studies. The September 2021 draft guidance incorporated content on investigator reporting under 21 CFR 312.64(b) from the 2012 final guidance.

In the **Federal Register** notice announcing the availability of the June 2021 draft guidance (86 FR 34020), FDA announced that when the June 2021 draft guidance and the September 2021 draft guidance were finalized, FDA planned to withdraw the 2012 final guidance because these guidances would replace the 2012 final guidance.

Elsewhere in this issue of the **Federal Register**, FDA also has announced the availability of a final guidance entitled ''Investigator Responsibilities—Safety Reporting for Investigational Drugs and Devices.'' Accordingly, FDA is withdrawing the 2012 final guidance at this time.

This guidance finalizes the June 2021 draft guidance. FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include revisions to the recommended approaches for aggregate analyses to reduce the need for unblinding to evaluate safety data; additional considerations for small programs and rare diseases; updated information for electronic submission of IND safety reports; and editorial changes for clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Sponsor Responsibilities—Safety Reporting Requirements and Safety Assessment for Investigational New Drug Application and Bioavailability/Bioequivalence Studies.'' 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

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 OMB under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 pertaining to the content and format of IND applications and the collections of information in § 320.31 for IND-exempt BA/BE safety reporting requirements for human drug and biological products have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 for safety report submissions for applicants with an approved new drug application and an abbreviated new drug application have been approved under OMB control number 0910–0001. The collections of information for submitting Form FDA 3500A and for FDA adverse event reporting and electronic submissions using the Electronic Submission Gateway and the Safety Reporting Portal have been approved under OMB control number 0910–0291. The collections of information in 21 CFR part 11 pertaining to electronic records and signatures have been approved under OMB control number 0910–0303. The collections of information in 21 CFR part 50 and part 56 pertaining to the protection of human subjects and institutional review boards, respectively, have been approved under OMB control number 0910–0130. The collections of information in 21 CFR 314.80 for submitting periodic adverse drug experience reports have been approved under OMB control number 0910–0230. The collections of information in 21 CFR 600.80 for submitting periodic adverse experience reports for biological products have been approved under OMB control number 0910–0308.

III. Electronic Access

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

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–22870 Filed 12–15–25; 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; The National Health Service Corps and Nurse Corps Interest Capture Form—OMB No. 0915–0337—Revision

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 January 15, 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 particular 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: The National Health Service Corps and Nurse Corps Interest Capture Form OMB No. 0915–0337—Revision.

Abstract: HRSA's National Health Service Corps (NHSC) and the Nurse Corps Scholarship and Loan Repayment Programs are committed to improving the health of the nation's underserved by uniting communities in need with caring health professionals and by supporting communities' efforts to build better systems of care. The NHSC and Nurse Corps Interest Capture Form, which can be accessed on the HRSA website at *https://bhw.hrsa.gov/about-us/ask-question,* is an optional form that a health profession student, licensed clinician, faculty member, clinical site administrator, or other interested individual can complete and submit to HRSA online. The purpose of the form is to enable individuals and clinical sites to ask questions about the NHSC and/or Nurse Corps Scholarship and Loan Repayment Programs, and to provide their contact information so that HRSA may provide them with periodic program updates and other general information via email. Completed forms will contain information such as the names and roles of the individual(s),

their phone number(s) and email address(es), and the HRSA program(s) in which they are interested or about which they have questions. The revisions in this ICR include an increase in the annualized information collection burden due to a higher number of respondents.

A 60-day notice published in the **Federal Register** on July 30, 2025, vol. 90, No. 144. 35914–15. There were no public comments.

Need and Proposed Use of the Information: The need and purpose of this information collection is to share resources and information regarding the NHSC and Nurse Corps Scholarship and Loan Repayment Programs with interested HRSA website (*https://www.hrsa.gov/*) visitors.

Likely Respondents: Health profession students, licensed clinicians, faculty members, clinical site administrators or other individuals who are interested in learning more or have questions about NHSC and Nurse Corps Scholarship and Loan Repayment Programs.

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.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form Name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours *
NHSC and Nurse Corps Interest Capture Form	17,676	1	17,676	0.025	442
Total	17,676		17,676		442

* Total Burden Hours are rounded up to the nearest whole number.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2025–22930 Filed 12–15–25; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Commission on Childhood Vaccines

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Commission on Childhood Vaccines (ACCV) will hold public meetings for calendar year (CY) 2025. Information about the ACCV, agendas, and materials for these meetings can be found on the ACCV website at *https://www.hrsa.gov/advisory-committees/vaccines/index.html.*

DATES: ACCV meetings will be held on December 29, 2025, at 11:30 a.m. Eastern Time (ET); 12:00 p.m. ET; 12:30 p.m. ET; and 1:00 p.m. ET.

ADDRESSES: Meetings will be held by Microsoft Teams webinar. For meeting information updates, go to the ACCV website meeting page at *https://www.hrsa.gov/advisory-committees/vaccines/meetings.html.*

FOR FURTHER INFORMATION CONTACT: Pita Gomez, Principal Staff Liaison, Division of Injury Compensation Programs, HRSA, 5600 Fishers Lane, 14W–18, Rockville, Maryland 20857; 800–338–2382; or *ACCV@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The ACCV provides advice and recommendations to the Secretary of Health and Human Services on policy, program development, and other issues related to implementation of the National Vaccine Injury Compensation Program and concerning other matters as described under section 2119 of the Public Health Service Act (42 U.S.C. 300aa–19).

Since priorities dictate meeting times, be advised that start times, end times, and agenda items are subject to change. Refer to the ACCV website listed above for any meeting updates that may occur. For CY 2025 meetings, agenda items may include but are not limited to: updates from the Division of Injury Compensation Programs, Department of Justice, and Department of Health and Human Services' Divisions. The purpose of the four virtual meetings is for discussion only; the Commission will not conduct any voting or decision-making. Refer to the ACCV website listed above for all current and updated information concerning the CY 2025 ACCV meetings, including draft agendas and meeting materials that will be posted before the meeting.

These meetings are open to the public. Meetings held on Microsoft Teams require registration. Registration details will be provided on our ACCV website at *https://www.hrsa.gov/advisory-committees/vaccines/meetings.html.* All registrants will be asked to provide their name, affiliation, and email address. After registration, individuals will receive Microsoft Teams information via email.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting(s). Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement to the ACCV should be sent to Pita Gomez using the contact information above at least 5 business days before the meeting date(s).

Individuals who need special assistance or another reasonable accommodation should notify Pita Gomez using the contact information listed above.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2025–22982 Filed 12–15–25; 8:45 am]

BILLING CODE 4165–15–P