Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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*.

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FDA is announcing the availability of a revised draft guidance for industry entitled ''Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs.''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 This revised draft guidance provides recommendations for robust verification systems for the determination, quarantine, and investigation of suspect products, as well as the quarantine,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 This revised draft guidance also addresses: The manner in which FDA recommends that trading partners submit cleared product notifications (*i.e.,* notifications that a suspect product is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In the **Federal Register** of October 25, 2018 (83 FR 53880), FDA announced the availability of a draft guidance entitled ''Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs'' dated October 24, 2018. FDA received several comments on the draft guidance, which have been taken into consideration. In response to comments received from stakeholders, this draft guidance revises the October 2018 draft guidance to: (1) Provide FDA's interpretation of what ''possession or control'' means as used throughout the DSCSA; (2) explain that the guidance uses the term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.*

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