

U.S. Customs and Border Protection



NOTICE OF ISSUANCE OF FINAL DETERMINATION CONCERNING CERTAIN ETHERNET SWITCH PRODUCTS

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

ACTION: Notice of final determination.

SUMMARY: This document provides notice that U.S. Customs and Border Protection (“CBP”) has issued a final determination concerning the country of origin of certain ethernet switch products known as Nyquist Ethernet Switches. Based upon the facts presented, CBP has concluded that the country of origin of the Nyquist Ethernet Switches is Mexico for purposes of U.S. Government procurement.

DATES: The final determination was issued on January 30, 2018. 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 March 7, 2018.

FOR FURTHER INFORMATION CONTACT: Yuliya A. Gulis, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade, at (202) 325–0042.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on January 30, 2018 pursuant to subpart B of part 177, U.S. Customs and Border Protection Regulations (19 CFR part 177, subpart B), CBP issued a final determination concerning the country of origin of certain ethernet switch products known as Nyquist Ethernet Switches, which may be offered to the U.S. Government under an undesignated government procurement contract. This final determination, HQ H282390, was issued under procedures set forth at 19 CFR part 177, subpart B, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511–18). In the final determination, CBP concluded that the last substantial transformation took place in Mexico. Therefore, the country of origin of the Nyquist Ethernet Switches is Mexico for purposes of U.S. Government procurement.

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

Dated: January 30, 2018.

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

HQ H282390

January 30, 2018
OT:RR:CTF:VS H282390 YAG
CATEGORY: Origin

Ms. CAROLYN MUHLSTEIN
SENIOR MANAGER, GLOBAL CUSTOMS
CISCO SYSTEMS, INC.
170 WEST TASMAN DRIVE
SAN JOSE, CA 95134

RE: U.S. Government Procurement; Country of Origin of Ethernet Switch;
Substantial Transformation

DEAR Ms. MUHLSTEIN:

This is in response to your letter, dated May 6, 2016, on behalf of Cisco Systems, Inc. (“Cisco”), requesting a final determination concerning the country of origin of Cisco’s Nyquist Ethernet Switch (“NES”), pursuant to subpart B of Part 177, U.S. Customs and Border Protection (“CBP”) Regulations (19 CFR § 177.21, *et seq.*). As a domestic importer of merchandise, Cisco is a party-at-interest within the meaning of 19 CFR § 177.22(d)(1) and is entitled to request this final determination. In addition, we have reviewed and granted the request for confidentiality pursuant to 19 CFR § 177.2(b)(7), with respect to certain information submitted.

FACTS:

Cisco plans to import the NES from Mexico. The NES is designed to interconnect devices on a computer network, while offering new capabilities, such as enabling new applications, differentiated security, dense wireless, and simplified and diverse network architecture. Each NES consists of one or more printed circuit board assemblies (“PCBA”), two power supplies, an uplink module, a protective metal housing, and ancillary devices to support additional features. The NES is configured with Cisco’s configuration data. The configuration data programs the logic gates of the hardware components on the PCBA, which imparts physical changes to the patterns of interconnections in the hardware circuitry, defining the behavior of each component. The NES operates using Cisco’s Polaris Operating System Software (“Polaris OS”).

In China, PCBAs are manufactured using: application specific integrated circuit (“ASIC”) components, which are assembled to final form in Korea incorporating materials from Taiwan and Japan in a process that takes between 12 and 25 weeks; central processing unit (“CPU”) components from Taiwan; synchronous dynamic random access memory (“SDRAM”) components from Taiwan or Korea; and, flash components from Korea and China. The PCBAs are tested to ensure that the PCBA components can properly interact with one another, and they are packaged and shipped to Mexico.

In Mexico, the following operations take place:

1. One or more PCBAs are installed into the NES chassis.
2. Two power supplies are installed in the NES chassis.
3. One uplink module is installed in the NES chassis.
4. Ancillary devices that support additional NES features are installed into the chassis.
5. A metal housing is added to complete the NES chassis assembly.

6. The power-on and bootloader initialization take place to activate the power system and fan modules of the NES, followed by the activation and preliminary testing of the CPU, ASIC, and ancillary devices.

7. The Polaris OS and configuration data developed in the United States are loaded onto a non-volatile flash memory, and then pushed out to the components of the PCBA.

8. The NES is tested to ensure the product functions as designed.

Cisco states that the Polaris OS and configuration data are downloaded onto the NES using in-circuit programming. According to Cisco, traditionally, each component of a PCBA (*e.g.*, ASICs) is completely programmed at or prior to assembly onto the PCBA; however, with in-circuit programming the hardware components are designed to be programmed after the PCBA is completely assembled. Cisco states that while the Polaris OS and configuration data are simultaneously downloaded onto the NES through the in-circuit programming, the Polaris OS and configuration data have different purposes and affect the NES differently and in sequence. Cisco explains that the configuration data does not operate on the hardware in the manner that the Polaris OS does. Rather, the configuration data completes the hardware programming, and the Polaris OS runs on the completed hardware.

According to Cisco, the PCBAs will have no commercial functionality when exported from China to Mexico because without the configuration data and the Polaris OS, the NES cannot function as intended. Cisco states that the NES will have large quantities of configurable elements, which require the configuration data to provide the firmware, modes and configuration settings, timing parameters, and physical properties for the components to function in the NES. Cisco states that the Polaris OS will provide I/O processor, route processor, and forwarding processor capabilities to the hardware, allowing the components to communicate with each other. Cisco notes that approximately 95 percent of the configuration data and 70 to 80 percent of the software code that will be loaded onto the NES in Mexico will be completely new and tailored based on customer needs and specifications.

ISSUE:

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

LAW AND ANALYSIS:

CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain “Buy American” restrictions in U.S. law or practice for products offered for sale to the U.S. Government, pursuant to subpart B of Part 177, 19 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.*).

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 order to determine whether a substantial transformation occurs when the components of various origins are assembled to form completed articles, CBP considers the totality of the circumstances and makes decisions on a case-by-case basis.

In *Data General v. United States*, 4 C.I.T. 182 (1982), the court determined that 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 the United States, the programming bestowed upon each integrated 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. The essence of the article, its interconnections or stored memory, was established by programming. See also, *Texas Instruments v. United States*, 681 F.2d 778, 782 (CCPA 1982) (stating the substantial transformation issue is a “mixed question of technology and customs law”).

Accordingly, the programming of a device that defines its use generally constitutes substantial transformation. See Headquarters Ruling (“HQ”) 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); but see 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 had already been determined when the importer imported it).

Cisco argues that the country of origin of the NES will be Mexico because the final assembly of the NES and installation of the Polaris OS and configuration data onto the NES in Mexico will substantially transform the PCBA into the NES. While the configuration data is specific to the NES, Cisco notes that the ASIC is not, and can be used in other Cisco products with different configuration data. Additionally, Cisco states that the Polaris OS allows the NES to switch and route packets, which is the critical functional element of the NES. Cisco states that the configuration data physically changes the electrical values of the logic gates present in the ASICs and other components, by connecting the gates in combinations that tell the components how to function and communicate within the system. Cisco argues that the configuration data installed on the NES should be distinguished from software installations because the configuration data completes the hardware programming, physically changing the hardware itself. Cisco states the software’s incorporation onto the NES is different because it runs on the completed hardware as opposed to being a part of the hardware itself.

Cisco cites HQ 563012, dated May 4, 2004, in support of its position. In HQ 563012, CBP held that the PCBA and casing that were manufactured for a switch in China, were substantially transformed in the United States or Hong Kong, where U.S.-origin software was loaded, and the PCBA was further assembled with a power supply, fans, and an A/C filter of various origins to form the final fabric switch. CBP noted that in addition to the actual assembly, the configuration and software download operations performed in either Hong Kong or in the United States transformed the switch from a non-functional device into a fabric switch that was capable of performing various storage network functions.

Similar to the scenario in HQ 563012, where Hong Kong was found to be the origin, in this case, the major components of the NES, particularly the

PCBA comprised of the ASIC, CPU, SDRAM, and flash components, will be manufactured in China, and then shipped to another country where the final assembly (adding the casing, power supply, uplink modules, and ancillary devices to the PCBA), software loading, configuration, and testing take place. Here, the other country is Mexico, which is different from the country where the U.S.-origin software is developed. While CBP has normally focused on where the origin of the software and where the programming took place, applying CBP's precedent in HQ 563012 to Cisco's manufacturing operations in Mexico, we find that the PCBAs from China will be substantially transformed by the final assembly, software loading, configuration, and testing operations in Mexico, and thus the country of origin for purposes of U.S. Government procurement will be Mexico.¹

HOLDING:

Based on the facts provided, the PCBAs from China will be substantially transformed into the NES by the processes that take place in Mexico. As such, the NES will be considered a product of Mexico for purposes of U.S. Government procurement.

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, February 5, 2018 (83 FR 5139)]

¹ See HQ H175415, dated October 4, 2011 (CBP held that imported Ethernet switches underwent a substantial transformation after U.S.-origin software was downloaded onto the devices' flash memory in the United States, which allowed the devices to function); see also HQ H052325, dated March 31, 2009 (holding that imported network devices underwent a substantial transformation in the United States after U.S.-origin software was downloaded onto the devices in the United States, which gave the devices their functionality); and, HQ H034843, dated May 5, 2009 (holding that Chinese USB flash drives underwent a substantial transformation in Israel when Israeli-origin software was loaded onto the devices, which made the devices functional). CBP has also held that when software is programmed in one country, and loaded onto a switch in different countries, the process of loading the software is not a sufficient operation by itself to result in a substantial transformation. See HQ H241177, dated December 3, 2013; and, HQ H240199, dated March 10, 2015.

COMMERCIAL CUSTOMS OPERATIONS ADVISORY COMMITTEE (COAC)

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

ACTION: Committee management; notice of Federal advisory committee meeting.

SUMMARY: The Commercial Customs Operations Advisory Committee (COAC) will hold its quarterly meeting on Wednesday, February 28, 2018, in Miami, Florida. The meeting will be open to the public.

DATES: The COAC will meet on Wednesday, February 28, 2018, from 1:00 p.m. to 5:00 p.m. EST. Please note that the meeting may close early if the committee has completed its business.

ADDRESSES: The meeting will be held at the DoubleTree Hotel, 711 NW 72nd Avenue, Miami, FL 33126. For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact Ms. Florence Constant-Gibson, Office of Trade Relations, U.S. Customs & Border Protection, at (202) 344-1440 as soon as possible.

Pre-Registration. Meeting participants may attend either in person or via webinar after pre-registering using one of the methods indicated below:

For members of the public who plan to attend the meeting in person, please register by 5:00 p.m. EST February 27, 2018, either online at https://apps.cbp.gov/te_reg/index.asp?w=124; by email to tradeevents@dhs.gov; or by fax to (202) 325-4290. You must register prior to the meeting in order to attend the meeting in person.

For members of the public who plan to participate via webinar, please register online at https://apps.cbp.gov/te_reg/index.asp?w=123 by 5:00 p.m. EST, February 27, 2018.

Please feel free to share this information with other interested members of your organization or association.

Members of the public who are pre-registered to attend and later need to cancel, please do so by February 27, 2018, utilizing the following links: https://apps.cbp.gov/te_reg/cancel.asp?w=124 to cancel an in person registration or https://apps.cbp.gov/te_reg/cancel.asp?w=123 to cancel a webinar registration.

To facilitate public participation, we are inviting public comment on the issues the committee will consider prior to the formulation of recommendations as listed in the Agenda section below.

Comments must be submitted in writing no later than February 26, 2018, and must be identified by Docket No. USCBP–2018–0004, and may be submitted by *one (1)* of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Email:* tradeevents@dhs.gov. Include the docket number in the subject line of the message.
- *Fax:* (202) 325–4290, Attention Florence Constant-Gibson.
- *Mail:* Ms. Florence Constant-Gibson, Office of Trade Relations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Room 3.5A, Washington, DC 20229.

Instructions: All submissions received must include the words “Department of Homeland Security” and the docket number (USCBP–2018–0004) for this action. Comments received will be posted without alteration at <http://www.regulations.gov>. Please do not submit personal information to this docket.

Docket: For access to the docket or to read background documents or comments, go to <http://www.regulations.gov> and search for Docket Number USCBP–2018–0004. To submit a comment, click the “Comment Now!” button located on the top-right hand side of the docket page.

There will be multiple public comment periods held during the meeting on February 28, 2018. Speakers are requested to limit their comments to two (2) minutes or less to facilitate greater participation. Contact the individual listed below to register as a speaker. Please note that the public comment period for speakers may end before the time indicated on the schedule that is posted on the CBP web page, <http://www.cbp.gov/trade/stakeholder-engagement/coac>.

FOR FURTHER INFORMATION CONTACT: Ms. Florence Constant-Gibson, Office of Trade Relations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Room 3.5A, Washington, DC 20229; telephone (202) 344–1440; facsimile (202) 325–4290; or Mr. Bradley Hayes, Executive Director and Designated Federal Officer at (202) 344–1440.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. Appendix. The Commercial Customs Operations Advisory Committee (COAC) provides advice to the Secretary of Homeland Security, the Secretary of the Treasury, and the Commissioner of U.S. Customs and Border Protection (CBP) on matters pertaining to the commercial operations of CBP and related functions within the Department of Homeland Security and the Department of the Treasury.

Agenda

The COAC will hear from the following subcommittees on the topics listed below and then will review, deliberate, provide observations, and formulate recommendations on how to proceed:

1. The Trusted Trader Subcommittee will present an update from the C-TPAT Minimum Security Criteria Working Group on its recommendations regarding CBP's plans to roll out new C-TPAT criteria. The subcommittee will also provide an update on the progress on the Trusted Trader Strategy.

2. The One U.S. Government Subcommittee will continue discussions on the progress of the Fish & Wildlife Service Working Group and will present the white paper on the Harmonized Tariff Schedule project. The subcommittee will also discuss an update from CBP's Trade Transformation Office on ACE Deployment G Release 4 and also from the Technical and Operational Outages Working Group.

3. The Exports Subcommittee will discuss the final work of the Export Manifest Working Group, which has been developing comprehensive recommendations on the following topics: Timelines, filing regime, targeting regime, hold issuance and shipment interception process, and an account-based penalties regime. There will also be an update on the automated export manifest pilots, and on progress in implementing a post-departure filing pilot as part of the ocean pilot.

4. The Trade Modernization Subcommittee will discuss the International Engagement and Trade Facilitation Working Group's efforts to prioritize the recommendations it made in 2017. The subcommittee will discuss the establishment of the Regulation Modernization Working Group and its efforts to identify and prioritize areas of regulations administered by CBP that can be reformed. In addition, the subcommittee will discuss the establishment of the Trade Facilitation and Trade Enforcement Act (TFTEA) Educational Mandate Working Group that will identify educational opportunities as referenced in Section 104 of TFTEA. Finally, the subcommittee will discuss the progress being made in the e-Commerce Working Group.

5. The Global Supply Chain Subcommittee will present the status of a pilot that will test the utilization of existing Automated Commercial Environment (ACE) automation in the pipeline mode of transportation. The committee will also discuss the progress of the Global Supply Chain Subcommittee's Emerging Technologies Working Group. The subcommittee will discuss the activities of the newly formed In-Bond Working Group that will focus on identifying issues within the scope of the "Changes to the In-Bond Process" final rule published in the **Federal Register** on September 28, 2017 regarding their implementation.

6. The Trade Enforcement & Revenue Collection (TERC) Subcommittee will provide necessary updates from the Anti-Dumping and Countervailing Duty, Bond, Forced Labor and Intellectual Property Rights Working Groups.

Meeting materials will be available by February 23, 2018 at: <http://www.cbp.gov/trade/stakeholder-engagement/coac/coac-public-meetings>.

Dated: January 31, 2018.

BRADLEY F. HAYES,
Executive Director,
Office of Trade Relations.

[Published in the Federal Register, February 6, 2018 (83 FR 5268)]

NOTICE OF ISSUANCE OF FINAL DETERMINATIONS CONCERNING CERTAIN PHARMACEUTICAL PRODUCTS

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

ACTION: Notice of final determinations.

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

DATES: These final determinations were issued on January 30, 2018. Copies of the final determinations are attached. Any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of these final determinations within March 7, 2018.

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

SUPPLEMENTARY INFORMATION: Notice is hereby given that on January 30, 2018 CBP issued 11 final determinations concerning the country of origin of certain pharmaceutical products, which may be offered to the U.S. Government under an undesignated government procurement contract pursuant to subpart B of part 177, CBP Regulations (19 CFR part 177, subpart B). These final determinations (H289700, H289701, H289702, H289704, H289706, H289710, H289711, H289712, H289713, H289714, and H289715), were issued under procedures set forth at 19 CFR part 177, subpart B, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511–18). In the final determinations, CBP concluded that the processing in the United States does not result in a substantial transformation. Therefore, the country of origin for purposes of U.S. Government procurement of the pharmaceutical products is India, the country where the active pharmaceutical ingredient was produced.

Section 177.29, CBP Regulations (19 CFR 177.29), provides that a notice of final determination shall be published in the **Federal Register** within 60 days of the date the final determination is issued.

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

Dated: January 30, 2018.

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

HQ H289700

January 30, 2018

OT:RR:CTF: VS H289700 EE

CATEGORY: Origin

STEPHEN E. RUSCUS
MORGAN, LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE,
NW WASHINGTON, DC 20004

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

DEAR MR. RUSCUS:

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

This final determination concerns the country of origin of the Rosuvastatin Calcium tablets. We note that Acetris is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

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

FACTS:

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

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

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

(“API”) of the Rosuvastatin Calcium tablets is Rosuvastatin Calcium, which Aurolife sources from company X in India.

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

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

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

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

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

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

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

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

ISSUE:

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

LAW AND ANALYSIS:

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

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

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

See also 19 C.F.R. § 177.22(a).

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

. . . an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

48 C.F.R. § 25.003.

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

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

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

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

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

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

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

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

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

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

HOLDING:

The country of origin of the Rosuvastatin Calcium tablets for U.S. Government procurement purposes is India.

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

Sincerely,

ALICE A. KIPEL
Executive Director
Regulations and Rulings
Office of Trade

HQ H289701

January 30, 2018
OT:RR:CTF:VS H289701 EE
CATEGORY: OriginSTEPHEN E. RUSCUS
MORGAN, LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE
NW WASHINGTON, DC 20004RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979
(19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Levofloxacin
tablets

DEAR MR. RUSCUS:

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

This final determination concerns the country of origin of the Levofloxacin tablets. We note that Acetris is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

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

FACTS:

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

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

You state that the Levofloxacin tablets supplied to Acetris are the result of a complex production process that occurs in Aurolife’s New Jersey facility involving the combination of the API with multiple inactive ingredients,

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

including some intermediates that are mixed in order to aid the conversion of the multiple ingredients. The production of Levofloxacin tablets employs processes that convert these ingredients into finished, medically effective dosage tablets (250 mg, 500 mg, and 750 mg tablets). You state that this processing changes the properties and characteristics of the API, materially enhancing the pharmacokinetics of the resulting drug.

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

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

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

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

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

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

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

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

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

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

ISSUE:

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

LAW AND ANALYSIS:

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

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

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

See also 19 C.F.R. § 177.22(a).

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

. . . an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

48 C.F.R. § 25.003.

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

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

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

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

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

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

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

processing of the API, sourced in India, with other ingredients must occur to change the API's properties and make it into a stable drug whose medical effectiveness as a drug is sustainable.

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

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

HOLDING:

The country of origin of the Levofloxacin tablets for U.S. Government procurement purposes is India.

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

Sincerely,

ALICE A. KIPEL

Executive Director

Regulations and Rulings

Office of Trade

HQ H289702

January 30, 2018
OT:RR:CTF:VS H289702 EE
CATEGORY: Origin

STEPHEN E. RUSCUS
MORGAN, LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE,
NW WASHINGTON, DC 20004

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

DEAR MR. RUSCUS:

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

This final determination concerns the country of origin of the Levetiracetam tablets. We note that Acetris is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

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

FACTS:

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

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

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

Levetiracetam tablets is Levetiracetam, which Aurolife sources from company X in India.

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

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

Material	Country
Levetiracetam USP	India
Corn Starch USNF (Maize Starch B)	Country A
Povidone USP (Kollidon 30).....	USA
Colloidal Silicon Dioxide USNF.....	USA
Talc USP.....	USA
Magnesium Stearate USNF.....	USA
Opadry Blue OY-S-30913	USA
Opadry Yellow 05F82840	USA
Opadry Orange OY-S-33016.....	USA
Opadry White Y-1-7000	USA

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

- Corn starch is added as a bulking agent for better manufacturability and to have a suitable tablet weight so that the patient can easily take the medication. Corn starch is mixed with the API, enhancing that the compressibility of the API, so that the product can be easily administered.
- Povidone is added as a binder to aid formation of flowable granules during manufacturing, thereby achieving the uniformity of the drug leading to therapeutic efficacy.
- Talc and Colloidal silicon dioxide are added to create a gliding property in the blend particles and to provide a lubrication effect during the manufacturing process.
- Magnesium stearate is added to create a hydrophobic environment around particles which provides a lubrication effect during the production process. Lubricant mixing is carefully done to ensure that the drug releasing profile and pharmacokinetics are not influenced by this hydrophobic environment.

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

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

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

ISSUE:

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

LAW AND ANALYSIS:

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

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

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

See also 19 C.F.R. § 177.22(a).

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

. . . an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

48 C.F.R. § 25.003.

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

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

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

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

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

HQ H233356, dated December 26, 2012, concerned the country of origin of Ponstel, a pharmaceutical product used for the relief of mild to moderate pain caused by primary dysmenorrhea. Mefenamic acid, which is the API in Ponstel, was manufactured in India, and imported into the United States,

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

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

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

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

HOLDING:

The country of origin of the Levetiracetam tablets for U.S. Government procurement purposes is India.

Notice of this final determination will be given in the *Federal Register*, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party

which requested this final determination may request, pursuant to 19 C.F.R. § 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-interest may, within 30 days after publication of the *Federal Register* notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

ALICE A. KIPEL

*Executive Director
Regulations and Rulings
Office of Trade*

HQ H289704

January 30, 2018

OT:RR:CTF:VS H289704 EE

CATEGORY: Origin

STEPHEN E. RUSCUS
MORGAN, LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE,
NW WASHINGTON, DC 20004

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

DEAR MR. RUSCUS:

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

This final determination concerns the country of origin of the Metoprolol Tartrate tablets. We note that Acetris is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

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

FACTS:

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

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

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

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

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

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

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

- Microcrystalline cellulose and corn starch are added as bulking agents for better manufacturability and to have suitable tablet weight so that the patient can easily take the medication. The API is mixed with these diluents which alters the physical form of the API such that the compressibility of the API is enhanced and the product can be easily administered.
- Sodium starch glycolate is added as a disintegrant to provide easy dispersion of the tablet when ingested by the patient, which indirectly enhances the drug release process and bioavailability/absorption, leading to pharmacokinetic profiles equivalent to the brand product (Lopressor®) for therapeutic equivalency.
- Talc and colloidal silicon dioxide are added to create a gliding property in the blend particles, contributing to the unit-to-unit uniformity of the drug during the manufacturing process.
- Magnesium stearate is added to create a hydrophobic environment around particles which provides a lubrication effect during the production process. Lubricant mixing is carefully done to ensure that the drug releasing profile and pharmacokinetics are not influenced by this hydrophobic environment.

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

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

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

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

ISSUE:

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

LAW AND ANALYSIS:

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

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

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

See also 19 C.F.R. § 177.22(a).

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

. . . an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

48 C.F.R. § 25.003.

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

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

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

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

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

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

mefenamic acid because its chemical character remained the same and, therefore, CBP found that the country of origin of the Ponstel capsules was India.

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

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

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

HOLDING:

The country of origin of the Metoprolol Tartrate tablets for U.S. Government procurement purposes is India.

Notice of this final determination will be given in the *Federal Register*, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R.

§ 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-interest may, within 30 days after publication of the *Federal Register* notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

ALICE A. KIPEL

Executive Director

Regulations and Rulings

Office of Trade

HQ H289706

January 30, 2018

OT:RR:CTF:VS H289706 EE

CATEGORY: Origin

STEPHEN E. RUSCUS
MORGAN, LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE,
NW WASHINGTON, DC 20004

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

DEAR MR. RUSCUS:

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

This final determination concerns the country of origin of the Gabapentin capsules. We note that Acetris is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

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

FACTS:

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

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

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

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

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

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

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

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

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

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

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

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

ISSUE:

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

LAW AND ANALYSIS:

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

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

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

See also 19 C.F.R. § 177.22(a).

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

. . . an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

48 C.F.R. § 25.003.

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

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

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

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

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

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

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

reasons, you claim that extensive additional processing of the API, sourced in India, with other ingredients must occur to change the API's properties and make it into a stable drug product.

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

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

HOLDING:

The country of origin of the Gabapentin capsules for U.S. Government procurement purposes is India.

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

Sincerely,

ALICE A. KIPEL

Executive Director

Regulations and Rulings

Office of Trade

HQ H289710

January 30, 2018
OT:RR:CTF:VS H289710 EE
CATEGORY: Origin

STEPHEN E. RUSCUS
MORGAN, LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE,
NW WASHINGTON, DC 20004

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

DEAR MR. RUSCUS:

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

This final determination concerns the country of origin of the Carvedilol tablets. We note that Acetris is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

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

FACTS:

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

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

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

abroad. The active pharmaceutical ingredient (“API”) of the Carvedilol tablets is Carvedilol, which Aurolife sources from company X in India.

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

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

Material	Country
Carvedilol USP	India
Lactose Monohydrate USNF.....	Country A
Colloidal Silicon Dioxide USNF.....	USA
Crospovidone USNF	USA
Povidone USP	USA
Sucrose USNF.....	USA
Magnesium Stearate USNF.....	USA
Opadry White 12B18631.....	USA

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

- Lactose monohydrate is added as a bulking agent for better manufacturability and to have suitable tablet weight so that the patient can easily take the medication. The API is mixed with these diluents to achieve uniformity of the API, so that the product can be easily administered.
- Crospovidone is added as a disintegrant to provide easy dispersion of the tablet when ingested by the patient which enhances the drug release process, bioavailability and absorption leading to pharmacokinetic profiles equivalent to the brand product (Coreg®) for therapeutic equivalency.
- Povidone and sucrose are added as binders to aid formation of flowable granules during production, thereby achieving the uniformity of the drug leading to therapeutic efficacy.
- Colloidal silicon dioxide is added to create a gliding property in the blend particles, thereby contributing to the unit-to-unit uniformity of the drug during the manufacturing process.
- Magnesium stearate is added to create a hydrophobic environment around particles which provides a lubrication effect during the production process. Lubricant mixing is carefully done to ensure that the drug releasing profile and pharmacokinetics are not influenced by this hydrophobic environment.

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

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

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

ISSUE:

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

LAW AND ANALYSIS:

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

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

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

See also 19 C.F.R. § 177.22(a).

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

. . . an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

48 C.F.R. § 25.003.

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

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

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

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

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

HQ H233356, dated December 26, 2012, concerned the country of origin of Ponstel, a pharmaceutical product used for the relief of mild to moderate pain caused by primary dysmenorrhea. Mefenamic acid, which is the API in Ponstel, was manufactured in India, and imported into the United States,

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

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

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

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

HOLDING:

The country of origin of the Carvedilol tablets for U.S. Government procurement purposes is India.

Notice of this final determination will be given in the *Federal Register*, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R.

§ 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-interest may, within 30 days after publication of the *Federal Register* notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

ALICE A. KIPEL

Executive Director

Regulations and Rulings

Office of Trade

HQ H289711

January 30, 2018
OT:RR:CTF:VS H289711 EE
CATEGORY: Origin

STEPHEN E. RUSCUS
MORGAN, LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE,
NW WASHINGTON, DC 20004

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

DEAR MR. RUSCUS:

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

This final determination concerns the country of origin of the Paroxetine Hydrochloride tablets. We note that Acetris is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

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

FACTS:

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

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

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

(“API”) of the Paroxetine Hydrochloride tablets is Paroxetine Hydrochloride, which Aurolife sources from company X in India.

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

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

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

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

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

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

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

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

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

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

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

ISSUE:

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

LAW AND ANALYSIS:

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

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

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

See also 19 C.F.R. § 177.22(a).

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

. . . an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

48 C.F.R. § 25.003.

A substantial transformation occurs when an article emerges from a process with a new name, character or use different from that possessed by the article prior to processing. A substantial transformation will not result from a minor manufacturing or combining process that leaves the identity of the

article intact. *See United States v. Gibson-Thomsen Co.*, 27 C.C.P.A. 267 (1940); and, *National Juice Products Association v. United States*, 628 F. Supp. 978 (Ct. Int'l Trade 1986).

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

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

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

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

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

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

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

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

HOLDING:

The country of origin of the Paroxetine Hydrochloride tablets for U.S. Government procurement purposes is India.

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

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

Sincerely,

ALICE A. KIPEL
Executive Director
Regulations and Rulings
Office of Trade

HQ H289712

January 30, 2018
OT:RR:CTF:VS H289712 EE
CATEGORY: OriginSTEPHEN E. RUSCUS
MORGAN, LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE,
NW WASHINGTON, DC 20004RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979
(19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Entecavir
tablets

DEAR MR. RUSCUS:

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

This final determination concerns the country of origin of the Entecavir tablets. We note that Acetris is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

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

FACTS:

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

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

You state that the Entecavir tablets supplied to Acetris are the result of a complex production process that occurs in Aurolife’s New Jersey facility involving the combination of the API with multiple inactive ingredients, including some intermediates that are mixed in order to aid the conversion of

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

the multiple ingredients. The production of Entecavir tablets employs processes that convert these ingredients into finished, medically effective dosage tablets (0.5 mg and 1 mg tablets). You state that this processing changes the properties and characteristics of the API, materially enhancing the pharmacokinetics of the resulting drug.

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

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

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

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

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

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

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

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

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

ISSUE:

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

LAW AND ANALYSIS:

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

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

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

See also 19 C.F.R. § 177.22(a).

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

. . . an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

48 C.F.R. § 25.003.

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

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

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

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

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

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

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

properties and make it into a stable drug product that achieves the targeted disintegration and dissolution and exhibits appropriate physicochemical properties, the desired pharmacokinetics and therapeutic efficacy.

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

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

HOLDING:

The country of origin of the Entecavir tablets for U.S. Government procurement purposes is India.

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

Sincerely,

ALICE A. KIPEL

Executive Director

Regulations and Rulings

Office of Trade

HQ H289713

January 30, 2018
OT:RR:CTF:VS H289713 EE
CATEGORY: OriginSTEPHEN E. RUSCUS
MORGAN, LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE,
NW WASHINGTON, DC 20004

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

DEAR MR. RUSCUS:

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

This final determination concerns the country of origin of the Montelukast Sodium tablets. We note that Acetris is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

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

FACTS:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

formation of sulfoxide impurity, thereby transform it into a more stable product whose therapeutic effectiveness as a drug is sustainable.

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

ISSUE:

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

LAW AND ANALYSIS:

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

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

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

See also 19 C.F.R. § 177.22(a).

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

. . . an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

48 C.F.R. § 25.003.

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

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

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

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

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

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

You state that the FDA requires that a unique National Drug Code (“NDC”) be assigned to every drug product such as Montelukast Sodium tablets, but prohibits that same NDC from being associated with any API, such as Montelukast Sodium, that has not been demonstrated to be safe and effective and cannot be sold for the treatment of any human disease condition. You also

state that the FDA requires the name of the drug product (Montelukast Sodium tablet) to appear on every drug product label and prohibits use of that name on the label for the API. Further, you state that API is intended only for use by producers for further processing or for research since it is unstable and not fit for medical use and may not be sold to consumers. Additionally, you state that the API degrades in potency, has poor flow qualities, and has a bitter taste. For these reasons, you claim that extensive additional processing of the API, sourced in India, with other ingredients must occur to change the API's properties and make it into a stable drug product whose medical effectiveness as a drug is sustainable.

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

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

HOLDING:

The country of origin of the Montelukast Sodium tablets for U.S. Government procurement purposes is India.

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

Sincerely,

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

HQ H289714

January 30, 2018

OT:RR:CTF:VS H289714 EE

CATEGORY: Origin

STEPHEN E. RUSCUS
MORGAN, LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE,
NW WASHINGTON, DC 20004

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

DEAR MR. RUSCUS:

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

This final determination concerns the country of origin of the Simvastatin tablets. We note that Acetris is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

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

FACTS:

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

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

You state that the Simvastatin tablets supplied to Acetris are the result of a complex production process that occurs in Aurolife’s New Jersey facility involving the combination of the API with multiple inactive ingredients,

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

including some intermediates that are mixed in order to aid the conversion of the multiple ingredients. The production of Simvastatin tablets employs processes that convert these ingredients into finished, medically effective dosage tablets (5 mg, 10 mg, 20 mg, 40 mg, and 80 mg tablets). You state that this processing changes the properties and characteristics of the API, materially enhancing the pharmacokinetics of the resulting drug.

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

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

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

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

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

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

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

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

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

ISSUE:

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

LAW AND ANALYSIS:

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

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

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

See also 19 C.F.R. § 177.22(a).

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

. . . an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

48 C.F.R. § 25.003.

A substantial transformation occurs when an article emerges from a process with a new name, character or use different from that possessed by the article prior to processing. A substantial transformation will not result from a minor manufacturing or combining process that leaves the identity of the article intact. *See United States v. Gibson-Thomsen Co.*, 27 C.C.P.A. 267

(1940); and, *National Juice Products Association v. United States*, 628 F. Supp. 978 (Ct. Int'l Trade 1986).

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

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

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

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

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

You state that the FDA requires that a unique National Drug Code (“NDC”) be assigned to every drug product such as Simvastatin tablets, but prohibits that same NDC from being associated with any API, such as Simvastatin,

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

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

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

HOLDING:

The country of origin of the Simvastatin tablets for U.S. Government procurement purposes is India.

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

Sincerely,

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

HQ H289715

January 30, 2018
OT:RR:CTF:VS H289715 EE
CATEGORY: OriginSTEPHEN E. RUSCUS
MORGAN, LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE,
NW WASHINGTON, DC 20004RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979
(19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Donepezil
Hydrochloride tablets

DEAR MR. RUSCUS:

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

This final determination concerns the country of origin of the Donepezil Hydrochloride tablets. We note that Acetris is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination.

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

FACTS:

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

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

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

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

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

Material	Country
Donepezil hydrochloride Hydrochloride monohydrate USP	India
Lactose Monohydrate USNF.....	Country A
Microcrystalline Cellulose USNF (UNITAB 102).....	USA
Pregelatinized Starch	USA
Low substituted Hydroxypropyl Cellulose USNF	Country B
Magnesium Stearate USNF.....	USA
Opadry Yellow 03F82726 IH.....	USA
Opadry White 03F180009	USA

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

- The particle size of the API is tailored to have a good flowability during the production process so that there is no unit-to-unit variability in the labeled quantity in each tablet.
- Lactose monohydrate and microcrystalline cellulose directly compressible grades are added as bulking agents for better flowability, manufacturability and to have suitable tablet weight so that the patient can easily take the medication.
- Pregelatinized starch and low substituted hydroxypropyl cellulose are added as disintegrants to provide easy dispersion of the tablet when ingested by the patient, which enhances the release process, bioavailability and absorption leading to pharmacokinetic profiles equivalent to the brand product (Aricept®) for therapeutic equivalency.
- Magnesium stearate is added to create a hydrophobic environment around particles which provides a lubrication effect during the production process. Lubricant mixing is carefully done to ensure that the drug releasing profile and pharmacokinetics are not influenced by this hydrophobic environment.
- Coloring agents and film coating are added to give an aesthetic appearance. Film coating is performed using polymers which imparts a protective barrier for the drug.
- Finally the tablets are packed into suitable containers which are capable of retaining the overall integrity of the quality attributes and minimizing the formation of oxidative impurity, thereby transforming it into a more stable product whose therapeutic effectiveness as a drug is sustainable.

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

ISSUE:

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

LAW AND ANALYSIS:

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

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

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

See also 19 C.F.R. § 177.22(a).

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

. . . an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

48 C.F.R. § 25.003.

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

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article

retains the essential identity and character of the raw material. To that end, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

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

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

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

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

You state that the FDA requires that a unique National Drug Code (“NDC”) be assigned to every drug product such as Donepezil Hydrochloride tablets, but prohibits that same NDC from being associated with any API, such as Donepezil Hydrochloride, that has not been demonstrated to be safe and effective and cannot be sold for the treatment of any human disease condition. You also state that the FDA requires the name of the drug product (Donepezil Hydrochloride tablet) to appear on every drug product label and prohibits use of that name on the label for the API. Further, you state that

Donepezil Hydrochloride is intended only for use by producers for further processing or for research since it is unstable and not fit for medical use and may not be sold to consumers. Additionally, you state that the API is poisonous and has poor flow properties. For these reasons, you claim that extensive additional processing of the API, sourced in India, with other ingredients must occur to change the API's properties and make it into a stable drug product.

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

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

HOLDING:

The country of origin of the Donepezil Hydrochloride tablets for U.S. Government procurement purposes is India.

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

Sincerely,

ALICE A. KIPEL

Executive Director

Regulations and Rulings

Office of Trade

**PROPOSED REVOCATION OF THREE RULING LETTERS
AND MODIFICATION OF ONE RULING LETTER, AND
REVOCATION OF TREATMENT RELATING TO THE
TARIFF CLASSIFICATION OF RADIO REMOTE
CONTROLLERS FOR VIDEO GAME CONSOLES**

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

ACTION: Notice of proposed revocation of three ruling letters and modification of one ruling letter, and revocation of treatment relating to the tariff classification of radio remote controllers for video game consoles.

SUMMARY: Pursuant to section 625(c), Tariff Act of 1930 (19 U.S.C. § 1625(c)), as amended by section 623 of title VI (Customs Modernization) of the North American Free Trade Agreement Implementation Act (Pub. L. 103–182, 107 Stat. 2057), this notice advises interested parties that U.S. Customs and Border Protection (CBP) intends to revoke three ruling letters and modify one ruling letter concerning tariff classification of radio remote controllers for video game consoles under the Harmonized Tariff Schedule of the United States (HTSUS). Similarly, CBP intends to revoke any treatment previously accorded by CBP to substantially identical transactions. Comments on the correctness of the proposed actions are invited.

DATE: Comments must be received on or before March 23, 2018.

ADDRESS: Written comments are to be addressed to U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, Attention: Trade and Commercial Regulations Branch, 90 K St., NE, 10th Floor, Washington, DC 20229–1177. Submitted comments may be inspected at the address stated above during regular business hours. Arrangements to inspect submitted comments should be made in advance by calling Mr. Joseph Clark at (202) 325–0118.

FOR FURTHER INFORMATION CONTACT: Dwayne Rawlings, Electronics, Machinery, Automotive and International Nomenclature Branch, Regulations and Rulings, Office of Trade, at (202) 325–0092.

SUPPLEMENTARY INFORMATION:

BACKGROUND

Current customs law includes two key concepts: informed compliance and shared responsibility. Accordingly, the law imposes an

obligation on CBP to provide the public with information concerning the trade community's responsibilities and rights under the customs and related laws. In addition, both the public and CBP share responsibility in carrying out import requirements. For example, under section 484 of the Tariff Act of 1930, as amended (19 U.S.C. § 1484), the importer of record is responsible for using reasonable care to enter, classify and value imported merchandise, and to provide any other information necessary to enable CBP to properly assess duties, collect accurate statistics, and determine whether any other applicable legal requirement is met.

Pursuant to 19 U.S.C. § 1625(c)(1), this notice advises interested parties that CBP is proposing to revoke three ruling letters and modify one ruling letter pertaining to the tariff classification of radio remote controllers for video game consoles. Although in this notice, CBP is specifically referring to New York Ruling Letters ("NY") L83006, dated April 22, 2005 (Attachment A); NY M86614, dated October 11, 2006 (Attachment B); NY N118298, dated August 30, 2010 (Attachment C); and NY N143476, dated February 2, 2011 (Attachment D), this notice also covers any rulings on this merchandise which may exist, but have not been specifically identified. CBP has undertaken reasonable efforts to search existing databases for rulings in addition to the four identified. No further rulings have been found. Any party who has received an interpretive ruling or decision (i.e., a ruling letter, internal advice memorandum or decision, or protest review decision) on the merchandise subject to this notice should advise CBP during the comment period.

Similarly, pursuant to 19 U.S.C. § 1625(c)(2), CBP is proposing to revoke any treatment previously accorded by CBP to substantially identical transactions. Any person involved in substantially identical transactions should advise CBP during this comment period. An importer's failure to advise CBP of substantially identical transactions or of a specific ruling not identified in this notice may raise issues of reasonable care on the part of the importer or its agents for importations of merchandise subsequent to the effective date of the final decision on this notice.

In NY L83006, NY M86614, NY N118298 and NY N143476, CBP classified radio remote controllers in heading 9504, HTSUS, specifically in subheading 9504.10.00, HTSUS, which provides for "Articles for arcade, table or parlor games ...: Video games of a kind used with a television receiver and parts and accessories thereof." CBP has reviewed NY L83006, NY M86614, NY N118298 and NY N143476, and has determined the ruling letters to be in error. It is now CBP's position that the radio remote controllers are properly classified in

heading 8526, HTSUS, specifically in subheading 8526.92.10, HTSUS, which provides for “Radar apparatus, radio navigational aid apparatus and radio remote control apparatus: ...: Radio remote control apparatus for video game consoles.”

Pursuant to 19 U.S.C. § 1625(c)(1), CBP is proposing to revoke NY L83006, NY N143476, and NY N118298, and modify NY M86614, as well as to revoke or modify any other ruling not specifically identified to reflect the analysis contained in the proposed Headquarters Ruling Letter (“HQ”) H235178, set forth as Attachment E to this notice. Additionally, pursuant to 19 U.S.C. § 1625(c)(2), CBP is proposing to revoke any treatment previously accorded by CBP to substantially identical transactions.

Before taking this action, consideration will be given to any written comments timely received.

Dated: December 18, 2017

GREG CONNOR

for

MYLES B. HARMON,

Director

Commercial and Trade Facilitation Division

Attachments

ATTACHMENT A

NY L83006

April 22, 2005

CLA-2-95:RR:NC:2:224 L83006

CATEGORY: Classification

TARIFF NO.: 9504.10.0000

MR. STEVEN W. BAKER
STEVEN W. BAKER AND ASSOCIATES
1 SUTTER STREET, SUITE 1004
SAN FRANCISCO, CA 94104-4919

RE: The tariff classification of a Nintendo "Wavebird" Wireless Controller from China

DEAR MR. BAKER:

In your letter dated March 22, 2005, you requested a tariff classification ruling, on behalf of Nintendo of America, Inc., your client.

The merchandise, labeled as the "Wavebird" Controller, is a wireless controller for the Nintendo Game Cube. The "Wavebird" Controller uses a RF transmitter that sends joystick and button information to a RF receiver that is designed to plug into the front of the Game Cube console. The "Wavebird" wireless controller replaces standard controllers, and it allows people to play the Nintendo Game Cube from anywhere in the room without wires. A picture of the controller was submitted, instead of a sample.

Legal Note 3 to chapter 95, HTSUS, states that: "subject to note 1 above, parts and accessories which are suitable for use solely or principally with articles of this chapter are to be classified with those articles." Based upon the application of Legal Note 3 to chapter 95, this office finds that the "Wavebird" Controller is classifiable under subheading 9504.10.00, HTSUS, which provides for parts and accessories of video games of a kind used with a television receiver.

The applicable subheading for the "Wavebird" Controller will be 9504.10.0000, Harmonized Tariff Schedule of the United States (HTS), which provides for articles for arcade, table or parlor games, including pinball machines, bagatelle, billiards and special tables for casino games...parts and accessories thereof: video games of a kind used with a television receiver and parts and accessories thereof. The rate of duty will be free.

This ruling is being issued under the provisions of Part 177 of the Customs Regulations (19 C.F.R. 177).

A copy of the ruling or the control number indicated above should be provided with the entry documents filed at the time this merchandise is imported. If you have any questions regarding the ruling, contact National Import Specialist Tom McKenna at 646-733-3025.

Sincerely,

ROBERT B. SWIERUPSKI
Director,

National Commodity Specialist Division

ATTACHMENT B

NY M86614

October 11, 2006

CLA-2-95:RR:NC:2:224 M86614

CATEGORY: Classification

TARIFF NO.: 9504.10.0000

MR. STEVEN W. BAKER
250 BEL MARIN KEYS BLVD.
SUITE B-6
NOVATO, CA 94949-5707

RE: The tariff classification of a video game system and components from China

DEAR MR. BAKER:

In your letter dated September 22, 2006, you requested a tariff classification ruling, on behalf of Nintendo of America, Inc., your client.

You are requesting the tariff classification on a Nintendo video game system known as "Wii", designed for use with a television receiver. The "Wii" system incorporates the components of a traditional video game: a central processor, internal flash memory with 512 megabytes, and a graphics-processing unit. The unit will be capable of playing single or double layered 12 centimeter proprietary optical disks for "Wii", as well as 8 centimeter disks for the Nintendo Game Cube. The unit may be connected to hand held controllers for input of commands and to a television for visual display. The "Wii" controller is a motion sensitive, wireless device. The remote includes an expansion port, a speaker, a rumble feature, and may also be used as a pointer. A remote accessory called a nunchuck provides an analog control stick, and C and Z buttons.

The unit includes 4 ports for classic Nintendo Game Cube controllers, 2 slots for Nintendo Game Cube memory cards, and an AV multi-output port for component, composite, or S-video. The "Wii" system will be imported as an integrated unit including the game console, proprietary media optical disks, and 2 or more hand-held controllers. In addition, the central unit, game disks, and controllers may be imported separately and may be packaged in the United States for subsequent sale, or sold as individual units.

The applicable subheading for the "Wii" Video Game System and Components, either imported separately or together, will be 9504.10.0000, Harmonized Tariff Schedule of the United States (HTSUS), which provides for articles for arcade, table or parlor games...parts and accessories thereof: video games of a kind used with a television receiver and parts and accessories thereof. The rate of duty will be free.

Duty rates are provided for your convenience and are subject to change. The text of the most recent HTSUS and the accompanying duty rates are provided on World Wide Web at <http://www.usitc.gov/tata/hts/>.

This ruling is being issued under the provisions of Part 177 of the Customs Regulations (19 C.F.R. 177).

A copy of the ruling or the control number indicated above should be provided with the entry documents filed at the time this merchandise is

imported. If you have any questions regarding the ruling, contact National Import Specialist Tom McKenna at 646-733-3025.

Sincerely,

ROBERT B. SWIERUPSKI
*Director,
National Commodity
Specialist Division*

ATTACHMENT C

N118298

August 30, 2010

CLA-2-95:OT:RR:NC:N4:424

CATEGORY: Classification

TARIFF NO.: 9504.10.0000

MR. FRANK GOMEZ
WORLD EXCHANGE, INC.
8840 BELLANCA AVE
LOS ANGELES, CA 90045

RE: The tariff classification of three video game components from China

DEAR MR. GOMEZ:

In your letter dated July 29, 2010 you requested a tariff classification ruling on behalf of HSB & Associates Inc.

Samples of three video game components were received with your inquiry. The first item, the Snakebyte Premium Fitness Board (White), item number SB90412, is designed to be used with the Nintendo Wii video game system and is compatible with Wii Fit and other similar games that utilize the board's technology. The Premium Fitness Board acts as a game controller, similar in design and function to Nintendo's Balance Board, and contains four sensors that measure one's weight and body balance, necessary for proper playing of the video games, and then replicates the body movements in the game. The Fitness Board, which connects wirelessly to the Wii via Bluetooth technology, emits a blue light on two sides when activated and also has a small LCD screen which displays one's weight as well as a timer that measures one's exercise duration. While providing a display to show one's weight may be informative, the item's ability to measure one's weight is essential for the proper game play. It is principally designed as a video game device.

The second item, the Snakebyte Premium Remote XL+, item number SB905278, is also designed for use with the Nintendo Wii. The item is packaged with a Wii compatible remote with motion plus technology, two wrist straps, two rechargeable batteries and a generic USB cable for charging the remote. The essential character of the set is imparted by the Wii remote.

The last item, the Snakebyte Premium Bluetooth Controller, item number SB904714, is designed for use with Sony's PlayStation 3 (PS3) video game console. The item is packaged with a PS3 compatible remote, two bonus clip-on triggers and a generic USB cable for charging the remote. The essential character of the set is imparted by the PS3 remote.

Note 3, to chapter 95, states that "subject to note 1 above, parts and accessories which are suitable for use solely or principally with articles of this chapter are to be classified with those articles." All three items meet this requirement as they can only be used in conjunction with the Nintendo Wii or PS3 video game systems and will be classified as such.

The applicable subheading for the Snakebyte Premium Fitness Board, Snakebyte Premium Remote XL+ and the Snakebyte Premium Bluetooth Controller will be 9504.10.0000, Harmonized Tariff Schedule of the United States (HTSUS), which provides for "Articles for arcade, table or parlor games...: Video games of a kind used with a television receiver and parts and accessories thereof." The rate of duty is free.

Duty rates are provided for your convenience and are subject to change. The text of the most recent HTSUS and the accompanying duty rates are provided on World Wide Web at <http://www.usitc.gov/tata/hts/>.

This ruling is being issued under the provisions of Part 177 of the Customs Regulations (19 C.F.R. 177).

A copy of the ruling or the control number indicated above should be provided with the entry documents filed at the time this merchandise is imported. If you have any questions regarding the ruling, contact National Import Specialist James Forkan at (646) 733-3025.

Sincerely,

ROBERT B. SWIERUPSKI

Director

National Commodity Specialist Division

ATTACHMENT D

N143476

February 2, 2011

CLA-2-95:OT:RR:NC:N4:424

CATEGORY: Classification

TARIFF NO.: 9504.10.0000

MR. FRED DARDASHTI
SONIC GAMES INC
1025 EAST 14TH STREET
LOS ANGELES, CA 90021

RE: The tariff classification of a Wii compatible remote controller from China

DEAR MR. DARDASHTI:

In your letter dated January 11, 2011, you requested a tariff classification ruling.

A sample of a remote controller was submitted with your inquiry. The product is a remote controller that is compatible with the Wii console. The controller measures approximately 6" long x 1.5" wide. The remote controller features a clear jacket skin, an attached wrist strap and includes pointer, motion sensor and speaker functions. The item will be packaged and sold in a hanging box. The sample will be returned as requested.

The applicable subheading for the Wii compatible remote controller will be 9504.10.0000, Harmonized Tariff Schedule of the United States (HTSUS), which provides for "Articles for arcade, table or parlor games...: Video games of a kind used with a television receiver and parts and accessories thereof." The rate of duty will be free.

Duty rates are provided for your convenience and are subject to change. The text of the most recent HTSUS and the accompanying duty rates are provided on World Wide Web at <http://www.usitc.gov/tata/hts/>.

Importations of this product may be subject to the provisions of Section 133 of the Customs Regulations if they copy or simulate a registered trademark, trade name or copyright recorded with U.S. Customs and Border Protection. If you are an authorized importer of the product we recommend notifying your local CBP office prior to importation.

This ruling is being issued under the provisions of Part 177 of the Customs Regulations (19 C.F.R. 177).

A copy of the ruling or the control number indicated above should be provided with the entry documents filed at the time this merchandise is imported. If you have any questions regarding the ruling, contact National Import Specialist James Forkan at (646) 733-3025.

Sincerely,

ROBERT B. SWIERUPSKI

Director

National Commodity Specialist Division

ATTACHMENT E

HQ H235178

CLA-2: OT:RR:CTF:TCM H235178 DSR

CATEGORY: Classification

TARIFF NO.: 8526.92.10

MR. STEVEN W. BAKER
LAW OFFICES OF STEVEN W. BAKER
448 IGNACIO BOULEVARD #323
NOVATO, CA 94949

RE: Revocation of NY L83006 (classification of a Nintendo “Wavebird” Wireless Controller from China); Modification of NY M86614 (classification of a Wii controller from China); Revocation of NY N118298 (classification of three video game components from China); Revocation of NY N143476 (classification of a Wii compatible remote controller from China)

DEAR MR. BAKER:

This letter is in reference to four New York Ruling Letters (NY) in which certain wireless video game controllers, or retail sets containing such controllers, were classified under subheading 9504.10.00, Harmonized Tariff Schedule of the United States (HTSUS), which covers parts and accessories of video games of a kind used with a television receiver. The four rulings are NY L83006 (April 22, 2005); NY M86614 (October 11, 2006); NY N118298 (August 30, 2010); and NY N143476 February 2, 2011). We have re-examined those rulings and now believe that we incorrectly classified the subject articles. This letter serves to revoke or modify the rulings, as explained below.

FACTS:

In NY L83006, the merchandise, labeled as the “Wavebird” controller, is a wireless controller for the Nintendo Game Cube. The controller contains an RF transmitter that sends joystick and button information to an RF receiver that is designed to plug into the front of the Game Cube console. The controller replaces standard controllers, and it allows people to play the Nintendo Game Cube from anywhere in the room without wires.

In NY M86614, the merchandise at issue here, labeled as the “Wii” controller, is a handheld, motion-sensitive wireless device. The controller contains an RF transmitter that sends joystick and button information to control a Wii video game console.

In NY N118298, the first item, the Snakebyte Premium Fitness Board (White), item number SB90412, is designed to be used with the Nintendo Wii video game system and is compatible with the Wii Fit video game and other similar games that utilize the board’s technology. The Premium Fitness Board acts as a game controller, similar in design and function to Nintendo’s Balance Board, and contains four sensors that measure one’s weight and body balance, necessary for proper playing of the video games, and then replicates the body movements in the game. The Fitness Board, which connects wirelessly to the Wii via Bluetooth technology, emits a blue light on two sides when activated and also has a small LCD screen which displays one’s weight as well as a timer that measures one’s exercise duration. While providing a display to show one’s weight may be informative, the item’s ability to measure one’s weight is essential for proper game play. It is principally designed as a

video game device. The second item, the Snakebyte Premium Remote XL+, item number SB905278, is also designed for use with the Nintendo Wii. The item is packaged as a set containing a Wii compatible remote with motion plus technology, two wrist straps, two rechargeable batteries and a generic USB cable for charging the remote. The last item, the Snakebyte Premium Bluetooth Controller, item number SB904714, is designed for use with Sony's PlayStation 3 (PS3) video game console. The item is packaged as a set containing a PS3 compatible remote, two bonus clip-on triggers and a generic USB cable for charging the remote.

In NY N143476, the product is a radio remote controller that is compatible with the Wii console. The controller measures approximately 6" long x 1.5" wide. The remote controller features a clear jacket skin, an attached wrist strap and includes pointer, motion sensor and speaker functions. The item will be packaged and sold in a hanging box.

ISSUE:

Whether the articles are properly classified under heading 9405, HTSUS, as video game accessories or under heading 8526, HTSUS, as radio remote control apparatus for video game consoles.

LAW AND ANALYSIS:

Merchandise imported into the United States is classified under the HTSUS. Tariff classification is governed by the principles set forth in the General Rules of Interpretation (GRIs). GRI 1 requires that classification be determined first according to the terms of the heading of tariff schedule and any relative section or chapter notes, and unless otherwise required, according to the remaining GRIs taken in their appropriate order. The HTSUS provisions under consideration in this case are as follows:

8526	Radar apparatus, radio navigational aid apparatus and radio remote control apparatus:
	Other:
8526.92	Radio remote control apparatus:
8526.92.10	Radio remote control apparatus for video game consoles.
* * *	
9504	Video game consoles and machines, articles for arcade, table or parlor games, including pinball machines, bagatelle, billiards and special tables for casino games; automatic bowling alley equipment; parts and accessories thereof :
9504.50.00	Video game consoles and machines, other than those of subheading 9504.30, and parts and accessories thereof.
* * * *	

With particular regard to NY N118298, the Snakebyte Premium Fitness Board is imported alone. However, the Snakebyte Premium Remote XL+ and the Snakebyte Premium Bluetooth Controller are imported as retail sets subject to GRI 3. Our position is unchanged that the essential character of the Snakebyte Premium Remote XL+ set is imparted by the included Wii remote, while the essential character of the Snakebyte Premium Bluetooth Controller set is imparted by the included PS3 remote.

Note 3 to Chapter 95, HTSUS, states that “Subject to Note 1 [to Chapter 95, HTSUS], parts and accessories which are suitable for use solely or principally with articles of this chapter are to be classified with those articles.” However, Note 1(m) to Chapter 95, HTSUS, states that the chapter does not cover, in relevant part, “radio remote control apparatus (heading 8526).” Bluetooth technology is based upon radio frequencies, and the subject controllers in each of the rulings at issue employ Bluetooth technology to control video game consoles. Applying Note 1(m) to Chapter 95, HTSUS, the controllers are excluded from classification in Chapter 95 because they fit squarely within the scope of *eo nomine* heading 8526, HTSUS, which provides for, in pertinent part, “radio remote control apparatus.” They are specifically provided for under subheading 8526.92.10, HTSUS, which covers “radio remote control apparatus for video game consoles.”

HOLDING:

By application of GRI 1, the subject articles are classified in heading 8526, HTSUS. Specifically, they are classified in subheading 8526.92.10, HTSUS, which provides for “Radar apparatus, radio navigational aid apparatus and radio remote control apparatus: Other: Radio remote control apparatus: Radio remote control apparatus for video game consoles.” The column one, general rate of duty is “Free.”

Duty rates are provided for your convenience and subject to change. The text of the most recent HTSUS and the accompanying duty rates are provided at www.usitc.gov.

EFFECT ON OTHER RULINGS:

NY L83006, NY N118298 and NY N143476 are revoked in accordance with this decision. NY M86614 is modified in accordance with this decision with respect to the classification of the Wii controller. The classification of the other item described therein remains unchanged.

Sincerely,

MYLES B. HARMON,

Director

Commercial and Trade Facilitation Division

**PROPOSED REVOCATION OF ONE RULING LETTER AND
REVOCATION OF TREATMENT RELATING TO THE
TARIFF CLASSIFICATION OF TRAMPOLINE SAFETY
ENCLOSURE**

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

ACTION: Notice of proposed revocation of one ruling letter and revocation of treatment relating to the tariff classification of trampoline safety enclosure.

SUMMARY: Pursuant to section 625(c), Tariff Act of 1930 (19 U.S.C. §1625(c)), as amended by section 623 of title VI (Customs Modernization) of the North American Free Trade Agreement Implementation Act (Pub. L. 103–182, 107 Stat. 2057), this notice advises interested parties that U.S. Customs and Border Protection (CBP) intends to revoke one ruling letter concerning tariff classification of trampoline safety enclosure under the Harmonized Tariff Schedule of the United States (HTSUS). Similarly, CBP intends to revoke any treatment previously accorded by CBP to substantially identical transactions. Comments on the correctness of the proposed actions are invited.

DATE: Comments must be received on or before March 23, 2018.

ADDRESS: Written comments are to be addressed to U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, Attention: Trade and Commercial Regulations Branch, 90 K St., NE, 10th Floor, Washington, DC 20229–1177. Submitted comments may be inspected at the address stated above during regular business hours. Arrangements to inspect submitted comments should be made in advance by calling Mr. Joseph Clark at (202) 325–0118.

FOR FURTHER INFORMATION CONTACT: Michele A. Boyd, Chemicals, Petroleum, Metals and Miscellaneous Classification Branch, Regulations and Rulings, Office of Trade, at (202) 325–0136.

SUPPLEMENTARY INFORMATION:

BACKGROUND

Current customs law includes two key concepts: informed compliance and shared responsibility. Accordingly, the law imposes an obligation on CBP to provide the public with information concerning the trade community's responsibilities and rights under the customs and

related laws. In addition, both the public and CBP share responsibility in carrying out import requirements. For example, under section 484 of the Tariff Act of 1930, as amended (19 U.S.C. § 1484), the importer of record is responsible for using reasonable care to enter, classify and value imported merchandise, and to provide any other information necessary to enable CBP to properly assess duties, collect accurate statistics, and determine whether any other applicable legal requirement is met.

Pursuant to 19 U.S.C. §1625(c)(1), this notice advises interested parties that CBP is proposing to revoke one ruling letter pertaining to the tariff classification of trampoline safety enclosure. Although in this notice, CBP is specifically referring to New York Ruling Letter (“NY”) R03134, dated January 27, 2006 (Attachment A), this notice also covers any rulings on this merchandise which may exist, but have not been specifically identified. CBP has undertaken reasonable efforts to search existing databases for rulings in addition to the one identified. No further rulings have been found. Any party who has received an interpretive ruling or decision (i.e., a ruling letter, internal advice memorandum or decision, or protest review decision) on the merchandise subject to this notice should advise CBP during the comment period.

Similarly, pursuant to 19 U.S.C. §1625(c)(2), CBP is proposing to revoke any treatment previously accorded by CBP to substantially identical transactions. Any person involved in substantially identical transactions should advise CBP during this comment period. An importer’s failure to advise CBP of substantially identical transactions or of a specific ruling not identified in this notice may raise issues of reasonable care on the part of the importer or its agents for importations of merchandise subsequent to the effective date of the final decision on this notice.

In R03134, CBP classified trampoline safety enclosure in heading 9506, HTSUS, specifically in subheading 9506.99.6080, HTSUSA (Annotated), which provides for “Articles and equipment for general physical exercise, gymnastics, athletics, other sports...parts and accessories thereof: Other: Other: Other...Other.” CBP has reviewed NY R03134 and has determined the ruling letter to be in error. It is now CBP’s position that trampoline safety enclosure is properly classified, in heading 9506, HTSUS, specifically in subheading 9506.91.0030, HTSUSA, which provides for “Articles and equipment for general physical exercise, gymnastics or athletics; parts and accessories thereof...Other.”

Pursuant to 19 U.S.C. §1625(c)(1), CBP is proposing to revoke NY R03134 and to revoke or modify any other ruling not specifically

identified to reflect the analysis contained in the proposed Headquarters Ruling Letter (“HQ”) H292029, set forth as Attachment B to this notice. Additionally, pursuant to 19 U.S.C. §1625(c)(2), CBP is proposing to revoke any treatment previously accorded by CBP to substantially identical transactions.

Before taking this action, consideration will be given to any written comments timely received.

Dated: December 18, 2017

ALLYSON MATTANAH

for

MYLES B. HARMON,

Director

Commercial and Trade Facilitation Division

Attachments

ATTACHMENT A

January 27, 2006

CLA-2-95:RR:NC:2:224 R03134

CATEGORY: Classification

TARIFF NO.: 9506.99.6080

Ms. SHARON DIXON
TSA CORPORATE SERVICES INC.
1050 WEST HAMPDEN AVE.
ENGLEWOOD, CO 80110

RE: The tariff classification of a trampoline safety enclosure from China

DEAR Ms. DIXON:

In your letter dated January 19, 2006, you requested a tariff classification ruling.

You are requesting the tariff classification on a product that is identified as a trampoline safety enclosure. There is no item number indicated for the product at this time. The components of the item are as follows: PE (polyethylene) mesh netting assembled on a zinc steel frame with foam tubes. The foam tubes are designed so that they may be attached to a trampoline by means of zinc clamps. A sample was not submitted, however a detailed description was included with the ruling request. The trampoline safety enclosure will be classified in Chapter 95 of the HTSUS as an accessory for a trampoline.

The applicable subheading for the trampoline safety enclosure will be 9506.99.6080, Harmonized Tariff Schedule of the United States (HTSUS), which provides for articles and equipment for general physical exercise, gymnastics, athletics, other sports...or outdoor games...and parts and accessories thereof: other: other...other. The rate of duty will be 4% ad valorem.

Duty rates are provided for your convenience and are subject to change. The text of the most recent HTSUS and the accompanying duty rates are provided on World Wide Web at <http://www.usitc.gov/tata/hts/>.

This ruling is being issued under the provisions of Part 177 of the Customs Regulations (19 C.F.R. 177).

A copy of the ruling or the control number indicated above should be provided with the entry documents filed at the time this merchandise is imported. If you have any questions regarding the ruling, contact National Import Specialist Tom McKenna at 646-733-3025.

Sincerely,

ROBERT B. SWIERUPSKI

Director,

National Commodity Specialist Division

ATTACHMENT B

HQ H292029
CLA-2 OT:RR:CTF:CPM H292029 MAB
CATEGORY: Classification
TARIFF NO.: 9506.91.0030

TSA CORPORATE SERVICES INC.
1050 WEST HAMPDEN AVE.
ENGLEWOOD, CO 80110
ATTN: MS. SHARON DIXON

Re: Revocation of NY R03134; Classification of Trampoline Safety Enclosure

DEAR MS. DIXON:

This is in reference to New York Ruling Letter (NY) R03134 dated January 27, 2006, issued to TSA Corporate Services Inc., concerning the tariff classification of a trampoline safety enclosure under the Harmonized Tariff Schedule of the United States (HTSUS). In that ruling, U.S. Customs and Border Protection (CBP) classified the merchandise subheading 9506.99.6080, HTSUSA (Annotated). We have reviewed NY R03134 and find it to be in error with respect to the tariff classification. For the reasons set forth below, we propose revocation of NY R03134.

FACTS:

The subject merchandise at issue in NY R03134 is identified as a trampoline safety enclosure. The components of the item are as follows: polyethylene mesh netting assembled on a zinc steel frame with foam tubes. The foam tubes are designed to be attached to a trampoline by means of zinc clamps. The instant merchandise was classified in subheading 9506.99.6080 as "Articles and equipment for general physical exercise, gymnastics, athletics, other sports...parts and accessories thereof: Other: Other: Other...Other."

ISSUE:

Whether the Trampoline Safety Enclosure is of subheading 9506.91.0030, HTSUS, and classified as an accessory of general exercise equipment...Other or of subheading 9506.99.6080, HTSUS, and classified as an accessory of general exercise equipment...Other: Other: Other...Other.

LAW AND ANALYSIS:

Merchandise imported into the United States is classified under the HTSUS. Tariff classification is governed by the principles set forth in the General Rules of Interpretation (GRIs) and, in the absence of special language or context, which requires otherwise, by the Additional U.S. Rules of Interpretation. GRI 1 requires that classification be determined first according to the terms of the headings of the tariff schedule and any relative section or chapter notes and, unless otherwise required, according to the remaining GRIs taken in their appropriate order. The HTSUS provisions under consideration are the following:

9506	Articles and equipment for general physical exercise, gymnastics, athletics, other sports (including table-tennis) or outdoor games, not specified or included elsewhere in this chapter; swimming pools and wading pools; parts and accessories thereof:
	Other:
9506.91.00	Articles and equipment for general physical exercise, gymnastics or athletics; parts and accessories thereof
9506.91.0030	Other
9506.99	Other:
9506.99.60	Other
9506.99.6080	Other

Legal Note 3 to Chapter 95, HTSUS, provides the following:

3. Subject to note 1 above, parts and accessories which are suitable for use solely or principally with articles of this chapter are to be classified with those articles.

The Harmonized Commodity Description and Coding System Explanatory Notes (ENs) constitute the official interpretation of the Harmonized System (HS) at the international level. While not legally binding, the ENs provide a commentary on the scope of each heading of the HS and are thus useful in ascertaining the proper classification of merchandise. *See* T.D. 89–90, 54 Fed. Reg. 35127, 35128 (August 23, 1989).

The EN to heading 9506 states, in pertinent part, the following:

(A) Articles and equipment for general physical exercise, gymnastics or athletics, e.g., :

Trapeze bars and rings; horizontal and parallel bars; balance beams, vaulting horses; pommel horses; spring boards; climbing ropes and ladders; wall bars; Indian clubs; dumb bells and bar bells; medicine balls; rowing, cycling and other exercising apparatus; chest expanders; hand grips; starting blocks; hurdles; jumping stands and standards; vaulting poles; landing pit pads; javelins, discuses, throwing hammers and putting shots; punch balls (speed bags) and punch bags (punching bags); boxing or wrestling rings; assault course climbing walls.

CBP has classified recreational trampolines with galvanized steel frames, safety pads constructed of PVC, metal springs to provide bounce, and ranging in size from 11' – 14', in subheading 9506.91.0030, HTSUSA, as exercise equipment. *See* NY N144678 (dated February 14, 2011). More recently, in HQ H270403 (dated October 31, 2017), CBP classified the Skywalker Trampolines, measuring 16' x 14' in size with 96 springs to provide bounce, as exercise equipment in subheading 9506.91.0030, HTSUS. Trampoline safety enclosures that consist of mesh netting assembled on steel frames with foam tubes are common accessories that accompany most of these types of recreational trampolines.

Note 3 to Chapter 95 states that subject to note 1, “parts and accessories which are suitable for use solely or principally with articles of this chapter are to be classified with those articles.” As constructed, the instant Trampo-

line Safety Enclosure is identifiable as an accessory that is suitable for use solely or principally with recreational trampolines and will be classified accordingly.

Therefore, the applicable subheading for the instant Trampoline Safety Enclosure is subheading 9606.91.0030, HTSUSA, which references articles and equipment for general physical exercise.

HOLDING:

By application of GRIs 1 and 6, the Trampoline Safety Enclosure is classified in subheading 9506.91.0030, HTSUSA, which provides for “Articles and equipment for general physical exercise, gymnastics, athletics, other sports (including table-tennis) or outdoor games, not specified or included elsewhere in this chapter; swimming pools and wading pools; parts and accessories thereof: ... Other: Articles and equipment for general physical exercise, gymnastics or athletics; parts and accessories thereof ... Other.” The 2017 column one, general rate of duty is 4.6 percent *ad valorem*.

Duty rates are provided for your convenience and are subject to change. The text of the most recent HTSUS and the accompanying duty rates are provided on the internet at <http://www.usitc.gov>.

EFFECT ON OTHER RULINGS:

NY R03134, dated January 27, 2006, is hereby revoked.

Sincerely,

MYLES B. HARMON,

Director

Commercial and Trade Facilitation Division

PROPOSED REVOCATION OF ONE RULING LETTER AND REVOCATION OF TREATMENT RELATING TO THE TARIFF CLASSIFICATION OF JUMPSMART TRAMPOLINE

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

ACTION: Notice of proposed revocation of one ruling letter and revocation of treatment relating to the tariff classification of JumpSmart Trampoline.

SUMMARY: Pursuant to section 625(c), Tariff Act of 1930 (19 U.S.C. §1625(c)), as amended by section 623 of title VI (Customs Modernization) of the North American Free Trade Agreement Implementation Act (Pub. L. 103–182, 107 Stat. 2057), this notice advises interested parties that U.S. Customs and Border Protection (CBP) intends to revoke one ruling letter concerning tariff classification of JumpSmart Trampoline under the Harmonized Tariff Schedule of the United States (HTSUS). Similarly, CBP intends to revoke any treatment previously accorded by CBP to substantially identical transactions. Comments on the correctness of the proposed actions are invited.

DATE: Comments must be received on or before March 23, 2018.

ADDRESS: Written comments are to be addressed to U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, Attention: Trade and Commercial Regulations Branch, 90 K St., NE, 10th Floor, Washington, DC 20229–1177. Submitted comments may be inspected at the address stated above during regular business hours. Arrangements to inspect submitted comments should be made in advance by calling Mr. Joseph Clark at (202) 325–0118.

FOR FURTHER INFORMATION CONTACT: Michele A. Boyd, Chemicals, Petroleum, Metals and Miscellaneous Articles Branch, Regulations and Rulings, Office of Trade, at (202) 325–0136.

SUPPLEMENTARY INFORMATION:

BACKGROUND

Current customs law includes two key concepts: informed compliance and shared responsibility. Accordingly, the law imposes an obligation on CBP to provide the public with information concerning the trade community's responsibilities and rights under the customs and related laws. In addition, both the public and CBP share responsibility in carrying out import requirements. For example, under section 484 of the Tariff Act of 1930, as amended (19 U.S.C. § 1484), the

importer of record is responsible for using reasonable care to enter, classify and value imported merchandise, and to provide any other information necessary to enable CBP to properly assess duties, collect accurate statistics, and determine whether any other applicable legal requirement is met.

Pursuant to 19 U.S.C. §1625(c)(1), this notice advises interested parties that CBP is proposing to revoke one ruling letter pertaining to the tariff classification of JumpSmart Trampoline. Although in this notice, CBP is specifically referring to NY N012532, dated June 29, 2007 (Attachment A), this notice also covers any rulings on this merchandise which may exist, but have not been specifically identified. CBP has undertaken reasonable efforts to search existing databases for rulings in addition to the one ruling identified. No further rulings have been found. Any party who has received an interpretive ruling or decision (i.e., a ruling letter, internal advice memorandum or decision, or protest review decision) on the merchandise subject to this notice should advise CBP during the comment period.

Similarly, pursuant to 19 U.S.C. §1625(c)(2), CBP is proposing to revoke any treatment previously accorded by CBP to substantially identical transactions. Any person involved in substantially identical transactions should advise CBP during this comment period. An importer's failure to advise CBP of substantially identical transactions or of a specific ruling not identified in this notice may raise issues of reasonable care on the part of the importer or its agents for importations of merchandise subsequent to the effective date of the final decision on this notice.

In NY N012532, CBP classified JumpSmart Trampoline in heading 9503, HTSUS, specifically in subheading 9503.00.0080, HTSUSA, which provides for "Other toys; reduced-scale ("scale") models and similar recreational models, working or not; puzzles of all kinds; parts and accessories thereof...Other...Other."¹ CBP has reviewed NY N012532 and has determined the ruling letter to be in error. It is now CBP's position that JumpSmart Trampoline is properly classified, in heading 9506, HTSUS, specifically in subheading 9506.91.0030, HTSUS, which provides for "Articles and equipment for general physical exercise, gymnastics or athletics; parts and accessories thereof."

Pursuant to 19 U.S.C. §1625(c)(1), CBP is proposing to revoke NY N012532 and to revoke or modify any other ruling not specifically identified to reflect the analysis contained in the proposed Headquarters Ruling Letter ("HQ") H212596, set forth as Attachment B to this

¹ Please note that in N012532, the applicable subheading for the JumpSmart Trampoline was 9503.00.0080, HTSUS (2007). However, the "Other" provision in subheading 9503.00.0080, HTSUS (2007), has been replaced by 9503.00.0090, HTSUS (2017). The free rate of duty has not changed.

notice. Additionally, pursuant to 19 U.S.C. §1625(c)(2), CBP is proposing to revoke any treatment previously accorded by CBP to substantially identical transactions.

Before taking this action, consideration will be given to any written comments timely received.

Dated: December 20, 2017

ALLYSON MATTANAH
for

MYLES B. HARMON,
Director

Commercial and Trade Facilitation Division

Attachments

ATTACHMENT A

N012532

June 29, 2007

CLA-2-95:RR:NC:2:224

CATEGORY: Classification

TARIFF NO.: 9503.00.0080

MS. JENNIFER JOSTEN
BARTHCO CITY CENTRE, SUITE 208
223 E. CITY HALL AVE.
NORFOLK, VA 23510

RE: The tariff classification of Jump Smart Trampoline, Item #4849, from China

DEAR MS. JOSTEN:

In your letter dated June 7, 2007, on behalf of your client, Etoys Direct, Inc., you requested a tariff classification ruling.

The sample submitted, Jump Smart Trampoline, is a musical trampoline measuring approximately 42 inches by 36 inches and holds up to 80 pounds. The trampoline is made for children 3 to 8 years of age to enjoy playing and listening to music when jumping. The toy is put up for the amusement of children.

The applicable subheading for the Jump Smart Trampoline will be 9503.00.0080, Harmonized Tariff Schedule of the United States (HTSUS), which provides for Other toys; reduced-size ("scale") models and similar recreational models, working or not; puzzles of all kinds; parts and accessories thereof: Other: Other." The rate of duty will be Free.

Duty rates are provided for your convenience and are subject to change. The text of the most recent HTSUS and the accompanying duty rates are provided on World Wide Web at <http://www.usitc.gov/tata/hts/>.

This ruling is being issued under the provisions of Part 177 of the Customs Regulations (19 C.F.R. 177).

A copy of the ruling or the control number indicated above should be provided with the entry documents filed at the time this merchandise is imported. If you have any questions regarding the ruling, contact National Import Specialist Tom McKenna at 646-733-3025

Sincerely,

ROBERT B. SWIERUPSKI

Director,

National Commodity Specialist Division

ATTACHMENT B

HQ H212596

CLA-2 OT:RR:CTF:CPM H212596 MAB

CATEGORY: Classification

TARIFF NO.: 9506.91.0030

Toys “R” Us, Inc.

ONE GEOFFREY WAY

WAYNE, NJ 07470

ATTN: LEGAL AND RISK MANAGEMENT DEPARTMENT

Re: Revocation of NY N012532; Classification of JumpSmart Trampoline

TO WHOM IT MAY CONCERN:

This is in reference to New York Ruling Letter (NY) N012532 dated June 29, 2007, issued to legal counsel of Etoys Direct, Inc., a company acquired by Toys “R” Us, Inc., in 2009¹ concerning the tariff classification of a musical trampoline for children identified as the “JumpSmart Trampoline” under the Harmonized Tariff Schedule of the United States (HTSUS). In that ruling, U.S. Customs and Border Protection (CBP) classified the merchandise as a toy under heading 9503, HTSUS. More specifically, the instant merchandise was classified in subheading 9503.00.0080, HTSUSA (Annotated).² We have reviewed NY N012532 and find it to be in error with respect to the tariff classification. For the reasons set forth below, we propose revocation of NY N012532.

FACTS:

The subject merchandise at issue in NY N012532 is a musical trampoline for children called the JumpSmart Trampoline (item number 4849). It measures approximately 42 inches by 36 inches and is designed for children ages three to eight years of age, weighing up to 80 pounds. The trampoline has accompanying music and learning games when children are jumping on it.

In addition to the original descriptive information set forth in NY N012532, we have reviewed representative product specific literature that is available on the Internet³ and watched several YouTube videos.⁴ JumpSmart

¹ Assoc. Press, *Toys R Us acquires EToys.com*, L.A.TIMES (Feb. 13, 2009), <http://articles.latimes.com/2009/feb/13/business/fi-toys13>.

² Please note that in N012532, the applicable subheading for the JumpSmart Trampoline was 9503.00.0080, HTSUS (2007). However, the “Other” provision in subheading 9503.00.0080, HTSUS (2007), has been replaced by 9503.00.0090, HTSUS (2017). The free rate of duty has not changed.

³ TOYS R US, <https://www.toysrus.com> (last visited Nov. 14, 2017) provides information on the JumpSmart Trampoline. While the product is no longer in stock, the product information is considered representative for the instant merchandise at issue given that it is consistent with the other descriptive information previously provided in NY N012532. See <https://www.toysrus.com/buy/outdoor-play/jumpsmart-trampoline-00135-3553708> (last visited Nov. 14, 2017); see also AMAZON, https://www.amazon.com/Diggin-00135-JumpSmart-Trampoline/dp/B00264GIFO?SubscriptionId=AKIAJO7E5OLQ67NVPFZA&=&ascsubtag=412912137-16-&camp=2025&creative=165953&creativeASIN=B00264GIFO&linkCode=xm2&tag=d_2b_a_p-20 (last visited Nov. 14, 2017); WALMART, <https://www.walmart.com/ip/JumpSmart-Kids-Electronic-Trampoline/33455551> (last visited on Nov. 14, 2017).

⁴ YouTube, <http://www.youtube.com>: JumpSmart! Professional assembly required (timboutillier); JumpSmart Electronic Trampoline (Mastermind Toys); JumpSmart Kids Trampoline Review (twonewparents); Jump Smart Toy (prinket) (last visited on Nov. 14, 2017).

Trampoline is triangular-shaped with a trampoline mat secured to a metal frame by bungee cording. The mat appears to be composed of either polyvinyl chloride (PVC) or other fabric material. The bungee cording provides the trampoline mat its bounce. There is a second piece of cascading fabric that covers the bungees and the edges of the triangular metal frame. The JumpSmart Trampoline also has two waist-high handles that are similar to bicycle handles for children to hold onto, providing balance while jumping. There is a piece of what appears to be heavy-duty plastic connecting the two handlebars with a row of buttons that control the music, learning games, and volume. The instant merchandise requires three AA batteries that are not included.

JumpSmart Trampoline as seen on Amazon.com

ISSUE:

Whether the JumpSmart Trampoline is a toy of heading 9503, HTSUS, or an article for general physical exercise of heading 9506, HTSUS.

LAW AND ANALYSIS:

Merchandise imported into the United States is classified under the HTSUS. Tariff classification is governed by the principles set forth in the General Rules of Interpretation (GRIs) and, in the absence of special language or context, which requires otherwise, by the Additional U.S. Rules of Interpretation. GRI 1 requires that classification be determined first according to the terms of the headings of the tariff schedule and any relative section or chapter notes and, unless otherwise required, according to the remaining GRIs taken in their appropriate order. The HTSUS provisions under consideration are the following:

9503	Tricycles, scooters, pedal cars and similar wheeled toys; dolls' carriages; dolls, other toys; reduced-size ("scale") models and similar recreational models, working or not; puzzles of all kinds; parts and accessories thereof
9503.00.0090	Other: * * * * *
9506	Articles and equipment for general physical exercise, gymnastics, athletics, other sports (including table-tennis) or outdoor games, not specified or included elsewhere in this chapter; swimming pools and wading pools; parts and accessories thereof: Other:
9506.91.00	Articles and equipment for general physical exercise, gymnastics or athletics; parts and accessories thereof
9506.91.0030	Other

The Harmonized Commodity Description and Coding System Explanatory Notes (ENs) constitute the official interpretation of the Harmonized System (HS) at the international level. While not legally binding, the ENs provide a commentary on the scope of each heading of the HS and are thus useful in ascertaining the proper classification of merchandise. *See* T.D. 89-90, 54 Fed. Reg. 35127, 35128 (August 23, 1989).

Although the term “toy” is not specifically defined in the tariff, the ENs to chapter 95, HTSUS, state the following:

This Chapter covers toys of all kinds whether designed for the amusement of children or adults. It also includes equipment for indoor or outdoor games, appliances and apparatus for sports, gymnastics or athletics, certain requisites for fishing, hunting or shooting, and roundabouts and other fairground amusements.

The ENs to heading 9503 provide, in relevant part, as follows:

(D) Other toys.

This group covers toys intended essentially for the amusement of persons (children or adults)...This groups includes:

* * * * *

(ix) Toy sports equipment, whether or not in sets (e.g., gold sets, tennis sets, archery sets, billiard sets; baseball bats, cricket bats, hockey sticks).

The EN to heading 9506 states, in pertinent part, the following:

(A) Articles and equipment for general physical exercise, gymnastics or athletics, e.g., :

Trapeze bars and rings; horizontal and parallel bars; balance beams, vaulting horses; pommel horses; spring boards; climbing ropes and ladders; wall bars; Indian clubs; dumb bells and bar bells; medicine balls; rowing, cycling and other exercising apparatus; chest expanders; hand grips; starting blocks; hurdles; jumping stands and standards; vaulting poles; landing pit pads; javelins, discuses, throwing hammers and putting shots; punch balls (speed bags) and punch bags (punching bags); boxing or wrestling rings; assault course climbing walls.

As noted above, Chapter 95 divides “toys” and “equipment for general physical exercise” into two separate headings - 9503, HTSUS, for toys and 9506, HTSUS, for exercise equipment. In order to be considered a toy, an article must be principally designed for amusement and not practicality. *See, e.g., Streetsurfing LLC v. United States, 11 F. Supp. 3d 1287, 1298 (CIT 2014); Minnetonka Brands, Inc. v. United States, 110 F. Supp. 2d 1020, 1026 (CIT 2000)*). Furthermore, if the article consists of a utilitarian feature, it must be incidental to any amusement the item may provide. *See Ideal Toy Corp. v. United States, 78 Cust. Ct. 28, 33, C.D. 4688 (1977)*.

The term trampoline is undefined in the tariff. The courts and CBP construe statutorily undefined terms in accordance with their common and commercial meaning, which is presumed to be the same. *See E.M. Chems. v. United States, 920 F.3d 910, 913 (Fed. Cir. 1990)*. The Oxford Dictionary defines trampolines as: “[a] strong fabric sheet connected by springs to a frame, used as a springboard and landing area in doing acrobatic or gymnastic exercises. Miriam-Webster defines them as: “[a] resilient sheet or web (as of nylon) supported by springs in a metal frame and used as a springboard and landing area in tumbling” and Wikipedia states: “[a] trampoline is a device consisting of a piece of taut, strong fabric stretched over a steel frame using many coiled springs.”

Mini-trampolines, however, do not have springs, but use a number of tension resistance bands to provide the bounce. Like the resistant bands

found in these mini-trampolines, the JumpSmart Trampoline's bungee cords provide the same bouncing and jumping experience, thereby providing exercise.

In NY R01614 (dated March 22, 2005), CBP considered the issue of whether a child-sized "Mini Trampoline" that was circular in shape and measuring 37.4 inches in circumference, should be classified as a toy of heading 9503, HTSUS, or an article of exercise equipment of heading 9506, HTSUS. The trampoline's frame was constructed of steel and the trampoline mat, as well as the material covering the edges, was made of PVC. CBP classified the item in subheading 9506.91.0030, noting the following: "[f]or tariff purposes, we believe that the provision for exercise equipment specifically describes this item while the toy provision does not do so."

CBP has classified other more traditional-style recreational trampolines with galvanized steel frames, safety pads constructed of PVC, metal springs to provide bounce, and ranging in size from 11' – 14', in heading 9506, HTSUS, as exercise equipment. See NY N144678 (dated February 14, 2011). More recently, in HQ H270403 (dated October 31, 2017), CBP classified the Skywalker Trampolines, for outdoor use, measuring 16' x 14' in size with 96 springs and including the "Triple Toss Game" as exercise equipment in heading 9506, HTSUS.

The JumpSmart Trampoline also incorporates games into its smaller trampoline.

In HQ 963284 (dated June 21, 2001), Customs cited HQ 950758 which ruled that a "Mini-Court" miniature basketball game was a scaled version of standard basketball equipment, consisting of a metal basketball hoop with a net attached to a wooden backboard supported by a two-part metal tubular post approximately six feet tall. It was determined that it could function as a recreational article and provide physical activity, especially for children.

HQ 963284 went on to state that an item does not have to be a regulation or "official" size to be considered sports equipment, provided that it is sufficiently sturdy and challenging to qualify as a "junior edition" of more expensive, larger portable basketball systems. Following the decision in *New York Merchandise Co. v. United States*, 62 Cust. Ct. 38, C.D. 3671, 294 F.Supp. 971 (1969), appeal dismissed 56 C.C.P.A. 133 (1969), Customs explained:

...a junior edition of a larger, more expensive article will be classified under the provision of the more expensive article if the cheaper, smaller article performs the same function on a smaller scale. Therefore, sports equipment reduced in size and material quality for use by children is classified in heading 9506, HTSUS, as long as the equipment is of a character suitable for use in the serious organized play or practice of games or sports or athletic recreation.

The instant JumpSmart Trampoline is constructed of a sturdy metal frame and is capable of holding weight up to 80 pounds. Jumping on a child-sized trampoline provides physical recreation and athletic coordination similar to jumping on a larger one. The same Triple Toss Game on the outdoor trampoline is included in this miniature version. Outdoor games are classified in heading 9506, HTSUS.

In HQ 965431 (dated July 15, 2002), when discussing whether a one-wheeled skate was properly classified in the same provision as roller skates, Customs stated the following:

To hold the term ‘roller skate’ in marketing and sporting circles is restricted to the traditional concept of pairs of wheels, is to ignore an important function of the tariff schedule, namely to provide *eo nomine* classification for most of the articles in international trade. **HQ 086626**, dated January 15, 1991. ‘Tariff provisions should be open to the invention of new and different products.’ *Id.* ‘Congress could not have intended to foreclose future innovations in [goods] from classification under the [eo nomine] provisions.’ *Simmon Omega, Inc. v. United States*, 83 Cust.Ct. 14, C.D. 4815 (1979). ‘To hold otherwise would result in the classification of any and every new product in the basket provisions of the nomenclature.’ **HQ 086626**.

We note, too, that the instant trampoline being sold in some toy stores does not automatically qualify it as a toy for tariff purposes. *See* HQ 963284 (June 12, 2001) (Customs notes that well-known toy stores such as Toys R Us sell toys, sporting and recreational equipment, and other things directed at a young consumer, but the appearance of the product in a toy store does not automatically make it a toy for tariff purposes.)

Therefore, the Jump Start Trampoline, functioning the same as larger trampolines, while constructed without springs, should not be excluded from classification as a trampoline so long as it provides exercise via jumping. Trampolines are “other exercising apparatus,” making the junior versions classifiable under the same provision. The proper heading for the JumpSmart Trampoline should be in subheading 9606.91.0030, HTSUSA (Annotated), which references articles and equipment for general physical exercise.

HOLDING:

By application of GRIs 1 and 6, the JumpSmart Trampoline is classified under subheading 9506.91.0030, HTSUS, which provides for “Articles and equipment for general physical exercise, gymnastics, athletics, other sports (including table-tennis) or outdoor games, not specified or included elsewhere in this chapter; swimming pools and wading pools; parts and accessories thereof: ... Other: Articles and equipment for general physical exercise, gymnastics or athletics; parts and accessories thereof ... Other.” The 2017 column one, general rate of duty is 4.6 percent *ad valorem*.

Duty rates are provided for your convenience and are subject to change. The text of the most recent HTSUS and the accompanying duty rates are provided on the internet at <http://www.usitc.gov>.

EFFECT ON OTHER RULINGS:

NY N012532, dated June 29, 2007, is hereby revoked.

Sincerely,

MYLES B. HARMON,

Director

Commercial and Trade Facilitation Division

19 CFR PART 177**REVOCAION OF A RULING LETTER AND REVOCAION OF TREATMENT RELATING TO THE CLASSIFICATION OF A HANDBAG AND A TOTE BAG WITH A COIN PURSE, SPECTACLE CASE, AND IDENTIFICATION CARD CASE**

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

ACTION: Notice of revocation of a ruling letter and revocation of treatment relating to the classification of a handbag and tote bag with a coin purse, spectacle case, and identification card case.

SUMMARY: Pursuant to section 625(c), Tariff Act of 1930 (19 U.S.C. §1625(c)), as amended by section 623 of Title VI (Customs Modernization) of the North American Free Trade Agreement Implementation Act (Pub. L. 103–182, 107 Stat. 2057), this notice advises interested parties that U.S. Customs and Border Protection (CBP) is revoking one ruling letter concerning tariff classification of a handbag and tote bag with a coin purse, spectacle case, and identification card case, under the Harmonized Tariff Schedule of the United States (HTSUS). Similarly, CBP is revoking any treatment previously accorded by CBP to substantially identical transactions. Notice of the proposed action was published in the *Customs Bulletin*, Vol. 51, No. 44, on November 1, 2017. No comments were received in response to that notice.

EFFECTIVE DATE: This action is effective for merchandise entered or withdrawn from warehouse for consumption on or after April 23, 2018.

FOR FURTHER INFORMATION CONTACT: Michelle Garcia, Chemicals, Petroleum, Metals and Miscellaneous Articles Branch, Regulations and Rulings, Office of Trade, at (202) 325–1115.

SUPPLEMENTARY INFORMATION:**BACKGROUND**

Current customs law includes two key concepts: informed compliance and shared responsibility. Accordingly, the law imposes an obligation on CBP to provide the public with information concerning the trade community's responsibilities and rights under the customs and related laws. In addition, both the public and CBP share responsibility in carrying out import requirements. For example, under section 484 of the Tariff Act of 1930, as amended (19 U.S.C. § 1484), the importer of record is responsible for using reasonable care to enter, classify and value imported merchandise, and to provide any other

information necessary to enable CBP to properly assess duties, collect accurate statistics, and determine whether any other applicable legal requirement is met.

Pursuant to 19 U.S.C. §1625(c)(1), a notice was published in the *Customs Bulletin*, Vol. 51, No. 44, on November 1, 2017, proposing to revoke one ruling letter pertaining to the tariff classification of a handbag and tote bag with a coin purse, spectacle case, and identification card case. Any party who has received an interpretive ruling or decision (i.e., a ruling letter, internal advice memorandum or decision, or protest review decision) on the merchandise subject to this notice should have advised CBP during the comment period.

Similarly, pursuant to 19 U.S.C. §1625(c)(2), CBP is revoking any treatment previously accorded by CBP to substantially identical transactions. Any person involved in substantially identical transactions should have advised CBP during the comment period. An importer's failure to advise CBP of substantially identical transactions or of a specific ruling not identified in this notice may raise issues of reasonable care on the part of the importer or its agents for importations of merchandise subsequent to the effective date of this notice.

In NY N024929, dated April 14, 2008, CBP classified a handbag and a tote bag with a coin purse, spectacle case, and identification card case in heading 4202, HTSUS. Specifically, the handbag of style HB18102C was classified in subheading 4202.22, HTSUS, which provides, in part, for "Handbags, whether or not with shoulder strap, including those without handle." The tote bag of style HB18103C, was classified in subheading 4202.92, HTSUS, which provides, in part, for "Other" bags. The coin purse, spectacle case, and identification card case for the handbag of style HB18102C and the tote bag of style HB18103C were classified in subheading 4202.32, HTSUS, which provides, in part, for "Articles of a kind normally carried in the pocket or in the handbag."

CBP has reviewed NY N024929 and has determined the ruling letter to be in error. It is now CBP's position that the styles at issue are classified as a set and that it is the handbag or tote bag that imparts the essential character to the set.

Pursuant to 19 U.S.C. §1625(c)(1), CBP is revoking NY N024929, dated April 14, 2008, and revoking or modifying any other ruling not specifically identified to reflect the analysis contained in HQ H263986, set forth as an attachment to this notice. Additionally, pursuant to 19 U.S.C. §1625(c)(2), CBP is revoking any treatment previously accorded by CBP to substantially identical transactions.

In accordance with 19 U.S.C. §1625(c), that ruling will become effective 60 days after publication in the *Customs Bulletin*.

Dated: December 27, 2017

ALLYSON MATTANAH
for
MYLES B. HARMON,
Director
Commercial and Trade Facilitation Division

Attachment

HQ H263986

December 27, 2017

RR:CTF:CPM H263986 MG

CATEGORY: Classification

TARIFF NO.: 4202.22.8100; 4202.92.3131

MARGARET MAHAS
IMPORT COMPLIANCE MANAGER
KOHL'S DEPARTMENT STORES, INC.
N56 W17000 RIDGEWOOD DRIVE
MENOMONEE FALLS
WISCONSIN 53051

RE: Revocation of NY N024929, dated April 14, 2008; Tariff classification of handbags and tote bags with a coin purse, spectacle case, and an identification card case

DEAR Ms. MAHAS:

U.S. Customs and Border Protection (CBP) issued Kohl's Department Stores, Inc., New York Ruling Letter (NY) N024929, dated April 14, 2008, pertaining to the tariff classification under the Harmonized Tariff Schedule of the United States (HTSUS) of a handbag with a coin purse, spectacle case, and an identification card case and a tote bag with a coin purse, spectacle case, and an identification card case.

The samples at issue are referred as style HB18102C, which is a compartmentalized handbag and style HB18103C, which is a tote bag. Both styles are imported with a coin purse, spectacle case, and an identification card case. In N024929 we determined that, although sold together, the items at issue are not designed to meet a particular need or carry out a specific activity and do not constitute a set. CBP, therefore, determined that each item is classified separately under its appropriate subheading. We have since reviewed the tariff classification of the bags at issue and find it to be in error.

On November 1, 2017, pursuant to section 625(c)(1), Tariff Act of 1930 (19 U.S.C. 1625(c)(1), as amended by section 623 of Title VI, notice of the proposed action was published in the *Customs Bulletin* Vol. 51, No. 44. No comments were received in response to that notice.

FACTS:

The items at issue in N024929 are described as follows:

Style HB18102C is a compartmentalized handbag. It is constructed with an outer surface of 100% polyester textile material. The handbag is designed and sized to carry money, keys and other small accessories on a daily basis. It has a main textile-lined compartment with a zippered wall pocket and two open wall pockets. This compartment secures with a top zipper closure. On opposite sides of the main compartment are additional compartments with open tops and no added features. The bag has two carrying handles and it measures approximately 14" (W) x 9" (H) x 4.25" (D).

Style HB18103C is a tote bag. It is constructed with an outer surface of 100% polyester textile material. The tote bag is designed to provide storage, protection, portability, and organization to personal effects during travel. The bag has a textile-lined interior compartment with a zippered wall pocket and two open wall pockets. It has a top zipper closure

and two carrying handles. The bag has an exterior zippered pocket, and measures approximately 15.5" (W) x 12" (H) x 4.5" (W).

The coin purses of styles HB18102C and HB18103C are constructed with an outer surface of 100% polyester textile material. The purses feature a single textile-lined compartment. They have a top zipper closure and measure approximately 6" (W) x 3.5" (H) x 1.5" (D).

The eyeglass cases of styles HB18102C and HB18103C are traditional clamshell-type spectacle cases with an exterior surface of 100% polyvinyl chloride (PVC) plastic sheeting. They have hinged lids and plastic inserts that are covered with a flocked material. They measure approximately 7" (L) x 0.5" (D).

The identification card cases of styles HB18102C and HB18103C are constructed with an outer surface of 100% polyvinyl chloride (PVC) plastic sheeting. They have zippered compartments with clear plastic windows for identification. They have open pockets on the front and back exterior and metal key rings. They measure approximately 4.5" (W) x 3" (H).

ISSUE:

- 1) Whether the bags and accompanying coin purse, spectacle case, and identification card case are classified as a set pursuant to GRI 3(b).
- 2) If so, what is the tariff classification of the article that imparts the essential character to the set?

LAW AND ANALYSIS:

Classification under the HTSUS is made in accordance with the General Rules of Interpretation. GRI 1 provides that the classification of goods shall be determined according to the terms of the headings of the tariff schedule and any relative Section or Chapter Notes. In the event that the goods cannot be classified solely on the basis of GRI 1, and if the headings and legal notes do not otherwise require, the remaining GRIs may then be applied.

In understanding the language of the HTSUS, the Harmonized Commodity Description and Coding System Explanatory Notes (ENs) may be utilized. The ENs, though not dispositive or legally binding, provide commentary on the scope of each heading of the HTSUS, and are the official interpretation of the Harmonized System at the international level. CBP believes the ENs should always be consulted. *See* T.D. 89-80, 54 Fed. Reg. 35127, 35128 (August 23, 1989).

The applicable HTSUS provisions at issue are as follows:

- | | |
|------|---|
| 4202 | Trunks, suitcases, vanity cases, attaché cases, briefcases, school satchels, spectacle cases, binocular cases, camera cases, musical instrument cases, gun cases, holsters and similar containers; traveling bags, insulated food or beverage bags, toiletry bags, knapsacks and backpacks, handbags, shopping bags, wallets, purses, map cases, cigarette cases, tobacco pouches, tool bags, sports bags, bottle cases, jewelry boxes, powder cases, cutlery cases and similar containers, of leather or of composition leather, of sheeting of plastics, of textile materials, of vulcanized fiber or of paperboard, or wholly or mainly covered with such materials or with paper: |
|------|---|

				Handbags, whether or not with shoulder strap, including those without handle:
4202.22				With outer surface of sheeting of plastic or of textile materials:
				With outer surface of textile materials:
				Other:
				Other:
4202.22.81				Of man-made fibers
*	*	*	*	
				Articles of a kind normally carried in the pocket or in the handbag:
4202.32				With outer surface of sheeting of plastic or of textile materials:
				With outer surface of textile materials:
*	*	*	*	
				Other:
4202.92				With outer surface of sheeting of plastic or of textile materials:
				Travel, sports and similar bags:
				With outer surface of textile materials:
4202.92.31				Of man-made fibers
*	*	*	*	

There is no dispute that the subject merchandise is classified in heading 4202, HTSUS, nor is there any dispute about the classification of each article at the subheading level. GRI 6 provides that the classification of goods in the subheadings of a heading shall be determined according to the terms of those subheadings and any related subheading notes and, *mutatis mutandis*, to GRIs 1 through 5, on the understanding that only subheadings at the same level are comparable. For the purposes of this rule, the relative section, chapter and subchapter notes also apply, unless the context otherwise requires. Handbags are classified in subheading 4202.22, HTSUS, coin purses, spectacle cases and ID cases are classified in subheading 4202.32, HTSUS, and tote bags are classified in subheading 4202.92, HTSUS.

The subject merchandise contains several articles packaged together, which cannot be classified pursuant to a GRI 1 analysis because the articles are *prima facie*, classifiable in two different subheadings. If imported separately, the handbag would be classified in subheading 4202.22, HTSUS, which provides, in part, for “Handbags, whether or not with shoulder strap, including those without handle,” the tote would be classified in subheading 4202.92, HTSUS, which provides, in part, for “Other” bags; and the handbag or tote’s coin purse, spectacle case, and identification card case would be classified in subheading 4202.32, HTSUS, which provides, in part, for “Articles of a kind normally carried in the pocket or in the handbag.”

When goods are, *prima facie*, classifiable in two or more headings, they must be classified in accordance with GRI 3¹, which provides, in relevant part, as follows:

- (a) The heading which provides the most specific description shall be preferred to headings providing a more general description.

However, when two or more headings each refer to part only of the materials or substances contained in mixed or composite goods or to part only of the items in a set put up for retail sale, those headings are to be regarded as equally specific in relation to those goods, even if one of them gives a more complete or precise description of the goods.

- (b) Mixtures, composite goods consisting of different materials or made up of different components, and goods put up in sets for retail sale, which cannot be classified by reference to 3(a), shall be classified as if they consisted of the material or component which gives them their essential character, insofar as this criterion is applicable.

* * * *

GRI 3 establishes a hierarchy of methods for classifying goods that fall under two or more headings. GRI 3(a) states that the heading providing the most specific description is to be preferred to a heading, which provides a more general description. However, GRI 3(a) indicates that when two or more headings each refer to part only of the materials or substances in a composite good or to part only of the items in a set put up for retail sale, those headings are to be regarded as equally specific in relation to those goods, even if one of them gives a more complete or precise description than the other. In this case, the subheadings 4202.22, 4202.32 and 4202.92, HTSUS, each refer to only part of the items in the set. Thus, pursuant to GRI 3(a), we must consider the headings equally specific in relation to the goods. Accordingly, the goods are classifiable pursuant to GRI 3(b).

In classifying the articles pursuant to a GRI 3(b) analysis, the goods are classified as if they consisted of the component that gives them their essential character and a determination must be made as to whether or not these are “goods put up in sets for retail sale”. In relevant part, the ENs to GRI 3(b) state:

- (VII) In all these cases the goods are to be classified as if they consisted of the material or component which gives them their essential character, insofar as this criterion is applicable.

(VIII) The factor which determines essential character will vary as between different kinds of goods. It may, for example, be determined by the nature of the material or component, its bulk, quantity, weight or value, or by the role of a constituent material in relation to the use of the goods.

* * * *

- (X) For the purposes of this Rule, the term “goods put up in sets for retail sale” shall be taken to mean goods which:

¹ Pursuant to GRI 6, classification at the subheading level uses the same rules, *mutatis mutandis*, as classification at the heading level.

- a) consist of at least two different articles which are, *prima facie*, classifiable in different headings. Therefore, for example, six fondue forks cannot be regarded as a set within the meaning of this Rule;
- (b) consist of products or articles put up together to meet a particular need or carry out a specific activity; and
- (c) are put up in a manner suitable for sale directly to users without repacking (e.g., in boxes or cases or on boards).

In accordance with GRI 3(b), we find that the subject component articles are properly classified as “sets” because they consist of goods put up in a set for retail sale. In this instance, the coin purse, spectacle case, and identification card case are designed to coordinate with the handbag or tote bag in that they are constructed of the same pattern, style, material, and color coordination to match the patterns of the handbag or tote. The coin purse, spectacle case, and identification card case are also a typical accessory that one might expect to be sold with a handbag or tote. The handbag and tote along with coin purse, spectacle case, and identification card case serve the singular purpose of helping the user to carry various items. Furthermore, the components in this set are, *prima facie*, classifiable in different subheadings and have been put up in retail packaging suitable for sale directly to users without repacking. See also HQ H031400, dated February 5, 2009, NY G82760, dated October 10, 2000, and NY G87109, dated February 14, 2008.

In *Estee Lauder, Inc. v. United States*, 815 F. Supp. 2d 1287, 1299–1300 (CIT 2012), the Court of International Trade (“CIT”) clarified that a GRI 3(b) set should be classified according to the item that provided the essential character. Essential character is determined based on a review of “the nature of the [good], its bulk, quantity, weight or value, or by the role of a constituent [good] in relation to the use of the goods.” *Id.* at 1300. This list is not exhaustive. The essential character of an article is “that which is indispensable to the structure, core or condition of the article, i.e., what it is.” Further, “the existence of other materials which impart something to the article ought not to preclude an attempt to isolate the most outstanding and distinctive characteristic of the article.” *Structural Indus. v. United States*, 29 CIT 180, 185, 360 F. Supp. 2d 1330, 1336 (2005) (citations omitted). Court decisions that discuss “essential character” for purposes of GRI 3(b) have looked to the role of the constituent materials or components in relation to the use of the goods to determine essential character. See, *Better Home Plastics Corp. v. United States*, 916 F. Supp. 1265 (CIT 1996), *affirmed*, 119 F. 3d 969 (Fed. Cir. 1997); *Mita Copystar America, Inc. v. United States*, 966 F. Supp. 1245 (CIT 1997), *rehearing denied*, 994 F. Supp. 393 (CIT 1998), and *Vista International Packaging Co., v. United States*, 19 CIT 868, 890 F. Supp. 1095 (1995). See also, *Pillowtex Corp. v. United States*, 983 F. Supp. 188 (CIT 1997), *affirmed*, 171 F. 3d 1370 (Fed. Cir. 1999).

Consistent with our determination in HQ H031400, we find that the handbag of style HB18102C and the tote bag of style HB18103C serve to carry, keep and protect the coin purse, spectacle case, and identification card case and enhance the usefulness of these items when used in combination with the handbag or tote bag. Moreover, as the handbag or tote bag provide the bulk of the set and visual impact, it is the handbag or tote bag that imparts the essential character to the set.

HOLDING:

By application of GRI 1, Style HB18102C and Style HB18103C are classified in heading 4202. By application of GRI 6 and GRI 3(b), Style HB18102C is classified in subheading 4202.22.8100, HTSUSA (Annotated), which provides for: “Trunks, suitcases, vanity cases, attaché cases, briefcases, school satchels, spectacle cases, binocular cases, camera cases, musical instrument cases, gun cases, holsters and similar containers; traveling bags, insulated food or beverage bags, toiletry bags, knapsacks and backpacks, handbags, shopping bags, wallets, purses, map cases, cigarette cases, tobacco pouches, tool bags, sports bags, bottle cases, jewelry boxes, powder cases, cutlery cases and similar containers, of leather or of composition leather, of sheeting of plastics, of textile materials, of vulcanized fiber or of paperboard, or wholly or mainly covered with such materials or with paper: Handbags, whether or not with shoulder strap, including those without handle: With outer surface of sheeting of plastic or of textile materials: With outer surface of textile materials: Other: Other: Of man-made fibers.” The column one, general rate of duty is 17.6% *ad valorem*.

By application of GRI 6 and 3(b), Style HB18103C is classified in subheading 4202.92.3131, HTSUSA, which provides for “Trunks, suitcases, vanity cases, attaché cases, briefcases, school satchels, spectacle cases, binocular cases, camera cases, musical instrument cases, gun cases, holsters and similar containers; traveling bags, insulated food or beverage bags, toiletry bags, knapsacks and backpacks, handbags, shopping bags, wallets, purses, map cases, cigarette cases, tobacco pouches, tool bags, sports bags, bottle cases, jewelry boxes, powder cases, cutlery cases and similar containers, of leather or of composition leather, of sheeting of plastics, of textile materials, of vulcanized fiber or of paperboard, or wholly or mainly covered with such materials or with paper: Other: With outer surface of sheeting of plastic or of textile materials: Travel, sports and similar bags: With outer surface of textile materials: Of man-made fibers: Other.” The column one, general rate of duty is 17.6% *ad valorem*.

Duty rates are provided for your convenience and subject to change. The text of the most recent HTSUS and the accompanying duty rates are provided at www.usitc.gov/tata/hts/.

EFFECT ON OTHER RULINGS:

NY N024929, dated April 14, 2008, is hereby REVOKED, as regards the tariff classification of a handbag and tote bag with a coin purse, spectacle case, and identification card case.

In accordance with 19 U.S.C. 1625(c), this ruling will become effective 60 days after publication in the *Customs Bulletin*.

Sincerely,

ALLYSON MATTANAH

for

MYLES B. HARMON,

Director

Commercial and Trade Facilitation Division

19 CFR PART 177**REVOCAION OF ONE RULING LETTER, MODIFICATION OF ONE RULING LETTER, AND REVOCAION OF TREATMENT RELATING TO THE TARIFF CLASSIFICATION OF ALISKIREN HEMIFUMARATE**

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

ACTION: Notice of revocation and modification of two ruling letters, and revocation of treatment relating to the tariff classification of Aliskiren Hemifumarate.

SUMMARY: Pursuant to section 625(c), Tariff Act of 1930 (19 U.S.C. §1625(c)), as amended by section 623 of title VI (Customs Modernization) of the North American Free Trade Agreement Implementation Act (Pub. L. 103–182, 107 Stat. 2057), this notice advises interested parties that U.S. Customs and Border Protection (CBP) is revoking New York Ruling Letter (NY) N180809, dated September 16, 2011, and modifying NY N043304, dated November 7, 2008, concerning the tariff classification of Aliskiren Hemifumarate under the Harmonized Tariff Schedule of the United States (HTSUS). Similarly, CBP is revoking any treatment previously accorded by CBP to substantially identical transactions. Notice of the proposed action was published in the *Customs Bulletin*, Vol. 51, No. 44, on November 1, 2017. No comments were received in response to that notice.

EFFECTIVE DATE: This action is effective for merchandise entered or withdrawn from warehouse for consumption on or after April 23, 2018.

FOR FURTHER INFORMATION CONTACT: Claudia Garver, Chemicals, Petroleum, Metals and Miscellaneous Articles Branch, Regulations and Rulings, Office of Trade, at (202) 325–0024.

SUPPLEMENTARY INFORMATION:**BACKGROUND**

Current customs law includes two key concepts: informed compliance and shared responsibility. Accordingly, the law imposes an obligation on CBP to provide the public with information concerning the trade community's responsibilities and rights under the customs and related laws. In addition, both the public and CBP share responsibility in carrying out import requirements. For example, under section 484 of the Tariff Act of 1930, as amended (19 U.S.C. § 1484), the importer of record is responsible for using reasonable care to enter,

classify and value imported merchandise, and to provide any other information necessary to enable CBP to properly assess duties, collect accurate statistics, and determine whether any other applicable legal requirement is met.

Pursuant to 19 U.S.C. §1625(c)(1), a notice was published in the *Customs Bulletin*, Vol. 51, No. 44, on November 1, 2017, proposing to revoke one ruling letter and to modify one ruling letter pertaining to the tariff classification of Aliskiren Hemifumarate. Any party who has received an interpretive ruling or decision (i.e., a ruling letter, internal advice memorandum or decision, or protest review decision) on the merchandise subject to this notice should have advised CBP during the comment period.

Similarly, pursuant to 19 U.S.C. §1625(c)(2), CBP is revoking any treatment previously accorded by CBP to substantially identical transactions. Any person involved in substantially identical transactions should have advised CBP during the comment period. An importer's failure to advise CBP of substantially identical transactions or of a specific ruling not identified in this notice may raise issues of reasonable care on the part of the importer or its agents for importations of merchandise subsequent to the effective date of this notice.

In NY N180809 and NY N043304, CBP classified Aliskiren Hemifumarate in heading 2924, HTSUS, specifically in subheading 2924.29.62, HTSUS, which provides for Carboxamide-function compounds; amide-function compounds of carbonic acid: Cyclic amides (including cyclic carbamates) and their derivatives; salts thereof: Other: Aromatic: Other: Drugs: Other." Neither ruling addressed the eligibility of Aliskiren Hemifumarate for duty free treatment under General Note 13, HTSUS. CBP has reviewed NY N180809 and NY N043304 and has determined the ruling letters to be in error. It is now CBP's position that while the classification of Aliskiren Hemifumarate in subheading 2924.29.62, HTSUS, is correct, Aliskiren Hemifumarate is eligible for duty free treatment under General Note 13, HTSUS.

Pursuant to 19 U.S.C. §1625(c)(1), CBP is revoking NY N180809, modifying NY N043304, and revoking or modifying any other ruling not specifically identified to reflect the analysis contained in Headquarters Ruling Letter ("HQ") H202562, set forth as an attachment to this notice. Additionally, pursuant to 19 U.S.C. §1625(c)(2), CBP is revoking any treatment previously accorded by CBP to substantially identical transactions.

In accordance with 19 U.S.C. §1625(c), this ruling will become effective 60 days after publication in the *Customs Bulletin*.

Dated: December 18, 2017

ALLYSON MATTANAH
for
MYLES B. HARMON,
Director
Commercial and Trade Facilitation Division

Attachment

HQ H202562

December 18, 2017

CLA-2 OT:RR:CTF:CPM H202562 CkG

CATEGORY: Classification

TARIFF NO: 2924.29.62

MS. INGE FORSTENZER
 REN-PHARM INTERNATIONAL, LTD
 350 JERICHO TURNPIKE
 SUITE 204
 JERICHO, NY 11753

RE: Revocation of NY N180809 and Modification of NY N043304;
 classification of Aliskiren Hemifumarate

DEAR MS. FORSTENZER:

This letter is in relation to New York Ruling Letters (NY) N180809 and N043304, issued to you on September 16, 2011, and November 7, 2008, respectively, regarding the classification of aliskiren hemifumarate under the HTSUS.

In NY N180809 and NY N043304, aliskiren hemifumarate in bulk form was classified in subheading 2924.29.6250, Harmonized Tariff Schedule of the United States (HTSUS), which provides for “Carboxamide-function compounds; amide-function compounds of carbonic acid: Cyclic amides (including cyclic carbamates) and their derivatives; salts thereof: Other: Aromatic: Other: Drugs: Other: Other.” There is no dispute that aliskiren hemifumarate is properly classified in 2924.29.62, HTSUS; however, neither NY N180809 nor NY N043304 afforded aliskiren hemifumarate duty free treatment under General Note 13. For the reasons set forth below, we have determined that the failure to grant aliskiren hemifumarate duty free treatment pursuant to General Note 13 was in error.

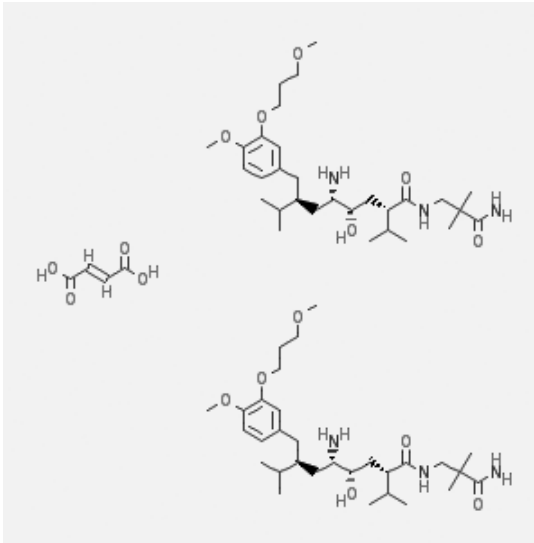
Pursuant to section 625(c)(1), Tariff Act of 1930 (19 U.S.C. §1625(c)(1)), as amended by section 623 of Title VI, notice proposing to revoke NY N180809 and NY N043304 was published on November 1, 2017, in Volume 51, Number 44 of the Customs Bulletin. No comments were received in response to the proposed action.

FACTS:

Aliskiren hemifumarate is an orally active renin inhibitor used in the treatment of hypertension. The chemical formula is $C_{64}H_{110}N_6O_{16}$. The prefix “hemi” refers to the ratio of fumarate to aliskiren molecules; specifically, 2 molecules of aliskiren for each molecule of fumarate.¹ The CAS number for aliskiren hemifumarate is 173334–58–2.

¹ See CBP Laboratory Report NY20112129, dated December 20, 2011

The chemical structure is included below:



ISSUE:

Whether aliskiren hemifumarate is eligible for duty free entry in accordance with General Note 13, HTSUS.

LAW AND ANALYSIS:

Merchandise is classifiable under the HTSUS in accordance with the General Rules of Interpretation (GRI). GRI 1 provides that classification shall be determined according to the terms of the headings and any relative Section or Chapter Notes. In the event that the goods cannot be classified solely on the basis of GRI 1, and if the headings or notes do not require otherwise, the remaining GRIs 2 through 6 may be applied.

The HTSUS provisions under consideration are as follows:

- 2924: Carboxamide-function compounds; amide-function compounds of carbonic acid:
 - Cyclic amides (including cyclic carbamates) and their derivatives; salts thereof:
- 2924.29: Other:
 - Aromatic:
 - Other:
 - Drugs:
 - 2924.29.62: Other...

* * * * *

The Harmonized Commodity Description and Coding System Explanatory Notes ("ENs") constitute the official interpretation of the Harmonized System at the international level. While neither legally binding nor dispositive, the ENs provide a commentary on the scope of each heading of the HTSUS and are generally indicative of the proper interpretation of these headings. See T.D. 89-80, 54 Fed. Reg. 35127, 35128 (August 23, 1989).

EN 29.24 provides as follows:

This heading covers amide derivatives of carboxylic acids and of carbonic acid (but **not** amide derivatives of other inorganic acids - **heading 29.29**).

Amides are compounds which contain the following characteristic groups :

$(-\text{CONH}_2)$	$((-\text{CO})_2\text{NH})$	$((-\text{CO})_3\text{N})$
Primary amide	Secondary amide	Tertiary amide

The hydrogen of the $(-\text{NH}_2)$ or $(>\text{NH})$ groups may be substituted by alkyl or aryl radicals, in which case the products are N- substituted amides.

Some amides of this heading also contain a diazotisable amine group. These amides and their salts, diluted to standard strengths for the production of azo dyes, are also included here.

(B) CYCLIC AMIDES

(1) Ureines and ureides.

The main ureines include :

- (i) *p* -Ethoxyphenylurea (dulcin).
- (ii) Diethyldiphenylurea (centralite)*.

(2) **Acetanilide, methyl- and ethylacetanilide, acet-*p*- phenetide** (phenacetin), *p*-acetamidophenol and *p*-acetamidosalol, used in medicine.

(3) Phenylacetamide.

(4) *N*-Acetoacetyl derivatives of cyclic amines, e.g., acetoacetanilide; **amides of hydroxynaphthoic acid**, e.g., 3-hydroxy-2-naphthanilide; **diatrizoic acid and its salts**, used as opacifiers in radiography. Some of these compounds are known in trade as "**arylides**".

(5) **2-Acetamidobenzoic acid**. Colourless to yellowish crystals in the form of needles, plates or rhomboids. Used as a precursor in the production of methaqualone (INN) (see the list of precursors at the end of Chapter 29).

(6) **Alachlor** (ISO). 2-Chloro-*N* -(2,6-diethylphenyl)-*N*-(methoxymethyl)acetamide. (C₁₄H₂₀ClNO₂).

This heading **excludes**, however, heterocyclic ureides, e.g., malonylurea (barbituric acid) and hydantoin (**heading 29.33**).

* * * *

There is no dispute that Aliskiren Hemifumarate is classified in heading 2924, specifically subheading 2924.29.62; the compound contains an organic amide group which makes Aliskiren Hemifumarate a cyclic amide as described in EN 29.24; the presence of an aromatic ring results in subheading 2924.29. As it is a drug, prescribed for the management of hypertension, and it is not provided for subheading 2924.29.57, Aliskiren Hemifumarate falls under subheading 2924.29.62, HTSUS, as an “other” aromatic drug.

The issue is whether Aliskiren Hemifumarate is eligible for duty free entry in accordance with General Note 13, HTSUS.

General Note 13 states as follows:

Pharmaceutical products. Whenever a rate of duty of “Free” followed by the symbol “K” in parentheses appears in the “Special” subcolumn for a heading or subheading, any product (by whatever name known) classifiable in such provision which is the product of a country eligible for tariff treatment under column 1 shall be entered free of duty, provided that such product is included in the pharmaceutical appendix to the tariff schedule. Products in the pharmaceutical appendix include the salts, esters and hydrates of the International Non-proprietary Name (INN) products enumerated in table 1 of the appendix that contain in their names any of the prefixes or suffixes listed in table 2 of the appendix, provided that any such salt, ester or hydrate is classifiable in the same 6-digit tariff provision as the relevant product enumerated in table 1.

Both aliskiren and fumarate are listed in the pharmaceutical appendix to the HTSUS; aliskiren in Table 1, and fumarate in Table 2. Any combination of a base product listed in Table 1 and a prefix or suffix listed in Table 2 of the appendix is eligible for treatment under GN 13, provided that such combination is classified in the same 6-digit provision as the relevant product in table 1. Although “hemifumarate” is not specifically listed in table 2, aliskiren hemifumarate is considered synonymous with aliskiren fumarate, as the prefix “hemi” merely identifies the ratio of fumarate to aliskiren molecules (i.e., one molecule of fumarate for every two of aliskiren). Both aliskiren fumarate and aliskiren hemifumarate share the same chemical formula ($C_{64}H_{110}N_6O_{16}$) and CAS number (173334–58–2); therefore, as aliskiren fumarate is eligible for duty free treatment under GN 13, so is aliskiren hemifumarate.

HOLDING:

By application of GRIs 1 and 6, aliskiren hemifumarate is classified in heading 2924, HTSUS, specifically subheading 2924.29.62, HTSUS, which provides for “Carboxamide-function compounds; amide-function compounds of carbonic acid: Cyclic amides (including cyclic carbamates) and their derivatives; salts thereof: Other: Aromatic: Other: Drugs: Other.”

Aliskiren hemifumarate is eligible for duty free treatment under General Note 13, HTSUS.

EFFECT ON OTHER RULINGS:

NY N180809, dated September 16, 2011, is hereby revoked. NY N043304, dated November 7, 2008, is hereby modified with respect to the rate of duty applicable to aliskiren hemifumarate.

In accordance with 19 U.S.C. §1625(c), this ruling will become effective 60 days after its publication in the Customs Bulletin.

Sincerely,

ALLYSON MATTANAH

for

MYLES B. HARMON,

Director,

Commercial and Trade Facilitation Division

19 CFR PART 177

MODIFICATION OF ONE RULING LETTER AND REVOCACTION OF TREATMENT RELATING TO THE TARIFF CLASSIFICATION OF WOODEN FURNITURE

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

ACTION: Notice of modification of one ruling letter and revocation of treatment relating to the tariff classification of wooden furniture

SUMMARY: Pursuant to section 625(c), Tariff Act of 1930 (19 U.S.C. §1625(c)), as amended by section 623 of title VI (Customs Modernization) of the North American Free Trade Agreement Implementation Act (Pub. L. 103–182, 107 Stat. 2057), this notice advises interested parties that U.S. Customs and Border Protection (CBP) is modifying New York Ruling Letter (NY) N104737, dated May 20, 2013, concerning the tariff classification of wooden furniture under the Harmonized Tariff Schedule of the United States (HTSUS). Similarly, CBP is revoking any treatment previously accorded by CBP to substantially identical transactions. Notice of the proposed action was published in the *Customs Bulletin*, Vol. 51, No. 44, on November 1, 2017. One comment was received in response to that notice.

EFFECTIVE DATE: This action is effective for merchandise entered or withdrawn from warehouse for consumption on or after April 23, 2018.

FOR FURTHER INFORMATION CONTACT: Claudia Garver, Chemicals, Petroleum, Metals and Miscellaneous Classification Branch, Regulations and Rulings, Office of Trade, at (202) 325–0024.

SUPPLEMENTARY INFORMATION:

BACKGROUND

Current customs law includes two key concepts: informed compliance and shared responsibility. Accordingly, the law imposes an obligation on CBP to provide the public with information concerning the trade community's responsibilities and rights under the customs and related laws. In addition, both the public and CBP share responsibility in carrying out import requirements. For example, under section 484 of the Tariff Act of 1930, as amended (19 U.S.C. § 1484), the importer of record is responsible for using reasonable care to enter, classify and value imported merchandise, and to provide any other

information necessary to enable CBP to properly assess duties, collect accurate statistics, and determine whether any other applicable legal requirement is met.

Pursuant to 19 U.S.C. §1625(c)(1), a notice was published in the *Customs Bulletin*, Vol. 51, No. 44, on November 1, 2017, proposing to modify one ruling letter pertaining to the tariff classification of wooden furniture. Any party who has received an interpretive ruling or decision (i.e., a ruling letter, internal advice memorandum or decision, or protest review decision) on the merchandise subject to this notice should have advised CBP during the comment period.

Similarly, pursuant to 19 U.S.C. §1625(c)(2), CBP is revoking any treatment previously accorded by CBP to substantially identical transactions. Any person involved in substantially identical transactions should have advised CBP during the comment period. An importer's failure to advise CBP of substantially identical transactions or of a specific ruling not identified in this notice may raise issues of reasonable care on the part of the importer or its agents for importations of merchandise subsequent to the effective date of this notice.

In NY N104737, CBP classified three wooden chests of drawers in heading 9403, HTSUS, specifically in subheading 9403.50.90, HTSUS, as wooden furniture of a kind used in the bedroom. CBP has reviewed NY N104737 and has determined the ruling letter to be in error with respect to one item, identified as item CM903. It is now CBP's position that item CM903 is properly classified, by operation of GRIs 1 and 6, in in subheading 9403.60.80, HTSUS, as other wooden furniture.

Pursuant to 19 U.S.C. §1625(c)(1), CBP is modifying NY N104737 and revoking or modifying any other ruling not specifically identified to reflect the analysis contained in Headquarters Ruling Letter ("HQ") H245888, set forth as an attachment to this notice. Additionally, pursuant to 19 U.S.C. §1625(c)(2), CBP is revoking any treatment previously accorded by CBP to substantially identical transactions.

In accordance with 19 U.S.C. §1625(c), this ruling will become effective 60 days after publication in the *Customs Bulletin*.

Dated: December 18, 2017

ALLYSON MATTANAH
for

MYLES B. HARMON,
Director

Commercial and Trade Facilitation Division

Attachment

HQ H245888

December 18, 2017

CLA-2 OT:RR:CTF:CPM H245888 CkG

CATEGORY: Classification

TARIFF NO.: 9403.50.90, 9403.60.80

PATRICIA SANDERS

CUSTOMS BROKERAGES, INC.

800 ATLANTA SOUTH PARKWAY, STE. 150

COLLEGE PARK, GA 30349

Re: Modification of NY *N104737*; classification of wooden furniture

DEAR Ms. SANDERS:

This is in response to your request of May 20, 2013, for the reconsideration¹ of New York Ruling Letter (NY) *N104737*, dated May 20, 2010, classifying three pieces of wooden furniture in subheading 9403.50, HTSUS, as wooden furniture of a kind used in the bedroom. For the reasons set forth below, we have determined that the classification of the CM903 chest in subheading 9403.50.90, HTSUS, was incorrect.

Pursuant to section 625(c)(1), Tariff Act of 1930 (19 U.S.C. §1625(c)(1)), as amended by section 623 of Title VI, notice proposing to modify NY *N104737* was published on November 1, 2017, in Volume 51, Number 44 of the Customs Bulletin. One comment was received in response to the proposed action, and is addressed below.

FACTS:

In NY *N104737*, the subject merchandise was described as follows:

Photographs have been submitted for three pieces of wooden furniture. Item number SW1001 is a three drawer accent chest made of MDF board with wood veneer and metal hardware. This item measures 32 inches high by 34 inches wide and 18 inches deep. Item number SW1002 is a six drawer narrow console made of MDF board with wood veneer and metal hardware. This item measures 37.5 inches high by 41 inches wide and 11 inches deep. Item number CM903 is a half moon accent table made of MDF board with wood veneer and metal hardware. This item measures 35.5 inches high by 38 inches wide and 17 inches deep. The drawers on all three pieces are sufficiently large to accommodate storage of clothing and accessories.

The products at issue are unadorned and contain no decorative markings or carvings.

You further submit scanned copies of catalog pages for the importer, Old South Lamps and Accents, but nothing directly featuring the goods at issue.

ISSUE:

Whether the instant furniture pieces are classified in subheading 9403.50, HTSUS, as wooden furniture of a kind used the bedroom, or in subheading 9403.60, HTSUS, as other wooden furniture.

¹ We note that the CF 19 provided in your submission does not appear to have been filed with a port, and that in any case a Protest is not the appropriate vehicle for a request for reconsideration of a CBP ruling; thus, we are treating your “protest” as a request for the revocation of NY *N104737*.

LAW AND ANALYSIS:

Merchandise imported into the United States is classified under the HTSUS. Tariff classification is governed by the principles set forth in the General Rules of Interpretation (GRIs) and, in the absence of special language or context, which requires otherwise, by the Additional U.S. Rules of Interpretation. GRI 1 requires that classification be determined first according to the terms of the headings of the tariff schedule and any relative section or chapter notes and, unless otherwise required, according to the remaining GRIs taken in their appropriate order.

According to GRI 6, the classification of goods in the subheadings of a heading shall be determined according to the terms of those subheadings.

The 2017 HTSUS provisions under consideration are as follows:

- 9403: Other furniture and parts thereof:
- 9403.30: Wooden furniture of a kind used in offices:
- 9403.40: Wooden furniture of a kind used in the kitchen:
- 9403.50: Wooden furniture of a kind used in the bedroom:
- 9403.60: Other wooden furniture:

* * * *

Note 2 to Chapter 94 provides as follows:

- 2. The articles (other than parts) referred to in headings 9401 to 9403 are to be classified in those headings only if they are designed for placing on the floor or ground.

The following are, however, to be classified in the above-mentioned headings even if they are designed to be hung, to be fixed to the wall or to stand on the other.

- (a) Cupboards, bookcases, other shelved furniture (including single shelves presented with supports for fixing them to the wall) and unit furniture;
- (b) Seats and beds.

* * * *

Additional U.S. Rule of Interpretation 1(a), HTSUS, provides that:

- 1. In the absence of special language or context which otherwise requires:
 - (a) a tariff classification controlled by use (other than actual use) is to be determined in accordance with the use in the United States at, or immediately prior to, the date of importation, of goods of that class or kind to which the imported goods belong, and the controlling use is the principal use.

* * * *

The Harmonized Commodity Description and Coding System Explanatory Notes (ENs) constitute the official interpretation of the Harmonized System (HS) at the international level. While not legally binding, the ENs provide a commentary on the scope of each heading of the HS and are thus useful in ascertaining the proper classification of merchandise. *See* T.D. 89-90, 54 Fed. Reg. 35127, 35128 (August 23, 1989).

The EN to heading 9403 provides, in pertinent part:

This heading covers furniture and parts thereof, not covered by the previous headings. It includes furniture for general use (e.g., cupboards, show-cases, tables, telephone stands, writing-desks, escritoirs, book-cases, and other shelved furniture (including single shelves presented with supports for fixing them to the wall), etc.), and also furniture for special uses.

The heading includes furnitures for :

(1) Private dwellings, hotels, etc., such as : cabinets, linen chests, bread chests, log chests; chests of drawers, tallboys; pedestals, plant stands; dressing-tables; pedestal tables; wardrobes, linen presses; hall stands, umbrella stands; side-boards, dressers, cupboards; food-safes; bedside tables; beds (including wardrobe beds, camp-beds, folding beds, cots, etc.); needlework tables; stools and foot-stools (whether or not rocking) designed to rest the feet, fire screens; draught-screens; pedestal ashtrays; music cabinets, music stands or desks; play-pens; serving trolleys (whether or not fitted with a hot plate).

Headings 9401 to 9403, HTSUS, provide for furniture. Note 2 to Chapter 94 describes the merchandise covered by the term “furniture” as “articles...designed for placing on the floor or ground.” There is no dispute that the instant wooden chests are classified in heading 9403, HTSUS, as furniture. Under heading 9403, HTSUS, there are four separate subheadings for wooden furniture. Subheadings 9403.30, HTSUS, 9403.40, HTSUS, and 9403.50, HTSUS, each provide for wooden furniture of a kind used in offices, kitchens and bedrooms, respectively. Subheading 9403.60, HTSUS, is a residual provision for other wooden furniture. If the instant items are not classifiable in subheadings 9403.30 through 9403.50, HTSUS, they will be classified in subheading 9403.60, HTSUS.

Subheadings 9403.30, HTSUS, 9403.40, HTSUS, and 9403.50, HTSUS, each use the term “of a kind.” As such, these subheadings are principal use provisions. Under Additional U.S. Rule of Interpretation 1(a) (AUSR 1(a)), tariff classification under a principal use provision must be determined in accordance with the use in the United States of that class or kind to which the imported goods belong. The rule “call[s] for a determination as to the group of goods that are commercially fungible with the imported goods.” *BenQ Am. Corp. v. United States*, 646 F.3d 1371, 1379 (Fed. Cir. May 27, 2011), *Primal Lite, Inc. v. United States*, 182 F.3d 1362 (Fed. Cir. July 16, 1999). Accordingly, under a principal use provision, it is not the *actual* use of the product which determines the classification, but rather the *principal* use of the *class* or *kind* of goods to which the merchandise belongs.

Thus, in order to be classified as wooden furniture of a kind used in offices, kitchens or bedrooms, the instant articles must belong to the same kind or class of goods as such bedroom furniture. In *United States v. Carborundum Co.*, 536 F.2d 373, 377 (CCPA 1976), the U.S. Court of Customs and Patent Appeals stated that in order to determine whether an article is included in a particular class or kind of merchandise, the court must consider a variety of factors, including: (1) the general physical characteristics of the merchandise; (2) the channels, class or kind of trade in which the merchandise moves (where the merchandise is sold); (3) the expectation of the ultimate purchasers; (4) the environment of the sale (i.e., accompanying accessories and

marketing); (5) usage, if any, in the same manner as merchandise which defines the class; (6) the economic practicality of so using the import; and (7) the recognition in the trade of this use. *Id.* While these factors were developed under the Tariff Schedule of the United States (predecessor to the HTSUS), the courts have also applied them under the HTSUS. *See, e.g. Minnetonka v United States*, 110 F. Supp. 2d 1020, 1027 (Ct. Int'l Trade 2000); *see also Aromont USA, Inc. v. United States*, 671 F.3d 1310 (Fed. Cir. 2012), *Essex Manufacturing, Inc. v. United States*, 30 C.I.T. 1 (2006).

Neither the HTSUS nor the ENs provide a description or examples of furniture of a kind used in the bedroom that would give guidance to determine which furniture products are considered of a class or kind used in the bedroom. In order to obtain some guidance on what kind of furniture would be used in the bedroom, we have reviewed prior CBP rulings as well as several web sites that sell furniture promoted and advertised for use in a bedroom. *See* the following web links where furniture is sold: <http://www.pier1.com/dresser-armoire#nav=left>; https://www.walmart.com/browse/bedroom-furniture/dressers/4044_103150_102547_91839; <https://www.wayfair.com/furniture/sb0/dressers-c46091.html>; <http://www.ikea.com/us/en/catalog/categories/departments/bedroom/10451/>; https://www.westelm.com/shop/furniture/dressers-nightstands/dressers/?cm_type=lnav.

As illustrated in the links above, chests of drawers and dressers are a universally recognized category of bedroom furniture. The specific dimensions, finish, number of drawers, and other characteristics of such dressers vary widely, but they all share the common characteristic of being suitable for the storage of clothes and linens in the bedroom. The design of the SW1001 is typical of similar 3-drawer chests, which similarly feature three full size, stacked drawers and are typically made of wood or MDF. Larger bedroom dressers of four or more drawers, such as the SW1002, typically feature two or more smaller drawers at the top of the dresser for smaller items such as undergarments or socks, with larger drawers underneath for outer clothing. Moreover, the pictures submitted of the SW1001 and SW1002 are virtually identical to the numerous examples of bedroom chests and dressers sold in these and other furniture outlets. The SW1001 and SW1002 share the same classic and common style as pieces sold in furniture outlets such as IKEA, Wayfair, Pier One, and West Elm, and in the bedroom furniture departments of retailers such as Walmart and Target.² At 32" H x 34"W x 18" D and 37.4" H x 41"W x 11" D, the dimensions of the SW1001³ and

² See e.g., <http://www.ikea.com/us/en/catalog/categories/departments/bedroom/10451/>; <https://www.target.com/d/dressers-bedroom-furniture/-/N-5xtnd>; https://www.walmart.com/browse/bedroom-furniture/dressers/4044_103150_102547_91839; <https://www.wayfair.com/furniture/sb0/dressers-c46091.html>; http://www.pier1.com/dresser-armoire?nav=tile&icid=cat_furniture-subcat_bedroom_furniture-subcat_tile_dresser_armoire; https://www.westelm.com/shop/furniture/dressers-nightstands/dressers/?cm_type=lnav

³ To list but a fraction of 3-drawer chests of a similar size and style to the SW1001: the Malm 3-drawer chest from IKEA (30 ¾" H, Width: 31 1/2" W, 18 7/8" D), <http://www.ikea.com/us/en/catalog/products/80360461/>; the Brusali 3-drawer chest from IKEA <http://www.ikea.com/us/en/catalog/products/50360405/> (36 5/8" H, 31 ½" W, 18 7/8" D) <http://www.ikea.com/us/en/catalog/products/00360399/>; the DaVinci Kalani 3 Drawer Dresser from Target (35.37" H x 32.25" W x 21.5" D), at <https://www.target.com/p/davincikalani-3-drawer-dresser/-/A-52571125#lnk=newtab>; the Graco Kendall 3 Drawer Chest from Target (32.95" H x 33.74" W x 18" D), at <https://www.target.com/p/graco-174-kendall-3-drawer-chest/-/A-51179707#lnk=newtab>; from Wayfair.com, the Aster 3 Drawer Dresser

SW1002⁴ are also well within the range of sizes of chests of drawers used for bedroom storage.

Hence, the dimensions, overall appearance and functionality of the SW1001 and SW1002 are well within the range of what is commonly marketed, sold and used as bedroom furniture. The depth and size of the drawers make them particularly suitable for the storage of clothing. They could also conceivably be used for the storage of other items, of course—nothing in the design of these chests mandates their use for bedroom storage—but by far the most common and typical use of this kind of merchandise is for the storage of clothing in the bedroom. They are, furthermore, clearly distinct from console tables and cabinets used in the living room for general storage; similarly-sized chests used for storage and/or display of media in the living room, for example, have an open shelf at the top for easy access to set-top boxes and cables.⁵ The SW1001 and SW1002 also lack any specific decorative features such as carvings or engravings, ornamental leaf, or textured finish that would make them more suitable for display in a living or dining room as accent furniture.

However, we do agree that the half-moon design of the 3-drawer CM903 console, while not unsuitable for a bedroom, is an unusual design for bedroom furniture. It is somewhat less practical as a utilitarian storage solution, as the curvature of the chest reduces the interior space. Merchandise of a comparable size and style appears to be marketed for general storage or as accent furniture.⁶ As the CM903 does not clearly resemble typical bedroom furniture, and similar merchandise is sold for general home storage, a principal use in kitchens, offices or bedrooms cannot be established for this item.

You claim that the instant items are not actually used in the bedroom; however, you submit no evidence to support this claim with respect to the specific items at issue. The catalog pages from Old South Lamps and Accents

(30.5" H x 36" W x 17" D), at <https://www.wayfair.com/Red-Barrel-Studio-Aster-3-Drawer-Dresser-RDBL3685.html>, and the Susan 3 Drawer Chest (33" H x 35.25" W x 18.5" D), at <https://www.wayfair.com/Viv-Rae-Susan-3-Drawer-Chest-VVRO5316.html>.

⁴ Dressers of a size and style similar to the SW1002 include, for example: from Wayfair.com, the Breakwater Bay Roselle dresser (39.625" H x 44.625" W x 17.875" D), at <https://www.wayfair.com/Breakwater-Bay-Roselle-8-Drawer-Dresser-Chest-BRWT2387.html>; the Burbury Country Lodge 4 Drawer Chest (36" H x 39" W x 13" D), at <https://www.wayfair.com/Loon-Peak-Burbury-Country-Lodge-4-Drawer-Chest-LNPK8225.html>; the Ziggy Accent Chest (34" H x 40" W x 14" D), at <https://www.wayfair.com/House-of-Hampton-Ziggy-Accent-Chest-HOHN7396.html>; from WalMart, the Crestview Hampton Chest (36" H, 42" W, 12"D), at <https://www.walmart.com/ip/Crestview-Collection-Hampton-6-Drawer-Chest/38760540>.

⁵ See, e.g., <https://www.wayfair.com/Altra-Furniture-Oakridge-3-Drawer-Media-Chest-HQZ1717.html>, <https://www.wayfair.com/Red-Barrel-Studio-Cannonball-Way-3-Drawer-Media-Chest-RDBS1258.html>; and/or larger compartments with doors <http://www.pier1.com/heera-brown-mango-wood-cabinet/2589224.html?cgid=decorative-cabinets#nav=left&start=1> <http://www.ikea.com/us/en/catalog/products/80300660/>.

⁶ See, e.g., the Cantor Demilune Accent Chest, from Birch Lane (<https://www.birchlane.com/Cantor-Demilune-Accent-Chest-BL15443.html?PiID%5B%5D=17599239&source=hotdeals>); from Wayfair, the Maddison Demilune Hall 4 Drawer Accent Chest (32" H x 40" W x 19" D), at <https://www.wayfair.com/Canora-Grey-Maddison-Demilune-Hall-4-Drawer-Accent-Chest-CAGY1519.html>; or the Quintin 4 Drawer Chest (35" H x 36" W x 18" D), at <https://www.wayfair.com/Stein-World-Quintin-4-Drawer-Chest-SM6768.html>.

feature other, apparently unrelated, products, and no evidence has been presented that Old South exclusively sells furniture for other than bedroom use. Based on our observations of similar merchandise from multiple vendors, items sharing the essential characteristics—style, size, material, and finish—to the SW1001 and SW1002 are marketed and used for the storage of clothing in the bedroom. We further note that the physical dimensions of the SW1001 and SW1002 are very much in line with the typical dimensions of dressers and chests of drawers used for bedroom storage. We therefore find that the SW1001 and SW1002 are of a class or kind with bedroom furniture, and were properly classified in subheading 9403.50, HTSUS, as wooden furniture of a kind used in the bedroom. However, furniture of the general style, size, and design of the CM903 is marketed and used for general storage or as accent pieces for entryways or living rooms. Accordingly, we agree that the CM903 is not furniture of a kind used in the bedroom, and is therefore classified in subheading 9405.60, HTSUS, as other wooden furniture.

One comment was received in response to the notice of proposed action. The comment urges CBP to clarify that the determination by CBP that SW1001 and SW1002 are classified in subheading 9403.50, HTSUS, as bedroom furniture, does not bind the Department of Commerce with respect to a determination of the scope of an antidumping order or countervailing duties. As noted in the holding, a classification determination by CBP that a product is classified in an HTSUS provision subject to an antidumping or countervailing duty order does not require the DOC to find that that same merchandise is within the scope of the order.

HOLDING:

By application of GRIs 1 and 6, the SW1001 and SW1002 remain classified in heading 9403, HTSUS, specifically subheading 9403.50.90, HTSUS, which provides for “Other furniture and parts thereof: Wooden furniture of a kind used in the bedroom: Other: Other.” The 2017, column one, general rate of duty is Free.

The CM903 is classified in heading 9403, HTSUS, specifically subheading 9403.60.80, HTSUS, which provides for “Other furniture and parts thereof: Other wooden furniture: Other.” The 2017, column one, general rate of duty is Free.

The merchandise in question may be subject to antidumping duties or countervailing duties. We note that the Commerce Department is not necessarily bound by a country of origin or classification determination issued by CBP, with regard to the scope of antidumping orders or countervailing duties. Written decisions regarding the scope of AD/CVD orders are issued by the Department of Commerce and are separate from tariff classification and origin rulings issued by Customs and Border Protection. You can contact them at <http://www.trade.gov/ia/> (click on “Contact Us”). For your information, you can view a list of current AD/CVD cases at the United States International Trade Commission website at <http://www.usitc.gov> (“Antidumping and countervailing duty investigations”), and you can search AD/CVD deposit and liquidation messages using ACE, the system of record for AD/CVD messages, or the AD/CVD Search tool at <http://addecvd.cbp.gov/index.asp?ac=home>.

EFFECT ON OTHER RULINGS:

NY *N104737*, dated May 20, 2010, is hereby modified with respect to the classification of the CM903 accent chest.

Sincerely,

ALLYSON MATTANAH

for

MYLES B. HARMON,

Director

Commercial and Trade Facilitation Division+