

U.S. Customs and Border Protection



NOTICE OF ISSUANCE OF FINAL DETERMINATION CONCERNING COUNTRY OF ORIGIN OF TABLET COMPUTERS FOR HEALTH MOBILE AND HUB PLATFORMS

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

ACTION: Notice of final determination.

SUMMARY: This document provides notice that U.S. Customs and Border Protection (“CBP”) has issued a final determination concerning the country of origin of tablet computers known as Vivify Health Mobile and Hub Platforms. Based upon the facts presented, CBP has concluded in the final determination that for purposes of U.S. Government procurement in the installation of proprietary software on tablet computer does not substantially transform the imported tablet computers.

DATES: The final determination was issued on August 22, 2017. A copy of the final determination is attached. Any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of this final determination within September 27, 2017.

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

SUPPLEMENTARY INFORMATION:

Notice is hereby given that on August 22, 2017, pursuant to subpart B of Part 177, Customs and Border Protection (CBP) Regulations (19 CFR part 177, subpart B), CBP issued a final determination concerning the country of origin of tablet computers which may be offered to the United States Government under an undesignated government procurement contract. This final determination, HQ H284523, was issued at the request of Vivify Health Inc. under procedures set forth at 19 CFR part 177, subpart B, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511–18). In the final determination, CBP was asked to consider whether the loading of the specialized software onto a tablet computer that

Section 177.29, CBP Regulations (19 CFR 177.29), provides that notice of final determinations 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.

HQ H284523

August 22, 2017

OT:RR:CTF:VS: H2854523 RSD

CATEGORY: Origin

STUART P. SEIDEL, ESQ.
BAKER & MCKENZIE LLP
815 CONNECTICUT AVENUE,
WASHINGTON, DC 20006-4078

RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Tablet Computers, Health Mobile and Hub Platforms

DEAR MR. SEIDEL:

This is in response to your letter of March 20, 2017, on behalf of Vivify Health, Inc. (Vivify), requesting a final determination concerning the country origin of a product that you refer to as a “home health mobile platform and hub”, pursuant to subpart B of Part 177, U.S. Customs and Border Protection (CBP) Regulations (19 CFR 177.21, *et seq.*). Under the pertinent regulations, which implement 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. You state in your letter that this request is being made pursuant to a letter from the Department of Veterans Affairs (VA) to the prime contractor, Iron Bow Technologies, LLC (Iron Bow), requiring the filing of a request for a substantial transformation ruling from U.S. CBP.

As a domestic manufacturer, Vivify is a party-at-interest within the meaning of 19 CFR 177.22(d)(1) and is entitled to request this final determination.

FACTS:

The specific product at issue, referred to as the Vivify Mobile Device Platform and Hub Platform, begins as a tablet computer. The tablet computers are produced in Vietnam by one of the leading tablet manufacturers. The tablets are intended for purchase by the Veterans Health Administration for use by patients at home who will collect their health data that is measured by other peripheral devices such as blood pressure monitors, blood glucose monitors etc. These other devices are not imported with the tablet.

Vivify’s supplier purchases the tablets in the United States from an authorized reseller. In the United States, one of Vivify’s Hub production partners partially disassembles the case and adds a Bluetooth speaker microphone array that was assembled in Hong Kong, an “on-the-go” USB hub manufactured in China, and the housing, custom designed in the United States and Israel and manufactured in California, USA and Israel. All the above Hub Platform sub-components are shipped to facilities in Texas and in California for a final test fit, assembly, configuration and, then shipped for Quality Assurance testing in Tempe Arizona.

In order to collect the health data from each patient/user, Vivify installs specialized software (Vivify Health Pathways) onto the tablet computers. According to the information provided, the software was developed entirely in the United States, at Vivify’s corporate headquarters in Plano, Texas at a cost

of several million dollars using a team of more than 30 persons. The software enables patients to provide vital sign data and their responses to clinical questions. This application is installed on the tablet to meet the VA's requirements for medical devices, including patient confidentiality and interoperability with VA systems and protocols. In addition, this software disables the generic applications that would be normally used on the tablets. After the patient data is collected, it is next forwarded to VA clinicians over the VA intranet.

ISSUE:

Whether the imported tablets are substantially transformed by the installation of Vivify's proprietary software, so as to make them a product of the United States.

LAW AND ANALYSIS:

Pursuant to subpart B of Part 177, 19 CFR 177.21 *et seq.*, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq.*), CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers 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 CFR 177.22(a).

In rendering final determinations for purposes of U.S. Government procurement, CBP applies the provisions of subpart B of Part 177 consistent with the Federal Procurement Regulations. *See* 19 CFR 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 Trade Agreements Act. *See* 48 CFR 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 name, character, or use distinct from that of the article or articles from which it was transformed." *See* 48 CFR 25.003.

"The term 'character' is defined as 'one of the essentials of structure, form, materials, or function that together make up and usually distinguish the individual.'" *Uniden America Corporation v. United States*, 120 F. Supp. 2d. 1091, 1096 (citations omitted) (Ct. Int'l Trade 2000), *citing National Hand Tool Corp. v. United States*, 16 Ct. Int'l Trade 308, 311 (1992). In *Uniden*, concerning whether the assembly of cordless telephones and the installation of their detachable A/C (alternating current) adapters constituted instances of substantial transformation, the Court of International Trade applied the "essence test" and found that "[t]he essence of the telephone is housed in the base and the handset."

In *Data General v. United States*, 4 Ct. Int'l Trade 182 (1982), the court determined that for purposes of determining eligibility under item 807.00, Tariff Schedules of the United States (predecessor to subheading 9802.00.80, Harmonized Tariff Schedule of the United States), the programming of a foreign PROM (Programmable Read-Only Memory chip) in the United States substantially transformed the PROM into a U.S. article. In programming the imported PROMs, the U.S. engineers systematically caused various distinct electronic interconnections to be formed within each integrated circuit. The programming bestowed upon each circuit its electronic function, that is, its "memory" which could be retrieved. A distinct physical change was effected in the PROM by the opening or closing of the fuses, depending on the method of programming. This physical alteration, not visible to the naked eye, could be discerned by electronic testing of the PROM. The court noted that the programs were designed by a U.S. project engineer with many years of experience in "designing and building hardware." In addition, the court noted that while replicating the program pattern from a "master" PROM may be a quick one-step process, the development of the pattern and the production of the "master" PROM required much time and expertise. The court noted that it was undisputed that programming altered the character of a PROM. The essence of the article, its interconnections or stored memory, was established by programming. The court concluded that altering the non-functioning circuitry comprising a PROM through technological expertise in order to produce a functioning read only memory device, possessing a desired distinctive circuit pattern, was no less a "substantial transformation" than the manual interconnection of transistors, resistors and diodes upon a circuit board creating a similar pattern.

In *Texas Instruments v. United States*, 681 F.2d 778, 782 (CCPA 1982), the court observed that the substantial transformation issue is a "mixed question of technology and customs law." Accordingly, the programming of a device that confers its identity as well as defines its use generally constitutes a substantial transformation. *See also* Headquarters Ruling Letter ("HQ") 558868, dated February 23, 1995 (programming of SecureID Card substantially transforms the card because it gives the card its character and use as part of a security system, and the programming is a permanent change that cannot be undone); HQ 735027, dated September 7, 1993 (programming blank media (EEPROM) with instructions that allow it to perform certain functions that prevent piracy of software constitutes a substantial transformation); and, HQ 733085, dated July 13, 1990; *but see* HQ 732870, dated March 19, 1990 (formatting a blank diskette does not constitute a substantial transformation because it does not add value, does not involve complex or highly technical operations, and does not create a new or different product); and, HQ 734518, dated June 28, 1993 (motherboards are not substantially transformed by the implanting of the central processing unit on the board because, whereas in *Data General* use was being assigned to the PROM, the use of the motherboard has already been determined when the importer imported it).

HQ H258960, dated May 19, 2016, reviewed the country of origin of hardware components of certain transceivers in two scenarios that are instructive to the case at issue here. The hardware components of the transceivers were wholly manufactured in a foreign country and imported into the United States. In the first scenario, the transceivers were "blanks" and were completely non-functional and specialized proprietary software was developed

and downloaded in the United States, making the transceivers functional and compatible with the OEM technology. In the second scenario, the transceivers were preprogrammed with a generic program that was replaced with the specialized proprietary software. It was argued that in both scenarios, the imported hardware was substantially transformed by the development, configuration, and downloading operations of the United States origin software. As in this case, the expenses for the work performed in the United States were noted to far outweigh the work performed abroad. In the first scenario, we found that the non-functional transceivers were substantially transformed as a result of downloading performed in the United States, with proprietary software developed in the United States. However, in the second scenario, it was determined that since the transceivers had generic network functionality, programming them merely to customize their network compatibility would not actually change the identity of the imported transceivers. *See* also HQ H241177 *supra*. Accordingly, it was determined that the country where the last substantial transformation occurred was China or another Asian country where the hardware components were manufactured.

In this case, you contend that the software downloading operations performed in the United States transform the generic tablet computers into medical devices. You further explain that the cost of writing the software programming far outweighs the cost of the imported generic tablets. You emphasize that the U.S. operations disable the Android applications and install health monitoring software that cannot be undone by third parties during the normal course of operations. Therefore, you contend that this operation changes the classification of the tablet from Heading 8471 of the Harmonized Tariff Schedule of the United States (HTSUS) to a medical device of Heading 9018, HTSUS.

In essence, what is being done by the installation of the software in the United States, is to limit the original capacity of the imported tablets for the purpose of facilitating the reception, collection and transmission of a patient's medical data to VA clinicians for their review. The original tablet has the ability to perform these functions, but it was determined that for ease of use and for other reasons it is best to disable these functions and to consolidate them in one function via the specialized software. It is stated that the general functionality of the tablet is removed and replaced so that it is easier for patients to use the device and access the system. It is also stated that the security of the patient's medical data will be better protected.

It is clear that loading the specialized software onto the tablet computer that remains fully functional as a computer would be insufficient to constitute a new and different article of commerce, since all of the functionality of the original computer would be retained. In this case, however, in addition to the addition of the software, we are being asked to consider the effect of disabling the general applications that have been programmed onto the tablet. In our judgment, this added factor does not cause or require a different result. The functions of the original tablet produced in Vietnam that are necessary to receive and transmit data are in essence still present on the modified tablet, as aided by the software. While the tablet is no longer a freely programmable machine, we find the imposition of this limitation is insufficient to constitute a substantial transformation of the imported tablets.

Furthermore, we note that the converted tablets loaded with the Vivify Pathway Software do not actually measure any health related functions, such as blood pressure, or oxygen saturation levels, nor do they provide any

medical treatment to patients. Instead, the converted tablets function to receive medical data that is obtained from other peripheral devices, such as a blood pressure cuff or an oxygen sensor, and to transmit that medical data to a clinician for review. Therefore, it appears that after the proprietary software is downloaded onto the tablets, they function basically as a type of communications device.

It is also claimed that the FDA considers the Mobile Device Platform and the Hub Platform to be medical devices, and thus counsel contends that CBP should also consider the tablets loaded with the Vivify software to be medical devices rather than tablets. We note, however, that FDA's determinations on whether any items are considered medical devices are based upon different criteria from what CBP must apply in determining the country of origin of a product using the substantial transformation test. In HQ H019436, dated March 17, 2008, CBP considered the tariff classification of a SONA Sleep Apnea Avoidance Pillow (pillow), imported from China. The ruling noted that while the subject merchandise was considered a Class II therapeutic cervical pillow for snoring and mild sleep apnea by the FDA, this determination, did not control the tariff classification. Similarly in this case, the FDA's determination that the imported tablets are medical devices is of limited relevance to CBP's determination as to the country of origin of the devices.

In reviewing the processing performed in the United States on the imported tablets under consideration, we note that it is analogous to the situation of the transceivers described by the second scenario of HQ H258960. The imported tablets are preprogrammed with a generic program, which is the standard android operating system, prior to their importation. When they are first imported, the tablets can perform all of the standard functions of an android tablet, and could in their imported condition be used in conjunction with the proprietary software, but are customized for use. Accordingly, like the transceivers described in the second scenario of HQ H258960, we find that the name, character, and use of the imported tablet computers remain the same. Therefore, we further find that the imported tablets are not substantially transformed in the United States by the downloading of the proprietary software, which allows them to function with the VA Healthcare network. After the Vivify Health Pathways software is downloaded, the country of origin of the imported tablets remains the country where they were originally manufactured, which in this case is Vietnam.

HOLDING:

Based on the facts of this case, the imported tablets used with Home Health Hub platform are not substantially transformed by the installation of the proprietary Vivify Health Pathways software. Therefore, the country of origin of the tablets will remain the country where they were originally manufactured.

Notice of this final determination will be given in the **Federal Register**, as required by 19 CFR 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 CFR 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 CFR 177.30, any party-at-interest may, within 30 days

of publication of the **Federal Register** Notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

ALICE A. KIPPEL,
Executive Director
Regulations and Rulings,
Office of Trade.

[Published in the Federal Register, August 28, 2017 (82 FR 40783)]



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 September 27, 2017.

FOR FURTHER INFORMATION CONTACT: 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 con-

cerning 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.*

ATTACHMENT A

HQ H284690

August 22, 20917

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 CFR 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 CFR 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 CFR 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:

- []
- []

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

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

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

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

See also 19 CFR 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 CFR 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 CFR 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 CFR 177.30, any party-at-interest may, within 30 days of publication of the **Federal Register** Notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

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 CFR 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 CFR 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 CFR 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:

- []
- []
- []

- []
- []
- []

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

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

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

See also 19 CFR 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 transforma-

tion 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 CFR 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 CFR 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 CFR 177.30, any party-at-interest may, within 30 days of publication of the **Federal Register** Notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

ALICE A. KIPPEL,
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 CFR 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 CFR 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 CFR 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:

- []
- []
- []

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

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

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

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

See also 19 CFR 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 re-

ferred 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.

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

Sincerely,

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

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

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

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

See also 19 CFR 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 CFR 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 CFR 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 CFR 177.30, any party-at-interest may, within 30 days of

publication of the **Federal Register** Notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

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

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

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

See also 19 CFR 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 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 CFR 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 CFR 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 CFR 177.30, any party-at-interest may, within 30 days of publication of the **Federal Register** Notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

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 CFR 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 CFR 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 CFR 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:

- []
- []
- []

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

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

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

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

See also 19 CFR 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 CFR 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 CFR 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 CFR 177.30, any party-at-interest may, within 30 days of publication of the **Federal Register** Notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

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

[Published in the Federal Register, August 28, 2017 (82 FR 40786)]

ACCREDITATION AND APPROVAL OF INTERTEK USA, INC., AS A COMMERCIAL GAUGER AND LABORATORY

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

ACTION: Notice of accreditation and approval of Intertek USA, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Intertek USA, Inc., has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of September 15, 2016.

DATES: The accreditation and approval of Intertek USA, Inc., as commercial gauger and laboratory became effective on September 15, 2016. The next triennial inspection date will be scheduled for September 2019.

FOR FURTHER INFORMATION CONTACT: Christopher J. Mocella, Laboratories and Scientific Services Directorate, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Suite 1500N, Washington, DC 20229, tel. 202-344-1060.

SUPPLEMENTARY INFORMATION:

Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Intertek USA, Inc., 725 Oakridge Dr., Romeoville, IL

60446, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Intertek USA, Inc., is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API Chapters	Title
1	Vocabulary
3	Tank gauging
5	Metering
7	Temperature determination
8	Sampling
12	Calculations
17	Maritime measurement

Intertek USA, Inc., is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
Pending.....	D70	Density of Semi-solid Bituminous Materials (Pycnometer method).

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344-1060. The inquiry may also be sent to *CBPGaugersLabs@cbp.dhs.gov*. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. <http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories>.

Dated: August 21, 2017.

IRA S. REESE,
*Executive Director,
 Laboratories and Scientific
 Services Directorate.*

AGENCY INFORMATION COLLECTION ACTIVITIES:**Entry Summary**

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

ACTION: 30-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted (no later than September 28, 2017) to be assured of consideration.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to oir-submission@omb.eop.gov or faxed to (202) 395-5806.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to the CBP Paperwork Reduction Act Officer, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, Economic Impact Analysis Branch, 90 K Street NE., 10th Floor, Washington, DC 20229-1177, or via email CBP_PRA@cbp.dhs.gov. Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877-227-5511, (TTY) 1-800-877-8339, or CBP Web site at <https://www.cbp.gov/>.

SUPPLEMENTARY INFORMATION:

CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). This proposed information collection was previously published in the **Federal Register** (82 FR 28506) on June 22, 2017, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the fol-

lowing four points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Entry Summary.

OMB Number: 1651-0022.

Form Number: 7501, 7501A.

Current Actions: This submission is being made to extend the expiration date of this information collection with a decrease in burden hours due to increased automation. There is no change to the information collected on Form 7501 or 7501A.

Type of Review: Extension (without change).

Abstract: CBP Form 7501, Entry Summary, is used to identify merchandise entering the commerce of the United States, and to document the amount of duty and/or tax paid. CBP Form 7501 is submitted by the importer, or the importer's agent, for each import transaction. The data on this form is used by CBP as a record of the import transaction; to collect the proper duty, taxes, certifications and enforcement information; and to provide data to the U.S. Census Bureau for statistical purposes. CBP Form 7501 must be filed within 10 working days from the time of entry of merchandise into the United States.

CBP Form 7501A, Document/Payment Transmittal, is used to reconcile a supplemental payment after an initial Automated Clearing-house payment with the associated entry so the respondent's account is properly credited.

Collection of the data on these forms is authorized by 19 U.S.C. 1484 and provided for by 19 CFR 142.11 and CFR 141.61. CBP Form 7501 and accompanying instructions can be found at <http://www.cbp.gov/newsroom/publications/forms>.

Affected Public: Businesses.

CBP Form 7501—Formal Entries (Electronic Submission)

Estimated Number of Respondents: 2,336.
Estimated Number of Responses per Respondent: 9,903.
Estimated Total Annual Responses: 23,133,408.
Estimated Time per Response: 5 minutes.
Estimated Total Annual Burden Hours: 1,920,072.86.

CBP Form 7501—Formal Entries (Paper Submission)

Estimated Number of Respondents: 28.
Estimated Number of Responses per Respondents: 9,903.
Estimated Total Annual Responses: 277,284.
Estimated Time per Response: 20 minutes.
Estimated Total Annual Burden Hours: 92,335.57.

CBP Form 7501—Formal Entries With Softwood Lumber Act

Estimated Number of Respondents: 210.
Estimated Number of Responses per Respondent: 1,905.
Estimated Total Annual Responses: 400,050.
Estimated Time per Response: 40 minutes.
Estimated Total Annual Burden Hours: 266,433.

CBP Form 7501—Informal Entries (Electronic Submission)

Estimated Number of Respondents: 1,883.
Estimated Number of Responses per Respondent: 2,582.
Estimated Total Annual Responses: 4,861,906.
Estimated Time per Response: 5 minutes.
Estimated Total Annual Burden Hours: 403,538.20.

CBP Form 7501—Informal Entries (Paper Submission)

Estimated Number of Respondents: 19.
Estimated Number of Responses per Respondent: 2,582.
Estimated Total Annual Responses: 49,058.
Estimated Time per Response: 15 minutes.
Estimated Total Annual Burden Hours: 12,264.5.

CBP Form 7501A—Document / Payment Transmittal

Estimated Number of Respondents: 20.
Estimated Number of Responses per Respondent: 60.
Estimated Total Annual Responses: 1,200.

Estimated Time per Response: 15 minutes.

Estimated Total Annual Burden Hours: 300.

Dated: August 24, 2017.

SETH RENKEMA,
Branch Chief,
Economic Impact Analysis Branch,
U.S. Customs and Border Protection.

[Published in the Federal Register,]

[Published in the Federal Register, August 29, 2017 (82 FR 41041)]

AGENCY INFORMATION COLLECTION ACTIVITIES:
Automated Clearinghouse

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

ACTION: 30-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and will be accepted no later than September 28, 2017 to be assured of consideration.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395-5806.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to the CBP Paperwork Reduction Act Officer, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, Economic Impact Analysis Branch, 90 K Street NE., 10th Floor, Washington, DC 20229-1177, or via email *CBP_PRA@cbp.dhs.gov*. Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other

CBP programs should contact the CBP National Customer ServiceCenter at 877-227-5511, (TTY) 1-800-877-8339, or CBP Web site at <https://www.cbp.gov/>.

SUPPLEMENTARY INFORMATION:

CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). This proposed information collection was previously published in the **Federal Register** (82 FR 28505) on June 22, 2017, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Automated Clearinghouse.

OMB Number: 1651-0078.

Form Number: CBP Form 400.

Current Actions: CBP proposes to extend the expiration date of this information collection with no change to the burden hours or to the information collected.

Type of Review: Extension (without change).

Abstract: The Automated Clearinghouse (ACH) allows participants in the Automated Broker Interface (ABI) to transmit daily statements, deferred tax, and bill payments electronically through a financial institution directly to a CBP account. ACH debit allows the payer to exercise more control over the payment process. In order to participate in ACH debit, companies must complete CBP Form 400, *ACH Application*. Participants also use this form to notify CBP of changes to bank information or contact

information. The ACH procedure is authorized by 19 U.S.C. 58a–58c and 19 U.S.C. 66, and provided for by 19 CFR 24.25. CBP Form 400 is accessible at https://www.cbp.gov/sites/default/files/documents/CBP%20Form%20400_0.pdf

Affected Public: Businesses.

Estimated Number of Respondents: 1,443.

Estimated Number of Annual Responses per Respondent: 2.

Estimated Number of Total Annual Responses: 2,886.

Estimated Time per Response: 5 minutes.

Estimated Total Annual Burden Hours: 240.

Dated: August 24, 2017.

SETH RENKEMA,
Branch Chief,
Economic Impact Analysis Branch,
U.S. Customs and Border Protection.

[Published in the Federal Register, August 29, 2017 (82 FR 41042)]



AGENCY INFORMATION COLLECTION ACTIVITIES:

Declaration of Person Who Performed Repairs

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

ACTION: 30-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and will be accepted no later than September 28, 2017 to be assured of consideration.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to dhsdeskofficer@omb.eop.gov.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to the CBP Paperwork Reduction Act Officer, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, Economic Impact Analysis Branch, 90 K Street NE., 10th Floor, Washington, DC 20229–1177, or via email CBP_PRA@cbp.dhs.gov. Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP Web site at <https://www.cbp.gov/>.

SUPPLEMENTARY INFORMATION:

CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). This proposed information collection was previously published in the **Federal Register** (82 FR 28503) on June 22, 2017, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Declaration of Person Who Performed Repairs.

OMB Number: 1651–0048.

Form Number: N/A.

Current Actions: CBP proposes to extend the expiration date of this information collection with no change to the burden hours or to the information collected.

Type of Review: Extension (without change).

Abstract: The “Declaration of Persons Who Performed Repairs or Alterations,” as required by 19 CFR 10.8, is used in connection with the entry of articles entered under subheadings 9802.00.40 and 9802.00.50, Harmonized Tariff Schedule of the United States (HTSUS). Articles entered under these HTSUS provisions are articles that were in the U.S. and were exported temporarily for repairs. Upon their return, duty is only assessed on the value of the repairs performed abroad and not on the full value of the article. The declaration under 19 CFR 10.8 includes information such as a description of the article and the repairs; the value of the article and the repairs; and a declaration by the owner, importer, consignee, or agent having knowledge of the pertinent facts. The information in this declaration is used by CBP to determine the value of the repairs and assess duty only on the value of those repairs.

Affected Public: Businesses.

Estimated Number of Respondents: 10,236.

Estimated Number of Total Annual Responses: 20,472.

Estimated Number of Annual Responses per Respondent: 2.

Estimated Time per Response: 30 minutes.

Estimated Total Annual Burden Hours: 10,236.

Dated: August 24, 2017.

SETH RENKEMA,
Branch Chief,
Economic Impact Analysis Branch,
U.S. Customs and Border Protection.

[Published in the Federal Register, August 29, 2017 (82 FR 41040)]

AGENCY INFORMATION COLLECTION ACTIVITIES:

Bonded Warehouse Regulations

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

ACTION: 30-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act

of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and will be accepted no later than September 28, 2017 to be assured of consideration.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395-5806.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to the CBP Paperwork Reduction Act Officer, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, Economic Impact Analysis Branch, 90 K Street NE., 10th Floor, Washington, DC 20229-1177, or via email *CBP_PRA@cbp.dhs.gov*. Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877-227-5511, (TTY) 1-800-877-8339, or CBP Web site at <https://www.cbp.gov/>.

SUPPLEMENTARY INFORMATION:

CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This proposed information collection was previously published in the **Federal Register** (82 FR 28510) on June 22, 2017, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or

other forms of information technology, *e.g.*, permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Bonded Warehouse Regulations.

OMB Number: 1651-0041.

Current Actions: CBP proposes to extend the expiration date of this information collection with no change to the burden hours or to the information collected.

Type of Review: Extension (without change).

Abstract: Owners or lessees desiring to establish a bonded warehouse must make written application to the CBP port director of the port where the warehouse is located. The application must include the warehouse location, a description of the premises, and an indication of the class of bonded warehouse permit desired. Owners or lessees desiring to alter or to relocate a bonded warehouse may submit an application to the CBP port director of the port where the facility is located. The authority to establish and maintain a bonded warehouse is set forth in 19 U.S.C. 1555, and provided for by 19 CFR 19.2, 19 CFR 19.3, 19 CFR 19.6, 19 CFR 19.14, and 19 CFR 19.36.

Affected Public: Businesses.

Estimated Number of Respondents: 198.

Estimated Number of Responses per Respondent: 46.7.

Estimated Total Annual Responses: 9,254.

Estimated Time per Response: 32 minutes.

Estimated Total Annual Burden Hours: 4,932.

Dated: August 24, 2017.

SETH RENKEMA,
Branch Chief,
Economic Impact Analysis Branch,
U.S. Customs and Border Protection.