You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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; or the Office of Surveillance and Compliance, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Tara Gooen Bizjak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4330, Silver Spring, MD, 20993–0002, 301–796–3257; Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911; John W. Diehl, Office of Inspections and Investigations, Food and Drug Administration, 1201 Main St., Ste. 7200, Dallas, TX 75202–3939, 214–253–5288, *OIIPolicyStaffs@fda.hhs.gov;* or Center for Veterinary Medicine, *AskCVM@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Responding to FDA Form 483 Observations at the Conclusion of a Drug CGMP Inspection.'' The guidance provides recommendations that manufacturing establishments should follow to prepare concise, factual, and effective corrective action responses to observations that FDA documents on an FDA 483 during an inspection. FDA has previously received inadequate responses to FDA 483 observations due to a lack or omission of relevant data, excessive amounts of data, and/or failure to address the root cause of observations in the FDA 483. Poor quality or incomplete responses make it difficult for FDA to ascertain what the establishment has corrected since the inspection and to evaluate remediation activities. This difficulty has ramifications for FDA's ability to help firms achieve voluntary compliance, take appropriate enforcement action, and most importantly, minimize exposing patients and the public to risks.

Adherence to FDA's CGMP requirements as set forth in 21 CFR parts 210, 211, and 212 for drug products is essential. FDA recommends a systematic approach to a risk-based analysis of a firm's operation to resolve the deviations from CGMP requirements observed during FDA inspections. The procedures recommended in this draft guidance are intended to help firms understand the significance of the observations, identify root causes, determine risk to patients, and swiftly implement effective corrective actions. Section V of the draft guidance includes recommendations for resolving scientific or technical disagreements related to FDA 483 observations.

This 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 ''Responding to FDA Form 483 Observations at the Conclusion of a Drug CGMP Inspection.'' 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 contains no collection 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 parts 210 and 211 (CGMPs) and 21 CFR part 212 (positron emission tomography CGMPs) have been approved under OMB control numbers 0910–0139 and 0910–0667, respectively. In addition, information collected by the Agency on a Form 483 is exempt from the PRA under 5 CFR 1320.3(h)(3) and 1320.4(a)(2); responses to a Form 483 from the subject of an ongoing inspection/investigation are exempt from the PRA under 44 U.S.C. 3518(c)(1)(B)(ii) and 5 CFR. 1320.4(a)(2).

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/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm,* or *https://www.regulations.gov.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–04578 Filed 3–6–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; HRSA Ryan White HIV/AIDS Program Part F National AIDS Education and Training Center Program Activities, OMB No. 0906–XXXX—New

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than April 8, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: HRSA Ryan White HIV/AIDS Program Part F National AIDS Education and

Training Center Program Activities, OMB No. 0906–XXXX New

Abstract: The Ryan White HIV/AIDS Program's (RWHAP) Part F AIDS Education and Training Center (AETC) Program, authorized under Title XXVI of the Public Health Service Act, supports a network of national and regional centers that conduct focused, multi-disciplinary education and training programs for health care providers. The RWHAP AETC Program provides health care providers with: (1) tailored education and training on HIV prevention, care, and treatment; (2) clinical consultation; and (3) technical assistance.

The national AETC Program currently has five distinct activities: (1) National AIDS Education and Training Center Support Center (NASC), (2) National Clinician Consultation Center (NCCC), (3) National HIV Curriculum (NHC) e-Learning Platform, (4) Integrating the National HIV Curriculum e-Learning Platform into Health Care Professions (NHC–IP) Programs, and (5) HIV Clinical Training Tracks for Primary Care Residents (HTR).

NASC supports workforce training and resource coordination for the AETC Program to enhance HIV care delivery. NCCC provides expert guidance to clinicians on HIV testing, prevention (*e.g.,* pre- and post-exposure prophylaxis), HIV treatment, hepatitis coinfections, perinatal HIV care, and substance use management through a national toll-free call center staffed by HIV experts. NHC offers comprehensive e-learning modules and tools for HIV prevention, diagnosis, and care, while providing free continuing education credits and resources for healthcare providers. NHC–IP focuses on incorporating HIV training into graduate-level medical, nursing, and pharmacy curricula to prepare future healthcare professionals. The HTR initiative develops HIV-focused tracks within primary care residency programs.

The RWHAP National AETC Program recipients have extensive reach to the HIV workforce. For example, from 2023–2024, the NASC website had over 165,694 viewers; NASC also had 457 registrants for the RWHAP Clinical Conference; NCCC supported 9,407 health care provider consultation requests; NHC engaged 15,773 individuals through online curriculum and learning modules; and NHC–IP supported 4,932 students and 122 faculty. Data is not yet available for the HTR program. The RWHAP National AETC Program recipients are now required to report data on training activities and trainees to HRSA once a year; they were not required to report data to HRSA's HIV/AIDS Bureau previously.

HRSA is requesting the approval of new AETC data collection forms to obtain more accurate data relating to National AETC activities, participants, and site information for all National recipients (NASC, NCCC, NHC, NHC–IP, and HTR). In addition, these forms will capture National AETC involvement in the HIV care and treatment workforce (1-year post-participation in an HTR), knowledge gained through participating in an AETC activity, and satisfaction with that activity. Given the distinct functions of each Center, it is essential to develop tailored forms specific to each Center's respective activities and its participants. Each center will be required to submit no more than five forms (see table 1 below). Different forms are necessary to accommodate the distinct activities and focus areas of each center. To ensure accurate and comprehensive data collection, these forms must be customized to meet the specific needs of each national center. A brief description of each form follows.

- The National Individual Participant Record (National IND–PAR) is completed at least once every reporting period by participants actively engaging in NASC, NHC, and HTR AETC activities. This form includes NASC, NHC, and HTR AETC participant demographic, workplace, and client-served data for the respective recipient. The IND–PAR is broken up into sections (All and HTR) so that recipients can tailor the form to include the relevant questions (*e.g.,* HTR would include questions from the All section as well as the HTR section).
- The NCCC IND–PAR is completed at least once every reporting period by NCCC callers. This form is shorter because it is only administered orally to those who call into NCCC.
- The Training Activity Record (National TAR) is completed at the end of each National AETC activity that takes place during the reporting period and is completed only by NASC, NHC, and NCCC national recipients. This form describes the activity in hours, modality, and topic(s).
- There are multiple Participant Post-Activity Surveys (PPA) to be answered by recipients and activity-specific participants. Specifically, the NASC–RWHAP–PPA is for participants of the RWHAP Clinical Conference to complete post-attendance; the HTR–SF–PPA is for students and faculty of HTR programs to complete post-participation in the HTR program; the NCCC–PPA will be administered via email and is for NCCC callers post call; the NHC–PPA is for registered learners of NHC after completing a self-study lesson or question bank topic from NHC; and the NHC–SF–PPA is for students and faculty of NHC–IPs to complete at the end of any course in which the NHC has been integrated. These forms collect information from participants immediately upon completion of an activity hosted by a national AETC.
- The NHC–IP Health Profession Program Characteristics/Outcomes Form (NHC–IP–HC) collects descriptive NHC Health Profession Program-level data for programs that integrate NHC into their curricula.
- The HTR Program Characteristics/Outcomes Form (HTR–PC) collects descriptive HTR-level data for all HTR programs, such as number of residents trained by profession/discipline during the reporting period.
- The HTR Long-Term form collects 1-year post-participation information only from HTR resident participants who engaged in an HTR program that trains primary care providers who are likely to practice in communities most impacted and at-risk for HIV.
- There are some forms that will be used to collect web-analytic information related to the NASC website (*i.e.,* NASC Web Analytics Form, or NASC-Web), NHC website (*i.e.,* NHC Training Utilization and Web Analytics Form, or NASC–TWeb), and related to consultation call topics discussed (*i.e.,* NCCC Tele-Consultation Utilization Form).

TABLE 1—NATIONAL AETCS SUMMARY OF FORMS BY RECIPIENT

Form/tool name	NASC	NCCC	NHC	NHC–IP	HTR
National IND–PAR	X		X		X
NCCC IND–PAR		X			
National TAR	X	X	X		
NASC Web Analytics (NASC-Web)	X				
NCCC Tele-consultation Utilization Form		X			

TABLE 1—NATIONAL AETCS SUMMARY OF FORMS BY RECIPIENT—Continued

Form/tool name	NASC	NCCC	NHC	NHC–IP	HTR
NHC Training Utilization and Web Analytics (NHC–TWeb)			X		
NHC–IP–HC				X	
HTR–PC					X
HTR Long-Term					X
NASC-Web-PPA	X				
NASC–RWHAP–PPA	X				
NCCC PPA		X			
NHC PPA			X		
NHC–SF–PPA				X	
HTR–SF–PPA					X
Total forms per National AETC Recipient	5	4	4	2	4

All forms for the national AETC package will be used by national center recipient; some forms may be used by multiple recipients.

A 60-day notice was published in the **Federal Register** on May 19, 2025, vol. 90, No. 95; pp. 21319–22. There were five public comments. The public comments provided feedback on the tools, including requests to clarify reporting periods and to revise questions; response options; and categories within specific data collection tools. Comments also recommended moving certain questions between tools to improve flow and accuracy, and one AETC provided input on instructions for collecting a unique identifier. In response, HRSA revised some of the information collection forms, when appropriate (*e.g.,* moving questions from one form to the other, removing forms for some recipients because they were not applicable based on current data workflow between recipients).

Need and Proposed Use of the Information: HRSA uses the data collected when conducting RWHAP AETC programmatic assessments to determine future program needs and program progress towards its objectives. These data allow HRSA to identify where gaps exist in training HIV professionals as well as to measure whether training activities are meeting the goals of the RWHAP statute.

Likely Respondents: RWHAP National AETC participants who attend activities hosted by NASC, NCCC, NHC, and HTR complete the Individual Participant Record at least once a reporting period (July 1–June 30). NASC and NCCC AETC recipients complete a Training Activity Record for each training activity they conduct during the reporting period. Participants who engage in recipient-specific activities will take the activity-specific Participant Post-Activity Survey (*e.g.,* participants of the RWHAP Clinical Conference will take the NASC–RWHAP–PPA). Resident participants in the HTR program will complete the HTR Long-Term form 1-year post-participation in the program. Finally, the NHC–IP recipients will complete the NHC–IP Health Profession Program Characteristics/Outcomes form at least once per reporting period, and HTR recipients will complete the HTR Program Characteristics/Outcomes form at least once per reporting period.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Due to the unique nature of the national AETCs, an additional column titled ''Type of Respondent'' was added to the table to indicate which national center respondent would be using the form in question. A form may be listed more than once because the form itself has recipient/respondent-specific sections. Providing this additional information allows the burden estimates to be more accurate to the respondent.

TABLE 2—TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form/tool name	Type of respondent or recipient	Number of respondents/ rows	Number of responses per recipient	Total responses	Average burden per response (in hours)	Total burden hours
National–TAR	NASC	1	1	1	0.21	0.21
NASC–Web	NASC	1	1	1	2.00	2.00
National IND–PAR	NASC participants	60,000	1	60,000	0.27	16,200.00
NASC–Web–PPA	NASC participants	200	1	200	0.06	12.00
NASC–RWHAP–PPA	NASC attendants of RWHAP Clinical Conference.	400	1	400	0.06	24.00
Combined Data Set	NASC	1	1	1	64.00	64.00
NASC Subtotal		60,603		60,603		16,302.21
National TAR	NCCC	50	1	50	0.21	10.50
NCCC Tele-Consultation Utilization Form.	NCCC	1	1	1	1.00	1.00
NCCC IND–PAR	NCCC Participants	10,000	1	10,000	0.15	1,500.00
NCCC–PPA	NCCC participant callers	10,000	1	10,000	0.06	600.00

TABLE 2—TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form/tool name	Type of respondent or recipient	Number of respondents/ rows	Number of responses per recipient	Total responses	Average burden per response (in hours)	Total burden hours
Combined Data Set	NCCC	1	1	1	64.00	64.00
NCCC Subtotal		20,052		20,052		2,175.50
NHC–TWeb	NHC	1	1	1	8.00	8.00
National TAR	NHC	1	1	1	0.21	0.21
National IND–PAR	NHC and NHC–IP participants.	16,000	1	16,000	0.27	4,320.00
NHC–PPA	NHC participants	16,000	35	560,000	0.06	33,600.00
Combined Data Set	NHC	1	1	1	64.00	64.00
NHC Subtotal		32,003		576,003		37,992.21
NHC–IP–HC	NHC–IP	1	10	10	0.31	3.10
NHC–IP–SF–PPA	NHC–IP students and faculty.	25	10	250	0.06	15.00
Combined Data Set	NHC–IP	10	1	10	64.00	640.00
NHC–IP Subtotal		36		270		658.10
HTR–PC	HTR	1	4	4	0.09	0.36
National IND–PAR	HTR residents	200	4	800	0.27	216.00
HTR–SF–PPA	HTR residents and faculty	200	4	800	0.06	48.00
Combined Data Set	HTR	4	1	4	64.00	256.00
HTR Subtotal		405		1,608		520.36
Total		113,099		658,536		57,648.38

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2026–04535 Filed 3–6–26; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institute of Allergy and Infectious Diseases (NIAID), an institute of the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is giving notice of the invention listed below, which is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Inquiries related to this licensing opportunity should be directed to: Chris Kornak at 240–565–2632, or *chris.kornak@nih.gov.* Licensing information may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852: tel. 301–496–2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

SUPPLEMENTARY INFORMATION: Technology description follows:

Novel malaria vaccine candidates comprising engineered nanoparticles.

Description of Technology

Using proteins derived from the malaria *Plasmodium falciparum* parasite, NIAID has developed three different nanoparticle platforms to serve as scaffolds for displaying multiple copies of malaria antigens in an organized, repetitive manner to enhance vaccine effectiveness. The first platform uses the pyridoxal 5′-phosphate (PLP) synthase protein to form a nanoparticle displaying 48 copies of up to 4 different proteins. The second platform uses the chaperone 60 (Cpn60), which can display 28 copies of up to 2 different proteins. The third platform uses a caseinolytic protease (Clp) which can display 28 copies of up to two different proteins.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- Malaria vaccinology.

Competitive Advantages:

- Pre-clinical data indicates that nanoparticles displaying the malaria circumsporozoite protein (CSP) confer 100% sterilizing immunity in mice.

Developmental Stage:

- Pre-Clinical.

Inventors: Dr. Niraj H. Tolia, Dr. Dashuang Shi, Mr. Vu Nguyen, and Dr. Thayne H. Dickey, all of NIAID.

Publications: Shi D, et al. A Plasmodium-derived nanoparticle vaccine elicits sterile protection against malaria in mice. *Nat Microbiol.* 2026;11(1):67–80. doi:10.1038/s41564–025–02209–y.

Intellectual Property: HHS Reference No. E–182–2024–0. U.S. Provisional Patent Application No. 63/695,288, filed on September 16, 2024, and PCT Patent Application No. PCT/US2025/046419, filed on September 15, 2025.

Licensing Contact: To license this technology, please contact Chris Kornak at 240–565–2632, or *chris.kornak@nih.gov,* and reference E–182–2024–0.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. For collaboration opportunities, please