

detailing the applicant's relevant experience for the position applied for, and (c) a brief biography. Applications should be submitted via email with subject line "NCTSAC Vacancy Application" to *Ethan.T.Beard@uscg.mil*.

FOR FURTHER INFORMATION CONTACT:

Lieutenant Ethan Beard, Assistant Designated Federal Officer of the National Chemical Transportation Safety Advisory Committee; telephone 571-607-8905 or email at *Ethan.T.Beard@uscg.mil*.

SUPPLEMENTARY INFORMATION: The National Chemical Transportation Safety Advisory Committee is a Federal advisory committee. The National Chemical Transportation Safety Advisory Committee was established by section 601 of the *Frank LoBiondo Coast Guard Authorization Act of 2018* (Pub. L. 115-282, 132 Stat. 4192), and is codified in 46 U.S.C. 15101. The Committee operates under the provisions of the *Federal Advisory Committee Act* (5 U.S.C. ch. 10) and 46 U.S.C. 15109. The Committee provides advice and recommendations to the Secretary of Homeland Security on matters relating to the safe and secure marine transportation of hazardous materials.

The Committee is required to meet at least once a year in accordance with 46 U.S.C. 15109(a)(1). We expect the Committee to meet at least twice a year, but it may meet more frequently. The meetings are generally held in Washington, DC and Houston, Texas.

Under 46 U.S.C. 15109(f)(6)(A), if you are appointed as a member of the Committee, your membership term will expire on December 31st of the third full year after the effective date of your appointment. In accordance with 46 U.S.C. 15109(f)(4), applicants for membership may be required to pass an appropriate security background examination before their appointment to the Committee.

All members serve at their own expense and receive no salary or other compensation from the Federal Government. If you are appointed as member of the Committee, you will be required to sign a Non-Disclosure Agreement and a Gratuitous Services Agreement.

In this solicitation for Committee Members, we will consider applications from members representing the following:

- Chemical manufacturing entities
- Entities related to marine handling or transportation of chemicals
- Marine safety or security entities

- Marine environmental protection entities

The members who will fill the positions described above will be appointed to represent the interest of their respective groups and viewpoints and are not "special Government employees," as defined in 18 U.S.C. 202(a).

In order for the Department to fully leverage broad-ranging experience and education, the National Chemical Transportation Safety Advisory Committee must be diverse with regard to professional and technical expertise. The Department is committed to pursuing opportunities, consistent with applicable law, to compose a committee that reflects the diversity of the Nation's people.

If you are interested in applying to become a member of the Committee, email your application to *Ethan.T.Beard@uscg.mil* as provided in the **ADDRESSES** section of this notice. Applications must include: (a) a cover letter expressing interest in an appointment to the National Chemical Transportation Safety Advisory Committee, (b) a resume detailing the applicant's relevant experience for the position applied for, and (c) a brief biography of the applicant by the deadline in the **DATES** section of this notice.

The U.S. Coast Guard will not consider incomplete or late applications.

Privacy Act Statement

Purpose: To obtain qualified applicants to fill six vacancies on the National Chemical Transportation Safety Advisory Committee. When you apply for appointment to the National Chemical Transportation Safety Advisory Committee, Department of Homeland Security (DHS) will collect your name, contact information, and any other personal information that you submit in conjunction with your application. DHS will use this information to evaluate your candidacy for Committee membership. If you are chosen to serve as a Committee member, your name will appear in publicly available Committee documents, membership lists, and Committee reports.

Authorities: 14 U.S.C. 504; 46 U.S.C. 15101 and 15109; and 18 U.S.C. 202(a), and Department of Homeland Security Delegation No. 00915.

Routine Uses: Authorized U.S. Coast Guard personnel will use this information to consider and obtain qualified candidates to serve on the Committee. Any external disclosures of information within this record will be

made in accordance with DHS/ALL-009, Department of Homeland Security Advisory Committee (73 FR 57642, October 3, 2008).

Consequences of Failure to Provide Information: Furnishing this information is voluntary. However, failure to furnish the requested information may result in your application not being considered for the Committee.

Dated: March 28, 2024.

Jeffrey G. Lantz,

Director of Commercial Regulations and Standards.

[FR Doc. 2024-07050 Filed 4-2-24; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determination Concerning Omega-3-Acid Ethyl Esters 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 Omega-3-Acid Ethyl Esters Capsules. Based upon the facts presented, CBP has concluded that the Norwegian-origin Omega-3-Acid Ethyl Esters do not undergo a substantial transformation in China when combined with certain inactive ingredients and encapsulated into dosage form.

DATES: The final determination was issued on March 28, 2024. 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 May 3, 2024.

FOR FURTHER INFORMATION CONTACT: Mitchell Emery, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade, at (202) 325-0321.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on March 28, 2024, U.S. Customs and Border Protection (CBP) issued a final determination concerning the country of origin of Omega-3-Acid Ethyl Esters Capsules for purposes of title III of the Trade Agreements Act of 1979. This final determination, Headquarters Ruling (HQ) H331488, was issued at the request of Epic Pharma LLC, 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 Omega-3-Acid Ethyl Esters are not substantially transformed in China when combined with certain inactive ingredients and encapsulated into dosage form.

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**.

Alice A. Kipel,

Executive Director, Regulations and Rulings, Office of Trade.

HQ H331488

OT:RR:CTF: VS H331488 MLE

CATEGORY: Origin

Mr. Pei Zhang, Ph.D., Associate

Director, Regulatory Affairs, Epic
Pharma, LLC, 227–15 N Conduit
Avenue, Laurelton, NY 11413

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 Omega-3-Acid Ethyl Esters Capsules.

Dear Mr. Zhang:

This is in response to your March 29, 2023 request, on behalf of Epic Pharma, LLC, for a final determination concerning the country of origin of certain Omega-3-Acid Ethyl Esters capsules pursuant to Title III of the Trade Agreements Act of 1979 (“TAA”), as amended (19 U.S.C. 2511 *et seq.*), and subpart B of Part 177, U.S. Customs and Border Protection (“CBP”) Regulations (19 CFR 177.21, *et seq.*). Epic Pharma, LLC, is a party-at-interest within the meaning of 19 CFR 177.22(d)(1) and 177.23(a) and is therefore entitled to request this final determination.

FACTS

Epic Pharma is a New York-based company specializing in the production of generic pharmaceuticals. At issue in this case are Omega-3-Acid Ethyl Esters capsules, which you describe are intended as an “adjunct to diet to reduce triglyceride (“TG”) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.” You state that Omega-3-Acid Ethyl Esters, which are the sole Active Pharmaceutical

Ingredient (“API”) in the final product, are produced in Norway. You state that in China the API is combined with inactive ingredients of various origins to produce the finished capsules.

The manufacturing processes in China include the following: first, inactive ingredients including gelatin glycerin, and purified water are combined to create an encapsulating gel. Second, the API is encapsulated into dosage form. Third, imprinting ink is applied for any trademark or content information.

You state that “[n]o change in name occurs in China because the product is referred to as ‘Omega-3-Acid Ethyl Esters’ both before and after encapsulation.” You also state that the processes performed to produce the final product do not result in any changes to the chemical characteristics of the Omega 3-Acid Ethyl Esters, or to any other ingredients. Finally, you claim that no change in use occurs, as the product retains the same predetermined medicinal use. In short, you characterize the operations in China as purely mechanical, intended to process the Omega-3-Acid Ethyl Esters into dosage form.

ISSUE

What is the country of origin of the Omega-3-Acid Ethyl Esters capsules for the 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 177.21–177.31, 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. *Emphasis added.*

The Secretary of the Treasury’s authority mentioned above, along with other customs revenue functions, are delegated to CBP in the Appendix to 19

CFR Part 0—Treasury Department Order No. 100–16, 68 Fed. Reg. 28, 322 (May 23, 2003).

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.

See also 19 CFR 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 the Federal Procurement Regulation (“FAR”). *See* 19 CFR 177.21. In this regard, CBP recognizes that the FAR restricts 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 CFR 25.403(c)(1).

The FAR, 48 CFR 25.003, defines “designated country end product” as: a WTO GPA [World Trade Organization Government Procurement Agreement] country end product, an FTA [Free Trade Agreement] country end product, a least developed country end product, or a Caribbean Basin country end product.

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.

As indicated above, the Omega-3-Acid Ethyl Esters are produced in Norway, which is a WTO GPA country. *See* FAR, 48 CFR 25.003. The encapsulation process takes place in China, which is not a designated country for the purpose of government procurement.

In order to determine whether a substantial transformation occurs, CBP

considers the totality of the circumstances and makes such determinations on a case-by-case basis. The country of origin of the item's components, extent of the processing that occurs within a country, and whether such processing renders a product with a new name, character, and use are primary considerations in such cases. Additionally, CBP considers factors such as the resources expended on product design and development, the extent and nature of post-assembly inspection and testing procedures, and worker skill required during the actual manufacturing process when determining whether a substantial transformation has occurred. No one factor is determinative.

In deciding whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, CBP has held that the processing of pharmaceutical products from bulk form into measured doses does not result in a substantial transformation of the product, even when the API is combined with other inactive ingredients. *See, e.g.*, Headquarters Ruling ("HQ") 561975, dated April 3, 2002; HQ 561544, dated May 1, 2000; HQ 735146, dated November 15, 1993; HQ H267177, dated November 5, 2016; HQ H233356, dated December 26, 2012; HQ H284694, dated August 22, 2017, and New York Ruling ("NY") C85112, dated March 27, 1998.

For instance, in HQ 561975, CBP held that the processing of imported bulk Japanese-origin anesthetic drugs into dosage form in the United States did not constitute a substantial transformation. Although the bulk form of the drug underwent testing operations, filtering, and packaging in the United States, these processes did not change the chemical or physical properties of the drug. Furthermore, there was no change in the product's name, which was referred to as sevoflurane in both its bulk and processed form. Additionally, because the imported bulk drug had a predetermined medicinal use as an anesthetic drug, the processing in the United States did not result in a change in the product's use. The country of origin of the finished product was therefore Japan.

More recently, in HQ H284694, CBP reviewed the country of origin of quinine sulfate capsules. In that case, the German-manufactured API quinine sulfate was exported to India in bulk form, where it was combined with

several inactive ingredients, granulated, sieved and placed into gelatin capsules. No change in its name occurred because the product was referred to as "quinine sulfate" both before and after processing. Additionally, no change in character occurred because the product maintained the same chemical and physical properties in its processed form. Finally, because the product had a predetermined medical use as an antimalarial drug, no change in use occurred after processing. Therefore, the country of origin of the final product remained Germany.

Similar to the encapsulation here, in NY C85112, CBP reviewed the country of origin of leuprolide acetate, sold under the trade name Lupron Depot 7.5 mg. In that case, U.S.-manufactured leuprolide acetate powder was exported to Japan where it was combined with certain excipients and encapsulated into sterile microspheres. The purpose of microencapsulating the leuprolide acetate was to modify its delivery rate from daily into a form that would be released in the human body over a period of one to four months. CBP determined that the fundamental character of the leuprolide acetate was unchanged by the encapsulation processing and that the foreign processing did not result in a substantial transformation of the U.S.-manufactured leuprolide acetate.

The facts here closely follow the cases cited above, as does our decision. The processing of bulk imported pharmaceuticals into dosage form, even with the addition of inactive ingredients, will not result in a substantial transformation. In this case, the processing begins with the Norwegian-origin bulk Omega-3-Acid Ethyl Esters, and after the product is processed and combined with inactive ingredients in China, it results in Omega-3-Acid Ethyl Esters capsules. There is no change in name after processing. Furthermore, no change in character occurs in China, as the Omega-3-Acid Ethyl Esters maintain the same chemical and physical properties both before and after processing. Finally, because the Omega-3-Acid Ethyl Esters have a predetermined medical use to "reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia," no change in use occurs after it is processed in China. Under these circumstances, and consistent with previous CBP rulings, we find that the country of origin of the final product is Norway, where the active pharmaceutical ingredient was produced.

HOLDING

Based on the information outlined above, we determine that the Omega-3-Acid Ethyl Esters made in Norway, do not undergo a substantial transformation when encapsulated into individual doses and combined with inactive ingredients in China. Therefore, the country of origin of the Omega-3-Acid Ethyl Esters capsules for purposes of U.S. Government procurement is Norway.

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 U.S. Court of International Trade.

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

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BILLING CODE 3314-88-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-HQ-FAC-2024-N014;
FXFR1336090000-FF09F14000-245]

Aquatic Nuisance Species Task Force Meeting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of meeting.

SUMMARY: The U.S. Fish and Wildlife Service gives notice of a public meeting of the Aquatic Nuisance Species (ANS) Task Force, in accordance with the Federal Advisory Committee Act. The ANS Task Force's purpose is to develop and implement a program for U.S. waters to prevent introduction and dispersal of aquatic invasive species; to monitor, control, and study such species; and to disseminate related information.

DATES: The ANS Task Force will meet Wednesday and Thursday on May 8-9, 2024, from 8 a.m. to 5 p.m. each day (eastern time). On Wednesday, May 8, 2024, there will be a site visit from 1 p.m. to 5 p.m. The site visit will include presentations on, and viewing of,