

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CDER at at 1-800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Sarah Venti, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3130, [drugtrackandtrace@fda.hhs.gov](mailto:drugtrackandtrace@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a revised draft guidance for industry entitled “Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs.” The DSCSA (Title II of Pub. L. 113-54) was signed into law on November 27, 2013. Section 202 of the DSCSA added section 582 to the FD&C Act (21 U.S.C. 360eee-1), which established the requirement that trading partners have systems in place to enable them to comply with certain verification obligations. This revised draft guidance provides recommendations for robust verification systems for the determination, quarantine, and investigation of suspect products, as well as the quarantine, notification, and disposition of illegitimate products. This revised draft guidance also addresses: The manner in which FDA recommends that trading partners submit cleared product notifications (*i.e.*, notifications that a suspect product is not an illegitimate product); the statutory requirements for responding to requests for verification; and the statutory requirements for processing saleable returns.

In the **Federal Register** of October 25, 2018 (83 FR 53880), FDA announced the availability of a draft guidance entitled “Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs” dated October 24, 2018. FDA received several comments on the draft guidance, which have been taken into consideration. In response to comments received from stakeholders, this draft guidance revises the October 2018 draft guidance to: (1) Provide FDA’s interpretation of what

“possession or control” means as used throughout the DSCSA; (2) explain that the guidance uses the term *verification* in referring to both the broad set of requirements set forth in paragraphs (b)(4), (c)(4), (d)(4), and (e)(4) of section 582 of the FD&C Act in addition to using the term with the meaning defined in section 581(28) of the FD&C Act, where appropriate to the context; (3) recognize that, in cases where the DSCSA directs trading partners to coordinate with one another during investigations and dispositions of products, certain types of trading partners are typically better suited to handle specific aspects of those statutory requirements; (4) clarify that FDA will make requests for verification if a trading partner is in possession or control of a product that the Agency has determined to be suspect product; (5) clarify FDA’s understanding of what “electronic quarantine” means; (6) clarify when samples of illegitimate product should be retained; (7) clarify FDA’s expectations related to the requirements for responding to requests for verification from authorized trading partners; (8) inform trading partners of the information that should be communicated among trading partners when determining whether a suspect product is illegitimate; and (9) inform trading partners of the information that should be included when responding to requests for verification from FDA and other trading partners (where applicable), and verifying saleable returned product. In addition, editorial changes were made to improve clarity.

This revised draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

##### **II. Paperwork Reduction Act of 1995**

This draft guidance includes information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3520) (PRA). FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent substantive or material modifications to those previously

approved collections of information found in FDA regulations or guidance.

##### **III. Electronic Access**

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs> or <https://www.regulations.gov>.

Dated: March 1, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022-05018 Filed 3-9-22; 8:45 am]

**BILLING CODE 4164-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **National Center for Advancing Translational Science; Notice of Charter Renewal**

In accordance with Title 42 of the U.S. Code of Federal Regulations, Section 217a, notice is hereby given that the Charter for the National Center for Advancing Translational Sciences Advisory Council was renewed for an additional two-year period on February 7, 2022.

It is determined that the National Center for Advancing Translational Sciences Advisory Council is in the public interest in connection with the performance of duties imposed on the National Institutes of Health by law, and that these duties can best be performed through the advice and counsel of this group.

Inquiries may be directed to Claire Harris, Director, Office of Federal Advisory Committee Policy, Office of the Director, National Institutes of Health, 6701 Democracy Boulevard, Suite 1000, Bethesda, Maryland 20892 (Mail Stop Code 4875), Telephone (301) 496-2123, or [harriscl@mail.nih.gov](mailto:harriscl@mail.nih.gov).

Dated: March 4, 2022.

**David W. Freeman,**

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

[FR Doc. 2022-05029 Filed 3-9-22; 8:45 am]

**BILLING CODE 4140-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as

amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute on Alcohol Abuse and Alcoholism Initial Review Group; Neuroscience and Behavior Study Section.

*Date:* June 7, 2022.

*Time:* 10:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Beata Buzas, Ph.D., Scientific Review Officer, Extramural Project Review Branch, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Room 2116, MSC 6902, Bethesda, MD 20892, 301-443-0800, [bbuzas@mail.nih.gov](mailto:bbuzas@mail.nih.gov). (Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS)

Dated: March 7, 2022.

**Melanie J. Pantoja,**

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

[FR Doc. 2022-05075 Filed 3-9-22; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[Docket No. USCG-2022-0151]

### Information Collection Request to Office of Management and Budget; OMB Control Number: 1625-0096

**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: 1625-0096, Report of Oil or Hazardous Substance Discharge; and Report of Suspicious Maritime Activity; without change. 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 May 9, 2022.

**ADDRESSES:** You may submit comments identified by Coast Guard docket number [USCG-2022-0151] to the Coast Guard using the Federal eRulemaking Portal at <https://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 <https://www.regulations.gov>. Additionally, copies are available from: COMMANDANT (CG-6P), 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:** A.L. Craig, Office of Privacy Management, telephone 202-475-3528, 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. 3501 *et seq.*, 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-2022-0151], and must be received by May 9, 2022.

### Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at <https://www.regulations.gov>. If your material cannot be submitted using <https://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 <https://www.regulations.gov> and can be viewed by following that website'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 <https://www.regulations.gov> and will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

### Information Collection Request

*Title:* Report of Oil or Hazardous Substance Discharge; and Report of Suspicious Maritime Activity.

*OMB Control Number:* 1625-0096.

*Summary:* Any discharge of oil or a hazardous substance must be reported to the National Response Center (NRC) so that the pre-designated on-scene coordinator can be informed and appropriate spill mitigation action carried out. The NRC also receives suspicious activity reports from the public and disseminates this information to appropriate entities.

*Need:* 33 CFR 153.203, 40 CFR 263.30 and 264.56, and 49 CFR 171.15 mandate that the NRC be the central place for the public to report all pollution spills. 33