is the country of origin of the Rybix (tramadol hydrochloride) tablets 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: Karen S. Greene, Valuation and Special Programs Branch: (202) 325-0041.

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 Rybix (tramadol hydrochloride) tablets, which may be offered to the U.S. Government under an undesignated government procurement contract. This final determination, in HQ H215656, was issued at the

request of Shionogi Inc., 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, tramadol hydrochloride from India, blended with excipients and packaged into dosage form in France, was not substantially transformed in France, such that India is the country of origin of the finished Rybix (tramadol hydrochloride) tablets 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: December 26, 2012

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

Attachment

HQ H215656

December 26, 2012

MAR-02 OT:RR:CTF:VS KSG

CATEGORY: Origin

Alan M. Kirschenbaum
Hyman, Phelps & Amp; McNamara P.C.
700 13th Street, N.W.
Suite 1200
Washington, D.C. 20815

RE: U.S. Government procurement; Trade Agreement Act; Country of Origin of Rybix ODT; substantial transformation

Dear Mr. Kirschenbaum:

This is in response to your eruling request, submitted April 6, 2012, requesting a final determination on behalf of Shionogi Inc., pursuant to subpart B of Part 177 of the U.S. Customs and Border Protection ("CBP") Regulations (19 CFR Part 177) which was forwarded to this office for a response. 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 Rybix ODT(tramadol hydrochloride orally disintegrating tablets). As a U.S. importer, Shionogi Inc. is a party-at-interest within the meaning of 19 CFR 177.22(d)(1), and is entitled to request this final determination.

FACTS:

Rybix ODT is a pharmaceutical product used for the management of moderate to moderately severe pain in adults. The active pharmaceutical ingredient ("API"), tramadol hydrochloride, is manufactured in India. The API is shipped to France where it undergoes four stages of manufacturing. Inactive ingredients (excipients) used in production in France are: aspartame, copovidone, crospovidone, ethylcellulose, magnesium stearate, mannitol 60, mannitol M300, mint rootbeer flavor, and silicon dioxide.

The first stage of French manufacturing is preparation of tramadol hydrochloride granules (the API). The API and silicon dioxide are de-lumped and granulated with a suspension of ethylcellulose, copovidone, silicon dioxide, and ethanol. The uncoated granules are sieved and sized. These granules are then coated and sieved to remove any granules larger than 710 microns.

The second stage of French manufacturing is preparation of the tablet blend. A number of excipients such as mint rootbeer flavor, aspartame, crospovidone, mannitol 60, and mannitol M300, are de-lumped by passing them through a sieve. An excipient is defined on www.thefreedictionary.com as "an inactive substance that serves asthe vehicle or medium for a drug" or "a substance, such as sugar or gum, used to prepare a drug or drugs in a form suitable for administration." The excipients are combined to make a flavor preblend. The tramadol hydrochloride coated granules are also de-lumped by passing them through a screen and then the flavor preblend is added and blended. The blended product is discharged into polyethylene-lined drums.

The third stage of French manufacturing is tablet compression. Magnesium stearate is sprayed onto upper and lower punch faces on a tablet press (to prevent sticking) and tablets are formed. The bulk tablets are collected in polyethylene-lined foil bags, which are heat-sealed and packaged in fiberboard drums.

The fourth stage of French manufacturing is packaging in child-resistant blister packs. The tablets are fed through a tablet feeder and packaged into cold form blisters sealed with child-resistant blister lidstock. The blister pack cards are then packed into cartons of 30 tablets each with FDA-compliant labeling, packaged in cartons and shipped to the importer's warehouses in the U.S.

ISSUE:

What is the country of origin ofimported Rybix ODT (tramadol hydrochloride), processed as described above?

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 if 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 CFR 177.22(a).

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, filteringand packaging does not result in a substantial transformation. See Headquarters Ruling Letter ("HRL") H197582, dated August 9, 2012, HRL 561975, dated April 3, 2002, HRL 561544, dated May 1, 2000.

In HRL 561975, dated April 3, 2002, an anesthetic drug known as sevofurane was imported in bulk form from Japan and in the U.S., processed into dosage form, filtered and subjected to FDA testing. CBP held that the imported good did not undergo a substantial transformation in the U.S.—the chemical and physical properties of the drug remained the same, and the medicinal use did not change.

Likewise, in HRL 561544, dated May 1, 2000, 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 HRL H040735, dated January 21, 2009, CBP considered whether imported Sumatriptan was substantially transformed in the UK, where it was compounded with sodium chloride and water using helium USP for a processing aid to reduce dissolved air. The pharmaceutical then went through a series of sterilizing filters, and was filled into an empty capsule subassembly. The drug capsule subassembly, which contained the dose of sumatriptan succinate, and the actuator subassembly, which consisted of a nitrogen gas powered ram and piston, were then combined. CBP held that the active ingredient which was produced in India, did not undergo a substantial transformation even though the injection system was sophisticated and valuable. The active ingredient did not undergo a change in character.

In this case, the processing in France does not result in a change in the medicinal use of the finished product and the active ingredient retains its chemical and physical properties and is merely put into a dosage form and packaged. The active ingredient does not undergo a change in name, character or use. Accordingly, we find that there no substantial transformation occurs in France, and the imported product would be considered a product of India for purposes of government procurement.

HOLDING:

Based upon the facts in this case, we find that the imported Rybix ODT (tramadol hydrochloride) is not substantially transformed in France. The country of origin for government procurement purposes is India.

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 CFR 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 CFR 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
Office of Regulations and Rulings,
Office of International Trade

[FR Doc. 2013-00414 Filed 01/10/2013 at 8:45 am; Publication Date: 01/11/2013]