and 114 deaths due to WNV. During 2009–2018, a total of 21,869 confirmed or probable cases of WNV disease, including 12,835 (59%) WNV neuroinvasive disease cases, were reported to CDC from all 50 states, the District of Columbia, and Puerto Rico.

WNV presents a significant public health threat. This epidemiological trend of WNV suggests that the United States can expect periodic WNV outbreaks, underscoring the need for a safe and effective vaccine to protect at-risk populations, especially older adults.

WNV is also a significant worldwide public health threat. Starting in the mid-1990s, the frequency, severity, and geographic range of WNV outbreaks increased. The virus can be found throughout Africa, regions of Europe and the Middle East, West Asia, Australia, Canada, Venezuela, and the United States. Outbreak areas are typically found along major bird migratory routes, with the largest outbreaks having occurred in Greece, Israel, Russia, Romania, and the United States. In the approximately eighty (80) years since its discovery, the virus has propagated to a vast region of the globe and is now considered the most important causative agent of viral encephalitis worldwide.

No vaccine exists today to prevent WNV in humans. The methods and compositions of this invention provide a means for prevention of WNV infection by immunization with live attenuated, immunogenic viral vaccines against WNV.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Institute of Allergy and Infectious Diseases receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent commercialization license. In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available. License applications submitted in response to this Notice will be presumed to contain business confidential information, and any release of information in these license applications will be made only as required and upon a request under the *Freedom of Information Act,* 5 U.S.C. 552.

Dated: September 7, 2021.

Surekha Vathyam,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2021–19566 Filed 9–9–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determination Concerning Certain Calcitriol Soft-Shell Capsules

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 Calcitriol soft-shell capsules. Based upon the facts presented, CBP has concluded in the final determination that the Calcitriol capsules would be products of a foreign country or instrumentality designated pursuant to CBP regulations for purposes of U.S. Government procurement.

DATES: The final determination was issued on August 27, 2021. 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 no later than October 12, 2021.

FOR FURTHER INFORMATION CONTACT: Albena Peters, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade, at (202) 325–0321.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on August 27, 2021, CBP issued a final determination concerning the country of origin of Calcitriol capsules for purposes of Title III of the Trade Agreements Act of 1979. This final determination, HQ H319605, was issued at the request of the party-at-interest, 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 has concluded that, based upon the facts presented, the Calcitriol soft-shell capsules would be products of a foreign country or instrumentality designated pursuant to 19 U.S.C. 2511(b) 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: September 3, 2021.

Alice A. Kipel,

Executive Director, Regulations and Rulings, Office of Trade.

HQ H319605

August 27, 2021

OT:RR:CTF:VS H319605 AP

CATEGORY: Origin

Steven Lerner, Supply Chain Analyst, Sun Pharmaceutical Industries Ltd., 2 Independence Way, Princeton, NJ 08540

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

Dear Mr. Lerner:

This is in response to your July 13, 2021 request, on behalf of Sun Pharmaceutical Industries Ltd. (''Sun Pharma''), for a final determination concerning the country of origin of Calcitriol soft-shell capsules. This request is being sought because the company wants to confirm eligibility of the merchandise for U.S. government procurement purposes under Title III of the Trade Agreements Act of 1979 (''TAA''), as amended (19 U.S.C. 2511 *et seq*.). Sun Pharma is a party-at-interest within the meaning of 19 CFR 177.22(d)(1) and 177.23(a).

FACTS:

Sun Pharma is among the largest specialty generic pharmaceutical companies in the world with more than 40 manufacturing facilities.[1] The company manufactures and imports Calcitriol [2] in the form of soft-shell capsules (0.25 mcg and 0.5 mcg). The

[1] *See* Sun Pharma, About Us, *https://sunpharma.com/about-us/* (last visited Aug. 2, 2021).

[2] The Calcitriol's National Drug Code Directory numbers are: 62756–967–83, 62756–967–88 and 62756–968–88.

Calcitriol capsules are used for vitamin D3 deficiency.

The raw ingredients originate from Switzerland. The active ingredient is Calcitriol USP. The inactive ingredients, which serve as coloring agents, preservatives, and fillers, consist of medium-chain triglycerides, butylated hydroxyanisole, butylated hydroxytoluene, noncrystallizing liquid sorbitol, glycerin, gelatin, methyl paraben, propylparaben, ferric oxide (red and yellow), titanium dioxide, triethyl citrate, isopropyl alcohol, and opacode black.

All of the Swiss ingredients are shipped to India where capsules are manufactured. During the manufacturing process, the Calcitriol is dissolved in medium chain triglycerides along with other inactive ingredients to form a clear drug solution. Gelatin is mixed along with purified water and other inactive ingredients under specific temperature and vacuumed with help of a gelatin melter. The resulting gelatin mass is fed into an encapsulation machine to form soft gelatin capsules with drug solution inside. The capsules pass into a tumble dryer to remove excess moisture. After the capsules are dried and polished, they are printed with food grade ink. Finally, the capsules are inspected, packed in containers, and labelled.

ISSUE:

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

LAW AND ANALYSIS:

U.S. Customs and Border Protection (''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 177.21–177.31, which implements Title III of the TAA, as amended (19 U.S.C. 2511–2518).

CBP's authority to issue advisory rulings and final determinations is set forth in 19 U.S.C. 2515(b)(1), which states:

> For the purposes of this subchapter, the Secretary of the Treasury shall provide for the prompt issuance of advisory rulings and final determinations on whether, under section 2518(4)(B) of this title, an article is or would be a product of a foreign country or instrumentality designated pursuant to section 2511(b) of this title.

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

> 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.

A product of a foreign country or instrumentality designated pursuant to 19 U.S.C. 2511(b)(1), in pertinent part, is a country or instrumentality which is a party to the Agreement on Government Procurement (''GPA''), referred to in 19 U.S.C. 3511(d)(17), and as annexed to the World Trade Organization (''WTO'') Agreement.[3] Switzerland is a WTO GPA country.

Title 48, CFR Section 25.003 defines ''WTO GPA country end product'' as an article that:

> (1) Is wholly the growth, product, or manufacture of a WTO GPA country; or
>
> (2) In the case of an article that consists in whole or in part of materials from another country, has been substantially transformed in a WTO GPA country 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. The term refers to a product offered for purchase under a supply contract, but for purposes of calculating the value of the end product includes services (except transportation services) incidental to the article, provided that the value of those incidental services does not exceed that of the article itself.

Sun Pharma asserts that no substantial transformation occurs in India because the identity of the raw materials originating from Switzerland remains intact. We concur. The processing of the Calcitriol into dosage form as soft gel capsules will not result in a substantial transformation. *See* Headquarters Ruling Letter (''HQ'') H284694, dated Aug. 22, 2017 (Dutch-origin bulk calcium acetate produced in the Netherlands and combined with inactive ingredients in India resulted in calcium acetate capsules originating from the Netherlands); HQ H233356, dated Dec. 26, 2012 (The blending of the mefenamic acid of Indian origin with inactive ingredients in the U.S. to form mefenamic acid capsules did not substantially transform the mefenamic acid from India). The Calcitriol is produced in Switzerland and is encapsulated in India. No change in name occurs in India because the product is referred to as ''Calcitriol'' both before and after encapsulation. The Calcitriol is the only active ingredient. After being mixed with the inactive ingredients serving as coloring agents, preservatives, and fillers, it retains its chemical and physical properties and is merely put into a dosage form in India. Finally, no change in use occurs in India because the Calcitriol retains the same predetermined medicinal use for vitamin D3 deficiency. As a result, no substantial transformation occurs during the encapsulation process in India and the country of origin of the final Calcitriol capsules remains Switzerland, a WTO GPA country, where the Calcitriol is produced.

Accordingly, the instant Calcitriol capsules would be products of a foreign country or instrumentality designated pursuant to 19 U.S.C. 2511(b)(1).

HOLDING:

Based on the facts presented, the country of origin of the Calcitriol capsules is Switzerland, a WTO GPA country, for purposes of U.S. Government procurement. Therefore, the Calcitriol soft-shell capsules would be products of a foreign country or instrumentality designated pursuant to 19 U.S.C. 2511(b)(1).

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

Sincerely,

Alice A. Kipel,

Executive Director, Regulations and Rulings, Office of Trade.

[FR Doc. 2021–19515 Filed 9–9–21; 8:45 am]

BILLING CODE 9111–14–P

[3] *See* World Trade Organization, Agreement on Government Procurement, Parties, Observers and Accessions, *https://www.wto.org/english/tratop_e/gproc_e/memobs_e.htm* (last visited Aug. 2, 2021).