

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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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-HQ-FAC-2024-N014;
FXFR13360900000-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,

aquatic invasive species control projects.

Registration: Registration is required. The deadline for registration is May 3, 2024. Also see “Public Input,” below.

Accessibility: The deadline for accessibility accommodation requests is May 3, 2024. Please see “Accessibility Information,” below.

ADDRESSES: The meeting will take place at the Gideon Putnam Room, Saratoga Spa State Park, 19 Roosevelt Drive, Saratoga Springs, NY 12866. Virtual participation will also be available via teleconference and broadcast over the internet. To register and receive the web address and telephone number for virtual participation, contact the Executive Secretary (see **FOR FURTHER INFORMATION CONTACT**) or visit the ANS Task Force website at <https://www.fws.gov/program/aquatic-nuisance-species-task-force>.

FOR FURTHER INFORMATION CONTACT: Susan Pasko, Executive Secretary, ANS Task Force, by telephone at (571) 623-0608, or by email at Susan_Pasko@fws.gov. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

Introduction

The Aquatic Nuisance Species (ANS) Task Force was established by the Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990, as amended (16 U.S.C. 4721-4728), and is composed of Federal and ex-officio members. 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.

Meeting Information

This meeting is open to the public. The meeting agenda will include reports from ANS Task Force members, regional panels, and subcommittees; discussion on priority outputs to advance the goals identified in the ANS Task Force Strategic Plan for 2020-2025; presentations highlighting regional invasive species challenges and innovative measures for ANS management and control; recommendations by the ANS Task Force regional panels; and public

comment. The site visit will include presentations on, and viewing of, aquatic invasive species control projects within the area, including marine rapid assessment surveys conducted at local marinas and *Hydrilla* control and containment efforts in the Connecticut River. The final agenda and other related meeting information will be posted on the ANS Task Force website, <https://www.fws.gov/program/aquatic-nuisance-species-task-force>.

Public Input

If you wish to provide oral public comment or provide a written comment for the ANS Task Force to consider, contact the ANS Task Force Executive Secretary (see **FOR FURTHER INFORMATION CONTACT**) no later than May 1, 2024.

Depending on the number of people who want to comment and the time available, the amount of time for individual oral comments may be limited. Interested parties should contact the ANS Task Force Executive Secretary, in writing (see **FOR FURTHER INFORMATION CONTACT**), for placement on the public speaker list for this meeting. Requests to address the ANS Task Force during the meeting will be accommodated in the order the requests are received. Registered speakers who wish to expand upon their oral statements, or those who had wished to speak but could not be accommodated on the agenda, may submit written statements to the Executive Secretary up to 30 days following the meeting.

Accessibility Information

Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. Please contact the ANS Task Force Executive Secretary (see **FOR FURTHER INFORMATION CONTACT**) no later than May 3, 2024, to give the U.S. Fish and Wildlife Service sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis.

Public Disclosure

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 5 U.S.C. ch. 10.

David A. Miko,

Co-Chair, Aquatic Nuisance Species Task Force.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-HQ-FAC-2024-N017; FF09F42300 FVWF97920900000 XXX]

Sport Fishing and Boating Partnership Council; Public 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 Sport Fishing and Boating Partnership Council (Council), in accordance with the Federal Advisory Committee Act.

DATES: The Council will meet on Tuesday, May 14, 2024, from 8:30 a.m. to 4:45 p.m. and Wednesday, May 15, 2024, from 8:30 a.m. to 12:30 p.m. eastern time.

Registration: Registration is required. The deadline for registration is May 10, 2024.

Accessibility: The deadline for accessibility accommodation requests is May 7, 2024. Please see *Accessibility Information*, below.

ADDRESSES: The meeting will take place at the Department of the Interior, 1849 C Street NW, Washington, DC 20240. Virtual participation will also be available via teleconference and broadcast over the internet. To register and receive the web address and telephone number for virtual participation, contact the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Tom McCann, Designated Federal Officer, by email at thomas_mccann@fws.gov, or by telephone at 571-329-3206. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: Established in 1993, the Sport Fishing and Boating Partnership Council (Council) advises the Secretary of the