The goal of the early meeting discussions granted under this program is to provide advice on how specific, proposed MIDD approaches can be used in a particular drug development program. FDA has committed to accepting one to two appropriate meeting requests quarterly each fiscal year. The meetings granted will include an initial and followup meeting on the same drug development issues. The second meeting will occur within approximately 60 days of receiving the briefing package.

II. Eligibility and Selection for Participation in the MIDD Program

The sponsor should be a drug/biologics development company (interested consortia or software/device developer should come in partnership with a drug development company) and have an investigational new drug application (IND) or pre-IND (PIND) number for the relevant program. FDA welcomes submissions related to any relevant MIDD topics, such as:

- Dose selection or estimation (*e.g.,* for dose/dosing regimen selection or refinement)
- Clinical trial simulation (*e.g.,* based on drug-trial-disease models to inform the duration of a trial, select appropriate response measures, predict outcomes, etc.)
- Predictive or mechanistic safety evaluation (*e.g.,* use of systems pharmacology/mechanistic models for predicting safety or identifying critical biomarkers of interest)

III. Procedures and Submission Information

A. General Information

The MIDD program will be jointly administered by CDER's Office of Clinical Pharmacology, in the Office of Translational Sciences, which is the point of contact for all communications for CDER products, and CBER's Office of Biostatistics and Pharmacovigilance, which is the point of contact for all communications for CBER products.

B. How To Submit a Meeting Request and Meeting Package

Meeting requests should be submitted electronically to the relevant application (*i.e.,* PIND, IND) with ''MIDD Program Meeting Request for CDER'' (CDER applications) or ''MIDD Program Meeting Request for CBER'' (CBER applications) in the subject line. Information about providing regulatory submissions in electronic format is available at: *https://www.fda.gov/drugs/development-approval-process-drugs/forms-submission-requirements.*

C. Content and Format of the Meeting Request

Include the following information in the meeting request (no more than three to four pages):

1. Product name.
2. Application number.
3. Chemical name and structure.
4. Proposed indication(s) or context of product development.
5. A brief statement of the purpose and objectives of the meeting. The statement should include a brief background of the MIDD issues underlying the agenda.
6. MIDD approach(es) considered for the product under development and how MIDD can assess uncertainties about issues (*e.g.,* dosing, duration, patient selection) in a way that can inform regulatory decision-making.
7. A list of issues for discussion with the Agency about the specific MIDD proposed approach for the applicable drug development program.

D. Content and Format of the Meeting Information Package

Sponsors whose meeting requests are granted as part of the program should submit a meeting information package electronically with ''MIDD Program Meeting Package for CDER'' (CDER applications) or ''MIDD Program Meeting Package for CBER'' (CBER applications) in the subject line no later than 47 days before the initial meeting and 60 days before the follow-up meeting. This meeting package should include the following information:

1. Product name.
2. Application number.
3. Chemical name and structure.
4. Proposed indications or context of product development.
5. Background section that includes a brief history of the development program and the events leading up to the meeting as well as the status of product development.
6. Proposed agenda, including estimated times needed for discussion of each agenda item.
7. List of questions for discussion along with a brief summary explaining the question of interest and the context of use for each question. State whether the model will be used to inform future trials, to provide mechanistic insight, or in lieu of a clinical trial.
8. The drug development issue (*e.g.,* dosing, clinical trial design, safety prediction, etc.), the proposed MIDD approach to the solution, information to support discussion (*e.g.,* a description of the data utilized for developing the models, model development, simulation plan, results), assessment of model risk, and how the Agency can help guide any next steps relative to the regulatory decision-making process should be summarized and clearly articulated with any supporting data imperative to the discussion.

E. Meeting Summaries

A meeting summary will be sent to the requester within 30 days of each meeting.

IV. Paperwork Reduction Act of 1995

While this notice contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this notice. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information pertaining to Prescription Drug User Fee Program have been approved under OMB control number 0910–0297. The collections of information for requesting meetings with FDA about drug development programs have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 312 for INDs and clinical trials have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 601 for biologics license applications have been approved under OMB control number 0910–0338.

Dated: January 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–00389 Filed 1–10–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3091]

Advisory Committee; Cardiovascular and Renal Drugs Advisory Committee; Renewal; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled ''Advisory Committee; Cardiovascular and Renal Drugs Advisory Committee; Renewal'' that appeared in the **Federal Register** of December 13, 2022. The document announced the renewal of the

Cardiovascular and Renal Drugs Advisory Committee. The document was published with the incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy, Planning, Legislation and International Affairs, Food and Drug Administration, 301–796–9115, *Lisa.Granger@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Tuesday, December 13, 2022 (87 FR 76197), in FR Doc. 2022–27014, on page 76197 the following correction is made:

1. On page 76197, in the first column of the header of the document, ''Docket No. FDA–2022–N–3091'' is corrected to read ''Docket No. FDA–2018–N–3091''.

Dated: January 3, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–00390 Filed 1–10–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: The National Health Service Corps and Nurse Corps Interest Capture Form—Revision

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than March 13, 2023.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the acting HRSA Information Collection Clearance Officer, at 301–594–4394.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The National Health Service Corps (NHSC) and Nurse Corps Interest Capture Form OMB No. 0915–0337—Revision.

Abstract: The NHSC and the Nurse Corps Scholarship and Loan Repayment Programs of HRSA are both 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 are as follows:

a. The discontinuation of the print version of the NHSC and Nurse Corps Interest Capture Form, previously used by HRSA staff for sharing program information with health profession students and providers at national and regional conferences and campus recruiting events.

b. The addition of an online version of the NHSC and Nurse Corps Interest Capture Form, located on the HRSA website at *https://bhw.hrsa.gov/about-us/ask-question.*

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 (*hrsa.gov*) visitors.

Likely Respondents: Individuals and potential service sites interested in the NHSC or 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	16,144	1	16,144	.025	404
Total	16,144		16,144		404