DEPARTMENT OF HOMELAND SECURITY

U.S. CUSTOMS AND BORDER PROTECTION

NOTICE OF ISSUANCE OF FINAL DETERMINATIONS CONCERNING CERTAIN PHARMACEUTICAL PRODUCTS

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

ACTION: Notice of final determinations.

SUMMARY: This document provides notice that U.S. Customs and Border Protection ("CBP") has issued 11 final determinations concerning the country of origin of certain pharmaceutical products. Based upon the facts presented, CBP has concluded that the country of origin of the Rosuvastatin Calcium Tablets, Levofloxacin Tablets, Levetiracetam Tablets, Metoprolol Tartrate Tablets, Gabapentin Capsules, Carvedilol Tablets, Paroxetine Hydrochloride Tablets, Entecavir Tablets, Montelukast Sodium Tablets, Simvastatin Tablets, Donepezil Hydrochloride Tablets is India for purposes of U.S. Government procurement.

DATES: These final determinations were issued on January 30, 2018. Copies of the final determinations are attached. Any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of these final determinations within [insert 30 days from date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Elif Eroglu, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade, (202) 325-0277.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on January 30, 2018 CBP issued 11 final determinations concerning the country of origin of certain pharmaceutical products, which may be offered to the U.S. Government under an undesignated government procurement contract pursuant to subpart B of Part 177, CBP Regulations (19 CFR part 177,

subpart B). These final determinations (H289700, H289701, H289702, H289704, H289706, H289710, H289711, H289712, H289713, H289714, and H289715), were 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 determinations, CBP concluded that the processing in the United States does not result in a substantial transformation. Therefore, the country of origin for purposes of U.S. Government procurement of the pharmaceutical products is India, the country where the active pharmaceutical ingredient was produced.

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: January 30, 2018

Alice A. Kipel
Executive Director
Regulations and Rulings
Office of Trade

HQ H289700

January 30, 2018

OT:RR:CTF:VS H289700 EE

CATEGORY: Origin

Stephen E. Ruscus
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, NW
Washington, DC 20004

RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Rosuvastatin Calcium tablets

Dear Mr. Ruscus:

This is in response to your correspondence of July 7, 2017, requesting a final determination on behalf of Acetris Health, ("Acetris")[1], pursuant to subpart B of Part 177, U.S. Customs and Border Protection ("CBP") Regulations (19 C.F.R. § 177.21 *et seq*.). A meeting was held with the counsel for Acetris on August 8, 2017.

This final determination concerns the country of origin of the Rosuvastatin Calcium tablets. We note that Acetris 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.

You have asked that certain information submitted in connection with this ruling request be treated as confidential. Inasmuch as this request conforms to the requirements of 19 C.F.R. § 177.2(b)(7), the request for confidentiality is approved. The information contained within brackets in your request will not be released to the public and will be withheld from published versions of this ruling.

FACTS:

The merchandise at issue are Rosuvastatin Calcium tablets. You state that Acetris is a generic pharmaceutical distributor specializing in providing cost effective products to the U.S. Government. Acetris has its principal place of business in Allendale, NJ. Among the products Acetris sells to the U.S. Government are Rosuvastatin Calcium tablets, members of a family of statin drugs prescribed for the reduction of cholesterol and triglyceride levels and prevention of heart attacks and strokes.

You state that Acetris procures the Rosuvastatin Calcium tablets from Aurolife Pharma LLC ("Aurolife"), located in Dayton, NJ. Aurolife, which is a wholly-owned subsidiary of company X in India, is a generic pharmaceutical product manufacturer in the specialty and niche

[1] Counsel for Acetris states that on May 19, 2017, Acetris executed a novation with Lucid Pharma LLC and the Department of Veterans Affairs whereby the VA recognized Acetris as the successor in interest to Department of Veterans Affairs Contract No. VA 797P-16-C-0034, the subject contract of the underlying request.

areas. Aurolife manufactures the Rosuvastatin Calcium tablets supplied to Acetris in a U.S. Food & Drug Administration ("FDA") approved cGMP compliant manufacturing facility, located in Dayton, NJ, from several active and inactive ingredients procured domestically and abroad. The active pharmaceutical ingredient ("API") of the Rosuvastatin Calcium tablets is Rosuvastatin Calcium, which Aurolife sources from company X in India.

You state that the Rosuvastatin Calcium tablets supplied to Acetris are the result of a complex production process that occurs in Aurolife's New Jersey facility involving the combination of the API with several inactive ingredients, including some intermediates that are mixed in order to aid the conversion of the multiple ingredients. The production of Rosuvastatin employs processes that convert these ingredients into finished, medically effective dosage tablets (5 mg, 10 mg, 20 mg, and 40 mg tablets). You state that this processing changes the properties and characteristics of the API, materially enhancing the pharmacokinetics of the resulting drug.

You state that the process of converting these multiple ingredients into the Rosuvastatin Calcium tablets occurs entirely within the United States. The ingredients processed in the United States are sourced from a variety of suppliers, both United States and foreign, as follows:

Material	**Country**
Rosuvastatin Calcium	India
Lactose Monohydrate (Super Tab 30GR) USP-NF	Country A
Dibasic Calcium Phosphate, Anhydrous USP (Fujicalin SG)	Country B
Microcrystalline Cellulose USNF (Avicel PH-102)/ Microcrystalline Cellulose USNF (Pharmel 102)	United States/ Country C
Crospovidone USNF (Polyplasdone XL-10)	United States
Magnesium Stearate NF Hyqual Veg Source #2257	United States
Opadry II Pink 31K84972	United States

The processing that occurs in the United States includes the following:

- Microcrystalline cellulose, lactose monohydrate, and dibasic calcium phosphate anhydrous are added to the Rosuvastatin Calcium API as adjuvant to improve the bioavailability/absorption, leading to pharmacokinetic profiles equivalent to the brand product (Crestor®) for therapeutic equivalency. These four excipients are blended according to a set protocol and blending times to ensure proper mixing. Dibasic Calcium Phosphate anhydrous is a key ingredient, addition of which results in a drug product with a higher pH than the API, preventing the instability, variable potency and formation of hazardous degradation byproducts that otherwise are present in the API, significantly enhancing the stability of the finished product.

- Magnesium stearate is added to create a hydrophobic environment around particles which provides a lubrication effect during the production process. Lubricant mixing is carefully done to ensure that the drug releasing profile and pharmacokinetics are not influenced by this hydrophobic environment.

- Finally, different coloring agents and film coating are added to give each strength a distinct name and character. Film coating is performed using polymers which imparts a protective barrier for each strength of the drug and to mask the taste.

You submitted product labels for the Rosuvastatin Calcium tablets. You also submitted a shipping label and the Materials Safety Data Sheet ("MSDS") for the API, Rosuvastatin Calcium. Additionally, you provided a manufacturing flow chart depicting the various steps which occur in the United States to make the final Rosuvastatin Calcium tablets.

ISSUE:

What is the country of origin of the Rosuvastatin Calcium tablets for purposes of U.S. Government procurement?

LAW AND ANALYSIS:

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, 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.*).

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 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 or 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, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

In HQ H240193, dated July 29, 2013, which concerned the country of origin marking of the brand-name Crestor® (Rosuvastatin Calcium salt) tablets, CBP found that the API imported from two different countries was not substantially transformed when combined with stabilizers and excipients, and manufactured into tablet form in the United States.

HQ H267177, dated November 5, 2015, concerned Acyclovir, a pharmaceutical product used as a synthetic nucleoside analogue active against herpes viruses. The API was manufactured in China and India and shipped to the United States where it underwent five manufacturing steps including the sizing of the active and inactive ingredients, preparation of Acyclovir granules, preparation of the tablet blend, tablet compression, and packaging in high density polyethylene plastic bottles. CBP determined that the processing performed in the United States did not result in a change in the medicinal use of the finished product and the active ingredient. The active ingredient retained its chemical and physical properties and was merely put into dosage form and packaged for sale. The active ingredient did not undergo a change in name, character or use. Therefore, CBP held that no substantial transformation occurred in United States, and Acyclovir tablets were considered a product of the country in which the active ingredient was produced.

HQ H215656, dated January 11, 2013, concerned the country of origin of Rybix ODT, a pharmaceutical product used for the management of moderate to moderately severe pain in adults. The API, tramadol hydrochloride, manufactured in India, was shipped to France where it underwent four processes of manufacturing consisting of the preparation of the API, preparation of the tablet blend, tablet compression, and packaging in blister packs. CBP determined that the processing in France did not result in a change in the medicinal use of the finished product, and the API retained its chemical and physical properties and was merely put into dosage form and packaged. Accordingly, CBP held that no substantial transformation occurred in France.

HQ H233356, dated December 26, 2012, concerned the country of origin of Ponstel, a pharmaceutical product used for the relief of mild to moderate pain caused by primary

dysmenorrhea. Mefenamic acid, which is the API in Ponstel, was manufactured in India, and imported into the United States, where it was blended with inactive ingredients and packaged into dosage form. CBP determined that this process did not substantially transform the mefenamic acid because its chemical character remained the same and, therefore, CBP found that the country of origin of the Ponstel capsules was India.

You state that the FDA requires that a unique National Drug Code ("NDC") be assigned to every drug product such as Rosuvastatin Calcium tablets, but prohibits that same NDC from being associated with any API, such as Rosuvastatin Calcium, that has not been demonstrated to be safe and effective and cannot be sold for the treatment of any human disease condition. You also state that the FDA requires the name of the drug product (Rosuvastatin Calcium tablet) to appear on every drug product label and prohibits use of that name on the label for the API. Further, you state that Rosuvastatin Calcium is intended only for use by producers for further processing or for research since it is unstable and not fit for medical use and may not be sold to consumers. Additionally, you state that Rosuvastatin Calcium degrades so as to both reduce potency and create hazardous byproducts. For these reasons, you claim that extensive additional processing of the API, sourced in India, with other ingredients must occur to change the API's properties and make it into a stable drug with established potency, that meets all requirements for levels of impurity, including those produced as harmful degradation byproducts, and can be safely administered for the treatment of a human disease or condition.

This office consulted with CBP's Laboratories and Scientific Services Directorate concerning the instant case, which informed us that the imported API, Rosuvastatin Calcium, retains its chemical and physical properties upon processing in the United States. Increasing the stability of the API and standardizing its concentration do not change the API. Further, the processing performed in the United States does not affect the medicinal use of the API. Based on the information presented, the API does not undergo a change in name, character or use. Therefore, in accordance with the rulings cited, we find that no substantial transformation occurs in United States, and the Rosuvastatin Calcium tablets would be considered a product of India, where the API was produced, for purposes of U.S. government procurement.

In addition, you asked whether the Rosuvastatin Calcium tablets are "manufactured in the United States" within the meaning of the term "U.S.-made end products", as set forth in Section 25.003 of the Federal Acquisition Regulations System, Title 48, Code of Federal Regulations (48 C.F.R. § 25.003), and implemented in 48 C.F.R. § 52.225-5. As stated in 19 C.F.R. § 177.21, subpart B is intended to be applied consistent with the Federal Acquisition Regulations (48 C.F.R. chapter 1). The definition of country of origin in subpart B, 19 C.F.R. § 177.22(a) has two rules (see above) as does 48 C.F.R. § 25.003. The term "manufactured in the United States" in 48 C.F.R. § 25.003 correlates to the first rule of 19 C.F.R. § 177.22(a) which provides that an article is a product of a country or instrumentality if "it is wholly the growth, product, or manufacture of that country or instrumentality". Since the production of Rosuvastatin Calcium tablets partially occurs in India, we do not find that they are manufactured in the United States.

HOLDING:

The country of origin of the Rosuvastatin Calcium tablets for U.S. 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 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 after publication of the *Federal Register* notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel
Executive Director
Regulations and Rulings
Office of Trade

HQ H289701

January 30, 2018

OT:RR:CTF:VS H289701 EE

CATEGORY: Origin

Stephen E. Ruscus
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, NW
Washington, DC 20004

RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Levofloxacin tablets

Dear Mr. Ruscus:

This is in response to your correspondence of July 7, 2017 and supplemental submission of August 7, 2017, requesting a final determination on behalf of Acetris Health, ("Acetris")[2], pursuant to subpart B of Part 177, U.S. Customs and Border

[2] Counsel for Acetris states that on May 19, 2017, Acetris executed a novation with Lucid Pharma LLC and the Department of Veterans Affairs whereby the VA recognized Acetris as the successor in interest to

Protection ("CBP") Regulations (19 C.F.R. § 177.21 *et seq*.). A meeting was held with the counsel for Acetris on August 8, 2017.

This final determination concerns the country of origin of the Levofloxacin tablets. We note that Acetris 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.

You have asked that certain information submitted in connection with this ruling request be treated as confidential. Inasmuch as this request conforms to the requirements of 19 C.F.R. § 177.2(b)(7), the request for confidentiality is approved. The information contained within brackets in your request will not be released to the public and will be withheld from published versions of this ruling.

FACTS:

The merchandise at issue are Levofloxacin tablets. You state that Acetris is a generic pharmaceutical distributor specializing in providing cost effective products to the U.S. Government. Acetris has its principal place of business in Allendale, NJ. Among the products Acetris sells to the U.S. Government are Levofloxacin tablets, which are a fluoroquinolone antibacterial used to treat mild, moderate, and severe infections.

You state that Acetris procures the Levofloxacin tablets from Aurolife Pharma LLC ("Aurolife"), located in Dayton, NJ. Aurolife, which is a wholly-owned subsidiary of company X in India, is a generic pharmaceutical product manufacturer in the specialty and niche areas. Aurolife manufactures the Levofloxacin tablets supplied to Acetris in a U.S. Food & Drug Administration ("FDA") approved cGMP compliant manufacturing facility, located in Dayton, NJ, from several active and inactive ingredients procured domestically and abroad. The active pharmaceutical ingredient ("API") of the Levofloxacin tablets is Levofloxacin, which Aurolife sources from company X in India.

You state that the Levofloxacin tablets supplied to Acetris are the result of a complex production process that occurs in Aurolife's New Jersey facility involving the combination of the API with multiple inactive ingredients, including some intermediates that are mixed in order to aid the conversion of the multiple ingredients. The production of Levofloxacin tablets employs processes that convert these ingredients into finished, medically effective dosage tablets (250 mg, 500 mg, and 750 mg tablets). You state that this processing changes the properties and characteristics of the API, materially enhancing the pharmacokinetics of the resulting drug.

You state that the process of converting these multiple ingredients into the Levofloxacin tablets occurs entirely within the United States. The ingredients processed in the United States are sourced from a variety of suppliers, both United States and foreign, as follows:

Material	**Country**

Department of Veterans Affairs Contract No. VA 797P-16-C-0034, the subject contract of the underlying request.

Levofloxacin USP	India
Croscarmellose Sodium USNF	USA
Microcrystalline Cellulose USNF (Avicel PH 101)	USA
Hypromellose USP	USA
Magnesium Stearate USNF	USA
Opadry White 13B58802 IH	USA
Opadry Orange 13B53926 IH	USA
Opadry Pink 13B84503 IH	USA

The processing that occurs in the United States includes the following:

- Croscarmellose sodium is added as a disintegrant to provide easy dispersion of the tablet when engulfed by the patient which indirectly enhances the drug release process and bioavailability/absorption leading to pharmacokinetic profiles equivalent to the brand product (Levaquin®) for therapeutic equivalency.

- Microcrystalline cellulose is added as a bulking agent for better manufacturability and to have suitable tablet weight so that the patient can easily take the medication.
- Hypromellose is added as a binder to aid formation of flowable granules during manufacturing thereby achieving the uniformity of the drug leading to therapeutic efficacy.

- Magnesium stearate is added to create a hydrophobic environment around particles which provides a lubrication effect during the production process. Lubricant mixing is carefully done to ensure that the drug releasing profile and pharmacokinetics are not influenced by this hydrophobic environment.

- Film coating is performed using polymers which imparts a protective barrier for the drug and to mask the taste.

- Finally, the tablets are packed into suitable containers which are capable of maintaining the overall integrity of the quality attributes and minimizing the formation of impurities thereby transforming it into a more stable drug product whose therapeutic effectiveness as a drug is sustainable.

You submitted product labels for the Levofloxacin tablets. You also submitted a shipping label and the Materials Safety Data Sheet ("MSDS") for the API, Levofloxacin. Additionally, you provided a manufacturing flow chart depicting the various steps which occur in the United States to make the final Levofloxacin tablets.

ISSUE:

What is the country of origin of the Levofloxacin tablets for purposes of U.S. Government procurement?

LAW AND ANALYSIS:

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, 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.*).

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 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 or 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, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

In HQ H240193, dated July 29, 2013, which concerned the country of origin marking of the brand-name Crestor® (Rosuvastatin Calcium salt) tablets, CBP found that the API imported from two different countries was not substantially transformed when combined with stabilizers and excipients, and manufactured into tablet form in the United States.

HQ H267177, dated November 5, 2015, concerned Acyclovir, a pharmaceutical product used as a synthetic nucleoside analogue active against herpes viruses. The API was manufactured in China and India and shipped to the United States where it underwent five manufacturing steps including the sizing of the active and inactive ingredients, preparation of Acyclovir granules, preparation of the tablet blend, tablet compression, and packaging in high density polyethylene plastic bottles. CBP determined that the processing performed in the United States did not result in a change in the medicinal use of the finished product and the active ingredient. The active ingredient retained its chemical and physical properties and was merely put into dosage form and packaged for sale. The active ingredient did not undergo a change in name, character or use. Therefore, CBP held that no substantial transformation occurred in United States, and Acyclovir tablets were considered a product of the country in which the active ingredient was produced.

HQ H215656, dated January 11, 2013, concerned the country of origin of Rybix ODT, a pharmaceutical product used for the management of moderate to moderately severe pain in adults. The API, tramadol hydrochloride, manufactured in India, was shipped to France where it underwent four processes of manufacturing consisting of the preparation of the API, preparation of the tablet blend, tablet compression, and packaging in blister packs. CBP determined that the processing in France did not result in a change in the medicinal use of the finished product, and the API retained its chemical and physical properties and was merely put into dosage form and packaged. Accordingly, CBP held that no substantial transformation occurred in France.

HQ H233356, dated December 26, 2012, concerned the country of origin of Ponstel, a pharmaceutical product used for the relief of mild to moderate pain caused by primary dysmenorrhea. Mefenamic acid, which is the API in Ponstel, was manufactured in India, and imported into the United States, where it was blended with inactive ingredients and packaged into dosage form. CBP determined that this process did not substantially transform the mefenamic acid because its chemical character remained the same and, therefore, CBP found that the country of origin of the Ponstel capsules was India.

You state that the FDA requires that a unique National Drug Code ("NDC") be assigned to every drug product such as Levofloxacin tablets, but prohibits that same NDC from being associated with any API, such as Levofloxacin, that has not been demonstrated to be safe and effective and cannot be sold for the treatment of any human disease condition. You also state that the FDA requires the name of the drug product (Levofloxacin tablet) to appear on every drug product label and prohibits use of that name on the label for the API. Further, you state that Levofloxacin is intended only for use by producers for further processing or for research since it is unstable and not fit for medical use and may not be sold to consumers. Additionally, you state that Levofloxacin exhibits poor flow properties, undergoes oxidative degradation, and has a bitter taste. For these reasons, you claim that extensive additional processing of the API, sourced in India, with other ingredients must occur to change the API's properties and make it into a stable drug whose medical effectiveness as a drug is sustainable.

This office consulted with CBP's Laboratories and Scientific Services Directorate concerning the instant case, which informed us that the imported API, Levofloxacin, retains its chemical and physical properties upon processing in the United States. Increasing the stability of the API and standardizing its concentration do not change the API. Further, the processing performed in the United States does not affect the medicinal use of the API. Based on the information presented, the API does not undergo a change in name, character or use. Therefore, in accordance with the rulings cited, we find that no substantial transformation occurs in United States, and the Levofloxacin tablets would be considered a product of India, where the API was produced, for purposes of U.S. government procurement.

In addition, you asked whether the Levofloxacin tablets are "manufactured in the United States" within the meaning of the term "U.S.-made end products", as set forth in Section 25.003 of the Federal Acquisition Regulations System, Title 48, Code of Federal Regulations (48 C.F.R. § 25.003), and implemented in 48 C.F.R. § 52.225-5. As stated in 19 C.F.R. § 177.21, subpart B is intended to be applied consistent with the Federal Acquisition Regulations (48 C.F.R. chapter 1). The definition of country of origin in subpart B, 19 C.F.R. § 177.22(a) has two rules (see above) as does 48 C.F.R. § 25.003. The term "manufactured in the United States" in 48 C.F.R. § 25.003 correlates to the first rule of 19 C.F.R. § 177.22(a) which provides that an article is a product of a country or instrumentality if "it is wholly the growth, product, or manufacture of that country or instrumentality". Since the production of Levofloxacin tablets partially occurs in India, we do not find that they are manufactured in the United States.

HOLDING:

The country of origin of the Levofloxacin tablets for U.S. 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 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 after publication of the *Federal Register* notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel
Executive Director
Regulations and Rulings
Office of Trade

HQ H289702

January 30, 2018

OT:RR:CTF:VS H289702 EE

CATEGORY: Origin

Stephen E. Ruscus
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, NW
Washington, DC 20004

RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Levetiracetam tablets

Dear Mr. Ruscus:

This is in response to your correspondence of July 7, 2017 and supplemental submission of August 7, 2017, requesting a final determination on behalf of Acetris Health, ("Acetris")[3], pursuant to subpart B of Part 177, U.S. Customs and Border Protection ("CBP") Regulations (19 C.F.R. § 177.21 *et seq*.). A meeting was held with the counsel for Acetris on August 8, 2017.

[3] Counsel for Acetris states that on May 19, 2017, Acetris executed a novation with Lucid Pharma LLC and the Department of Veterans Affairs whereby the VA recognized Acetris as the successor in interest to Department of Veterans Affairs Contract No. VA 797P-16-C-0034, the subject contract of the underlying request.

This final determination concerns the country of origin of the Levetiracetam tablets. We note that Acetris 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.

You have asked that certain information submitted in connection with this ruling request be treated as confidential. Inasmuch as this request conforms to the requirements of 19 C.F.R. § 177.2(b)(7), the request for confidentiality is approved. The information contained within brackets in your request will not be released to the public and will be withheld from published versions of this ruling.

FACTS:

The merchandise at issue are Levetiracetam tablets. You state that Acetris is a generic pharmaceutical distributor specializing in providing cost effective products to the U.S. Government. Acetris has its principal place of business in Allendale, NJ. Among the products Acetris sells to the U.S. Government are Levetiracetam tablets which are anti-epileptic medications indicated in treatment of partial onset seizures, myoclonic seizures in patients with juvenile myoclonic epilepsy, and primary generalized tonic-clonic seizures.

You state that Acetris procures the Levetiracetam tablets from Aurolife Pharma LLC ("Aurolife"), located in Dayton, NJ. Aurolife, which is a wholly-owned subsidiary of company X in India, is a generic pharmaceutical product manufacturer in the specialty and niche areas. Aurolife manufactures the Levetiracetam tablets supplied to Acetris in a U.S. Food & Drug Administration ("FDA") approved cGMP compliant manufacturing facility, located in Dayton, NJ, from several active and inactive ingredients procured domestically and abroad. The active pharmaceutical ingredient ("API") of the Levetiracetam tablets is Levetiracetam, which Aurolife sources from company X in India.

You state that the Levetiracetam tablets supplied to Acetris are the result of a complex production process that occurs in Aurolife's New Jersey facility involving the combination of the API with multiple inactive ingredients, including some intermediates that are mixed in order to aid the conversion of the multiple ingredients. The production of Levetiracetam tablets employs processes that convert these ingredients into finished, medically effective dosage tablets (250 mg, 500 mg, 750 mg, and 1000 mg tablets). You state that this processing changes the properties and characteristics of the API, materially enhancing the pharmacokinetics of the resulting drug.

You state that the process of converting these multiple ingredients into the Levetiracetam tablets occurs entirely within the United States. The ingredients processed in the United States are sourced from a variety of suppliers, both United States and foreign, as follows:

Material	**Country**
Levetiracetam USP	India
Corn Starch USNF (Maize Starch B)	Country A

Povidone USP (Kollidon 30)	USA
Colloidal Silicon Dioxide USNF	USA
Talc USP	USA
Magnesium Stearate USNF	USA
Opadry Blue OY-S-30913	USA
Opadry Yellow 05F82840	USA
Opadry Orange OY-S-33016	USA
Opadry White Y-1-7000	USA

The processing that occurs in the United States includes the following:

- Corn starch is added as a bulking agent for better manufacturability and to have a suitable tablet weight so that the patient can easily take the medication. Corn starch is mixed with the API, enhancing that the compressibility of the API, so that the product can be easily administered.

- Povidone is added as a binder to aid formation of flowable granules during manufacturing, thereby achieving the uniformity of the drug leading to therapeutic efficacy.

- Talc and Colloidal silicon dioxide are added to create a gliding property in the blend particles and to provide a lubrication effect during the manufacturing process.

- Magnesium stearate is added to create a hydrophobic environment around particles which provides a lubrication effect during the production process. Lubricant mixing is carefully done to ensure that the drug releasing profile and pharmacokinetics are not influenced by this hydrophobic environment.

- Coloring agents and film coating are added to give each tablet strength a distinct name and character. Film coating is performed, using polymers, which imparts a protective barrier to each strength of the drug and to mask the taste.

- Finally, the tablets are packed into suitable containers which maintain the overall integrity of the quality attributes, thereby producing a more stable drug product whose therapeutic effectiveness is sustainable.

You submitted product labels for the Levetiracetam tablets. You also submitted a shipping label and the Materials Safety Data Sheet ("MSDS") for the API, Levetiracetam. Additionally, you provided a manufacturing flow chart depicting the various steps which occur in the United States to make final Levetiracetam tablets.

ISSUE:

What is the country of origin of the Levetiracetam tablets for purposes of U.S. Government procurement?

LAW AND ANALYSIS:

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, 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.*).

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 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 or 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, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

In HQ H240193, dated July 29, 2013, which concerned the country of origin marking of the brand-name Crestor® (Rosuvastatin Calcium salt) tablets, CBP found that the API imported from two different countries was not substantially transformed when combined with stabilizers and excipients, and manufactured into tablet form in the United States.

HQ H267177, dated November 5, 2015, concerned Acyclovir, a pharmaceutical product used as a synthetic nucleoside analogue active against herpes viruses. The API was manufactured in China and India and shipped to the United States where it underwent five manufacturing steps including the sizing of the active and inactive ingredients, preparation of Acyclovir granules, preparation of the tablet blend, tablet compression, and packaging in high density polyethylene plastic bottles. CBP determined that the processing performed in the United States did not result in a change in the medicinal use of the finished product and the active ingredient. The active ingredient retained its chemical and physical properties and was merely put into dosage form and packaged for sale. The active ingredient did not undergo a change in name, character or use. Therefore, CBP held that no substantial transformation occurred in United States, and Acyclovir tablets were considered a product of the country in which the active ingredient was produced.

HQ H215656, dated January 11, 2013, concerned the country of origin of Rybix ODT, a pharmaceutical product used for the management of moderate to moderately severe pain in adults. The API, tramadol hydrochloride, manufactured in India, was shipped to France where it underwent four processes of manufacturing consisting of the preparation of the API, preparation of the tablet blend, tablet compression, and packaging in blister packs. CBP determined that the processing in France did not result in a change in the medicinal use of the finished product, and the API retained its chemical and physical properties and was merely put into dosage form and packaged. Accordingly, CBP held that no substantial transformation occurred in France.

HQ H233356, dated December 26, 2012, concerned the country of origin of Ponstel, a pharmaceutical product used for the relief of mild to moderate pain caused by primary dysmenorrhea. Mefenamic acid, which is the API in Ponstel, was manufactured in India, and imported into the United States, where it was blended with inactive ingredients and packaged into dosage form. CBP determined that this process did not substantially transform the mefenamic acid because its chemical character remained the same and, therefore, CBP found that the country of origin of the Ponstel capsules was India.

You state that the FDA requires that a unique National Drug Code ("NDC") be assigned to every drug product such as Levetiracetam tablets, but prohibits that same NDC from being associated with any API, such as Levetiracetam, that has not been demonstrated to be safe and effective and cannot be sold for the treatment of any human disease condition. You also state that the FDA requires the name of the drug product (Levetiracetam tablet) to appear on every drug product label and prohibits use of that name on the label for the API. Further, you state that API is intended only for use by producers for further processing or for research since it is unstable and not fit for medical use and may not be sold to consumers. Additionally, you state that the API has a bitter taste and poor compressibility properties. For these reasons, you claim that extensive additional processing of the API, sourced in India, with other ingredients must occur to change the API's properties and make it into a stable drug product that achieves the targeted disintegration and dissolution, is more suitable and stable, and possesses the desired physicochemical properties.

This office consulted with CBP's Laboratories and Scientific Services Directorate concerning the instant case, which informed us that the imported API, Levetiracetam, retains its chemical and physical properties upon processing in the United States. Increasing the stability of the API and standardizing its concentration do not change the API. Further, the processing performed in the United States does not affect the medicinal use of the API. Based on the information presented, the API does not undergo a change in name, character or use. Therefore, in accordance with the rulings cited, we find that no substantial transformation occurs in United States, and the Levetiracetam tablets would be considered a product of India, where the API was produced, for purposes of U.S. government procurement.

In addition, you asked whether the Levetiracetam tablets are "manufactured in the United States" within the meaning of the term "U.S.-made end products", as set forth in Section 25.003 of the Federal Acquisition Regulations System, Title 48, Code of Federal Regulations (48 C.F.R. § 25.003), and implemented in 48 C.F.R. § 52.225-5. As stated in 19 C.F.R. § 177.21, subpart B is intended to be applied consistent with the Federal Acquisition Regulations (48 C.F.R. chapter 1). The definition of country of origin in subpart B, 19 C.F.R. § 177.22(a) has two rules (see above) as does 48 C.F.R. § 25.003. The term "manufactured in the United States" in 48 C.F.R. § 25.003 correlates to the first rule of 19 C.F.R. § 177.22(a) which provides that an article is a product of a country or instrumentality if "it is wholly the growth, product, or manufacture of that country or instrumentality". Since the production of Levetiracetam tablets partially occurs in India, we do not find that they are manufactured in the United States.

HOLDING:

The country of origin of the Levetiracetam tablets for U.S. 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 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 after publication of the *Federal Register* notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel
Executive Director
Regulations and Rulings
Office of Trade

HQ H289704

January 30, 2018

OT:RR:CTF:VS H289704 EE

CATEGORY: Origin

Stephen E. Ruscus
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, NW
Washington, DC 20004

RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Metoprolol Tartrate tablets

Dear Mr. Ruscus:

This is in response to your correspondence of July 7, 2017 and supplemental submission of August 7, 2017, requesting a final determination on behalf of Acetris Health, ("Acetris")[4], pursuant to subpart B of Part 177, U.S. Customs and Border Protection ("CBP") Regulations (19 C.F.R. § 177.21 *et seq*.). A meeting was held with the counsel for Acetris on August 8, 2017.

[4] Counsel for Acetris states that on May 19, 2017, Acetris executed a novation with Lucid Pharma LLC and the Department of Veterans Affairs whereby the VA recognized Acetris as the successor in interest to Department of Veterans Affairs Contract No. VA 797P-16-C-0034, the subject contract of the underlying request.

This final determination concerns the country of origin of the Metoprolol Tartrate tablets. We note that Acetris 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.

You have asked that certain information submitted in connection with this ruling request be treated as confidential. Inasmuch as this request conforms to the requirements of 19 C.F.R. § 177.2(b)(7), the request for confidentiality is approved. The information contained within brackets in your request will not be released to the public and will be withheld from published versions of this ruling.

FACTS:

The merchandise at issue are Metoprolol Tartrate tablets. You state that Acetris is a generic pharmaceutical distributor specializing in providing cost effective products to the U.S. Government. Acetris has its principal place of business in Allendale, NJ. Among the products Acetris sells to the U.S. Government are Metoprolol Tartrate tablets, which are used in the treatment of hypertension, angina pectoris and myocardial infarction.

You state that Acetris procures the Metoprolol Tartrate tablets from Aurolife Pharma LLC ("Aurolife"), located in Dayton, NJ. Aurolife, which is a wholly-owned subsidiary of company X in India, is a generic pharmaceutical product manufacturer in the specialty and niche areas. Aurolife manufactures the Metoprolol Tartrate tablets supplied to Acetris in a U.S. Food & Drug Administration ("FDA") approved cGMP compliant manufacturing facility, located in Dayton, NJ, from several active and inactive ingredients procured domestically and abroad. The active pharmaceutical ingredient ("API") of the Metoprolol Tartrate tablets is Metoprolol Tartrate, which Aurolife sources from company X in India.

You state that the Metoprolol Tartrate tablets supplied to Acetris are the result of a complex production process that occurs in Aurolife's New Jersey facility involving the combination of the API with multiple inactive ingredients, including some intermediates that are mixed in order to aid the conversion of the multiple ingredients. The production of Metoprolol Tartrate tablets employs processes that convert these ingredients into finished, medically effective dosage tablets (25 mg, 50 mg, and 100 mg tablets). You state that this processing changes the properties and characteristics of the API, materially enhancing the pharmacokinetics of the resulting drug.

You state that the process of converting these multiple ingredients into the Metoprolol Tartrate tablets occurs entirely within the United States. The ingredients processed in the United States are sourced from a variety of suppliers, both United States and foreign, as follows:

Material	Country
Metoprolol Tartrate USP	India
Microcrystalline Cellulose USNF	Country A / USA
Corn Starch USNF (Maize Starch B)	Country B
Sodium Starch Glycolate USNF	Country C
Colloidal Silicon Dioxide USNF	USA
Sodium Lauryl Sulfate USNF	Country D
Talc USNF	USA
Magnesium Stearate USNF	USA
Opadry White 13B58867	USA
Opadry Pink 13B54175	USA
Opadry Blue 13B50500	USA

The processing that occurs in the United States includes the following:

- Microcrystalline cellulose and corn starch are added as bulking agents for better manufacturability and to have suitable tablet weight so that the patient can easily take the medication. The API is mixed with these diluents which alters the physical form of the API such that the compressibility of the API is enhanced and the product can be easily administered.

- Sodium starch glycolate is added as a disintegrant to provide easy dispersion of the tablet when ingested by the patient, which indirectly enhances the drug release process and bioavailability/absorption, leading to pharmacokinetic profiles equivalent to the brand product (Lopressor®) for therapeutic equivalency.

- Talc and colloidal silicon dioxide are added to create a gliding property in the blend particles, contributing to the unit-to-unit uniformity of the drug during the manufacturing process.

- Magnesium stearate is added to create a hydrophobic environment around particles which provides a lubrication effect during the production process. Lubricant mixing is carefully done to ensure that the drug releasing profile and pharmacokinetics are not influenced by this hydrophobic environment.

- Sodium Lauryl Sulfate is added as a wetting agent to enhance the solubilization process and bioavailability/absorption, leading to pharmacokinetic profiles equivalent to the brand product for therapeutic equivalency.

- Coloring agents and film coating are added to give each tablet strength a distinct name and character. Film coating is performed using polymers which imparts a protective barrier for each tablet strength and to mask the taste.

- Finally, the tablets are packed into suitable containers which are capable of retaining the overall integrity of the quality attributes and minimizing the formation

of impurity, transforming it into a more stable product whose therapeutic effectiveness as a drug is sustainable.

You submitted product labels for the Metoprolol Tartrate tablets. You also submitted a shipping label and the Materials Safety Data Sheet ("MSDS") for the API, Metoprolol Tartrate. Additionally, you provided a manufacturing flow chart depicting the various steps which occur in the United States to make the final Metoprolol Tartrate tablets.

ISSUE:

What is the country of origin of the Metoprolol Tartrate tablets for purposes of U.S. Government procurement?

LAW AND ANALYSIS:

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, 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.*).

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 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 or 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, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

In HQ H240193, dated July 29, 2013, which concerned the country of origin marking of the brand-name Crestor® (Rosuvastatin Calcium salt) tablets, CBP found that the API imported from two different countries was not substantially transformed when combined with stabilizers and excipients, and manufactured into tablet form in the United States.

HQ H267177, dated November 5, 2015, concerned Acyclovir, a pharmaceutical product used as a synthetic nucleoside analogue active against herpes viruses. The API was manufactured in China and India and shipped to the United States where it underwent five manufacturing steps including the sizing of the active and inactive ingredients, preparation of Acyclovir granules, preparation of the tablet blend, tablet compression, and packaging in high density polyethylene plastic bottles. CBP determined that the processing performed in the United States did not result in a change in the medicinal use of the finished product and the active ingredient. The active ingredient retained its chemical and physical properties and was merely put into dosage form and packaged for sale. The active ingredient did not undergo a change in name, character or use. Therefore, CBP held that no substantial transformation occurred in United States, and Acyclovir tablets were considered a product of the country in which the active ingredient was produced.

HQ H215656, dated January 11, 2013, concerned the country of origin of Rybix ODT, a pharmaceutical product used for the management of moderate to moderately severe pain in adults. The API, tramadol hydrochloride, manufactured in India, was shipped to France where it underwent four processes of manufacturing consisting of the preparation of the API, preparation of the tablet blend, tablet compression, and packaging in blister packs. CBP determined that the processing in France did not result

in a change in the medicinal use of the finished product, and the API retained its chemical and physical properties and was merely put into dosage form and packaged. Accordingly, CBP held that no substantial transformation occurred in France.

HQ H233356, dated December 26, 2012, concerned the country of origin of Ponstel, a pharmaceutical product used for the relief of mild to moderate pain caused by primary dysmenorrhea. Mefenamic acid, which is the API in Ponstel, was manufactured in India, and imported into the United States, where it was blended with inactive ingredients and packaged into dosage form. CBP determined that this process did not substantially transform the mefenamic acid because its chemical character remained the same and, therefore, CBP found that the country of origin of the Ponstel capsules was India.

You state that the FDA requires that a unique National Drug Code ("NDC") be assigned to every drug product such as Metoprolol Tartrate tablets, but prohibits that same NDC from being associated with any API, such as Metoprolol Tartrate, that has not been demonstrated to be safe and effective and cannot be sold for the treatment of any human disease condition. You also state that the FDA requires the name of the drug product (Metoprolol Tartrate tablet) to appear on every drug product label and prohibits use of that name on the label for the API. Further, you state that Metoprolol Tartrate is intended only for use by producers for further processing or for research since it is unstable and not fit for medical use and may not be sold to consumers. Additionally, you state that the Metoprolol Tartrate degrades under hydrolysis and has poor flow properties. For these reasons, you claim that extensive additional processing of the API, sourced in India, with other ingredients must occur to change the API's properties and make it into a stable drug product with the desired pharmacokinetics, therapeutic efficacy and physicochemical properties.

This office consulted with CBP's Laboratories and Scientific Services Directorate concerning the instant case, which informed us that the imported API, Metoprolol Tartrate, retains its chemical and physical properties upon processing in the United States. Increasing the stability of the API and standardizing its concentration do not change the API. Further, the processing performed in the United States does not affect the medicinal use of the API. Based on the information presented, the API does not undergo a change in name, character or use. Therefore, in accordance with the rulings cited, we find that no substantial transformation occurs in United States, and the Metoprolol Tartrate tablets would be considered a product of India, where the API was produced, for purposes of U.S. government procurement.

In addition, you asked whether the Metoprolol Tartrate tablets are "manufactured in the United States" within the meaning of the term "U.S.-made end products", as set forth in Section 25.003 of the Federal Acquisition Regulations System, Title 48, Code of Federal Regulations (48 C.F.R. § 25.003), and implemented in 48 C.F.R. § 52.225-5. As stated in 19 C.F.R. § 177.21, subpart B is intended to be applied consistent with the Federal Acquisition Regulations (48 C.F.R. chapter 1). The definition of country of origin in subpart B, 19 C.F.R. § 177.22(a) has two rules (see above) as does 48 C.F.R.

§ 25.003. The term "manufactured in the United States" in 48 C.F.R. § 25.003 correlates to the first rule of 19 C.F.R. § 177.22(a) which provides that an article is a product of a country or instrumentality if "it is wholly the growth, product, or manufacture of that country or instrumentality". Since the production of Metoprolol Tartrate tablets partially occurs in India, we do not find that they are manufactured in the United States.

HOLDING:

The country of origin of the Metoprolol Tartrate tablets for U.S. 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 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 after publication of the *Federal Register* notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel
Executive Director
Regulations and Rulings
Office of Trade

HQ H289706

January 30, 2018

OT:RR:CTF:VS H289706 EE

CATEGORY: Origin

Stephen E. Ruscus
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, NW
Washington, DC 20004

RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Gabapentin Capsules

Dear Mr. Ruscus:

This is in response to your correspondence of July 7, 2017 and supplemental submission of August 7, 2017, requesting a final determination on behalf of Acetris Health, ("Acetris")[5], pursuant to subpart B of Part 177, U.S. Customs and Border Protection ("CBP") Regulations (19 C.F.R. § 177.21 *et seq*.). A meeting was held with the counsel for Acetris on August 8, 2017.

This final determination concerns the country of origin of the Gabapentin capsules. We note that Acetris 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.

You have asked that certain information submitted in connection with this ruling request be treated as confidential. Inasmuch as this request conforms to the requirements of 19 C.F.R. § 177.2(b)(7), the request for confidentiality is approved. The information contained within brackets in your request will not be released to the public and will be withheld from published versions of this ruling.

FACTS:

The merchandise at issue are Gabapentin capsules. You state that Acetris is a generic pharmaceutical distributor specializing in providing cost effective products to the U.S. Government. Acetris has its principal place of business in Allendale, NJ. Among the products Acetris sells to the U.S. Government are Gabapentin capsules, which are used for the management and/or treatment of postherpetic neuralgia in adults and partial onset seizures.

You state that Acetris procures the Gabapentin capsules from Aurolife Pharma LLC ("Aurolife"), located in Dayton, NJ. Aurolife, which is a wholly-owned subsidiary of company X in India, is a generic pharmaceutical product manufacturer in the specialty and niche areas. Aurolife manufactures the Gabapentin capsules supplied to Acetris in a U.S. Food & Drug Administration ("FDA") approved cGMP compliant manufacturing facility, located in Dayton, NJ, from several active and inactive ingredients procured domestically and abroad. The active pharmaceutical ingredient ("API") of the Gabapentin capsules is Gabapentin, which Aurolife sources from company X in India.

You state that the Gabapentin capsules supplied to Acetris are the result of a complex production process that occurs in Aurolife's New Jersey facility involving the combination of the API with multiple inactive ingredients, including some intermediates that are mixed in order to aid the conversion of the multiple ingredients. The production of Gabapentin capsules employs processes that convert these ingredients into finished, medically effective dosage capsules (100 mg, 300 mg, and 400 mg capsules). You state that this processing changes the properties and characteristics of the API, materially enhancing the pharmacokinetics of the resulting drug.

[5] Counsel for Acetris states that on May 19, 2017, Acetris executed a novation with Lucid Pharma LLC and the Department of Veterans Affairs whereby the VA recognized Acetris as the successor in interest to Department of Veterans Affairs Contract No. VA 797P-16-C-0034, the subject contract of the underlying request.

You state that the process of converting these multiple ingredients into the Gabapentin capsules occurs entirely within the United States. The ingredients processed in the United States are sourced from a variety of suppliers, both United States and foreign, as follows:

Material	**Country**
Gabapentin USP	India
Corn Starch USNF	Country A
Talc USP	USA
White/White size '3' Capsule shell imprinted with 'D' on white cap and '02' on white body	Country B / USA / USA
Yellow/Yellow size '1' Capsule shell imprinted with 'D' on yellow cap and '03' on yellow body	Country C / USA / USA
Orange/Orange size '0' Capsule shell imprinted with 'D' on Orange cap and '04' on Orange body	Country D / USA / USA

The processing that occurs in the United States includes the following:

- The API exhibits poor flow property whereby it will affect the manufacturability. Hence, the particle size is tailored to have good flowability during the manufacturing process so that there is no unit-to-unit variability in the labeled quantity in each capsule.

- Corn starch is added as a bulking agent for better manufacturability and to have suitable fill weight so that the patient can easily take the medication. Corn starch is mixed with the gabapentin where the drug particles get coated with the said excipient, enhancing stability.

- Talc is added to create a gliding property in the blend particles and also provides a lubrication effect during the production process. Lubricant mixing is carefully done to ensure that the drug releasing profile and pharmacokinetics are not influenced by this hydrophobic environment.

- Finally, the blend is filled into hard gelatin shells to give each strength a distinct name and character. Encapsulation of the blend gives a protective barrier for each strength of the drug and masks the metallic taste of the drug particles.

You submitted product labels for the Gabapentin capsules. You also submitted a shipping label and the Materials Safety Data Sheet ("MSDS") for the API, Gabapentin. Additionally, you provided a manufacturing flow chart depicting the various steps which occur in the United States to make the final the final Gabapentin capsules.

ISSUE:

What is the country of origin of the Gabapentin capsules for purposes of U.S. Government procurement?

LAW AND ANALYSIS:

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, 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.*).

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 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 or 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, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

In HQ H240193, dated July 29, 2013, which concerned the country of origin marking of the brand-name Crestor® (Rosuvastatin Calcium salt) tablets, CBP found that the API imported from two different countries was not substantially transformed when combined with stabilizers and excipients, and manufactured into tablet form in the United States.

HQ H267177, dated November 5, 2015, concerned Acyclovir, a pharmaceutical product used as a synthetic nucleoside analogue active against herpes viruses. The API was manufactured in China and India and shipped to the United States where it underwent five manufacturing steps including the sizing of the active and inactive ingredients, preparation of Acyclovir granules, preparation of the tablet blend, tablet compression, and packaging in high density polyethylene plastic bottles. CBP determined that the processing performed in the United States did not result in a change in the medicinal use of the finished product and the active ingredient. The active ingredient retained its chemical and physical properties and was merely put into dosage form and packaged for sale. The active ingredient did not undergo a change in name, character or use. Therefore, CBP held that no substantial transformation occurred in United States, and Acyclovir tablets were considered a product of the country in which the active ingredient was produced.

HQ H215656, dated January 11, 2013, concerned the country of origin of Rybix ODT, a pharmaceutical product used for the management of moderate to moderately severe pain in adults. The API, tramadol hydrochloride, manufactured in India, was shipped to France where it underwent four processes of manufacturing consisting of the preparation of the API, preparation of the tablet blend, tablet compression, and packaging in blister packs. CBP determined that the processing in France did not result in a change in the medicinal use of the finished product, and the API retained its chemical and physical properties and was merely put into dosage form and packaged. Accordingly, CBP held that no substantial transformation occurred in France.

HQ H233356, dated December 26, 2012, concerned the country of origin of Ponstel, a pharmaceutical product used for the relief of mild to moderate pain caused by primary dysmenorrhea. Mefenamic acid, which is the API in Ponstel, was manufactured in India, and imported into the United States, where it was blended with inactive ingredients and packaged into dosage form. CBP determined that this process did not substantially transform the mefenamic acid because its chemical character remained

the same and, therefore, CBP found that the country of origin of the Ponstel capsules was India.

You state that the FDA requires that a unique National Drug Code ("NDC") be assigned to every drug product such as Gabapentin capsules, but prohibits that same NDC from being associated with any API, such as Gabapentin, that has not been demonstrated to be safe and effective and cannot be sold for the treatment of any human disease condition. You also state that the FDA requires the name of the drug product (Gabapentin capsule) to appear on every drug product label and prohibits use of that name on the label for the API. Further, you state that Gabapentin is intended only for use by producers for further processing or for research since it is unstable and not fit for medical use and may not be sold to consumers. Additionally, you state that Gabapentin has a tendency to degrade and has poor flow properties. For these reasons, you claim that extensive additional processing of the API, sourced in India, with other ingredients must occur to change the API's properties and make it into a stable drug product.

This office consulted with CBP's Laboratories and Scientific Services Directorate concerning the instant case, which informed us that the imported API, Gabapentin, retains its chemical and physical properties upon processing in the United States. Increasing the stability of the API and standardizing its concentration do not change the API. Further, the processing performed in the United States does not affect the medicinal use of the API. Based on the information presented, the API does not undergo a change in name, character or use. Therefore, in accordance with the rulings cited, we find that no substantial transformation occurs in United States, and the Gabapentin capsules would be considered a product of India, where the API was produced, for purposes of U.S. government procurement.

In addition, you asked whether the Gabapentin capsules are "manufactured in the United States" within the meaning of the term "U.S.-made end products", as set forth in Section 25.003 of the Federal Acquisition Regulations System, Title 48, Code of Federal Regulations (48 C.F.R. § 25.003), and implemented in 48 C.F.R. § 52.225-5. As stated in 19 C.F.R. § 177.21, subpart B is intended to be applied consistent with the Federal Acquisition Regulations (48 C.F.R. chapter 1). The definition of country of origin in subpart B, 19 C.F.R. § 177.22(a) has two rules (see above) as does 48 C.F.R. § 25.003. The term "manufactured in the United States" in 48 C.F.R. § 25.003 correlates to the first rule of 19 C.F.R. § 177.22(a) which provides that an article is a product of a country or instrumentality if "it is wholly the growth, product, or manufacture of that country or instrumentality". Since the production of Gabapentin capsules partially occurs in India, we do not find that they are manufactured in the United States.

HOLDING:

The country of origin of the Gabapentin capsules for U.S. 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 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 after publication of the *Federal Register* notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel
Executive Director
Regulations and Rulings
Office of Trade

HQ H289710

January 30, 2018

OT:RR:CTF:VS H289710 EE

CATEGORY: Origin

Stephen E. Ruscus
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, NW
Washington, DC 20004

RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Carvedilol tablets

Dear Mr. Ruscus:

This is in response to your correspondence of July 7, 2017 and supplemental submission of August 7, 2017, requesting a final determination on behalf of Acetris Health, ("Acetris")[6], pursuant to subpart B of Part 177, U.S. Customs and Border Protection ("CBP") Regulations (19 C.F.R. § 177.21 *et seq*.). A meeting was held with the counsel for Acetris on August 8, 2017.

[6] Counsel for Acetris states that on May 19, 2017, Acetris executed a novation with Lucid Pharma LLC and the Department of Veterans Affairs whereby the VA recognized Acetris as the successor in interest to Department of Veterans Affairs Contract No. VA 797P-16-C-0034, the subject contract of the underlying request.

This final determination concerns the country of origin of the Carvedilol tablets. We note that Acetris 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.

You have asked that certain information submitted in connection with this ruling request be treated as confidential. Inasmuch as this request conforms to the requirements of 19 C.F.R. § 177.2(b)(7), the request for confidentiality is approved. The information contained within brackets in your request will not be released to the public and will be withheld from published versions of this ruling.

FACTS:

The merchandise at issue are Carvedilol tablets. You state that Acetris is a generic pharmaceutical distributor specializing in providing cost effective products to the U.S. Government. Acetris has its principal place of business in Allendale, NJ. Among the products Acetris sells to the U.S. Government are Carvedilol tablets, members of a family of drugs prescribed for treating mild to severe chronic heart failure, left ventricular dysfunction following myocardial infarction, and hypertension.

You state that Acetris procures the Carvedilol tablets from Aurolife Pharma LLC ("Aurolife"), located in Dayton, NJ. Aurolife, which is a wholly-owned subsidiary of company X in India, is a generic pharmaceutical product manufacturer in the specialty and niche areas. Aurolife manufactures the Carvedilol tablets supplied to Acetris in a U.S. Food & Drug Administration ("FDA") approved cGMP compliant manufacturing facility, located in Dayton, NJ, from several active and inactive ingredients procured domestically and abroad. The active pharmaceutical ingredient ("API") of the Carvedilol tablets is Carvedilol, which Aurolife sources from company X in India.

You state that the Carvedilol tablets supplied to Acetris are the result of a complex production process that occurs in Aurolife's New Jersey facility involving the combination of the API with multiple inactive ingredients, including some intermediates that are mixed in order to aid the conversion of the multiple ingredients. The production of Carvedilol tablets employs processes that convert these ingredients into finished, medically effective dosage tablets (3.125 mg, 6.25 mg, 12.5 mg, and 25 mg tablets). You state that this processing changes the properties and characteristics of the API, materially enhancing the pharmacokinetics of the resulting drug.

You state that the process of converting these multiple ingredients into the Carvedilol tablets occurs entirely within the United States. The ingredients processed in the United States are sourced from a variety of suppliers, both United States and foreign, as follows:

Material	**Country**
Carvedilol USP	India
Lactose Monohydrate USNF	Country A
Colloidal Silicon Dioxide USNF	USA
Crospovidone USNF	USA

Povidone USP	USA
Sucrose USNF	USA
Magnesium Stearate USNF	USA
Opadry White 12B18631	USA

The processing that occurs in the United States includes the following:

- Lactose monohydrate is added as a bulking agent for better manufacturability and to have suitable tablet weight so that the patient can easily take the medication. The API is mixed with these diluents to achieve uniformity of the API, so that the product can be easily administered.

- Crospovidone is added as a disintegrant to provide easy dispersion of the tablet when ingested by the patient which enhances the drug release process, bioavailability and absorption leading to pharmacokinetic profiles equivalent to the brand product (Coreg®) for therapeutic equivalency.

- Povidone and sucrose are added as binders to aid formation of flowable granules during production, thereby achieving the uniformity of the drug leading to therapeutic efficacy.

- Colloidal silicon dioxide is added to create a gliding property in the blend particles, thereby contributing to the unit-to-unit uniformity of the drug during the manufacturing process.

- Magnesium stearate is added to create a hydrophobic environment around particles which provides a lubrication effect during the production process. Lubricant mixing is carefully done to ensure that the drug releasing profile and pharmacokinetics are not influenced by this hydrophobic environment.

- Coloring and film coating agents are added. Film coating is performed using polymers which imparts a protective barrier for each tablet strength and to mask the taste.

- Finally, the tablets are packed into suitable containers which are capable of retaining the overall integrity of the quality attributes and minimizing the formation of impurities thereby producing a more stable drug product whose therapeutic effectiveness as a drug is sustainable.

You submitted product labels for the Carvedilol tablets. You also submitted a shipping label and the Materials Safety Data Sheet ("MSDS") for the API, Carvedilol. Additionally, you provided a manufacturing flow chart depicting the various steps which occur in the United States to make the final Carvedilol tablets.

ISSUE:

What is the country of origin of the Carvedilol tablets for purposes of U.S. Government procurement?

LAW AND ANALYSIS:

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, 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.*).

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 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 or 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, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

In HQ H240193, dated July 29, 2013, which concerned the country of origin marking of the brand-name Crestor® (Rosuvastatin Calcium salt) tablets, CBP found that the API imported from two different countries was not substantially transformed when combined with stabilizers and excipients, and manufactured into tablet form in the United States.

HQ H267177, dated November 5, 2015, concerned Acyclovir, a pharmaceutical product used as a synthetic nucleoside analogue active against herpes viruses. The API was manufactured in China and India and shipped to the United States where it underwent five manufacturing steps including the sizing of the active and inactive ingredients, preparation of Acyclovir granules, preparation of the tablet blend, tablet compression, and packaging in high density polyethylene plastic bottles. CBP determined that the processing performed in the United States did not result in a change in the medicinal use of the finished product and the active ingredient. The active ingredient retained its chemical and physical properties and was merely put into dosage form and packaged for sale. The active ingredient did not undergo a change in name, character or use. Therefore, CBP held that no substantial transformation occurred in United States, and Acyclovir tablets were considered a product of the country in which the active ingredient was produced.

HQ H215656, dated January 11, 2013, concerned the country of origin of Rybix ODT, a pharmaceutical product used for the management of moderate to moderately severe pain in adults. The API, tramadol hydrochloride, manufactured in India, was shipped to France where it underwent four processes of manufacturing consisting of the preparation of the API, preparation of the tablet blend, tablet compression, and packaging in blister packs. CBP determined that the processing in France did not result in a change in the medicinal use of the finished product, and the API retained its chemical and physical properties and was merely put into dosage form and packaged. Accordingly, CBP held that no substantial transformation occurred in France.

HQ H233356, dated December 26, 2012, concerned the country of origin of Ponstel, a pharmaceutical product used for the relief of mild to moderate pain caused by primary dysmenorrhea. Mefenamic acid, which is the API in Ponstel, was manufactured in India, and imported into the United States, where it was blended with inactive ingredients and packaged into dosage form. CBP determined that this process did not substantially transform the mefenamic acid because its chemical character remained

the same and, therefore, CBP found that the country of origin of the Ponstel capsules was India.

You state that the FDA requires that a unique National Drug Code ("NDC") be assigned to every drug product such as Carvedilol tablets, but prohibits that same NDC from being associated with any API, such as Carvedilol, that has not been demonstrated to be safe and effective and cannot be sold for the treatment of any human disease condition. You also state that the FDA requires the name of the drug product (Carvedilol tablet) to appear on every drug product label and prohibits use of that name on the label for the API. Further, you state that API is intended only for use by producers for further processing or for research since it is unstable and not fit for medical use and may not be sold to consumers. Additionally, you state that the API has poor flow quality and is susceptible to inadequate content uniformity. For these reasons, you claim that extensive additional processing of the API, sourced in India, with other ingredients must occur to change the API's properties and make it into a stable drug product.

This office consulted with CBP's Laboratories and Scientific Services Directorate concerning the instant case, which informed us that the imported API, Carvedilol, retains its chemical and physical properties upon processing in the United States. Increasing the stability of the API and standardizing its concentration do not change the API. Further, the processing performed in the United States does not affect the medicinal use of the API. Based on the information presented, the API does not undergo a change in name, character or use. Therefore, in accordance with the rulings cited, we find that no substantial transformation occurs in United States, and the Carvedilol tablets would be considered a product of India, where the API was produced, for purposes of U.S. government procurement.

In addition, you asked whether the Carvedilol tablets are "manufactured in the United States" within the meaning of the term "U.S.-made end products", as set forth in Section 25.003 of the Federal Acquisition Regulations System, Title 48, Code of Federal Regulations (48 C.F.R. § 25.003), and implemented in 48 C.F.R. § 52.225-5. As stated in 19 C.F.R. § 177.21, subpart B is intended to be applied consistent with the Federal Acquisition Regulations (48 C.F.R. chapter 1). The definition of country of origin in subpart B, 19 C.F.R. § 177.22(a) has two rules (see above) as does 48 C.F.R. § 25.003. The term "manufactured in the United States" in 48 C.F.R. § 25.003 correlates to the first rule of 19 C.F.R. § 177.22(a) which provides that an article is a product of a country or instrumentality if "it is wholly the growth, product, or manufacture of that country or instrumentality". Since the production of Carvedilol tablets partially occurs in India, we do not find that they are manufactured in the United States.

HOLDING:

The country of origin of the Carvedilol tablets for U.S. 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 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 after publication of the *Federal Register* notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel
Executive Director
Regulations and Rulings
Office of Trade

HQ H289711

January 30, 2018

OT:RR:CTF:VS H289711 EE

CATEGORY: Origin

Stephen E. Ruscus
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, NW
Washington, DC 20004

RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Paroxetine Hydrochloride tablets

Dear Mr. Ruscus:

This is in response to your correspondence of July 7, 2017 and supplemental submission of August 7, 2017, requesting a final determination on behalf of Acetris Health, ("Acetris")[7], pursuant to subpart B of Part 177, U.S. Customs and Border

[7] Counsel for Acetris states that on May 19, 2017, Acetris executed a novation with Lucid Pharma LLC and the Department of Veterans Affairs whereby the VA recognized Acetris as the successor in interest to

Protection ("CBP") Regulations (19 C.F.R. § 177.21 *et seq*.). A meeting was held with the counsel for Acetris on August 8, 2017.

This final determination concerns the country of origin of the Paroxetine Hydrochloride tablets. We note that Acetris 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.

You have asked that certain information submitted in connection with this ruling request be treated as confidential. Inasmuch as this request conforms to the requirements of 19 C.F.R. § 177.2(b)(7), the request for confidentiality is approved. The information contained within brackets in your request will not be released to the public and will be withheld from published versions of this ruling.

FACTS:

The merchandise at issue are Paroxetine Hydrochloride tablets. You state that Acetris is a generic pharmaceutical distributor specializing in providing cost effective products to the U.S. Government. Acetris has its principal place of business in Allendale, NJ. Among the products Acetris sells to the U.S. Government are Paroxetine Hydrochloride tablets, which are psychotropic drugs used in the treatment of major depressive disorder, obsessive compulsive disorder, pain disorder, social anxiety disorder, generalized anxiety disorder, and post-traumatic stress disorder.

You state that Acetris procures the Paroxetine Hydrochloride tablets from Aurolife Pharma LLC ("Aurolife"), located in Dayton, NJ. Aurolife, which is a wholly-owned subsidiary of company X in India, is a generic pharmaceutical product manufacturer in the specialty and niche areas. Aurolife manufactures the Paroxetine Hydrochloride tablets supplied to Acetris in a U.S. Food & Drug Administration ("FDA") approved cGMP compliant manufacturing facility, located in Dayton, NJ, from several active and inactive ingredients procured domestically and abroad. The active pharmaceutical ingredient ("API") of the Paroxetine Hydrochloride tablets is Paroxetine Hydrochloride, which Aurolife sources from company X in India.

You state that the Paroxetine Hydrochloride tablets supplied to Acetris are the result of a complex production process that occurs in Aurolife's New Jersey facility involving the combination of the API with multiple inactive ingredients, including some intermediates that are mixed in order to aid the conversion of the multiple ingredients. The production of Paroxetine Hydrochloride tablets employs processes that convert these ingredients into finished, medically effective dosage tablets (10mg, 20mg, 30mg, and 40mg tablets). You state that this processing changes the properties and characteristics of the API, materially enhancing the pharmacokinetics of the resulting drug.

Department of Veterans Affairs Contract No. VA 797P-16-C-0034, the subject contract of the underlying request.

You state that the process of converting these multiple ingredients into the Paroxetine Hydrochloride tablets occurs entirely within the United States. The ingredients processed in the United States are sourced from a variety of suppliers, both United States and foreign, as follows:

Material	**Country**
Paroxetine Hydrochloride USP	India
Dibasic Calcium Phosphate Dihydrate	USA
Dibasic Calcium Phosphate Anhydrous	Country A
Lactose Monohydrate USNF	Country B
Sodium Starch Glycolate USNF	Country C
Magnesium Stearate USNF	USA
Opadry yellow 13F52249 IH	USA
Opadry Pink 15B54027 IH	USA
Opadry Blue 12B50610 IH	USA

The processing that occurs in the United States includes the following:

- Dibasic calcium phosphate dihydrate and dibasic calcium phosphate anhydrous are non-hygroscopic hydrophobic diluents added to the paroxetine hydrochloride to improve drug stability.

- Lactose monohydrate is added as a bulking agent for better manufacturability and to have suitable tablet weight so that the patient can easily take the medication.

- Sodium starch glycolate is added as a disintegrant to provide easy dispersion of the tablet when ingested by the patient, which enhances the drug release process, bioavailability and absorption leading to pharmacokinetic profiles equivalent to the brand product (Paxil®) for therapeutic equivalency.

- Magnesium stearate is added to create a hydrophobic environment around particles which provides a lubrication effect during the production process. Lubricant mixing is carefully done to ensure that the drug releasing profile and pharmacokinetics are not influenced by this hydrophobic environment.

- Coloring agents and film coating are added to give each strength a distinct name and character. Film coating is performed using polymers which imparts a protective barrier for each strength of the drug and to mask the taste.

- Finally, the tablets are packed into suitable containers which are capable of retaining the overall integrity of the quality attributes and minimizing discoloration, thereby permitting a more stable product whose therapeutic effectiveness as a drug is sustainable.

You submitted product labels for the Paroxetine Hydrochloride tablets. You also submitted a shipping label and the Materials Safety Data Sheet ("MSDS") for the API, Paroxetine Hydrochloride. Additionally, you provided a manufacturing flow chart depicting the

various steps which occur in the United States to make the API and other ingredients into the final Paroxetine Hydrochloride tablets.

ISSUE:

What is the country of origin of the Paroxetine Hydrochloride tablets for purposes of U.S. Government procurement?

LAW AND ANALYSIS:

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, 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.*).

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 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 or 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, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

In HQ H240193, dated July 29, 2013, which concerned the country of origin marking of the brand-name Crestor® (Rosuvastatin Calcium salt) tablets, CBP found that the API imported from two different countries was not substantially transformed when combined with stabilizers and excipients, and manufactured into tablet form in the United States.

HQ H267177, dated November 5, 2015, concerned Acyclovir, a pharmaceutical product used as a synthetic nucleoside analogue active against herpes viruses. The API was manufactured in China and India and shipped to the United States where it underwent five manufacturing steps including the sizing of the active and inactive ingredients, preparation of Acyclovir granules, preparation of the tablet blend, tablet compression, and packaging in high density polyethylene plastic bottles. CBP determined that the processing performed in the United States did not result in a change in the medicinal use of the finished product and the active ingredient. The active ingredient retained its chemical and physical properties and was merely put into dosage form and packaged for sale. The active ingredient did not undergo a change in name, character or use. Therefore, CBP held that no substantial transformation occurred in United States, and Acyclovir tablets were considered a product of the country in which the active ingredient was produced.

HQ H215656, dated January 11, 2013, concerned the country of origin of Rybix ODT, a pharmaceutical product used for the management of moderate to moderately severe pain in adults. The API, tramadol hydrochloride, manufactured in India, was shipped to France where it underwent four processes of manufacturing consisting of the preparation of the API, preparation of the tablet blend, tablet compression, and packaging in blister packs. CBP determined that the processing in France did not result in a change in the medicinal use of the finished product, and the API retained its chemical and physical properties and was merely put into dosage form and packaged. Accordingly, CBP held that no substantial transformation occurred in France.

HQ H233356, dated December 26, 2012, concerned the country of origin of Ponstel, a pharmaceutical product used for the relief of mild to moderate pain caused by primary dysmenorrhea. Mefenamic acid, which is the API in Ponstel, was manufactured in India, and imported into the United States, where it was blended with inactive ingredients and packaged into dosage form. CBP determined that this process did not substantially transform the mefenamic acid because its chemical character remained the same and, therefore, CBP found that the country of origin of the Ponstel capsules was India.

You state that the FDA requires that a unique National Drug Code ("NDC") be assigned to every drug product such as Paroxetine Hydrochloride tablets, but prohibits that same NDC from being associated with any API, such as Paroxetine Hydrochloride, that has not been demonstrated to be safe and effective and cannot be sold for the treatment of any human disease condition. You also state that the FDA requires the name of the drug product (Paroxetine Hydrochloride tablet) to appear on every drug product label and prohibits use of that name on the label for the API. Further, you state that Paroxetine Hydrochloride is intended only for use by producers for further processing or for research since it is unstable and not fit for medical use and may not be sold to consumers. Additionally, you state that Paroxetine Hydrochloride experiences degradation. For these reasons, you claim that extensive additional processing of the API, sourced in India, with other ingredients must occur to change the API's properties and make it into a stable drug product whose medical effectiveness as a drug is sustainable.

This office consulted with CBP's Laboratories and Scientific Services Directorate concerning the instant case, which informed us that the imported API, Paroxetine Hydrochloride, retains its chemical and physical properties upon processing in the United States. Increasing the stability of the API and standardizing its concentration do not change the API. Further, the processing performed in the United States does not affect the medicinal use of the API. Based on the information presented, the API does not undergo a change in name, character or use. Therefore, in accordance with the rulings cited, we find that no substantial transformation occurs in United States, and the Paroxetine Hydrochloride tablets would be considered a product of India, where the API was produced, for purposes of U.S. government procurement.

In addition, you asked whether the Paroxetine Hydrochloride tablets are "manufactured in the United States" within the meaning of the term "U.S.-made end products", as set forth in Section 25.003 of the Federal Acquisition Regulations System, Title 48, Code of Federal Regulations (48 C.F.R. § 25.003), and implemented in 48 C.F.R. § 52.225-5. As stated in 19 C.F.R. § 177.21, subpart B is intended to be applied consistent with the Federal Acquisition Regulations (48 C.F.R. chapter 1). The definition of country of origin in subpart B, 19 C.F.R. § 177.22(a) has two rules (see above) as does 48 C.F.R. § 25.003. The term "manufactured in the United States" in 48 C.F.R. § 25.003 correlates to the first rule of 19 C.F.R. § 177.22(a) which provides that an article is a product of a country or instrumentality if "it is wholly the growth, product, or manufacture of that country or instrumentality". Since the production of Paroxetine Hydrochloride tablets partially occurs in India, we do not find that they are manufactured in the United States.

HOLDING:

The country of origin of the Paroxetine Hydrochloride tablets for U.S. 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 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 after publication of the *Federal Register* notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel
Executive Director
Regulations and Rulings
Office of Trade

HQ H289712

January 30, 2018

OT:RR:CTF:VS H289712 EE

CATEGORY: Origin

Stephen E. Ruscus
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, NW
Washington, DC 20004

RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Entecavir tablets

Dear Mr. Ruscus:

This is in response to your correspondence of July 7, 2017 and supplemental submission of August 7, 2017, requesting a final determination on behalf of Acetris Health, ("Acetris")[8], pursuant to subpart B of Part 177, U.S. Customs and Border Protection ("CBP") Regulations (19 C.F.R. § 177.21 *et seq*.). A meeting was held with the counsel for Acetris on August 8, 2017.

This final determination concerns the country of origin of the Entecavir tablets. We note that Acetris 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.

[8] Counsel for Acetris states that on May 19, 2017, Acetris executed a novation with Lucid Pharma LLC and the Department of Veterans Affairs whereby the VA recognized Acetris as the successor in interest to Department of Veterans Affairs Contract No. VA 797P-16-C-0034, the subject contract of the underlying request.

You have asked that certain information submitted in connection with this ruling request be treated as confidential. Inasmuch as this request conforms to the requirements of 19 C.F.R. § 177.2(b)(7), the request for confidentiality is approved. The information contained within brackets in your request will not be released to the public and will be withheld from published versions of this ruling.

FACTS:

The merchandise at issue are Entecavir tablets. You state that Acetris is a generic pharmaceutical distributor specializing in providing cost effective products to the U.S. Government. Acetris has its principal place of business in Allendale, NJ. Among the products Acetris sells to the U.S. Government are Entecavir tablets for treating the Hepatitis B virus (HBV).

You state that Acetris procures the Entecavir tablets from Aurolife Pharma LLC ("Aurolife"), located in Dayton, NJ. Aurolife, which is a wholly-owned subsidiary of company X in India, is a generic pharmaceutical product manufacturer in the specialty and niche areas. Aurolife manufactures the Entecavir tablets supplied to Acetris in a U.S. Food & Drug Administration ("FDA") approved cGMP compliant manufacturing facility, located in Dayton, NJ, from several active and inactive ingredients procured domestically and abroad. The active pharmaceutical ingredient ("API") of the Entecavir tablets is Entecavir, which Aurolife sources from company X in India.

You state that the Entecavir tablets supplied to Acetris are the result of a complex production process that occurs in Aurolife's New Jersey facility involving the combination of the API with multiple inactive ingredients, including some intermediates that are mixed in order to aid the conversion of the multiple ingredients. The production of Entecavir tablets employs processes that convert these ingredients into finished, medically effective dosage tablets (0.5 mg and 1 mg tablets). You state that this processing changes the properties and characteristics of the API, materially enhancing the pharmacokinetics of the resulting drug.

You state that the process of converting these multiple ingredients into the Entecavir tablets occurs entirely within the United States. The ingredients processed in the United States are sourced from a variety of suppliers, both United States and foreign, as follows:

Material	**Country**
Entecavir USP	India
Lactose Monohydrate USNF	Country A
Microcrystalline Cellulose PH 101 USNF	USA / Country B
Crospovidone USNF (Kollidon CL)	Country C
Microcrystalline Cellulose PH 101 USNF	USA / Country D
Magnesium Stearate USNF	USA
Aquarius BP18257 cool Vanilla IH	USA

The processing that occurs in the United States includes the following:

- Lactose monohydrate and microcrystalline cellulose are added as bulking agents for better manufacturability and to have suitable tablet weight so that the patient can easily take the medication. These diluents also aid in achieving the desired uniformity with the help of processing steps like co-sifting.

- Crospovidone is added as a disintegrant to provide easy dispersion of the tablet when ingested by the patient which enhances the drug release process, bioavailability and absorption leading to pharmacokinetic profiles equivalent to the brand product (Baraclude®) for therapeutic equivalency.

- Magnesium stearate is added to create a hydrophobic environment around particles, which provides a lubrication effect during the production process. Lubricant mixing is carefully done to ensure that the drug releasing profile and pharmacokinetics are not influenced by this hydrophobic environment.

- Film coating agent is added to give each strength a distinct character. Film coating is performed using polymers which imparts a protective barrier for each strength of the drug, making it appropriate for patient use.

- Finally, the tablets are packed into suitable containers which are capable of retaining the overall integrity of the quality attributes, thereby producing a more stable drug product whose therapeutic effectiveness as a drug is sustainable.

You submitted product labels for the Entecavir tablets. You also submitted a shipping label and the Materials Safety Data Sheet ("MSDS") for the API, Entecavir. Additionally, you provided a manufacturing flow chart depicting the various steps which occur in the United States to make the final Entecavir tablets.

ISSUE:

What is the country of origin of the Entecavir tablets for purposes of U.S. Government procurement?

LAW AND ANALYSIS:

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, pursuant to subpart B of Part 177, 19 C.F.R. § 177.21 *et seq.*, which implements Title lll of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq.*).

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 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 or 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, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

In HQ H240193, dated July 29, 2013, which concerned the country of origin marking of the brand-name Crestor® (Rosuvastatin Calcium salt) tablets, CBP found that the API imported from two different countries was not substantially transformed when combined with stabilizers and excipients, and manufactured into tablet form in the United States.

HQ H267177, dated November 5, 2015, concerned Acyclovir, a pharmaceutical product used as a synthetic nucleoside analogue active against herpes viruses. The API was manufactured in China and India and shipped to the United States where it underwent five manufacturing steps including the sizing of the active and inactive ingredients, preparation of Acyclovir granules, preparation of the tablet blend, tablet compression, and packaging in high density polyethylene plastic bottles. CBP determined that the processing performed in the United States did not result in a change in the medicinal use of the finished product and the active ingredient. The active ingredient retained its chemical and physical properties and was merely put into dosage form and packaged for sale. The active ingredient did not undergo a change in name, character or use. Therefore, CBP held that no substantial transformation occurred in United States, and Acyclovir tablets were considered a product of the country in which the active ingredient was produced.

HQ H215656, dated January 11, 2013, concerned the country of origin of Rybix ODT, a pharmaceutical product used for the management of moderate to moderately severe pain in adults. The API, tramadol hydrochloride, manufactured in India, was shipped to France where it underwent four processes of manufacturing consisting of the preparation of the API, preparation of the tablet blend, tablet compression, and packaging in blister packs. CBP determined that the processing in France did not result in a change in the medicinal use of the finished product, and the API retained its chemical and physical properties and was merely put into dosage form and packaged. Accordingly, CBP held that no substantial transformation occurred in France.

HQ H233356, dated December 26, 2012, concerned the country of origin of Ponstel, a pharmaceutical product used for the relief of mild to moderate pain caused by primary dysmenorrhea. Mefenamic acid, which is the API in Ponstel, was manufactured in India, and imported into the United States, where it was blended with inactive ingredients and packaged into dosage form. CBP determined that this process did not substantially transform the mefenamic acid because its chemical character remained the same and, therefore, CBP found that the country of origin of the Ponstel capsules was India.

You state that FDA requires that a unique National Drug Code ("NDC") be assigned to every drug product such as Entecavir tablets, but prohibits that same NDC from being associated with any API, such as Entecavir, that has not been demonstrated to be safe and effective and cannot be sold for the treatment of any human disease condition. You also state that the FDA requires the name of the drug product (Entecavir tablet) to appear on every drug product label and prohibits use of that name on the label for the API. Further, you state that API is intended only for use by producers for further processing or for research since it is unstable and not fit for medical use and may not be sold to consumers. Additionally, you state that the API is susceptible to inadequate content uniformity and undergoes oxidative degradation. For these reasons, you claim that extensive additional processing of the API, sourced in India, with other ingredients must occur to change the API's properties and make it into a stable drug product that

achieves the targeted disintegration and dissolution and exhibits appropriate physicochemical properties, the desired pharmacokinetics and therapeutic efficacy.

This office consulted with CBP's Laboratories and Scientific Services Directorate concerning the instant case, which informed us that the imported API, Entecavir, retains its chemical and physical properties upon processing in the United States. Increasing the stability of the API and standardizing its concentration do not change the API. Further, the processing performed in the United States does not affect the medicinal use of the API. Based on the information presented, the API does not undergo a change in name, character or use. Therefore, in accordance with the rulings cited, we find that no substantial transformation occurs in United States, and the Entecavir tablets would be considered a product of India, where the API was produced, for purposes of U.S. government procurement.

In addition, you asked whether the Entecavir tablets are "manufactured in the United States" within the meaning of the term "U.S.-made end products", as set forth in Section 25.003 of the Federal Acquisition Regulations System, Title 48, Code of Federal Regulations (48 C.F.R. § 25.003), and implemented in 48 C.F.R. § 52.225-5. As stated in 19 C.F.R. § 177.21, subpart B is intended to be applied consistent with the Federal Acquisition Regulations (48 C.F.R. chapter 1). The definition of country of origin in subpart B, 19 C.F.R. § 177.22(a) has two rules (see above) as does 48 C.F.R. § 25.003. The term "manufactured in the United States" in 48 C.F.R. § 25.003 correlates to the first rule of 19 C.F.R. § 177.22(a) which provides that an article is a product of a country or instrumentality if "it is wholly the growth, product, or manufacture of that country or instrumentality". Since the production of Entecavir tablets partially occurs in India, we do not find that they are manufactured in the United States.

HOLDING:

The country of origin of the Entecavir tablets for U.S. 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 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 after publication of the *Federal Register* notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel
Executive Director

Regulations and Rulings
Office of Trade

HQ H289713

January 30, 2018

OT:RR:CTF:VS H289713 EE

CATEGORY: Origin

Stephen E. Ruscus
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, NW
Washington, DC 20004

RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Montelukast Sodium tablets

Dear Mr. Ruscus:

This is in response to your correspondence of July 7, 2017 and supplemental submission of August 7, 2017, requesting a final determination on behalf of Acetris Health, ("Acetris")[9], pursuant to subpart B of Part 177, U.S. Customs and Border Protection ("CBP") Regulations (19 C.F.R. § 177.21 *et seq*.). A meeting was held with the counsel for Acetris on August 8, 2017.

This final determination concerns the country of origin of the Montelukast Sodium tablets. We note that Acetris 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.

You have asked that certain information submitted in connection with this ruling request be treated as confidential. Inasmuch as this request conforms to the requirements of 19 C.F.R. § 177.2(b)(7), the request for confidentiality is approved. The information contained within

[9] Counsel for Acetris states that on May 19, 2017, Acetris executed a novation with Lucid Pharma LLC and the Department of Veterans Affairs whereby the VA recognized Acetris as the successor in interest to Department of Veterans Affairs Contract No. VA 797P-16-C-0034, the subject contract of the underlying request.

brackets in your request will not be released to the public and will be withheld from published versions of this ruling.

FACTS:

The merchandise at issue are Montelukast Sodium tablets. You state that Acetris is a generic pharmaceutical distributor specializing in providing cost effective products to the U.S. Government. Acetris has its principal place of business in Allendale, NJ. Among the products Acetris sells to the U.S. Government are Montelukast Sodium tablets, which are drugs prescribed for the prevention and/or treatment of asthma, bronchoconstriction and allergic rhinitis.

You state that Acetris procures the Montelukast Sodium tablets from Aurolife Pharma LLC ("Aurolife"), located in Dayton, NJ. Aurolife, which is a wholly-owned subsidiary of company X in India, is a generic pharmaceutical product manufacturer in the specialty and niche areas. Aurolife manufactures the Montelukast Sodium tablets supplied to Acetris in a U.S. Food & Drug Administration ("FDA") approved cGMP compliant manufacturing facility, located in Dayton, NJ, from several active and inactive ingredients procured domestically and abroad. The active pharmaceutical ingredient ("API") of the Montelukast Sodium tablets is Montelukast Sodium, which Aurolife sources from company Y in India.

You state that the Montelukast Sodium tablets supplied to Acetris are the result of a complex production process that occurs in Aurolife's New Jersey facility involving the combination of the API with multiple inactive ingredients, including some intermediates that are mixed in order to aid the conversion of the multiple ingredients. The production of Montelukast Sodium tablets employs processes that convert these ingredients into finished, medically effective dosage tablets (10 mg tablets). You state that this processing changes the properties and characteristics of the API, materially enhancing the pharmacokinetics of the resulting drug.

You state that the process of converting these multiple ingredients into the Montelukast Sodium tablets occurs entirely within the United States. The ingredients processed in the United States are sourced from a variety of suppliers, both United States and foreign, as follows:

Material	**Country**
Montelukast Sodium IH	India
Lactose MonohydrateUSNF	Country A
Microcrystalline Cellulose USNF (AVICEL PH101)	USA
Croscaramellose Sodium USNF	USA
Hydroxypropyl Cellulose USNF	USA
Magnesium Stearate USNF	USA
Opadry Yellow 20A82539 IH	USA

The processing that occurs in the United States includes the following:

- Lactose monohydrate, microcrystalline cellulose are added as bulking agents for better manufacturability so that the patient can easily take the medication.

- Hydroxyproyl cellulose is added as a binder to aid formation of flowable granules during manufacturing, thereby achieving the uniformity of the drug leading to therapeutic efficacy.

- Croscarmellose sodium is added as a disintegrant to provide easy dispersion of the tablet when ingested by the patient, which enhances the drug release process, bioavailability and absorption leading to pharmacokinetic profiles equivalent to the brand product (Singular®) for therapeutic equivalency.

- Colloidal silicon dioxide is added to create a gliding property in the blend particles, thereby contributing to the unit-to-unit uniformity of the drug during the manufacturing process.

- Magnesium stearate is added to create a hydrophobic environment around particles which provides a lubrication effect during the production process. Lubricant mixing is carefully done to ensure that the drug releasing profile and pharmacokinetics are not influenced by this hydrophobic environment.

- Coloring agent and film coating are added to give an aesthetic appearance. Film coating is performed using polymers which imparts a protective barrier for the drug and to mask the taste.

- Finally, the tablets are packed into suitable containers which are capable of retaining the overall integrity of the quality attributes and minimizing the formation of sulfoxide impurity, thereby transform it into a more stable product whose therapeutic effectiveness as a drug is sustainable.

You submitted product labels for the Montelukast Sodium tablets. You also submitted a shipping label and the Materials Safety Data Sheet ("MSDS") for the API, Montelukast Sodium. Additionally, you provided a manufacturing flow chart depicting the various steps which occur in the United States to make the final Montelukast Sodium tablets.

ISSUE:

What is the country of origin of the Montelukast Sodium tablets for purposes of U.S. Government procurement?

LAW AND ANALYSIS:

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, 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.*).

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 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 or 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, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

In HQ H240193, dated July 29, 2013, which concerned the country of origin marking of the brand-name Crestor® (Rosuvastatin Calcium salt) tablets, CBP found that the API imported from two different countries was not substantially transformed when combined with stabilizers and excipients, and manufactured into tablet form in the United States.

HQ H267177, dated November 5, 2015, concerned Acyclovir, a pharmaceutical product used as a synthetic nucleoside analogue active against herpes viruses. The API was manufactured in China and India and shipped to the United States where it underwent five manufacturing steps including the sizing of the active and inactive ingredients, preparation of Acyclovir granules, preparation of the tablet blend, tablet compression, and packaging in high density polyethylene plastic bottles. CBP determined that the processing performed in the United States did not result in a change in the medicinal use of the finished product and the active ingredient. The active ingredient retained its chemical and physical properties and was merely put into dosage form and packaged for sale. The active ingredient did not undergo a change in name, character or use. Therefore, CBP held that no substantial transformation occurred in United States, and Acyclovir tablets were considered a product of the country in which the active ingredient was produced.

HQ H215656, dated January 11, 2013, concerned the country of origin of Rybix ODT, a pharmaceutical product used for the management of moderate to moderately severe pain in adults. The API, tramadol hydrochloride, manufactured in India, was shipped to France where it underwent four processes of manufacturing consisting of the preparation of the API, preparation of the tablet blend, tablet compression, and packaging in blister packs. CBP determined that the processing in France did not result in a change in the medicinal use of the finished product, and the API retained its chemical and physical properties and was merely put into dosage form and packaged. Accordingly, CBP held that no substantial transformation occurred in France.

HQ H233356, dated December 26, 2012, concerned the country of origin of Ponstel, a pharmaceutical product used for the relief of mild to moderate pain caused by primary dysmenorrhea. Mefenamic acid, which is the API in Ponstel, was manufactured in India, and imported into the United States, where it was blended with inactive ingredients and packaged into dosage form. CBP determined that this process did not substantially transform the mefenamic acid because its chemical character remained the same and, therefore, CBP found that the country of origin of the Ponstel capsules was India.

You state that the FDA requires that a unique National Drug Code ("NDC") be assigned to every drug product such as Montelukast Sodium tablets, but prohibits that same NDC from being associated with any API, such as Montelukast Sodium, that has not been demonstrated to be safe and effective and cannot be sold for the treatment of any human disease condition. You also state that the FDA requires the name of the drug product (Montelukast Sodium tablet) to appear on every drug product label and prohibits use of that name on the label for the API. Further, you state that API is intended only for use by producers for further processing or for

research since it is unstable and not fit for medical use and may not be sold to consumers. Additionally, you state that the API degrades in potency, has poor flow qualities, and has a bitter taste. For these reasons, you claim that extensive additional processing of the API, sourced in India, with other ingredients must occur to change the API's properties and make it into a stable drug product whose medical effectiveness as a drug is sustainable.

This office consulted with CBP's Laboratories and Scientific Services Directorate concerning the instant case, which informed us that the imported API, Montelukast Sodium, retains its chemical and physical properties upon processing in the United States. Increasing the stability of the API and standardizing its concentration do not change the API. Further, the processing performed in the United States does not affect the medicinal use of the API. Based on the information presented, the API does not undergo a change in name, character or use. Therefore, in accordance with the rulings cited, we find that no substantial transformation occurs in United States, and the Montelukast Sodium tablets would be considered a product of India, where the API was produced, for purposes of U.S. government procurement.

In addition, you asked whether the Montelukast Sodium tablets are "manufactured in the United States" within the meaning of the term "U.S.-made end products", as set forth in Section 25.003 of the Federal Acquisition Regulations System, Title 48, Code of Federal Regulations (48 C.F.R. § 25.003), and implemented in 48 C.F.R. § 52.225-5. As stated in 19 C.F.R. § 177.21, subpart B is intended to be applied consistent with the Federal Acquisition Regulations (48 C.F.R. chapter 1). The definition of country of origin in subpart B, 19 C.F.R. § 177.22(a) has two rules (see above) as does 48 C.F.R. § 25.003. The term "manufactured in the United States" in 48 C.F.R. § 25.003 correlates to the first rule of 19 C.F.R. § 177.22(a) which provides that an article is a product of a country or instrumentality if "it is wholly the growth, product, or manufacture of that country or instrumentality". Since the production of Montelukast Sodium tablets partially occurs in India, we do not find that they are manufactured in the United States.

HOLDING:

The country of origin of the Montelukast Sodium tablets for U.S. 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 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 after publication of the *Federal Register* notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel
Executive Director
Regulations and Rulings
Office of Trade

HQ H289714

January 30,2018

OT:RR:CTF:VS H289714 EE

CATEGORY: Origin

Stephen E. Ruscus
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, NW
Washington, DC 20004

RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Simvastatin tablets

Dear Mr. Ruscus:

This is in response to your correspondence of July 7, 2017 and supplemental submission of August 7, 2017, requesting a final determination on behalf of Acetris Health, ("Acetris")[10], pursuant to subpart B of Part 177, U.S. Customs and Border Protection ("CBP") Regulations (19 C.F.R. § 177.21 *et seq*.). A meeting was held with the counsel for Acetris on August 8, 2017.

[10] Counsel for Acetris states that on May 19, 2017, Acetris executed a novation with Lucid Pharma LLC and the Department of Veterans Affairs whereby the VA recognized Acetris as the successor in interest to Department of Veterans Affairs Contract No. VA 797P-16-C-0034, the subject contract of the underlying request.

This final determination concerns the country of origin of the Simvastatin tablets. We note that Acetris 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.

You have asked that certain information submitted in connection with this ruling request be treated as confidential. Inasmuch as this request conforms to the requirements of 19 C.F.R. § 177.2(b)(7), the request for confidentiality is approved. The information contained within brackets in your request will not be released to the public and will be withheld from published versions of this ruling.

FACTS:

The merchandise at issue are Simvastatin tablets. You state that Acetris is a generic pharmaceutical distributor specializing in providing cost effective products to the U.S. Government. Acetris has its principal place of business in Allendale, NJ. Among the products Acetris sells to the U.S. Government are Simvastatin tablets, members of a family of statin drugs prescribed for lowering cholesterol and triglyceride levels and prevention of heart attacks and strokes.

You state that Acetris procures the Simvastatin tablets from Aurolife Pharma LLC ("Aurolife"), located in Dayton, NJ. Aurolife, which is a wholly-owned subsidiary of company X in India, is a generic pharmaceutical product manufacturer in the specialty and niche areas. Aurolife manufactures the Simvastatin tablets supplied to Acetris in a U.S. Food & Drug Administration ("FDA") approved cGMP compliant manufacturing facility, located in Dayton, NJ, from several active and inactive ingredients procured domestically and abroad. The active pharmaceutical ingredient ("API") of the Simvastatin tablets is Simvastatin, which Aurolife sources from company X in India.

You state that the Simvastatin tablets supplied to Acetris are the result of a complex production process that occurs in Aurolife's New Jersey facility involving the combination of the API with multiple inactive ingredients, including some intermediates that are mixed in order to aid the conversion of the multiple ingredients. The production of Simvastatin tablets employs processes that convert these ingredients into finished, medically effective dosage tablets (5 mg, 10 mg, 20 mg, 40 mg, and 80 mg tablets). You state that this processing changes the properties and characteristics of the API, materially enhancing the pharmacokinetics of the resulting drug.

You state that the process of converting these multiple ingredients into the Simvastatin tablets occurs entirely within the United States. The ingredients processed in the United States are sourced from a variety of suppliers, both United States and foreign, as follows:

Material	**Country**
Simvastatin USP	India
Ascorbic Acid USP (Micro powder)	Country A
Lactose Monohydrate USNF	Country B

Microcrystalline Cellulose PH 101 USNF	USA / Country C
Pregelatinized Starch USNF	USA
Citric Acid Monohydrate USP (Extra Pure powder)	Country D
Butylated Hydroxy anisole USNF	USA
Microcrystalline Cellulose PH 112 USNF	Country E
Magnesium Stearate USNF	USA
Opadry yellow 20A52229 IH	USA
Opadry Pink 20A54239 IH	USA
Opadry Pink 20A54211 IH	USA
Isopropyl Alcohol USP	USA

The processing that occurs in the United States includes the following:

- Butylated hydroxyanisole, ascorbic acid, and citric acid are added to the Simvastatin API to improve drug stability. BHA and ascorbic acid are included in the tablets as antioxidants. Citric acid is added because it has chelation properties with metal ions, which, in the absence of the citric acid, could catalyze the oxidation process and make the drug unstable. These three excipients are added according to a proprietary set of protocols with specified blending times to ensure proper mixing throughout the blend. Butylated hydroxyanisole, ascorbic acid, and citric acid are the key ingredients which create a protective environment for enhancing the stability of the finished product.

- Lactose monohydrate, microcrystalline cellulose are added as bulking agents for better manufacturability and to have suitable tablet weight so that the patient can easily take the medication.

- Pregelatinized starch is added as a disintegrant to provide easy dispersion of the tablet when engulfed by the patient which indirectly enhances the drug release process.

- Magnesium stearate is added to create a hydrophobic environment around particles which provides a lubrication effect during the production process. Lubricant mixing is carefully done to ensure that the drug releasing profile and pharmacokinetics are not influenced by this hydrophobic environment.

- Finally, different coloring agents and film coating are added to give each tablet strength a distinct name and character. Film coating is performed using polymers which imparts a protective barrier for each strength of the drug and to mask the taste.

You submitted product labels for the Simvastatin tablets. You also submitted a shipping label and the Materials Safety Data Sheet ("MSDS") for the API, Simvastatin. Additionally, you provided a manufacturing flow chart depicting the various steps which occur in the United States to make the final Simvastatin tablets.

ISSUE:

What is the country of origin of the Simvastatin tablets for purposes of U.S. Government procurement?

LAW AND ANALYSIS:

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, 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.*).

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 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 or 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, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

In HQ H240193, dated July 29, 2013, which concerned the country of origin marking of the brand-name Crestor® (Rosuvastatin Calcium salt) tablets, CBP found that the API imported from two different countries was not substantially transformed when combined with stabilizers and excipients, and manufactured into tablet form in the United States.

HQ H267177, dated November 5, 2015, concerned Acyclovir, a pharmaceutical product used as a synthetic nucleoside analogue active against herpes viruses. The API was manufactured in China and India and shipped to the United States where it underwent five manufacturing steps including the sizing of the active and inactive ingredients, preparation of Acyclovir granules, preparation of the tablet blend, tablet compression, and packaging in high density polyethylene plastic bottles. CBP determined that the processing performed in the United States did not result in a change in the medicinal use of the finished product and the active ingredient. The active ingredient retained its chemical and physical properties and was merely put into dosage form and packaged for sale. The active ingredient did not undergo a change in name, character or use. Therefore, CBP held that no substantial transformation occurred in United States, and Acyclovir tablets were considered a product of the country in which the active ingredient was produced.

HQ H215656, dated January 11, 2013, concerned the country of origin of Rybix ODT, a pharmaceutical product used for the management of moderate to moderately severe pain in adults. The API, tramadol hydrochloride, manufactured in India, was shipped to France where it underwent four processes of manufacturing consisting of the preparation of the API, preparation of the tablet blend, tablet compression, and packaging in blister packs. CBP determined that the processing in France did not result in a change in the medicinal use of the finished product, and the API retained its chemical and physical properties and was merely put into dosage form and packaged. Accordingly, CBP held that no substantial transformation occurred in France.

HQ H233356, dated December 26, 2012, concerned the country of origin of Ponstel, a pharmaceutical product used for the relief of mild to moderate pain caused by primary dysmenorrhea. Mefenamic acid, which is the API in Ponstel, was manufactured in India, and imported into the United States, where it was blended with inactive ingredients and packaged into dosage form. CBP determined that this process did not substantially transform the mefenamic acid because its chemical character remained the same and, therefore, CBP found that the country of origin of the Ponstel capsules was India.

You state that the FDA requires that a unique National Drug Code ("NDC") be assigned to every drug product such as Simvastatin tablets, but prohibits that same NDC from being associated with any API, such as Simvastatin, that has not been demonstrated to be safe and

effective and cannot be sold for the treatment of any human disease condition. You also state that the FDA requires the name of the drug product (Simvastatin tablet) to appear on every drug product label and prohibits use of that name on the label for the API. Further, you state that Simvastatin is intended only for use by producers for further processing or for research since it is unstable and not fit for medical use and may not be sold to consumers. For these reasons, you claim that extensive additional processing of the API, sourced in India, with other ingredients must occur to change the API's properties and make it into a stable drug product whose medical effectiveness as a drug is sustainable.

This office consulted with CBP's Laboratories and Scientific Services Directorate concerning the instant case, which informed us that the imported API, Simvastatin, retains its chemical and physical properties upon processing in the United States. Increasing the stability of the API and standardizing its concentration do not change the API. Further, the processing performed in the United States does not affect the medicinal use of the API. Based on the information presented, the API does not undergo a change in name, character or use. Therefore, in accordance with the rulings cited, we find that no substantial transformation occurs in United States, and the Simvastatin tablets would be considered a product of India, where the API was produced, for purposes of U.S. government procurement.

In addition, you asked whether the Simvastatin tablets are "manufactured in the United States" within the meaning of the term "U.S.-made end products", as set forth in Section 25.003 of the Federal Acquisition Regulations System, Title 48, Code of Federal Regulations (48 C.F.R. § 25.003), and implemented in 48 C.F.R. § 52.225-5. As stated in 19 C.F.R. § 177.21, subpart B is intended to be applied consistent with the Federal Acquisition Regulations (48 C.F.R. chapter 1). The definition of country of origin in subpart B, 19 C.F.R. § 177.22(a) has two rules (see above) as does 48 C.F.R. § 25.003. The term "manufactured in the United States" in 48 C.F.R. § 25.003 correlates to the first rule of 19 C.F.R. § 177.22(a) which provides that an article is a product of a country or instrumentality if "it is wholly the growth, product, or manufacture of that country or instrumentality". Since the production of Simvastatin tablets partially occurs in India, we do not find that they are manufactured in the United States.

HOLDING:

The country of origin of the Simvastatin tablets for U.S. 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 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 after publication of the *Federal Register* notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel
Executive Director
Regulations and Rulings
Office of Trade

HQ H289715

January 30, 2018

OT:RR:CTF:VS H289715 EE

CATEGORY: Origin

Stephen E. Ruscus
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, NW
Washington, DC 20004

RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Donepezil Hydrochloride tablets

Dear Mr. Ruscus:

This is in response to your correspondence of July 7, 2017 and supplemental submission of August 7, 2017, requesting a final determination on behalf of Acetris Health, ("Acetris")[11], pursuant to subpart B of Part 177, U.S. Customs and Border Protection ("CBP") Regulations (19 C.F.R. § 177.21 *et seq*.). A meeting was held with the counsel for Acetris on August 8, 2017.

[11] Counsel for Acetris states that on May 19, 2017, Acetris executed a novation with Lucid Pharma LLC and the Department of Veterans Affairs whereby the VA recognized Acetris as the successor in interest to Department of Veterans Affairs Contract No. VA 797P-16-C-0034, the subject contract of the underlying request.

This final determination concerns the country of origin of the Donepezil Hydrochloride tablets. We note that Acetris 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.

You have asked that certain information submitted in connection with this ruling request be treated as confidential. Inasmuch as this request conforms to the requirements of 19 C.F.R. § 177.2(b)(7), the request for confidentiality is approved. The information contained within brackets in your request will not be released to the public and will be withheld from published versions of this ruling.

FACTS:

The merchandise at issue are Donepezil Hydrochloride tablets. You state that Acetris is a generic pharmaceutical distributor specializing in providing cost effective products to the U.S. Government. Acetris has its principal place of business in Allendale, NJ. Among the products Acetris sells to the U.S. Government are Donepezil Hydrochloride tablets, members of a family of drugs prescribed for the treatment of dementia of the Alzheimer's type.

You state that Acetris procures the Donepezil Hydrochloride tablets from Aurolife Pharma LLC ("Aurolife"), located in Dayton, NJ. Aurolife, which is a wholly-owned subsidiary of company X in India, is a generic pharmaceutical product manufacturer in the specialty and niche areas. Aurolife manufactures the Donepezil Hydrochloride tablets supplied to Acetris in a U.S. Food & Drug Administration ("FDA") approved cGMP compliant manufacturing facility, located in Dayton, NJ, from several active and inactive ingredients procured domestically and abroad. The active pharmaceutical ingredient ("API") of the Donepezil Hydrochloride tablets is Donepezil Hydrochloride, which Aurolife sources from company X in India.

You state that the Donepezil Hydrochloride tablets supplied to Acetris are the result of a complex production process that occurs in Aurolife's New Jersey facility involving the combination of the API with multiple inactive ingredients, including some intermediates that are mixed in order to aid the conversion of the multiple ingredients. The production of Donepezil Hydrochloride tablets employs processes that convert these ingredients into finished, medically effective dosage tablets (5 mg and 10 mg tablets). You state that this processing changes the properties and characteristics of the API, materially enhancing the pharmacokinetics of the resulting drug.

You state that the process of converting these multiple ingredients into the Donepezil Hydrochloride tablets occurs entirely within the United States. The ingredients processed in the United States are sourced from a variety of suppliers, both United States and foreign, as follows:

Material	**Country**
Donepezil hydrochloride Hydrochloride monohydrate USP	India
Lactose Monohydrate USNF	Country A

Microcrystalline Cellulose USNF (UNITAB 102)	USA
Pregelatinized Starch	USA
Low substituted Hydroxypropyl Cellulose USNF	Country B
Magnesium Stearate USNF	USA
Opadry Yellow 03F82726 IH	USA
Opadry White 03F180009	USA

The processing that occurs in the United States includes the following:

- The particle size of the API is tailored to have a good flowability during the production process so that there is no unit-to-unit variability in the labeled quantity in each tablet.

- Lactose monohydrate and microcrystalline cellulose directly compressible grades are added as bulking agents for better flowability, manufacturability and to have suitable tablet weight so that the patient can easily take the medication.

- Pregelatinized starch and low substituted hydroxyproyl cellulose are added as disintegrants to provide easy dispersion of the tablet when ingested by the patient, which enhances the release process, bioavailability and absorption leading to pharmacokinetic profiles equivalent to the brand product (Aricept®) for therapeutic equivalency.

- Magnesium stearate is added to create a hydrophobic environment around particles which provides a lubrication effect during the production process. Lubricant mixing is carefully done to ensure that the drug releasing profile and pharmacokinetics are not influenced by this hydrophobic environment.

- Coloring agents and film coating are added to give an aesthetic appearance. Film coating is performed using polymers which imparts a protective barrier for the drug.

- Finally the tablets are packed into suitable containers which are capable of retaining the overall integrity of the quality attributes and minimizing the formation of oxidative impurity, thereby transforming it into a more stable product whose therapeutic effectiveness as a drug is sustainable.

You submitted product labels for the Donepezil Hydrochloride tablets. You also submitted a shipping label and the Materials Safety Data Sheet ("MSDS") for the API, Donepezil Hydrochloride. Additionally, you provided a manufacturing flow chart depicting the various steps which occur in the United States to make the final Donepezil Hydrochloride tablets.

ISSUE:

What is the country of origin of the Donepezil Hydrochloride tablets for purposes of U.S. Government procurement?

LAW AND ANALYSIS:

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, 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.*).

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 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 or 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, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

In HQ H240193, dated July 29, 2013, which concerned the country of origin marking of the brand-name Crestor® (Rosuvastatin Calcium salt) tablets, CBP found that the API imported from two different countries was not substantially transformed when combined with stabilizers and excipients, and manufactured into tablet form in the United States.

HQ H267177, dated November 5, 2015, concerned Acyclovir, a pharmaceutical product used as a synthetic nucleoside analogue active against herpes viruses. The API was manufactured in China and India and shipped to the United States where it underwent five manufacturing steps including the sizing of the active and inactive ingredients, preparation of Acyclovir granules, preparation of the tablet blend, tablet compression, and packaging in high density polyethylene plastic bottles. CBP determined that the processing performed in the United States did not result in a change in the medicinal use of the finished product and the active ingredient. The active ingredient retained its chemical and physical properties and was merely put into dosage form and packaged for sale. The active ingredient did not undergo a change in name, character or use. Therefore, CBP held that no substantial transformation occurred in United States, and Acyclovir tablets were considered a product of the country in which the active ingredient was produced.

HQ H215656, dated January 11, 2013, concerned the country of origin of Rybix ODT, a pharmaceutical product used for the management of moderate to moderately severe pain in adults. The API, tramadol hydrochloride, manufactured in India, was shipped to France where it underwent four processes of manufacturing consisting of the preparation of the API, preparation of the tablet blend, tablet compression, and packaging in blister packs. CBP determined that the processing in France did not result in a change in the medicinal use of the finished product, and the API retained its chemical and physical properties and was merely put into dosage form and packaged. Accordingly, CBP held that no substantial transformation occurred in France.

HQ H233356, dated December 26, 2012, concerned the country of origin of Ponstel, a pharmaceutical product used for the relief of mild to moderate pain caused by primary dysmenorrhea. Mefenamic acid, which is the API in Ponstel, was manufactured in India, and imported into the United States, where it was blended with inactive ingredients and packaged into dosage form. CBP determined that this process did not substantially transform the mefenamic acid because its chemical character remained

the same and, therefore, CBP found that the country of origin of the Ponstel capsules was India.

You state that the FDA requires that a unique National Drug Code ("NDC") be assigned to every drug product such as Donepezil Hydrochloride tablets, but prohibits that same NDC from being associated with any API, such as Donepezil Hydrochloride, that has not been demonstrated to be safe and effective and cannot be sold for the treatment of any human disease condition. You also state that the FDA requires the name of the drug product (Donepezil Hydrochloride tablet) to appear on every drug product label and prohibits use of that name on the label for the API. Further, you state that Donepezil Hydrochloride is intended only for use by producers for further processing or for research since it is unstable and not fit for medical use and may not be sold to consumers. Additionally, you state that the API is poisonous and has poor flow properties. For these reasons, you claim that extensive additional processing of the API, sourced in India, with other ingredients must occur to change the API's properties and make it into a stable drug product.

This office consulted with CBP's Laboratories and Scientific Services Directorate concerning the instant case, which informed us that the imported API, Donepezil Hydrochloride, retains its chemical and physical properties upon processing in the United States. Increasing the stability of the API and standardizing its concentration do not change the API. Further, the processing performed in the United States does not affect the medicinal use of the API. Based on the information presented, the API does not undergo a change in name, character or use. Therefore, in accordance with the rulings cited, we find that no substantial transformation occurs in United States, and the Donepezil Hydrochloride tablets would be considered a product of India, where the API was produced, for purposes of U.S. government procurement.

In addition, you asked whether the Donepezil Hydrochloride tablets are "manufactured in the United States" within the meaning of the term "U.S.-made end products", as set forth in Section 25.003 of the Federal Acquisition Regulations System, Title 48, Code of Federal Regulations (48 C.F.R. § 25.003), and implemented in 48 C.F.R. § 52.225-5. As stated in 19 C.F.R. § 177.21, subpart B is intended to be applied consistent with the Federal Acquisition Regulations (48 C.F.R. chapter 1). The definition of country of origin in subpart B, 19 C.F.R. § 177.22(a) has two rules (see above) as does 48 C.F.R. § 25.003. The term "manufactured in the United States" in 48 C.F.R. § 25.003 correlates to the first rule of 19 C.F.R. § 177.22(a) which provides that an article is a product of a country or instrumentality if "it is wholly the growth, product, or manufacture of that country or instrumentality". Since the production of Donepezil Hydrochloride tablets partially occurs in India, we do not find that they are manufactured in the United States.

HOLDING:

The country of origin of the Donepezil Hydrochloride tablets for U.S. 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 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 after publication of the *Federal Register* notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel
Executive Director
Regulations and Rulings
Office of Trade

[FR Doc. 2018-02245 Filed: 2/2/2018 8:45 am; Publication Date: 2/5/2018]