

4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Suranjan De, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4307, Silver Spring, MD 20993, 240–402–0498, or [FAERSESUB@fda.hhs.gov](mailto:FAERSESUB@fda.hhs.gov); or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

On February 21, 2014, FDA issued a **Federal Register** notice (79 FR 9908) announcing the availability of a final guidance for industry entitled “E2B (R3) Electronic Transmission of Individual Case Safety Reports (ICSRs) Implementation Guide—Data Elements and Message Specification” (ICH E2B(R3) guidance) and an appendix to the guidance entitled “ICSRs: Appendix to the Implementation Guide—Backwards and Forward Compatibility” (BFC appendix). The ICH E2B(R3) guidance and BFC appendix were issued as a package that included schema files and additional technical information to be used for creating compatible ICSR files. The preface to the ICH E2B(R3) implementation guidance makes clear that any future “technical specifications document associated with that guidance would be provided as a stand-alone document” but incorporated by reference into that guidance. Accordingly, in this notice, we are announcing the availability of a technical specifications document that will be incorporated into that final guidance.

This technical specifications document, which is available on the FDA Guidance Web page at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm274966.htm>, is to assist interested parties in electronically submitting individual case safety reports (ICSRs) (and any ICSR attachments) to CDER and CBER. This

document describes FDA’s technical approach for submitting ICSRs, for incorporating its regionally controlled terminology, and for adding its regional data elements that are not addressed in the ICH E2B (R3) guidance for the following FDA-regulated products: Drug products marketed for human use with approved new drug applications and abbreviated new drug applications; prescription drug products marketed for human use without an approved application; nonprescription (over-the-counter) human drug products marketed without an approved application; and biological products marketed for human use with approved biologic license applications.

**II. Electronic Access**

Persons with access to the Internet may obtain a copy of the FDA Regional Implementation Specifications for ICH E2B(R3) at <http://www.fda.gov/drugs/guidancecompliance/regulatoryinformation/surveillance/adversedrugeffects/ucm115894.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.regulations.gov>.

Dated: June 17, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

[Docket No. USCG–2016–0374]

**Waterway Suitability Assessment for Construction and Operation of Liquefied Gas Terminals; Sabine-Neches Waterway, Vidor, TX**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice and request for comments.

**SUMMARY:** Jefferson Railport Terminal 1 (Texas) LLC, has submitted a Letter of Intent and Preliminary Waterway Suitability Assessment to the Coast Guard Captain of the Port (COTP), Port Arthur, TX regarding the company’s plans to construct, own and operate a waterfront facility handling and storing Liquefied Hazardous Gas (LHG) at its Vidor, TX facility located on the Sabine-Neches Waterway. The Coast Guard is notifying the public of this action to solicit public comments on the proposed increase in LHG marine traffic on the Sabine-Neches Waterway.

**DATES:** Comments must be submitted to the online docket via <http://www.regulations.gov>, or reach the Docket Management Facility, on or before July 25, 2016.

**ADDRESSES:** You may submit comments identified by docket number USCG–2016–0374 using the Federal eRulemaking Portal at <http://www.regulations.gov>. See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

**FOR FURTHER INFORMATION CONTACT:** For further information about this notice, call or email Chief Petty Officer Jamie L. Merriman, U.S. Coast Guard; telephone 409–719–5033, email [jamie.l.merriman@uscg.mil](mailto:jamie.l.merriman@uscg.mil).

**SUPPLEMENTARY INFORMATION:**

**Public Participation and Comments**

We encourage you to submit comments or related material in response to this notice. We will consider all submissions and may adjust our final action based on your comments. If you submit a comment, please include the docket number for this notice, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking 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. Documents mentioned in this notice, and all public comments, are in our online docket at <http://www.regulations.gov> and can be viewed by following that Web site’s instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

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, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

**Discussion, Basis, and Purpose**

Under 33 CFR 127.007(a), an owner or operator planning to build a new facility

handling Liquefied Natural Gas (LNG) or Liquefied Hazardous Gas (LHG), where the construction, expansion, or modification would result in an increase in the size and/or frequency of LNG or LHG marine traffic on the waterway associated with the facility, must submit a Letter of Intent (LOI) to the COTP of the zone in which the facility is located. Under 33 CFR 127.007(e), an owner or operator planning such an expansion must also file or update a Waterway Suitability Assessment (WSA) that addresses the proposed increase in LNG or LHG marine traffic in the associated waterway. Jefferson Railport Terminal 1 (Texas) LLC, located in Vidor, TX submitted an LOI and WSA on March 7, 2016, regarding the company's proposed construction and operation of LHG capabilities at its Vidor, TX facility.

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

The purpose of this notice is to solicit public comments on the proposed increase in LHG marine traffic on the Sabine-Neches Waterway. The Coast Guard believes that input from the public may be useful to the COTP with respect to development of the LOR. Additionally, the Coast Guard intends to task the Area Maritime Security Committee, Port Arthur, TX and the Southeast Texas Waterways Advisory Council with forming a subcommittee comprised of affected port users and stakeholders. The goal of this subcommittee will be to gather information to help the COTP assess the suitability of the associated waterway for increased LHG marine traffic as it relates to navigational safety and security.

On January 24, 2011, the Coast Guard published Navigation and Vessel Inspection Circular (NVIC) 01-2011, "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. While NVIC 01-2011 is specific to LNG, it provides useful process information and guidance for owners and operators seeking approval to build and operate LHG facilities as well. The Coast Guard will refer to NVIC 01-2011 for process information and guidance in evaluating Jefferson Railport Terminal 1's WSA. A

copy of NVIC 01-2011 is available for viewing in the public docket for this notice and also on the Coast Guard's Web site at <http://www.uscg.mil/hq/cg5/nvic/2010s.asp>.

This notice is issued under authority of 33 U.S.C. 1223-1225, Department of Homeland Security Delegation Number 0170.1(70), 33 CFR 127.009, and 33 CFR 103.205.

Dated: May 27, 2016.

**R.S. Ogyrdziak,**

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

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## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection [1651-0111]

#### Agency Information Collection Activities: Arrival and Departure Record (Forms I-94 and I-94W) and Electronic System for Travel Authorization

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security.

**ACTION:** 60-Day Notice and request for comments; revision of an existing collection of information.

**SUMMARY:** U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: CBP Form I-94 (Arrival/Departure Record), CBP Form I-94W (Nonimmigrant Visa Waiver Arrival/Departure), and the Electronic System for Travel Authorization (ESTA). This is a proposed extension and revision of an information collection that was previously approved. CBP is proposing that this information collection be extended with a revision to the information collected. This document is published to obtain comments from the public and affected agencies.

**DATES:** Written comments should be received on or before August 22, 2016 to be assured of consideration.

**ADDRESSES:** Written comments may be mailed to U.S. Customs and Border Protection, Attn: Paperwork Reduction Act Officer, Regulations and Rulings, Office of Trade, 90 K Street NE., 10th Floor, Washington, DC 20229-1177.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information

should be directed to Paperwork Reduction Act Officer, U.S. Customs and Border Protection, Regulations and Rulings, Office of Trade, 90 K Street NE., 10th Floor, Washington, DC 20229-1177, or by telephone at 202-325-0123.

**SUPPLEMENTARY INFORMATION:** CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual cost burden to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for OMB approval. All comments will become a matter of public record. In this document, CBP is soliciting comments concerning the following information collection:

*Title:* Arrival and Departure Record, Nonimmigrant Visa Waiver Arrival/Departure, and Electronic System for Travel Authorization (ESTA).

*OMB Number:* 1651-0111.

*Form Numbers:* I-94 and I-94W.

#### Abstract

##### Background

CBP Forms I-94 (Arrival/Departure Record) and I-94W (Nonimmigrant Visa Waiver Arrival/Departure Record) are used to document a traveler's admission into the United States. These forms are filled out by aliens and are used to collect information on citizenship, residency, passport, and contact information. The data elements collected on these forms enable the Department of Homeland Security (DHS) to perform its mission related to the screening of alien visitors for potential risks to national security and the determination of admissibility to the United States. The Electronic System for Travel Authorization (ESTA) applies to aliens seeking to travel to the United States under the Visa Waiver Program (VWP) and requires that VWP travelers provide information electronically to CBP before embarking on travel to the