ANNUAL BURDEN TABLE

Instrument/activity	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden
Web Surveys					
SPC Web Survey	[1] 56	1	56	1	56
PATH Intermediary Web Survey	[2] 28	1	28	1	28
PATH Provider Web Survey	[3] 500	1	500	1	500
Telephone Interviews					
SPC Telephone Interview	[4] 28	1	28	1	28
PATH Intermediary Telephone Interview	[5] 14	1	14	1	14
PATH Provider Telephone Interview	[6] 60	1	60	1	60
Site Visit Interviews					
Opening Session with State Staff	[7] 25	1	25	2	50
SPC Session	[8] 5	1	5	2	10
State Stakeholder Session	[9] 25	1	25	1.5	37.5
Opening Session with PATH Provider Staff	[10] 50	1	50	2	100
PATH Provider PD Session	[11] 10	1	10	2	20
PATH Provider Direct Care Staff Session	[12] 50	1	50	2	100
Provider Stakeholder Session	[13] 50	1	50	1.5	75
Consumer Focus Groups	[14] 100	1	100	1.5	150
Total	1,001		1,001		1,228.5

[1] 1 respondent × 56 SPCs = 56 respondents.
[2] 1 respondent × 28 Intermediaries = 28 respondents.
[3] 1 respondent × 500 PATH providers =500 respondents.
[4] 1 respondent × 28 SPCs = 28 respondents.
[5] 1 respondent × 14 Intermediaries = 14 respondents.
[6] 1 respondent × 60 PATH providers = 60 respondents.
[7] 5 respondents × 5 site visits = 25 respondents.
[8] 1 respondent × 5 site visits = 5 respondents.
[9] 5 respondents × 5 site visits = 25 respondents.
[10] 5 respondents × 10 site visits (2 providers per state) = 50 respondents.
[11] 1 respondent × 10 site visits (2 providers per state) = 10 respondents.
[12] 5 respondents × 10 site visits (2 providers per state) = 50 respondents.
[13] 5 respondents × 10 site visits (2 providers per state) = 50 respondents.
[14] 10 respondents × 10 site visits (10 Consumers per provider (2 providers per state) = 100 respondents.

Written comments and recommendations concerning the proposed collection should be sent by DATE to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Services, commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov.* Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,

Statistician.

[FR Doc. 2017–18136 Filed 8–25–17; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

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. Kipel,

Executive Director Regulations and Rulings, Office of Trade.

[FR Doc. 2017–18202 Filed 8–25–17; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determinations Concerning Certain Pharmaceutical Products

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

ACTION: Notice of final determinations.

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

DATES: These final determinations were issued on August 22, 2017. Copies of the final determinations are attached. Any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of these final determinations within September 27, 2017.

FOR FURTHER INFORMATION CONTACT: Ross M. Cunningham, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade, (202) 325–0034.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on August 22, 2017 pursuant to subpart B of Part 177, U.S. Customs and Border Protection Regulations (19 CFR part 177, subpart B), CBP issued six final determinations concerning the country of origin of certain pharmaceutical products, which may be offered to the U.S. Government under an undesignated government procurement contract. These final determinations (HQ H284690, HQ H284961, HQ H284692, HQ H284694, HQ H284695, and HQ H284697), were issued under procedures set forth at 19 CFR part 177, subpart B, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511–18). In the final determinations, CBP concluded that the processing in India does not result in a substantial transformation. Therefore, the country of origin for purposes of U.S. Government procurement of the pharmaceutical products is the country in which the active pharmaceutical ingredient was produced.

Section 177.29, CBP Regulations (19 CFR 177.29), provides that a notice of final determination shall be published in the **Federal Register** within 60 days of the date the final determination is issued. Section 177.30, CBP Regulations (19 CFR 177.30), provides that any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the **Federal Register**.

Dated: August 22, 2017.

Alice A. Kipel,

Executive Director, Regulations and Rulings, Office of Trade.

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-inflammator[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.