DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determination Concerning the Visionary Advanced 2 Dietary Supplement Tablets

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 three Visionary Advanced 2 vitamin and mineral dietary supplement tablets. Based upon the facts presented, for purposes of U.S. Government procurement, CBP has concluded that the United States is the country of origin of the Advanced 2 vitamin and mineral dietary supplement tablets.

DATES: The final determination was issued on August 27, 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 [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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

SUPPLEMENTARY INFORMATION: Notice is hereby given that on August 27, 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 three versions of the Visionary Advanced 2 vitamin and mineral dietary

supplement tablets which may be offered to the U.S. Government under an undesignated government procurement contract. This final determination, HQ H299717, copy attached, 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). The three products are Visionary Advanced 2 coated tablets, Visionary Orange Advanced 2 chewable tablets, and Visionary Cherry Advanced 2 chewable tablets. Each of the dietary supplement tablets contains the same basic formula of vitamins and minerals, but with different flavorings. In the final determination, CBP concluded that the combining of the various vitamins and minerals in one tablet in the United States results in a product that has a name, character and use that is distinct from the individual ingredients that are used to make the dietary supplement.

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

Dated: August 27, 2018.

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

HQ H299717

August 27, 2018

OT:RR:CTF:VS H299717 RSD

CATEGORY: Origin

Mr. Marino Apollinari
Visionary Vitamin Co.
P.O. Box 1825
Dearborn, Michigan 48122

RE: U.S. Government Procurement; Country of Origin of Advanced 2 Multiple Vitamin and Mineral Dietary Supplement Tablets; Substantial Transformation

Dear Mr. Apollinari:

This is in response to the Visionary Vitamin Company's (Visionary's) request of June 4, 2018, for a final determination concerning the country of origin of products known as the Visionary Advanced 2 dietary supplements pursuant to subpart B of Part 177 of the U.S. Customs and Border protection ("CBP") Regulations (19 C.F.R. Part 177). The National Commodity Specialist Division forwarded your request to the Headquarters office of Regulations and Rulings to issue this final determination.

As an importer, Visionary 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.

FACTS:

Visionary is a manufacturer of dietary supplements. At issue are three different multiple vitamin and mineral dietary supplement tablets. The three dietary supplement tablets are the Advanced 2 Coated tablets, the Visionary Orange Advanced 2 chewable tablets, and the Visionary Cherry Advanced 2 chewable tablets.

The vitamin and mineral tablets contain the following raw materials:

Medicinal Ingredients	**Country of Origin**
Vitamin C DC grade (Ascorbic Acid) (97%)	China
Vitamin E (As DL-Alpha Tocopherol Acetate) 50%-Tab grad	China
Zinc (as oxide) (80.34%)	India
Copper (as cupric oxide) (78.3%)	USA

Lutein (5%) beadlets	China
Zeaxanthin (5%) beadlets from Omnixan	USA

Other ingredients

DI Calcium Phosphate	China
Micro crystalline Cellulose	India
Croscarmellose Sodium	Brazil
Silicon Dioxide	USA
Magnesium Stearate (vegetable source)	Spain
Stearic Acid Vegetable grade	Malaysia
Pharmaceutical Glaze (only used for coated tablets)	USA

Instead of pharmaceutical glaze, the chewable orange and cherry tablets contain a natural masking flavor from the United States, either in a natural orange flavor or natural cherry flavor. In addition, the chewable cherry and orange tablets also incorporate sucralose from China. You have indicated that the most expensive single ingredient used in making the Advanced 2 dietary supplement tablets is the Zeaxanthin Omnixan from the United States.

The manufacturing processes of the three products occurs at Visionary's facility in Michigan, United States. The same basic procedures are used to manufacture the three different dietary supplement tablets. A flow chart of the processes was submitted. The active and inactive ingredients in powder form are weighed and all vital information is logged in.

Next, the ingredients are dispensed, and the dry mix is blended. A vibro sifter is used to pass the raw powder materials through a 40-mesh screen, while being added to a drum for mixing. Weight and yield are recorded. Mixing and lubrication is performed by a blender.

The approved blend is then transferred to the compression area. The blend is loaded into the hopper of a tablet press. The tablet press is set for the specified parameters and the details are noted in a start-up test during the tablet compression. The weight of the first few tablets is taken and checked against the actual weight of the product. Adjustments in the weight of the tablets are made until the right weight is obtained. The hardness of the tablets is also adjusted by carefully turning the pressure rollers by hand until the correct hardness is obtained. The tablets are then compared to previous samples. A series of in-process quality checks are performed in various intervals while the tablets are produced. These include: 1) appearance; 2) average weight per 10 tablets; 3) tablet thickness); 4) disintegration of tablet; 5) friability; 6) hardness; and 7) temperature and humidity.

The coating solution is prepared by loading the tablets in a pan and recording the actual weight. The tablets are pre-heated until the temperature reaches 100 degrees Fahrenheit. The coating solution is sprayed on the tablets until all surfaces of the tablets are covered. The tablets are unloaded into trays and placed in an oven room for drying. The tablets are then sorted and damaged tablets (such as broken, color or thickness variance, capping issues, or black/foreign material) are rejected.

Next, the product moves to the packaging line using the following equipment: an unscrambler, a conveyor, a tablet counter, a cottoner, a capper labeler, induction sealer, heat tunnel, printer coder, accumulation table and weighing balance. A system of quality controls occurs to ensure that the tablets are properly packaged, coded, and labeled.

ISSUE:

What is the country of origin of the Visionary Advanced 2 Coated tablets, Visionary Orange Advanced 2 Chewable tablets, and Visionary Cherry Advanced 2 Chewable 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.) ("TAA").

Under the rule of origin set forth under 19 U.S.C. § 2518(4)(8):

> 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).

With respect to whether combining and mixing different materials results in a substantial transformation, CBP held in Headquarters Ruling Letter ("HQ") 731685, dated March 15, 1990, that converting fruit concentrates and other ingredients into fruit drinks in Mexico constituted a substantial transformation. The manufacturing process involved mixing the juice concentrates with other ingredients including water, artificial flavor, sodium benzoate, and food coloring. CBP held that, considering the totality of the circumstances, a substantial transformation had occurred because "[t]he juice concentrates are subsumed into a product that is no longer considered a juice." This situation is distinguished from a situation considered in *National Juice Products* Ass'n *v. United States,* 628 F. Supp. 978 (Ct. Int'l Trade 1986), in which the United States Court of International Trade ("CIT") upheld CBP's decision in HQ 728557, dated September 4, 1985, that imported orange juice concentrate was not substantially transformed when it was mixed with water, essential oils, flavoring ingredients and domestic fresh juice in order to produce frozen concentrated orange juice and reconstituted orange juice. CBP found that the manufacturing process did not create an article with a new name, character or use. The CIT agreed that the manufacturing process did not change the "fundamental character of the product" as "it was still essentially the juice of oranges". See HQ H237605 dated June 25, 2014. In HQ 731685, a substantial transformation was found because the raw ingredients had been converted into a different article of commerce through a process beyond simple combining, packaging or mere diluting.

In the context of 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. CBP has generally held that the processing of pharmaceutical products from bulk form into measured doses does not result in a substantial transformation. See, *e.g.,* HQ 561975, dated April 3, 2002; HQ 561544, dated May 1, 2000; HQ 735146, dated November 15, 1993; HQ H267177, dated November 5, 2016; HQ H233356, dated December 26, 2012; and, HQ 561975, dated April 3, 2002. However, where the processing from bulk form into measured doses involves the combination of two or more active ingredients and the resulting combination offers additional medicinal benefits compared to taking each alone, CBP has held that a substantial transformation occurs. See, *e.g.,* HQ 563207, dated June 1, 2005.

For example, in HQ 563207, CBP held that the combination of two APIs to form

Actoplus Met, an alternative treatment for type 2 diabetes, constituted a substantial transformation. The first API, Pioglitazone HCI sourced from Japan or other countries, functioned as an insulin sensitizer that targets insulin resistance in the body. The second API, biguanide sourced from Japan, Spain, and other countries, functioned to decrease the amount of glucose produced by the liver and to make muscle tissue more sensitive to insulin so glucose can be absorbed. In Japan, the two APIs were mixed together to form the Ectoplasm Met. In holding that a substantial transformation occurred when the two API's were combined, CBP emphasized that "[w]hile we note that pioglitazone and metformin may be prescribed separately, the final product, Actoplus Met, increases the individual effectiveness of piofliazone and metformin in treating type 2 diabetes patients."

Similarly, in HQ H253443, dated March 13, 2015, CSP held that the combination of two APIs in China to produce Prepopik, "a dual-acting osmotic and stimulant laxative bowel preparation for a colonoscopy in adults," constituted a substantial transformation. CBP found that taking Prepopik had "a more stimulative laxative effect" than taking each of the APIs individually. Further, in HQ H290684, dated July 2, 2018, CSP considered the country of origin of Malarone, a drug indicated for the prevention and treatment of acute, uncomplicated Plasmodium falciparum malaria. Two separate APIs were mixed to create a fixed combination drug that offered additional medicinal benefits compared to taking each API alone. The first API, atovaquone, was not indicated for the prevention or treatment of malaria, the second API, proguanil hydrochloride, was used to treat malaria, but was less effective than Malarone. Because of the "synergies in [the APIs'] method of action," which resulted in a product that "interfere[s] with 2 different pathways" to prevent and treat malaria, CBP held that the combination of atovaquone, proguanil hydrochloride, and inactive ingredients to form the Malarone tablets in Canada resulted in a substantial transformation.

In this case, to make the dietary supplement tablets, various ingredients from different countries of origin are mixed together based on a specific formula. This results in a finished product that differs from any of the individual ingredients. The vitamins and minerals are put together in one tablet for the purposes of creating a product that is designed to promote certain effects that are distinct from the effects if only the individual ingredients were taken. Similar to HQ H253443, the combination of the vitamins and minerals in a single tablet creates a product with a synergistic effect that promotes benefits that otherwise would only be possible by taking the individual ingredients separately. In other words, the combination of the various vitamins and minerals in one tablet results in a product that has an identity, character and use that is different from and more convenient to use than taking the individual raw materials. Accordingly, we find that the three Visionary dietary supplement tablets have a new name, character and use different from the individual vitamins, minerals, and the inert ingredients used in the production of the finished tablets. Therefore, we find that the country of origin of the

Visionary Advanced 2 multiple vitamin and mineral dietary supplement tablets is the United States, where the manufacturing process take place.

HOLDING:

The country of origin of the Visionary Advanced 2 Coated Tablets, Visionary Orange Advanced 2 Chewable Tablets, and Visionary Cherry Advanced 2 Chewable Tablets for purpose of U.S. Government procurement is the United States.

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

Sincerely,

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

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