



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 six final determinations concerning the country of origin of certain pharmaceutical products produced by Lupin Pharmaceuticals, Inc. Based upon the facts presented, CBP has concluded that the country of origin of the meloxicam tablets is Italy for purposes of U.S. Government procurement, that the country of origin of the bimatoprost ophthalmic solution is Taiwan for purposes of U.S. Government procurement, that the country of origin of the niacin ER tablets is Belgium or Switzerland for purposes of U.S. Government procurement, that the country of origin of the calcium acetate capsules is the Netherlands for purposes of U.S. Government procurement, that the country of origin of the quinine sulfate capsules is Germany for purposes of U.S. Government procurement, and that the country of origin of the pravastatin sodium tablets is Taiwan for purposes of U.S. Government procurement.

DATES: These final determinations were issued on August 22, 2017. 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: Ross M. Cunningham, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade, (202) 325-0034.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on August 22, 2017 pursuant to subpart B of Part 177, U.S. Customs and Border Protection Regulations (19 CFR Part 177, subpart B), CBP issued six 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. These final determinations (HQ H284690, HQ H284961, HQ H284692, HQ H284694, HQ H284695, and HQ H284697), 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 India does not result in a substantial transformation. Therefore, the country of origin for purposes of U.S. Government procurement of the pharmaceutical products is the country in which 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: August 22, 2017

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

Attachments

ATTACHMENT A

HQ H284690

August 22, 2017

OT:RR:CTF:VS H284690 RMC

CATEGORY: Origin

Kevin J. Maynard
Wiley Rein LLP
1776 K St. NW
Washington, DC 20006

Re: U.S. Government Procurement; Country of Origin of Meloxicam Tablets; Substantial Transformation

Dear Mr. Maynard:

This is in response to your letter, dated March 20, 2017, requesting a final determination on behalf of Lupin Pharmaceuticals, Inc. (“Lupin”) pursuant to subpart B of Part 177 of the U.S. Customs and Border Protection (“CBP”) Regulations (19 C.F.R. Part 177). Under these regulations, which implement Title III of the Trade Agreements Act of 1979 (“TAA”), as amended (19 U.S.C. § 2511 *et seq.*), CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain “Buy American” restrictions in U.S. law or for products offered for sale to the U.S. Government. This final determination concerns the country of origin of meloxicam tablets. As a U.S. importer, Lupin 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 and all attachments to this ruling request, forwarded to our office, will not be released to the public and will be withheld from published versions of this ruling.

FACTS:

Lupin is a subsidiary of Lupin Limited, one of the five largest pharmaceutical companies in India. At issue in this case are meloxicam tablets, in doses of 7.5 milligrams and 15 milligrams,

which you describe as “nonsteroidal anti-inflammatory[ies] used for the relief of the signs and symptoms of rheumatoid arthritis and osteoarthritis.”

The manufacturing process for Lupin’s meloxicam tablets begins in Italy, where the active pharmaceutical ingredient (“API”) meloxicam (chemical formula C₁₄H₁₃N₃O₄S₂) is produced. You state that the Italian meloxicam is the only active ingredient in the finished pharmaceutical product. However, the finished product contains a number of other inactive ingredients, which you describe as excipients. These ingredients are combined with the Italian API in India during the manufacturing process. The ingredients include the following chemicals, which you note are products of TAA-eligible countries:

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The manufacturing process in India involves four steps. First, the API and inactive ingredients are sifted and blended. Second, the materials are granulated, and the wet granulates are then sieved and dried. Third, the product is compressed into tablets. Finally, in the fourth step, the finished tablets are packaged into approved packaging.

You state that the processes performed to produce the finished meloxicam tablets do not result in any change to the chemical characteristics of the Italian API or to any other ingredients. You also state that the medicinal use, molecular formula, and solubility of the API are unchanged by the manufacturing operations in India. In short, you characterize the Indian operations as mere processing of bulk API into 7.5 milligram and 15 milligram dosage form.

ISSUE:

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

LAW AND ANALYSIS:

Pursuant to subpart B of Part 177, 19 C.F.R. § 177.21 *et seq.*, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq.*), CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain “Buy American” restrictions in U.S. law or practice for products offered for sale to the U.S. Government.

Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B):

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

See also 19 C.F.R. § 177.22(a).

A substantial transformation occurs when an article emerges from a process with a new name, character, and use different from that possessed by the article prior to processing. A substantial transformation will not result from a minor manufacturing or combining process that leaves the identity of the article intact. *See United States v. Gibson-Thomsen Co.*, 27 C.C.P.A. 267 (1940); and *National Juice Products Ass'n v. United States*, 628 F.Supp. 978 (Ct. Int'l Trade 1986).

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, CBP has generally held that the processing of pharmaceutical products from bulk form into measured doses does not result in a substantial transformation of the product. *See, e.g.*, Headquarters Ruling (“HQ”) 561975, dated April 3, 2002; HQ 561544, dated May 1, 2000; HQ 735146, dated November 15, 1993; HQ H267177, dated November 5, 2016; HQ H233356, dated December 26, 2012; and, HQ 561975, dated April 3, 2002.

For example, in HQ H267177, CBP held that Indian- and Chinese-origin Acyclovir was not substantially transformed in the United States when it was combined with excipients and processed into tablets. In that case, the Indian or Chinese Acyclovir was the only active pharmaceutical ingredient in the final product. Accordingly, we found that the processing performed in the United States did not result in a change in the medicinal use of the finished product. Furthermore, the Acyclovir maintained its chemical and physical characteristics and did not undergo a change in name, character, or use. Consistent with our previous rulings, we held that processing the Acyclovir into dosage form and packaging it for sale in the United States did not constitute a substantial transformation. Accordingly, the country of origin of the final product for purposes of U.S. Government procurement was either China or India, where the active ingredient was produced.

Similarly, in HQ H233356, CBP held that the processing and packaging of imported mefenamic acid into dosage form in the United States did not constitute substantial transformation. Based on previous CBP rulings, we found that the specific U.S. processing—which involved blending the active ingredients with inactive ingredients in a tumbler and then encapsulating and packaging the product—did not substantially transform the mefenamic acid because its chemical character remained the same. Accordingly, we held that the country of origin of the final product was India, where the mefenamic acid was produced.

In HQ 561975, we also held that the processing of imported bulk Japanese-origin anesthetic drugs into dosage form in the United States did not constitute substantial transformation. Although the bulk form of the drug underwent testing operations, filtering, and packaging in the United States, these processes did not change the chemical or physical properties of the drug. Furthermore, there was no change in the product's name, which was referred to as sevoflurane in both its bulk and processed form. Additionally, because the imported bulk drug had a predetermined medicinal use as an anesthetic drug, the processing in the United States did not result in a change in the product's use. The country of origin of the finished product was therefore Japan.

Here, as in the cases cited above, the processing of bulk imported pharmaceuticals into dosage form will not result in a substantial transformation. In this case, the processing begins with Italian-origin bulk meloxicam and, after this product is combined with inactive ingredients from TAA-eligible countries in India, results in meloxicam tablets in individual doses of either 7.5 milligrams or 15 milligrams. Because the product is referred to as "meloxicam" both before and after the Indian processing, no change in name occurs in India. Furthermore, no change in character occurs in India because the meloxicam maintains the same chemical and physical properties both before and after the Indian processing. Finally, because the imported, bulk-form meloxicam had a predetermined medicinal use as a nonsteroidal anti-inflammatory, no change in use occurs after processing in India. Under these circumstances, and consistent with previous CBP rulings, we find that the country of origin of the final product is Italy, where the active ingredient was produced.

HOLDING:

The country of origin of the meloxicam tablets for purposes of U.S. Government procurement is Italy.

Notice of this final determination will be given in the Federal Register, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R. § 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-interest may, within 30 days of publication of the Federal Register Notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel, Executive Director
Regulations & Rulings
Office of Trade

ATTACHMENT B

HQ H284691

August 22, 2017

OT:RR:CTF:VS H284691 RMC

CATEGORY: Origin

Kevin J. Maynard
Wiley Rein LLP
1776 K St. NW
Washington, DC 20006

Re: U.S. Government Procurement; Country of Origin of Bimatoprost Ophthalmic Solution;
Substantial Transformation

Dear Mr. Maynard:

This is in response to your letter, dated March 20, 2017, requesting a final determination on behalf of Lupin Pharmaceuticals, Inc. (“Lupin”) pursuant to subpart B of Part 177 of the U.S. Customs and Border Protection (“CBP”) Regulations (19 C.F.R. Part 177). Under these regulations, which implement Title III of the Trade Agreements Act of 1979 (“TAA”), as amended (19 U.S.C. § 2511 *et seq.*), CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain “Buy American” restrictions in U.S. law or for products offered for sale to the U.S. Government. This final determination concerns the country of origin of bimatoprost ophthalmic solution. As a U.S. importer, Lupin 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 and all attachments to this ruling request, forwarded to our office, will not be released to the public and will be withheld from published versions of this ruling.

FACTS:

Lupin is a subsidiary of Lupin Limited, one of the five largest pharmaceutical companies in India. At issue in this case are bimatoprost ophthalmic solution (0.03%), which you describe as “a ‘prostaglandin analog’ used to reduce elevated intraocular pressure.”

The manufacturing process for Lupin’s bimatoprost ophthalmic solution begins in Taiwan, where the active pharmaceutical ingredient (“API”) bimatoprost (chemical formula C₂₅H₃₇NO₄) is produced. You state that the Taiwanese bimatoprost is the only active ingredient in the finished pharmaceutical product. However, the finished product contains a number of other inactive ingredients, which you describe as excipients. These ingredients are combined with the Taiwanese API in India during the manufacturing process. The ingredients include the following:

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The manufacturing processes performed in India include the following four steps: First, the weights of the API and inactive ingredients are verified. Second, the active and inactive ingredients are dissolved in water. Third, the inactive and active ingredient solutions are combined and the pH level is adjusted if necessary. Finally, in the fourth step, the solution is filtered and placed into approved packaging.

You state that the processes performed to produce the finished bimatoprost ophthalmic solution do not result in any change to the chemical characteristics of the Taiwanese API or to any other ingredients. You also state that the medicinal use, molecular formula, and solubility of the API are unchanged by the manufacturing operations in India. In short, you characterize the Indian operations as mere processing of bulk API into 0.03%-strength dosage form.

ISSUE:

What is the country of origin of the bimatoprost ophthalmic solution for purposes of U.S. Government procurement?

LAW AND ANALYSIS:

Pursuant to subpart B of Part 177, 19 C.F.R. § 177.21 *et seq.*, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq.*), CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain “Buy American” restrictions in U.S. law or practice for products offered for sale to the U.S. Government.

Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B):

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in

the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

See also 19 C.F.R. § 177.22(a).

A substantial transformation occurs when an article emerges from a process with a new name, character, and use different from that possessed by the article prior to processing. A substantial transformation will not result from a minor manufacturing or combining process that leaves the identity of the article intact. *See United States v. Gibson-Thomsen Co.*, 27 C.C.P.A. 267 (1940); and *National Juice Products Ass'n v. United States*, 628 F.Supp. 978 (Ct. Int'l Trade 1986).

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, CBP has generally held that the processing of pharmaceutical products from bulk form into measured doses does not result in a substantial transformation of the product. *See, e.g.*, Headquarters Ruling (“HQ”) 561975, dated April 3, 2002; HQ 561544, dated May 1, 2000; HQ 735146, dated November 15, 1993; HQ H267177, dated November 5, 2016; HQ H233356, dated December 26, 2012; and, HQ 561975, dated April 3, 2002.

For example, in HQ H267177, CBP held that Indian- and Chinese-origin Acyclovir was not substantially transformed in the United States when it was combined with excipients and processed into tablets. In that case, the Indian or Chinese Acyclovir was the only active pharmaceutical ingredient in the final product. Accordingly, we found that the processing performed in the United States did not result in a change in the medicinal use of the finished product. Furthermore, the Acyclovir maintained its chemical and physical characteristics and did not undergo a change in name, character, or use. Consistent with our previous rulings, we held that processing the Acyclovir into dosage form and packaging it for sale in the United States did not constitute a substantial transformation. Accordingly, the country of origin of the final product for purposes of U.S. Government procurement was either China or India, where the active ingredient was produced.

Similarly, in HQ H233356, CBP held that the processing and packaging of imported mefenamic acid into dosage form in the United States did not constitute substantial transformation. Based on previous CBP rulings, we found that the specific U.S. processing—which involved blending the active ingredients with inactive ingredients in a tumbler and then encapsulating and packaging the product—did not substantially transform the mefenamic acid because its chemical character remained the same. Accordingly, we held that the country of origin of the final product was India, where the mefenamic acid was produced.

In HQ 561975, we also held that the processing of imported bulk Japanese-origin anesthetic drugs into dosage form in the United States did not constitute substantial transformation. Although the bulk form of the drug underwent testing operations, filtering, and packaging in the United States,

these processes did not change the chemical or physical properties of the drug. Furthermore, there was no change in the product's name, which was referred to as sevoflurane in both its bulk and processed form. Additionally, because the imported bulk drug had a predetermined medicinal use as an anesthetic drug, the processing in the United States did not result in a change in the product's use. The country of origin of the finished product was therefore Japan.

Here, as in the cases cited above, the processing of bulk imported pharmaceuticals into dosage form will not result in a substantial transformation. In this case, the processing begins with Taiwanese-origin bulk bimatoprost and, after this product is combined with inactive ingredients in India, results in bimatoprost ophthalmic solution in 0.03%-strength form. Because the product is referred to as "bimatoprost" both before and after the Indian processing, no change in name occurs in India. Furthermore, no change in character occurs in India because the bimatoprost maintains the same chemical and physical properties both before and after the Indian processing. Finally, because the imported, bulk-form bimatoprost had a predetermined medicinal use as a "prostaglandin analog" used to reduce elevated intraocular pressure, no change in use occurs after processing in India. Under these circumstances, and consistent with previous CBP rulings, we find that the country of origin of the final product is Taiwan, where the active ingredient was produced.

HOLDING:

The country of origin of the bimatoprost ophthalmic solution for purposes of U.S. Government procurement is Taiwan.

Notice of this final determination will be given in the Federal Register, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R. § 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-interest may, within 30 days of publication of the Federal Register Notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel, Executive Director
Regulations & Rulings
Office of Trade

ATTACHMENT C

HQ H284692

August 22, 2017

OT:RR:CTF:VS H284692 RMC

CATEGORY: Origin

Kevin J. Maynard
Wiley Rein LLP
1776 K St. NW
Washington, DC 20006

Re: U.S. Government Procurement; Country of Origin of Niacin ER Tablets; Substantial Transformation

Dear Mr. Maynard:

This is in response to your letter, dated March 20, 2017, requesting a final determination on behalf of Lupin Pharmaceuticals, Inc. (“Lupin”) pursuant to subpart B of Part 177 of the U.S. Customs and Border Protection (“CBP”) Regulations (19 C.F.R. Part 177). Under these regulations, which implement Title III of the Trade Agreements Act of 1979 (“TAA”), as amended (19 U.S.C. § 2511 *et seq.*), CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain “Buy American” restrictions in U.S. law or for products offered for sale to the U.S. Government. This final determination concerns the country of origin of niacin ER tablets. As a U.S. importer, Lupin 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 and all attachments to this ruling request, forwarded to our office, will not be released to the public and will be withheld from published versions of this ruling.

FACTS:

Lupin is a subsidiary of Lupin Limited, one of the five largest pharmaceutical companies in India. At issue in this case are niacin ER tablets, in doses of 500 milligrams, 750 milligrams, and

1000 milligrams, which you describe as “an antihyperlipidemic agent . . . used in patients with primary hyperlipidemia and mixed dyslipidemia.”

The manufacturing process for Lupin’s niacin ER tablets begins in either Belgium or Switzerland, where the active pharmaceutical ingredient (“API”) nicotinic acid (chemical formula C₆H₅NO₂) is produced. You state that the Belgian or Swiss nicotinic acid is the only active ingredient in the finished pharmaceutical product. However, the finished product contains a number of other inactive ingredients, which you describe as excipients. These ingredients are combined with the Belgian or Swiss API in India during the manufacturing process. The ingredients include the following:

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The manufacturing processes performed in India include the following four steps: First, the API and inactive ingredients are sifted and blended. Second, the materials are granulated, and then sieved. Third, the blend is compressed into tablets and the tablets are coated. Finally, in the fourth step, the finished tablets are packaged into approved packaging.

You state that the processes performed to produce the finished niacin ER tablets do not result in any change to the chemical characteristics of the Belgian or Swiss API or to any other ingredients. You also state that the medicinal use, molecular formula, and solubility of the API are unchanged by the manufacturing operations in India. In short, you characterize the Indian operations as mere processing of bulk API into 500-milligram, 750-milligram, and 1000-milligram dosage form.

ISSUE:

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

LAW AND ANALYSIS:

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

origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain “Buy American” restrictions in U.S. law or practice for products offered for sale to the U.S. Government.

Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B):

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

See also 19 C.F.R. § 177.22(a).

A substantial transformation occurs when an article emerges from a process with a new name, character, and use different from that possessed by the article prior to processing. A substantial transformation will not result from a minor manufacturing or combining process that leaves the identity of the article intact. *See United States v. Gibson-Thomsen Co.*, 27 C.C.P.A. 267 (1940); and *National Juice Products Ass’n v. United States*, 628 F.Supp. 978 (Ct. Int’l Trade 1986).

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, CBP has generally held that the processing of pharmaceutical products from bulk form into measured doses does not result in a substantial transformation of the product. *See, e.g.*, Headquarters Ruling (“HQ”) 561975, dated April 3, 2002; HQ 561544, dated May 1, 2000; HQ 735146, dated November 15, 1993; HQ H267177, dated November 5, 2016; HQ H233356, dated December 26, 2012; and, HQ 561975, dated April 3, 2002.

For example, in HQ H267177, CBP held that Indian- and Chinese-origin Acyclovir was not substantially transformed in the United States when it was combined with excipients and processed into tablets. In that case, the Indian or Chinese Acyclovir was the only active pharmaceutical ingredient in the final product. Accordingly, we found that the processing performed in the United States did not result in a change in the medicinal use of the finished product. Furthermore, the Acyclovir maintained its chemical and physical characteristics and did not undergo a change in name, character, or use. Consistent with our previous rulings, we held that processing the Acyclovir into dosage form and packaging it for sale in the United States did not constitute a substantial transformation. Accordingly, the country of origin of the final product for purposes of U.S. Government procurement was either China or India, where the active ingredient was produced.

Similarly, in HQ H233356, CBP held that the processing and packaging of imported mefenamic acid into dosage form in the United States did not constitute substantial transformation. Based on previous CBP rulings, we found that the specific U.S. processing—which involved

blending the active ingredients with inactive ingredients in a tumbler and then encapsulating and packaging the product—did not substantially transform the mefenamic acid because its chemical character remained the same. Accordingly, we held that the country of origin of the final product was India, where the mefenamic acid was produced.

In HQ 561975, we also held that the processing of imported bulk Japanese-origin anesthetic drugs into dosage form in the United States did not constitute substantial transformation. Although the bulk form of the drug underwent testing operations, filtering, and packaging in the United States, these processes did not change the chemical or physical properties of the drug. Furthermore, there was no change in the product's name, which was referred to as sevoflurane in both its bulk and processed form. Additionally, because the imported bulk drug had a predetermined medicinal use as an anesthetic drug, the processing in the United States did not result in a change in the product's use. The country of origin of the finished product was therefore Japan.

Here, as in the cases cited above, the processing of bulk imported pharmaceuticals into dosage form will not result in a substantial transformation. In this case, the processing begins with Belgian- or Swiss-origin bulk nicotinic acid and, after this product is combined with inactive ingredients in India, results in niacin ER tablets in individual doses of 500 milligrams, 750 milligrams, or 1000 milligrams. Although Lupin refers to the final product as niacin, it is also commonly known as nicotinic acid. See WebMD, *Niacin ER*, <http://webmd.com/drugs/2/drug-3745-9126/niacin-oral/niacin-extended-release-oral/details> (last visited June 22, 2017). Because the product is referred to as nicotinic acid both before and after the Indian processing, no change in name occurs in India. Furthermore, no change in character occurs in India because the nicotinic acid maintains the same chemical and physical properties both before and after the Indian processing. Finally, because the imported, bulk-form nicotinic acid had a predetermined medicinal use as an antihyperlipidemic agent, no change in use occurs after processing in India. Under these circumstances, and consistent with previous CBP rulings, we find that the country of origin of the final product is Belgium or Switzerland, where the active ingredient was produced.

HOLDING:

The country of origin of the niacin ER tablets for purposes of U.S. Government procurement is Belgium or Switzerland.

ATTACHMENT D

HQ H284694

August 22, 2017

OT:RR:CTF:VS H284694 RMC

CATEGORY: Origin

Kevin J. Maynard
Wiley Rein LLP
1776 K St. NW
Washington, DC 20006

Re: U.S. Government Procurement; Country of Origin of Calcium Acetate Capsules; Substantial Transformation

Dear Mr. Maynard:

This is in response to your letter, dated March 20, 2017, requesting a final determination on behalf of Lupin Pharmaceuticals, Inc. (“Lupin”) pursuant to subpart B of Part 177 of the U.S. Customs and Border Protection (“CBP”) Regulations (19 C.F.R. Part 177). Under these regulations, which implement Title III of the Trade Agreements Act of 1979 (“TAA”), as amended (19 U.S.C. § 2511 *et seq.*), CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain “Buy American” restrictions in U.S. law or for products offered for sale to the U.S. Government. This final determination concerns the country of origin of calcium acetate capsules. As a U.S. importer, Lupin 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 and all attachments to this ruling request, forwarded to our office, will not be released to the public and will be withheld from published versions of this ruling.

FACTS:

Lupin is a subsidiary of Lupin Limited, one of the five largest pharmaceutical companies in India. At issue in this case are calcium acetate capsules, in doses of 667 milligrams, which you describe as a “antihyperphosphatemic’ or ‘phosphate binder’ that is used to reduce the levels of phosphate in the blood.”

The manufacturing process for Lupin’s calcium acetate capsules begins in the Netherlands, where the active pharmaceutical ingredient (“API”) calcium acetate (chemical formula C₄H₆CaO₄) is produced. You state that the Dutch calcium acetate is the only active ingredient in the finished pharmaceutical product. However, the finished product contains a number of other inactive ingredients. These ingredients are combined with the Dutch API in India during the manufacturing process. The ingredients include the following:

- []
- []
- []

The manufacturing processes performed in India include the following three steps: First, the API and inactive ingredients are sifted and blended. Second, the blend is filled in gelatin capsules. Finally, in the third step, the finished capsules are packaged into approved packaging.

You state that the processes performed to produce the finished calcium acetate capsules do not result in any change to the chemical characteristics of the Dutch API or to any other ingredients. You also state that the medicinal use, molecular formula, and solubility of the API are unchanged by the manufacturing operations in India. In short, you characterize the Indian operations as mere processing of bulk API into 667 milligram dosage form.

ISSUE:

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

LAW AND ANALYSIS:

Pursuant to subpart B of Part 177, 19 C.F.R. § 177.21 *et seq.*, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq.*), CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain “Buy American” restrictions in U.S. law or practice for products offered for sale to the U.S. Government.

Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B):

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

See also 19 C.F.R. § 177.22(a).

A substantial transformation occurs when an article emerges from a process with a new name, character, and use different from that possessed by the article prior to processing. A substantial transformation will not result from a minor manufacturing or combining process that leaves the identity of the article intact. *See United States v. Gibson-Thomsen Co.*, 27 C.C.P.A. 267 (1940); and *National Juice Products Ass’n v. United States*, 628 F.Supp. 978 (Ct. Int’l Trade 1986).

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, CBP has generally held that the processing of pharmaceutical products from bulk form into measured doses does not result in a substantial transformation of the product. *See, e.g.*, Headquarters Ruling (“HQ”) 561975, dated April 3, 2002; HQ 561544, dated May 1, 2000; HQ 735146, dated November 15, 1993; HQ H267177, dated November 5, 2016; HQ H233356, dated December 26, 2012; and, HQ 561975, dated April 3, 2002.

For example, in HQ H267177, CBP held that Indian- and Chinese-origin Acyclovir was not substantially transformed in the United States when it was combined with excipients and processed into tablets. In that case, the Indian or Chinese Acyclovir was the only active pharmaceutical ingredient in the final product. Accordingly, we found that the processing performed in the United States did not result in a change in the medicinal use of the finished product. Furthermore, the Acyclovir maintained its chemical and physical characteristics and did not undergo a change in name, character, or use. Consistent with our previous rulings, we held that processing the Acyclovir into dosage form and packaging it for sale in the United States did not constitute a substantial transformation. Accordingly, the country of origin of the final product for purposes of U.S. Government procurement was either China or India, where the active ingredient was produced.

Similarly, in HQ H233356, CBP held that the processing and packaging of imported mefenamic acid into dosage form in the United States did not constitute substantial transformation. Based on previous CBP rulings, we found that the specific U.S. processing—which involved blending the active ingredients with inactive ingredients in a tumbler and then encapsulating and packaging the product—did not substantially transform the mefenamic acid because its chemical character remained the same. Accordingly, we held that the country of origin of the final product was India, where the mefenamic acid was produced.

In HQ 561975, we also held that the processing of imported bulk Japanese-origin anesthetic drugs into dosage form in the United States did not constitute substantial transformation. Although the bulk form of the drug underwent testing operations, filtering, and packaging in the United States, these processes did not change the chemical or physical properties of the drug. Furthermore, there was no change in the product’s name, which was referred to as sevoflurane in both its bulk and processed form. Additionally, because the imported bulk drug had a predetermined medicinal use as an anesthetic drug, the processing in the United States did not result in a change in the product’s use. The country of origin of the finished product was therefore Japan.

Here, as in the cases cited above, the processing of bulk imported pharmaceuticals into dosage form will not result in a substantial transformation. In this case, the processing begins with Dutch-origin bulk calcium acetate and, after this product is combined with inactive ingredients in India, results in calcium acetate capsules in individual doses of 667 milligrams. Because the product is referred to as “calcium acetate” both before and after the Indian processing, no change in name occurs in India. Furthermore, no change in character occurs in India because the calcium acetate maintains the same chemical and physical properties both before and after the Indian processing.

Finally, because the imported, bulk-form calcium acetate had a predetermined medicinal use as an antihyperphosphatemic or phosphate binder, no change in use occurs after processing in India. Under these circumstances, and consistent with previous CBP rulings, we find that the country of origin of the final product is the Netherlands, where the active ingredient was produced.

HOLDING:

The country of origin of the calcium acetate capsules for purposes of U.S. Government procurement is the Netherlands.

Notice of this final determination will be given in the Federal Register, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R. § 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-interest may, within 30 days of publication of the Federal Register Notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel, Executive Director
Regulations & Rulings
Office of Trade

Notice of this final determination will be given in the Federal Register, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R. § 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-interest may, within 30 days of publication of the Federal Register Notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel, Executive Director
Regulations & Rulings
Office of Trade

ATTACHMENT E

HQ H284695

August 22, 2017

OT:RR:CTF:VS H284695 RMC

CATEGORY: Origin

Kevin J. Maynard
Wiley Rein LLP
1776 K St. NW
Washington, DC 20006

Re: U.S. Government Procurement; Country of Origin of Quinine Sulfate Capsules; Substantial Transformation

Dear Mr. Maynard:

This is in response to your letter, dated March 20, 2017, requesting a final determination on behalf of Lupin Pharmaceuticals, Inc. (“Lupin”) pursuant to subpart B of Part 177 of the U.S. Customs and Border Protection (“CBP”) Regulations (19 C.F.R. Part 177). Under these regulations, which implement Title III of the Trade Agreements Act of 1979 (“TAA”), as amended (19 U.S.C. § 2511 *et seq.*), CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain “Buy American” restrictions in U.S. law or for products offered for sale to the U.S. Government. This final determination concerns the country of origin of quinine sulfate capsules. As a U.S. importer, Lupin 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

and all attachments to this ruling request, forwarded to our office, will not be released to the public and will be withheld from published versions of this ruling.

FACTS:

Lupin is a subsidiary of Lupin Limited, one of the five largest pharmaceutical companies in India. At issue in this case are quinine sulfate capsules, in doses of 324 milligrams, which you describe as “cinchona alkaloid[s]’ that [are] used for the treatment of malaria.”

The manufacturing process for Lupin’s quinine sulfate capsules begins in Germany, where the active pharmaceutical ingredient (“API”) quinine sulfate (chemical formula ((C₂₀H₂₄N₂O₂)₂H₂SO₄·2H₂O) is produced. You state that the German quinine sulfate is the only active ingredient in the finished pharmaceutical product. However, the finished product contains a number of other inactive ingredients, which you describe as excipients. These ingredients are combined with the German API in India during the manufacturing process. The ingredients include the following:

- []
- []
- []
- []

The manufacturing processes performed in India include the following four steps: First, the API and inactive ingredients are sifted and blended. Second, the materials are granulated, and then sieved. Third, the blend is filled in gelatin capsules. Finally, in the fourth step, the finished capsules are packaged into approved packaging.

You state that the processes performed to produce the finished quinine sulfate capsules do not result in any change to the chemical characteristics of the German API or to any other ingredients. You also state that the medicinal use, molecular formula, and solubility of the API are unchanged by the manufacturing operations in India. In short, you characterize the Indian operations as mere processing of bulk API into 324 milligram dosage form.

ISSUE:

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

LAW AND ANALYSIS:

Pursuant to subpart B of Part 177, 19 C.F.R. § 177.21 *et seq.*, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq.*), CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain “Buy American” restrictions in U.S. law or practice for products offered for sale to the U.S. Government.

Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B):

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

See also 19 C.F.R. § 177.22(a).

A substantial transformation occurs when an article emerges from a process with a new name, character, and use different from that possessed by the article prior to processing. A substantial transformation will not result from a minor manufacturing or combining process that leaves the identity of the article intact. *See United States v. Gibson-Thomsen Co.*, 27 C.C.P.A. 267 (1940); and *National Juice Products Ass'n v. United States*, 628 F.Supp. 978 (Ct. Int'l Trade 1986).

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, CBP has generally held that the processing of pharmaceutical products from bulk form into measured doses does not result in a substantial transformation of the product. *See, e.g.*, Headquarters Ruling (“HQ”) 561975, dated April 3, 2002; HQ 561544, dated May 1, 2000; HQ 735146, dated November 15, 1993; HQ H267177, dated November 5, 2016; HQ H233356, dated December 26, 2012; and, HQ 561975, dated April 3, 2002.

For example, in HQ H267177, CBP held that Indian- and Chinese-origin Acyclovir was not substantially transformed in the United States when it was combined with excipients and processed into tablets. In that case, the Indian or Chinese Acyclovir was the only active pharmaceutical ingredient in the final product. Accordingly, we found that the processing performed in the United States did not result in a change in the medicinal use of the finished product. Furthermore, the Acyclovir maintained its chemical and physical characteristics and did not undergo a change in name, character, or use. Consistent with our previous rulings, we held that processing the Acyclovir into dosage form and packaging it for sale in the United States did not constitute a substantial transformation. Accordingly, the country of origin of the final product for purposes of U.S. Government procurement was either China or India, where the active ingredient was produced.

Similarly, in HQ H233356, CBP held that the processing and packaging of imported mefenamic acid into dosage form in the United States did not constitute substantial transformation. Based on previous CBP rulings, we found that the specific U.S. processing—which involved blending the active ingredients with inactive ingredients in a tumbler and then encapsulating and packaging the product—did not substantially transform the mefenamic acid because its chemical

character remained the same. Accordingly, we held that the country of origin of the final product was India, where the mefanamic acid was produced.

In HQ 561975, we also held that the processing of imported bulk Japanese-origin anesthetic drugs into dosage form in the United States did not constitute substantial transformation. Although the bulk form of the drug underwent testing operations, filtering, and packaging in the United States, these processes did not change the chemical or physical properties of the drug. Furthermore, there was no change in the product's name, which was referred to as sevoflurane in both its bulk and processed form. Additionally, because the imported bulk drug had a predetermined medicinal use as an anesthetic drug, the processing in the United States did not result in a change in the product's use. The country of origin of the finished product was therefore Japan.

Here, as in the cases cited above, the processing of bulk imported pharmaceuticals into dosage form will not result in a substantial transformation. In this case, the processing begins with German-origin bulk quinine sulfate and, after this product is combined with inactive ingredients in India, results in quinine sulfate capsules in 324 milligram doses. Because the product is referred to as "quinine sulfate" both before and after the Indian processing, no change in name occurs in India. Furthermore, no change in character occurs in India because the quinine sulfate maintains the same chemical and physical properties both before and after the Indian processing. Finally, because the imported, bulk-form quinine sulfate had a predetermined medicinal use as an antimalarial drug, no change in use occurs after processing in India. Under these circumstances, and consistent with previous CBP rulings, we find that the country of origin of the final product is Germany, where the active ingredient was produced.

HOLDING:

The country of origin of the quinine sulfate capsules for purposes of U.S. Government procurement is Germany.

Notice of this final determination will be given in the Federal Register, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R. § 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-interest may, within 30 days of publication of the Federal Register Notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel, Executive Director
Regulations & Rulings
Office of Trade

ATTACHMENT F

HQ H284697

August 22, 2017

OT:RR:CTF:VS H284697 RMC

CATEGORY: Origin

Kevin J. Maynard
Wiley Rein LLP
1776 K St. NW
Washington, DC 20006

Re: U.S. Government Procurement; Country of Origin of Pravastatin Sodium Tablets;
Substantial Transformation

Dear Mr. Maynard:

This is in response to your letter, dated March 20, 2017, requesting a final determination on behalf of Lupin Pharmaceuticals, Inc. (“Lupin”) pursuant to subpart B of Part 177 of the U.S. Customs and Border Protection (“CBP”) Regulations (19 C.F.R. Part 177). Under these regulations, which implement Title III of the Trade Agreements Act of 1979 (“TAA”), as amended (19 U.S.C. § 2511 *et seq.*), CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain “Buy American” restrictions in U.S. law or for products offered for sale to the U.S. Government. This final determination concerns the country of origin of pravastatin sodium tablets. As a U.S. importer, Lupin 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 and all attachments to this ruling request, forwarded to our office, will not be released to the public and will be withheld from published versions of this ruling.

FACTS:

Lupin is a subsidiary of Lupin Limited, one of the five largest pharmaceutical companies in India. At issue in this case are pravastatin sodium tablets in doses of 10, 20, 40, and 80 milligrams,

which you describe as a pharmaceutical product that is “an antilipimic agent that is used to reduce the risk of myocardial infarction.”

The manufacturing process for Lupin’s pravastatin sodium tablets begins in Taiwan, where the active pharmaceutical ingredient (“API”) pravastatin sodium (chemical formula C₂₃H₃₅NaO₇) is produced. You state that the Taiwanese pravastatin sodium is the only active ingredient in the finished pharmaceutical product. However, the finished product contains a number of other inactive ingredients, which you describe as excipients. These ingredients are combined with the Taiwanese API in India during the manufacturing process. The ingredients include the following:

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- []
- []
- []
- []
- []
- []

The manufacturing processes performed in India include the following three steps: First, the API and inactive ingredients are sifted and blended. Second, the blend is compressed into tablets and the tablets are coated. Finally, in the third step, the finished tablets are packaged into approved packaging.

You state that the processes performed to produce the finished pravastatin sodium tablets do not result in any change to the chemical characteristics of the Taiwanese API or to any other ingredients. You also state that the medicinal use, molecular formula, and solubility of the API are unchanged by the manufacturing operations in India. In short, you characterize the Indian operations as mere processing of bulk API into 10-, 20-, 40-, and 80-milligram dosage form.

ISSUE:

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

LAW AND ANALYSIS:

Pursuant to subpart B of Part 177, 19 C.F.R. § 177.21 *et seq.*, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq.*), CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain “Buy American” restrictions in U.S. law or practice for products offered for sale to the U.S. Government.

Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B):

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

See also 19 C.F.R. § 177.22(a).

A substantial transformation occurs when an article emerges from a process with a new name, character, and use different from that possessed by the article prior to processing. A substantial transformation will not result from a minor manufacturing or combining process that leaves the identity of the article intact. *See United States v. Gibson-Thomsen Co.*, 27 C.C.P.A. 267 (1940); and *National Juice Products Ass'n v. United States*, 628 F.Supp. 978 (Ct. Int'l Trade 1986).

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, CBP has generally held that the processing of pharmaceutical products from bulk form into measured doses does not result in a substantial transformation of the product. *See, e.g.*, Headquarters Ruling (“HQ”) 561975, dated April 3, 2002; HQ 561544, dated May 1, 2000; HQ 735146, dated November 15, 1993; HQ H267177, dated November 5, 2016; HQ H233356, dated December 26, 2012; and, HQ 561975, dated April 3, 2002.

For example, in HQ H267177, CBP held that Indian- and Chinese-origin Acyclovir was not substantially transformed in the United States when it was combined with excipients and processed into tablets. In that case, the Indian or Chinese Acyclovir was the only active pharmaceutical ingredient in the final product. Accordingly, we found that the processing performed in the United States did not result in a change in the medicinal use of the finished product. Furthermore, the Acyclovir maintained its chemical and physical characteristics and did not undergo a change in name, character, or use. Consistent with our previous rulings, we held that processing the Acyclovir into dosage form and packaging it for sale in the United States did not constitute a substantial transformation. Accordingly, the country of origin of the final product for purposes of U.S. Government procurement was either China or India, where the active ingredient was produced.

Similarly, in HQ H233356, CBP held that the processing and packaging of imported mefenamic acid into dosage form in the United States did not constitute substantial transformation. Based on previous CBP rulings, we found that the specific U.S. processing—which involved blending the active ingredients with inactive ingredients in a tumbler and then encapsulating and packaging the product—did not substantially transform the mefenamic acid because its chemical character remained the same. Accordingly, we held that the country of origin of the final product was India, where the mefenamic acid was produced.

In HQ 561975, we also held that the processing of imported bulk Japanese-origin anesthetic drugs into dosage form in the United States did not constitute substantial transformation. Although the bulk form of the drug underwent testing operations, filtering, and packaging in the United States, these processes did not change the chemical or physical properties of the drug. Furthermore, there was no change in the product's name, which was referred to as sevoflurane in both its bulk and processed form. Additionally, because the imported bulk drug had a predetermined medicinal use as an anesthetic drug, the processing in the United States did not result in a change in the product's use. The country of origin of the finished product was therefore Japan.

Here, as in the cases cited above, the processing of bulk imported pharmaceuticals into dosage form will not result in a substantial transformation. In this case, the processing begins with Taiwanese-origin bulk pravastatin sodium and, after this product is combined with inactive ingredients in India, results in pravastatin sodium tablets in individual doses of 10, 20, 40, or 80 milligrams. Because the product is referred to as "pravastatin sodium" both before and after the Indian processing, no change in name occurs in India. Furthermore, no change in character occurs in India because the pravastatin sodium maintains the same chemical and physical properties both before and after the Indian processing. Finally, because the imported, bulk-form pravastatin sodium had a predetermined medicinal use as an antilipimic agent that is used to reduce the risk of myocardial infarction, no change in use occurs after processing in India. Under these circumstances, and consistent with previous CBP rulings, we find that the country of origin of the final product is Taiwan, where the active ingredient was produced.

HOLDING:

The country of origin of the pravastatin sodium tablets for purposes of U.S. Government procurement is Taiwan.

Notice of this final determination will be given in the Federal Register, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R. § 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-interest may, within 30 days of publication of the Federal Register Notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel, Executive Director
Regulations & Rulings
Office of Trade

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