compounds with both similar structure and similar mechanism of action, and in silico) may be more appropriate to estimate a starting dose in the FIH trial. In addition, QSP modeling may derive potential efficacy- and safety-related information and balance them in a quantitative manner to inform FIH dose selection. This guidance specifically addresses those needs by outlining how QSP models can be developed and used to estimate a MABEL for drugs and biological products entering FIH trials.

This 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 The draft guidance, when finalized, will represent the current thinking of FDA on ''Quantitative Systems Pharmacology (QSP)-Based Dose Selection for Minimum Anticipated Biological Effect Level (MABEL) in First-in-Human (FIH) Trials.'' 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.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. Paperwork Reduction Act of 1995

While this guidance document contains no new collections of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312, including the submission of rationale and dose determination, as set forth in part 312.23; the submission of detailed technical information, as set forth in part 312.31; and the submission of meeting requests and supporting documentation, as set forth in part 312.47, have been approved under OMB control number 0910–0014.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–12619 Filed 6–22–26; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Council of Councils.

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: Council of Councils.

Date: July 13, 2026.

Time: 03:00 p.m. to 04:00 p.m.

Agenda: To review and evaluate grant applications.

Address: Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, National Institutes of Health, Building 1, Room 260, 1 Center Drive, Bethesda, MD 20892.

Meeting Format: Virtual.

Contact Person: Robin I. Kawazoe, Deputy Director, Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, National Institutes of Health, Building 1, Room 260, 1 Center Drive, Bethesda, MD 20892, 301–402–9852, *kawazoer@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Council of Council's home page: *http://dpcpsi.nih.gov/council/* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: June 18, 2026.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–12617 Filed 6–23–26; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2026 Notice of Supplemental Funding Opportunity

AGENCY: Substance Abuse and Mental Health Services Administration, Department of Health and Human Services (HHS).

ACTION: Notice of intent to award supplemental funding.

SUMMARY: This notice is to inform the public that the Substance Abuse and Mental Health Services Administration (SAMHSA) is supporting an administrative supplement in scope of the parent award for one eligible grant recipient funded in FY 2024 under the Prevention Technology Transfer Centers Cooperative Agreements, Notice of Funding Opportunity (NOFO) SP–24–002. The recipient may receive up to $1,198,000. The recipient has a project end date of September 29, 2029. The supplemental funding supports the implementation of a substance use prevention fellowship program. The program will be developed in collaboration with national-level state and community organizations and aims to develop and sustain a highly trained and knowledgeable workforce of prevention professionals drawn from communities that have faced challenges in maintaining sufficient prevention staffing to meet the full scope of community needs. Fellows will be equipped to understand, apply, and exemplify the core principles and evidence-based best practices of substance use prevention. This program will support a state level fellowship program and a community level program. This program will also prepare fellows to achieve certification from the International Certification and Reciprocity Consortium (IC&RC). The supplemental funding will support fellows in the following areas: hands-on experience working in state agencies and community organizations while

supported by agency mentors; virtual and in-person training in professional development and prevention; acquiring proficiency in appropriate core competencies in preparation for the Certified Prevention Specialist exam; developing management and leadership skills; and preparing for potential employment opportunities within the prevention field.

FOR FURTHER INFORMATION CONTACT: Dr. Thia Walker, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, MD 20857, telephone 240–276–1835; email: *thia.walker@samhsa.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Funding Opportunity Title: FY 2024 Prevention Technology Transfer Centers Cooperative Agreements SP–24–002.

Assistance Listing Number: 93.492.

Authority: Section 516(a)(2) of the Public Health Service Act, as amended.

Justification: The PTTC Network provides training and technical assistance services to the substance use prevention field including professionals/pre-professionals, organizations, and others in the prevention community that serve and support children, young adults, families, parents, and other adults. They are the lead training and technical assistance authority for substance use prevention services nationally. The NCC is charged with the development and implementation of a coordinated and integrated Network approach for the identification of national, state, and local technical assistance needs and delivery of training and technical assistance by the ten PTTC Regional Centers to strengthen the impact of the overall program and prevent duplication of efforts. The NCC serves as the focal point for the PTTC network and provides leadership, infrastructure, and support for the ten PTTC Regional Centers in identifying and facilitating cross-network and regional-wide activities. In this capacity, they are well-situated to coordinate with substance use prevention associations to implement and execute a national-level fellowship program that will span all 10 regions.

This will be a single source supplement to the PTTC National Coordinator Center (NCC) to implement a state and community level fellowship program in populations with prevention workforce shortages. The NCC oversees national-level program implementation unlike the other grant recipients allowing them the ability to implement this type of program.

This is not a formal request for application. Assistance will only be provided to the one National Coordinating Center grant recipient funded in FY 2024 under the Prevention Technology Transfer Centers Cooperative Agreements SP–24–002 based on the receipt of a satisfactory application and associated budget that is approved by a review group.

Ann Ferrero,

Public Health Analyst.

[FR Doc. 2026–12646 Filed 6–23–26; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Test of the New Electronic Informal Entry Process for Mail

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

ACTION: General notice.

SUMMARY: This document announces that U.S. Customs and Border Protection (CBP) is conducting a test of a new electronic informal entry type for merchandise entering the United States through the international mail process. This notice provides a description of the new informal entry type 13—Informal Mail Entry, the eligible participants, and the requirements for filing the new informal entry type.

DATES: The test will commence on September 22, 2026 and will continue until concluded by an announcement published in the **Federal Register**. Comments will be accepted throughout the duration of the test.

ADDRESSES: Written comments concerning this notice and any aspect of the test may be submitted at any time during the test period via email to *cbpdm@cbp.dhs.gov*. In the subject line of the email, please write ''Comments on the Entry Type 13 Test.''

FOR FURTHER INFORMATION CONTACT: Christopher Mabelitini, Director, Intellectual Property Rights & E-Commerce Division, Office of Trade, U.S. Customs and Border Protection, 202–325–6915, *ecommerce@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

U.S. Customs and Border Protection (CBP) has indefinitely suspended the duty-free *de minimis* administrative exemption for mail under 19 U.S.C. 1321(a)(2)(C) for articles valued at $800 or less and imported by one person on one day, as implemented by the Indefinite Suspension of the De Minimis Exemption for Mail Shipments and New Postal Informal Entry Process interim final rule (IFR), and consistent with 19 U.S.C. 1321 and Executive Order (E.O.) 14324 of July 30, 2025 (Suspending Duty-Free De Minimis Treatment For All Countries) [1] and E.O. 14388 of February 20, 2026 (Continuing the Suspension of Duty-Free De Minimis Treatment for All Countries).[2] Please see the Indefinite Suspension of the De Minimis Exemption for Mail Shipments and New Postal Informal Entry Process IFR for more details on CBP's decision to suspend the duty-free *de minimis* administrative exemption for international mail shipments.

Because international mail shipments are no longer eligible for this *de minimis* administrative exemption, filers are unable to use the special informal entry procedures for shipments claiming the *de minimis* administrative exemption, and must instead use an appropriate existing entry type.[3] This includes formal entry, which is generally applicable to shipments of merchandise valued in excess of $2,500, or shipments valued at $2,500 or less that are not qualified for informal entry procedures because they are subject to additional requirements and/or duties. The formal entry procedures, as established by 19 U.S.C. 1484 and 1485, are set forth in part 142 of title 19 of the Code of Federal Regulations (CFR) (19 CFR part 142), with additional formal entry provisions for international mail contained in 19 CFR 145.12(a). For qualifying international mail shipments valued at $2,500 or less, CBP has established a new interim process for informal mail entries (*see* 19 CFR 145.12(b)) to replace the provisional process for international mail shipments formerly eligible for the *de minimis* administrative exemption, as established pursuant to E.O. 14324, as amended by E.O. 14388. However, international mail shipments valued at $2,500 or less subject to Partner Government Agency (PGA) data requirements, antidumping and countervailing duties (AD/CVD), quotas, or duties other than those set forth in Chapters 1–97 of the Harmonized Tariff Schedule of the United States (HTSUS), including duties under Chapters 98 or 99 of the HTSUS, are not eligible for entry under the new interim process for informal mail entries, as set forth in 19

[1] 90 FR 37775 (Aug. 5, 2025).

[2] 91 FR 9433 (Feb. 25, 2026).

[3] The suspension of the duty-free *de minimis* administrative exemption under 19 U.S.C. 1321(a)(2)(C) does not impact the availability of the *de minimis* exemption for qualifying bona fide gifts under 19 U.S.C. 1321(a)(2)(A) and 19 CFR 10.152.