

limitations imposed by the review and funding cycle.

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Mechanisms and Treatments of Lower Urinary Tract Dysfunction after Spinal Cord Injury.

*Date:* July 23, 2018.

*Time:* 1:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Paul A. Rushing, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7345, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-8895, [rushingp@extra.nidk.nih.gov](mailto:rushingp@extra.nidk.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Urologic P20 Applications.

*Date:* August 2-3, 2018.

*Time:* 8:00 a.m. to 1:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

*Contact Person:* Ryan G. Morris, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7015, 6707 Democracy Boulevard, Bethesda, MD 20892-2542, 301-594-4721, [ryan.morris@nih.gov](mailto:ryan.morris@nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Diabetes Ancillary Studies (R01).

*Date:* August 2, 2018.

*Time:* 1:30 p.m. to 4:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Ann A. Jerkins, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7119, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, 301-594-2242, [jerkinsa@nidk.nih.gov](mailto:jerkinsa@nidk.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: July 2, 2018.

**David D. Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2018-14648 Filed 7-6-18; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[Docket No. USCG-2017-0915]

### Waterway Suitability Assessment for Operation of Liquefied Natural Gas Terminal; Cameron, LA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of inquiry; request for comments.

**SUMMARY:** We are requesting your comments on a Letter of Intent and Preliminary Waterway Suitability Assessment we received from Sabine Pass LNG, L.P. (SPLNG) regarding SPLNG's plans to construct a new berth at its Cameron Parish, LA facility and to increase the number of liquefied natural gas vessels calling at the facility from approximately 400 to 580 annually. The Coast Guard is notifying the public of this proposed increase in LNG marine traffic on the Sabine-Neches Waterway and is soliciting comments relevant to the Coast Guard's preparation of a Letter of Recommendation for issuance to the federal, state, or local agency with jurisdiction over the proposed facility.

**DATES:** Comments and related material must be received on or before August 8, 2018.

**ADDRESSES:** You may submit comments identified by docket number USCG-2017-0915 using the Federal eRulemaking Portal at <http://www.regulations.gov>. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for further instructions on submitting comments.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this notice of inquiry, call or email Mr. Scott K. Whalen, Vessel Traffic Service Director, Marine Safety Unit Port Arthur, U.S. Coast Guard; telephone 409-719-5086, email [Scott.K.Whalen@uscg.mil](mailto:Scott.K.Whalen@uscg.mil).

#### SUPPLEMENTARY INFORMATION:

#### I. Table of Abbreviations

CFR Code of Federal Regulations  
COTP Captain of the Port Marine Safety Unit Port Arthur  
DHS Department of Homeland Security  
LNG Liquefied Natural Gas  
LOI Letter of Intent  
LOR Letter of Recommendation  
NVIC Navigation and Vessel Inspection Circular  
U.S.C. United States Code  
WSA Waterway Suitability Assessment

## II. Background and Purpose

Under 33 CFR 127.007(a), an owner or operator planning to build a new facility handling liquefied natural gas (LNG), or an owner or operator planning new construction to expand or modify marine terminal operations in an existing facility handling LNG, where the construction, expansion, or modification would result in an increase in the size and/or frequency of LNG marine traffic on the waterway associated with the proposed facility or modification to an existing facility, must submit a Letter of Intent (LOI) to the Captain of the Port of the zone in which the facility is or will be located. Under 33 CFR 127.007(e), an owner or operator planning such new construction or expansion of an existing facility must also file or update a Waterway Suitability Assessment (WSA) that addresses the proposed increase in LNG marine traffic in the associated waterway.

Under 33 CFR 127.009, after receiving an LOI, the Captain of the Port issues a Letter of Recommendation (LOR) as to the suitability of the waterway for LNG marine traffic to the appropriate jurisdictional authorities. The LOR is based on a series of factors listed in 33 CFR 127.009 that relate to the physical nature of the affected waterway and issues of safety and security associated with LNG marine traffic on the affected waterway.

## III. Information Requested

On January 29, 2018, Sabine Pass LNG, L.P. (SPLNG), located in Cameron Parish, LA, submitted an LOI and Preliminary WSA regarding the company's proposed plans to develop a new marine berth and expand the number of vessels calling on the facility each year from approximately 400 to 580. The purpose of this notice is to solicit public comments on the proposed increase in LNG marine traffic on the Sabine-Neches Waterway. The Coast Guard believes that public input may be useful to the Captain of the Port Marine Safety Unit Port Arthur (COTP) with respect to validating the information provided in SPLNG's Preliminary WSA and development of the LOR. A brief summary of SPLNG's proposal is available in the docket where indicated under **ADDRESSES**.

On January 24, 2011, the Coast Guard published Navigation and Vessel Inspection Circular (NVIC) 01-2011, titled "Guidance Related to Waterfront Liquefied Natural Gas (LNG) Facilities". NVIC 01-2011 provides guidance for owners and operators seeking approval to build and operate LNG facilities. The

Coast Guard will refer to NVIC 01–2011 for process information and guidance in evaluating SPLNG’s WSA. NVIC 01–2011 is available in the docket where indicated under **ADDRESSES** and also on the Coast Guard’s website at <https://www.dco.uscg.mil/Portals/9/DCO%20Documents/5p/5ps/NVIC/2011/NVIC%2001-2011%20Final.pdf>.

#### IV. Public Participation and Request for Comments

We encourage you to submit comments through the Federal portal at <http://www.regulations.gov>. If your material cannot be submitted using <http://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. In your submission, please include the docket number for this notice of inquiry and provide a reason for each suggestion or recommendation.

We accept anonymous comments. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have provided. For more about privacy and the docket, visit <http://www.regulations.gov/privacyNotice>.

Documents mentioned in this notice of inquiry as being available in the docket, and all public comments, will be in our online docket at <http://www.regulations.gov> and can be viewed by following that website’s instructions.

This document is issued under authority of 5 U.S.C. 552 (a).

Dated: July 2, 2018.

**Jacqueline Twomey,**

*Captain, U.S. Coast Guard, Captain of the Port Marine Safety Unit Port Arthur.*

[FR Doc. 2018–14596 Filed 7–6–18; 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 Malarone 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 Malarone tablets. Based upon the facts presented, CBP has concluded that the country of origin of the

Malarone tablets is Canada for purposes of U.S. Government procurement.

**DATES:** This final determination was issued on July 2, 2018. A copy of the final determination is attached. Any party-at-interest may seek judicial review of this final determination within August 8, 2018.

**FOR FURTHER INFORMATION CONTACT:** Ross M. Cunningham, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade, (202) 325–0034.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that on July 2, 2018, pursuant to subpart B of Part 177, U.S. Customs and Border Protection Regulations (19 CFR part 177, subpart B), CBP issued one final determination concerning the country of origin of Malarone tablets, which may be offered to the U.S. Government under an undesignated government procurement contract. This final determination (HQ H290684) 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 processing in Canada will result in a substantial transformation. Therefore, the country of origin for purposes of U.S. Government procurement of the Malarone tablets is Canada.

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: July 2, 2018.

**Alice A. Kipel,**

*Executive Director, Regulations and Rulings, Office of Trade.*

HQ H290684

July 2, 2018

OT:RR:CTF:VS H290684 RMC

CATEGORY: Origin

Nicolas Guzman  
Drinker Biddle & Reath LLP  
1500 K Street NW  
Suite 1100

Washington, DC 20005–1209

Re: U.S. Government Procurement;

Country of Origin of Malarone  
Tablets; Substantial Transformation

Dear Mr. Guzman:

This is in response to your letter, dated September 13, 2017, requesting a

final determination on behalf of GlaxoSmithKline LLP (“GSK”) pursuant to subpart B of Part 177 of the U.S. Customs and Border Protection (“CBP”) Regulations (19 C.F.R. Part 177). A teleconference was held with counsel for GSK on June 8, 2018.

This final determination concerns the country of origin of Malarone tablets. As a U.S. importer, GSK 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:

GSK is a global healthcare company that researches, develops, and manufactures pharmaceutical medicines, vaccines, and consumer healthcare products. At issue in this case are tablets sold under the brand name Malarone, which are indicated for the prevention and treatment of acute, uncomplicated *Plasmodium falciparum* malaria. GSK states that Malarone tablets have been shown to be effective in regions where other malaria drugs such as chloroquine, halofantrine, mefloquine, and amodiaquine may have unacceptable failure rates, presumably due to drug resistance.

According to the FDA prescribing information, Malarone is a fixed-dose combination of atovaquone and proguanil hydrochloride. See Prescribing Information, [https://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4089b1\\_05\\_05\\_atovaquone.pdf](https://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4089b1_05_05_atovaquone.pdf) (last visited Dec. 11, 2017). The chemical name of atovaquone 11 is trans-2-[4-(4-chlorophenyl)cyclohexyl]-3-hydroxy-1,4-naphthalenedione and the molecular formula for atovaquone is C<sub>22</sub>H<sub>19</sub>ClO<sub>3</sub>. The chemical name of proguanil hydrochloride is 1-(4-chlorophenyl)-5-isopropyl-biguanide hydrochloride and the chemical formula for proguanil hydrochloride is C<sub>11</sub>H<sub>16</sub>ClN<sub>5</sub>•HCl. Each Malarone Tablet contains 250 milligrams of atovaquone and 100 milligrams of proguanil hydrochloride.

The FDA prescribing information also describes the microbiology or “mechanism of action” of atovaquone and proguanil hydrochloride. It states that atovaquone and proguanil hydrochloride “interfere with 2 different pathways involved in the biosynthesis of pyrimidines required for nucleic acid replication. Atovaquone is a selective inhibitor of parasite mitochondrial electron transport. Proguanil hydrochloride primarily exerts its effect by means of the metabolite cycloguanil, a dihydrofolate reductase inhibitor. Inhibition of dihydrofolate reductase in the malaria