DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determination Concerning

Certain Oral Solution Products

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 certain oral solution products for cleansing of the colon known as Prepopik. Based upon the facts presented, CBP has concluded that, the country of origin of the oral solution is China for purposes of U.S. Government procurement.

DATED: The final determination was issued on March 13, 2015. 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 within [INSERT 30 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Grace A. Kim, Valuation and Special Programs Branch, Regulations and Rulings, Office of International Trade (202) 325-7941.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on March 13, 2015, pursuant to subpart B of Part 177, U.S. Customs and Border Protection Regulations (19 CFR part 177, subpart B), CBP issued a final determination concerning the country of origin of certain oral solution products known as Prepopik, which may be offered to the U.S. Government, Department of Veterans Affairs under its Federal Supply Schedule contract. This final

determination, HQ H253443, was issued 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 the processing in China results in a substantial transformation. Therefore, the country of origin of the oral solution is China 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**.

Dated: March 13, 2015.

Glen E. Vereb,
Acting Executive Director,
Regulations and Rulings,
Office of International Trade.

HQ H253443

March 13, 2015

OT:RR:CTF:VS H253443 GaK

CATEGORY: Origin

Michael T. Shor
Arnold & Porter LLP
555 12th Street, NW
Washington, DC 20004-1206

RE: U.S. Government Procurement; Country of Origin of PREPOPIK®; Substantial Transformation

Dear Mr. Shor:

This is in response to your letter dated April 23, 2014, and your supplemental submission dated July 18, 2014, requesting a final determination on behalf of your client, Ferring Pharmaceuticals Inc. ("Ferring"), 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 Ferring's PREPOPIK® for Oral Solution ("Prepopik"), which is a powder for oral solution for cleansing of the colon. We note that as a U.S. importer, Ferring 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.

Pursuant to 19 C.F.R. § 177.22(b)(7), you requested confidential treatment with respect to certain information submitted. As that information constitutes privileged or confidential matters, it has been bracketed and will be redacted from any published versions.

FACTS:

Prepopik is a dual-acting osmotic and stimulant laxative bowel preparation for a colonoscopy in adults. Prepopik is imported in packets containing one dose, to which a dosing cup is added in the U.S. Prepopik is ingested by dissolving the powder in water, using the supplied plastic dosing cup. To produce Prepopik, sodium picosulfate (manufactured in Country A [******]), magnesium oxide (manufactured in Country B [******]), anhydrous citric acid (manufactured in Country C [******]), and three inactive ingredients (sourced from Country C and Country D [******]) are sent to China in powder form or in fine particles. The manufacturing process, described in detail to CBP, consists of sieving, wet mixing the sodium picosulfate to form granules, mixing magnesium oxide and citric acid into a granule formulation, product flavoring, and final blending which is stated not to result in a chemical reaction during any of the steps carried out in China. The final product is placed into single dosage packets. Each Prepopik packet contains 10mg sodium picosulfate, 3.5g magnesium oxide, and 12g citric acid. The packets are sent to a third party in the U.S. to be packaged into child-resistant pouches along with the pre-marked, plastic dosing cup.

After importation, once water is added, the magnesium oxide and citric acid combine to form magnesium citrate. The magnesium citrate, is an osmotic laxative that stimulates the

absorption of water into the bowel, while the sodium picosulfate stimulates peristalsis in the bowel to expel its contents.[1]

ISSUE:

What is the country of origin of the Prepopik for purposes of U.S. government procurement and marking?

LAW AND ANALYSIS:

Country of Origin

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).

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 materials. To that end, CBP has generally held that the processing of pharmaceutical products from bulk form into measured doses, filtering and packaging does not result in a substantial transformation. *See* Headquarters Rulings Letter ("HQ") H197582, dated August 9, 2012; HQ H561975, dated April 3, 2002; and HQ H561544, dated May 1, 2000.

In HQ H215656, dated January 11, 2013, a pain reliever medicine called Rybix ODT was imported from France. The active pharmaceutical ingredient ("API") was manufactured in India, which was shipped to France and processed in four stages. In the first stage, the API was de-lumped and granulated with a suspension of inactive ingredients then sieved and sized. In the second stage, several inactive ingredients designed to assist in drug administration were added to

[1] *See* http://www.nlm.nih.gov/medlineplus/ency/article/002282.htm; *see also* *http://www.nlm.nih.gov/medlineplus/druginfo/meds/a613020.html*

the API to make a flavor preblend. In the third stage, the tablets were formed and collected in polyethylene-lined foil bags. In the last stage, the tablets were packaged in child-resistant blister packs and prepared for shipment to the U.S. CBP found that the imported good did not undergo a substantial transformation in France, because the processing in France did not result in a change in the medicinal use of the product and the API retained its chemical and physical properties.

However, in HQ 563207, dated June 1, 2005, Actoplus Met™ was produced in Japan by combining two APIs: pioglitazone HCl (pioglitazone), an insulin sensitizer metformin, a biguanide used to decrease the amount of glucose produced by the liver and make muscle tissue more sensitive to insulin so glucose can be absorbed. The two APIs were mixed together to form a fix combination drug. The decision noted that with the combination of the two APIs, type 2 diabetes patients will receive more medical benefits than taking metformin alone. CBP held that the finished pharmaceutical, Actoplus Met™ had a new name, character and use distinct from the two APIs used in the production of the finished product. It was noted that while pioglitazone and metformin could be prescribed separately, the final product, Actoplus Met™, increased the individual effectiveness of pioglitazone and metformin in treating type 2 diabetes patients. Therefore, a substantial transformation was found to take place in Japan where the two APIs were combined to produce Actoplus Met™.

Ferring states that as imported, the only API present in Prepopik is the sodium picosulfate which retains its chemical and physical properties and is merely put into a dosage form and packaged. Ferring further contends that the processing in China does not result in a change in the medicinal use of the finished product. However, we note that magnesium oxide may be used for different reasons, as an antacid to relieve heartburn, sour stomach, or acid indigestion; or as a laxative for short-term, rapid emptying of the bowel. *See* http://www.nlm.nih.gov/medlineplus/druginfo/meds/a601074.html; *see also* http://pubchem.ncbi.nlm.nih.gov/compound/magnesium_oxide (Magnesium oxide (MgO) is an inorganic compound that occurs in nature as the mineral periclase and in aqueous media combines quickly with water to form magnesium hydroxide. It is used as an antacid and mild laxative and has many nonmedicinal uses). We note that combining magnesium oxide with water results in magnesium hydroxide which is also known for its laxative effect. While the combination with water by the user may cause the "chemical reaction," we note that most medicines are taken with water, so we do not find that the addition of water in this case is what makes the magnesium oxide to function as a laxative. The combination of the magnesium oxide, citric acid and water may form the osmotic effect; however, the fundamental laxative property is already found in the magnesium oxide. Accordingly, we find that as in HQ 563207, the two ingredients (sodium picosulfate and magnesium oxide) contribute to the purpose of Prepopik. As the two ingredients are combined in China, we find that as in HQ 563207 a substantial transformation occurs in China. Individually, the sodium picosulfate and the magnesium oxide may be used to alleviate constipation, and together, when combined to form Prepopik, these ingredients have a more stiumlative effect. Therefore, we find that the country of origin of Prepopik is China.

Marking

Section 304 of the Tariff Act of 1930, as amended (19 U.S.C. § 1304), provides that, unless excepted, every article of foreign origin (or its container) imported into the United States shall be marked in a conspicuous place as legibly, indelibly and permanently as the nature of the article (or its container) will permit, in such a manner as to indicate to the ultimate purchaser in the United States the English name of the country of origin of the article. Congressional intent in enacting 19 U.S.C. § 1304 was "that the ultimate purchaser should be able to know by an inspection of the marking on the imported goods the country of which the goods is the product. The evident purpose is to mark the goods so that at the time of purchase the ultimate purchaser may, by knowing where the goods were produced, be able to buy or refuse to buy them, if such marking should influence his will." *United States v. Friedlaender & Co*., 27 CCPA 297, 302, C.A.D. 104 (1940). Part 134, CBP Regulations (19 C.F.R. § 134) implements the country of origin marking requirements and exceptions of 19 U.S.C. § 1304.

Section 134.1(b), CBP Regulations (19 C.F.R. § 134.1(b)), defines "country of origin" as:

> the country of manufacture, production or growth of any article of foreign origin entering the United States. Further work or material added to an article in another country must effect a substantial transformation in order to render such other country the "country of origin" within the meaning of this part;...

The country of origin of an article for U.S. tariff purposes is the country in which the last substantial transformation took place. A substantial transformation occurs when an article is used in a manufacturing process or operation that results in a new article that has a new name, character or use different from that of the original imported article. 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 Hand Tool Corp. v. United States*, 989 F.2d 1201 (Fed. Cir. 1992).

In the instant case, Ferring mixes all the ingredients by blending, sieving, and mixing. We find that this processing results in a substantial transformation. The combination of the two ingredients results in a more stimulative laxative effect for purposes of cleansing the bowels. Therefore, we find that the country of origin of Prepopik is China for country of origin marking purposes.

HOLDING:

Based on the facts in this case, we find that the imported Prepopik is substantially transformed in China. The country of origin for government procurement and marking purposes is China.

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,

Glen E. Vereb, Acting Executive Director,
Regulations and Rulings,
Office of International Trade.

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