

P-2044), under 21 CFR 10.30, requesting that the Agency determine whether REVEX (nalmefene hydrochloride injection), 0.1 mg base/mL and 1.0 mg base/mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition (and comments submitted to the docket) and reviewing Agency records, and based on the information we have at this time, FDA has determined under § 314.161 that REVEX (nalmefene hydrochloride injection), 0.1 mg base/mL and 1.0 mg base/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that REVEX (nalmefene hydrochloride injection), 0.1 mg base/mL and 1.0 mg base/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of REVEX (nalmefene hydrochloride injection), 0.1 mg base/mL and 1.0 mg base/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list REVEX (nalmefene hydrochloride injection), 0.1 mg base/mL and 1.0 mg base/mL, in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to this drug product may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: October 19, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[Docket No. USCG-2017-0109; Control Number: 1625-0030]

### Collection of Information Under Review by Office of Management and Budget; OMB

**AGENCY:** Coast Guard, DHS.

**ACTION:** Thirty-day notice requesting comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval for reinstatement, without change, of the following collection of information: 1625-0030, Oil and Hazardous Materials Transfer Procedures. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

**DATES:** Comments must reach the Coast Guard and OIRA on or before December 4, 2017.

**ADDRESSES:** You may submit comments identified by Coast Guard docket number [USCG-2017-0109] to the Coast Guard using the Federal eRulemaking Portal at <http://www.regulations.gov>. Alternatively, you may submit comments to OIRA using one of the following means:

(1) *Email:* [dhsdeskofficer@omb.eop.gov](mailto:dhsdeskofficer@omb.eop.gov)

(2) *Mail:* OIRA, 725 17th Street NW., Washington, DC 20503, attention Desk Officer for the Coast Guard.

A copy of the ICR is available through the docket on the Internet at <http://www.regulations.gov>. Additionally, copies are available from: Commandant (CG-612), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE., Stop 7710, Washington, DC 20593-7710.

**FOR FURTHER INFORMATION CONTACT:** Mr. Anthony Smith, Office of Information Management, telephone 202-475-3532, or fax 202-372-8405, for questions on these documents.

### SUPPLEMENTARY INFORMATION:

#### Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995;

44 U.S.C. 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection. The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request [USCG-2017-0109], and must be received by December 4, 2017.

### Submitting Comments

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.

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).

OIRA posts its decisions on ICRs online at <http://www.reginfo.gov/public/do/PRAMain> after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625–0030.

### Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day Notice (82 FR 35980, August 2, 2017) required by 44 U.S.C. 3506(c)(2).

We received three comments from two commenters to the 60-day Notice. The first comment was about the language used in our Notice. The commenter stated that the 33 CFR 155.720 transfer procedure requirements apply to a vessel with a capacity of 250 barrels or more of oil or hazardous materials, rather than our Notice language of a vessel with a cargo capacity of 250 barrels or more of oil or hazardous materials (emphasis added). We agree and have revised the language in our 30-day Notice to correct the error. While the language we used in the 60-day Notice was inaccurate, our burden calculation did include vessels with a capacity of 250 barrels or more of oil or hazardous materials.

The second and third comments were about the lightering requirements in 33 CFR 156.210(b). While these comments relate to ICR 1625–0042 “Requirements for Lightering of Oil and Hazardous Material Cargoes” and not the subject of this ICR Notice, we have responded to the comments below. The second comment stated that the Coast Guard should update the Headquarters point of contact (POC) in the regulations for submitting hazardous material lightering operation requests. We agree that the POC is unclear; submissions should be made to Commandant (CG–ENG) vice Commandant (CG–5). We will revise this item in an upcoming technical amendment rulemaking. The third comment requested that the Coast Guard update the regulation that they consider outdated. We will consider updating this requirement in a future rulemaking. The comments result in no changes to the Collection.

### Information Collection Request

*Title:* Oil and Hazardous Materials Transfer Procedures.

*OMB Control Number:* 1625–0030.

*Summary:* Vessels with a capacity of 250 barrels or more of oil or hazardous materials must develop and maintain transfer procedures. Transfer procedures provide basic safety information for operating transfer systems with the goal of pollution prevention.

*Need:* Title 33 U.S.C. 1231 authorizes the Coast Guard to prescribe regulations related to the prevention of pollution. Title 33 CFR 155 prescribes pollution prevention regulations including those related to transfer procedures.

*Forms:* None.

*Respondents:* Operators of certain vessels.

*Frequency:* On occasion.

*Hour Burden Estimate:* The estimated burden has decreased from 160 hours to 149 hours a year due to a decrease in the estimated annual number of responses.

*Authority:* The Paperwork Reduction Act of 1995; 44 U.S.C. 35, as amended.

Dated: October 31, 2017.

**James D. Roppel,**

*U.S. Coast Guard, Acting Chief, Office of Information Management.*

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**BILLING CODE 9110–04–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[Docket No. USCG–2017–0955]

### Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0031

**AGENCY:** Coast Guard, DHS.

**ACTION:** Sixty-day notice requesting comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0031, Plan Approval and Records for Electrical Engineering Regulations—Title 46 CFR Subchapter J. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

**DATES:** Comments must reach the Coast Guard on or before January 2, 2018.

**ADDRESSES:** You may submit comments identified by Coast Guard docket number [USCG–2017–0955] to the Coast Guard 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.

A copy of the ICR is available through the docket on the Internet at <http://www.regulations.gov>.

[www.regulations.gov](http://www.regulations.gov). Additionally, copies are available from: Commandant (CG–612), ATTN: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE., Stop 7710, Washington, DC 20593–7710.

### FOR FURTHER INFORMATION CONTACT:

Contact Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

### SUPPLEMENTARY INFORMATION:

### Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection’s purpose, the Collection’s likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) the practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request [USCG–2017–0955], and must be received by January 2, 2018.

### Submitting Comments

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