DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determination Concerning

Acyclovir 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 certain Acyclovir tablets. Based upon the facts presented, CBP has concluded that the country of origin of the Acyclovir Tablets is China and India for purposes of U.S. Government procurement.

DATES: The final determination was issued on November 5, 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 no later than [insert 30 days from date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Robert Dinerstein, Valuation and Special Programs Branch, Regulations and Rulings, Office of International Trade (202) 325-0132.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on November 5, 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 Acyclovir Tablets, which may be offered to the U.S. Government under an undesignated government procurement contract. This final

determination, HQ267177, 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 the United States does not result in a substantial transformation. Therefore, the country of origin of the Acyclovir tablets is China and India 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: November 5, 2015.

Myles B. Harmon,
Acting Executive Director,
Regulations and Rulings,
Office of International Trade.

HQ H267177

November 5, 2015

MAR-2 OT:RR:CTF:VS H267177 RSD

CATEGORY: ORIGIN

Ms. Karen Yu
Regulatory Affairs
Carlsbad Technology Inc.
5923 Balfour Court
Carlsbad, California 92008

RE: U.S. Government procurement; Trade Agreements Act; Country of Origin of Acyclovir Tablets; Substantial Transformation

Dear Ms. Yu:

This is in response to your ruling request dated July 7, 2015, requesting a final determination on behalf of Carlsbad Technology Inc., (Carlsbad) 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 Acyclovir Tablets. As a U.S. manufacturer of a like product, Carlsbad 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:

Acyclovir is a pharmaceutical product used as a synthetic nucleoside analogue active against herpes viruses. The active pharmaceutical ingredient ("API"), Acyclovir is manufactured in China and India. The API is shipped to the U.S., where it undergoes five manufacturing steps. Inactive ingredient (excipients) used in the production of the product in the U.S. are corn starch, microcrystalline cellulose, magnesium stearate, and sodium starch glycolate.

The first stage of U.S. manufacturing is the sizing of the active and inactive ingredients including the corn starch glycolate, by passing them through a sieve to remove any larger granules.

The second stage of U.S. manufacturing is the preparation of Acyclovir granules. The Acyclovir API, corn starch, and sodium starch glycolate are de-lumped and granulated with a binding suspension of corn starch. The wet granules are then sieved through a comil and discharged into stainless steel drums. These granules are then moved to a tray dryer for a drying process for 10 to 18 hours or until it meets its dryness specification. The dried granules will then be sieved through a comil again and discharged into stainless steel drums. The third stage of U.S. manufacturing is the preparation of the tablet blend. The inactive ingredients, microcrystalline cellulose and sodium starch glycolated are de-lumped by passing them through a sieve and added to the de-lumped acyclovir granules for preblend. Then the magnesium stearate is sieved and added to the final blend. All the blended product is discharged into stainless steel drums. The fourth stage of U.S. manufacturing is tablet compression. The blended granules are then fed to a tablet press machine where the tablets are formed. The bulk tablets are collected into plastic bags, which are sealed and packaged in containers.

The fifth stage of U.S. manufacturing is packaging in high density polyethylene plastic bottles. These bottles are then put into cartons for distribution in the U.S.

ISSUE:

What is the country of origin of the Acyclovir tablets processed as described above for purposes U.S. Government procurement?

LAW AND ANALYSIS:

Pursuant to Subpart B of Part 177, 19 C.F.R. 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 C.F.R. § 177.22(a).

In rendering advisory rulings and final determinations for purposes of U.S. government procurement, CBP applies the provisions of subpart B of part 177 consistent with the Federal Acquisition Regulations. *See* 19 C.F.R. § 177.21. In this regard, CBP recognizes that the Federal Acquisition Regulations restrict the U.S. Government's purchase of products to U.S.-made or designated country end products for acquisitions subject to the TAA. *See* 48 C.F.R. § 25.403(c)(1). The Federal Acquisition Regulations define "U.S.-made end product" as:

> …an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States 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 transformed.

48 C.F.R. § 25.003

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. It was found that the process in the United States did not substantially transform the imported product because the product was referred to as acetaminophen before importation and after U.S. processing, its use was 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 HQ H233356 dated December 26, 2012, mefenamic acid imported from India was blended with excipients and packaged into dosage form in the United States. Based on prior rulings, we found that the specific processing consisting of blending the active ingredients with inactive ingredients in a tumbler and then encapsulating and packaging the product did not substantially transform the mefenamic acid because its chemical character remained the same. As such, we found that the country of origin of

the Ponstel (mefenamic acid) capsules was India, where the mefanamic acid was manufactured.

In this case, the processing performed in the U.S. does not result in a change in the medicinal use of the finished product and the active ingredient. The Acyclovir retains its chemical and physical properties and is merely put into a dosage form and is packaged for sale. The active ingredient does not undergo a change in name, character or use. Therefore, in accordance with our prior rulings, we find that no substantial transformation occurs in U.S., and for purposes of government procurement, the Acyclovir tablets would be considered a product where the active ingredient was produced, which would be China and India.

HOLDING:

Based upon the facts in this case, we find that the imported Acyclovir is not substantially transformed in U.S. Accordingly, the country of origin for government procurement purposes of the Acyclovir tablets is China and India, where the active ingredient is produced.

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 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,

Myles B. Harmon, Acting Executive Director
Office of Regulations and Rulings
Office of International Trade

[FR Doc. 2015-28827 Filed: 11/12/2015 8:45 am; Publication Date: 11/13/2015]