both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

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

Submit written requests for single copies of this 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 that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Anuradha Ramamoorthy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3118, Silver Spring, MD 20993, 240–402–6426, *Anuradha.Ramamoorthy@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Evaluation of Gastric pH-Dependent Drug Interactions With Acid-Reducing Agents: Study Design, Data Analysis, and Clinical Implications.'' ARAs such as antacids, histamine H2-receptor antagonists, and proton pump inhibitors (PPIs) are widely used, and many of these drugs are available over-the-counter. Because ARAs can elevate the gastric pH, concomitant administration of a drug with an ARA could alter the solubility, dissolution, and bioavailability of the drug, potentially resulting in a loss of efficacy for weak-base drugs or increased toxicity for weak-acid drugs. Therefore, it is important to assess the susceptibility of an investigational drug to gastric pH change-mediated DDIs early in drug development, characterize the DDI effect with clinical studies when needed, and communicate the relevant findings in the drug product labeling. This guidance addresses when clinical DDI studies with ARAs should be conducted, the design and conduct of clinical pH-dependent DDI studies, alternative approaches for evaluating pH-dependent DDIs, and extrapolating clinical DDI study results among drug classes of ARAs.

This guidance finalizes the draft guidance entitled ''Evaluation of Gastric pH-Dependent Drug Interactions With Acid-Reducing Agents: Study Design, Data Analysis, and Clinical Implications'' issued on December 1, 2020 (85 FR 77222). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include: (1) adding footnotes to update the framework to evaluate the pH-DDI liability of an investigational drug based on solubility and dissolution of a drug product, (2) additional literature and FDA guidance references included to provide additional clarity, (3) modified examples of PPIs and their doses for clinical DDI studies, and (4) editorial changes to improve 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 ''Evaluation of Gastric pH-Dependent Drug Interactions With Acid-Reducing Agents: Study Design, Data Analysis, and Clinical Implications.'' 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. 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 guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information for submissions of investigational new drug applications, new drug applications, and biologic license applications in 21 CFR parts 312, 314, and 601 have been approved under OMB control numbers 0910–0014, 0910–0001, and 0910–0338, respectively. The collections of information in 21 CFR 201.56 and 201.57 pertaining to the submission of prescription drug labeling have been approved under OMB control number 0910–0572.

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/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: March 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–05067 Filed 3–10–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Office of Minority Health Research Coordination (OMHRC) Research Training and Mentor Programs Applications (National Institute of Diabetes and Digestive and Kidney Diseases)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institutes of Health National Institute of Diabetes and Digestive and Kidney Diseases will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Ms. Winnie Martinez, Project Officer, 6707 Democracy Blvd., 9th

Floor, Bethesda, MD 20892 or call non-toll-free number (301) 435–2988 or Email your request, including your address to: *Winnie.Martinez@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Office of Minority Health Research Coordination Training and Mentor Programs Applications 0925–0748, REVISION, exp., date 8/31/2023 National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH).

Need and Use of Information Collection: In 2000, the National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health established the Office of Minority Health Research Coordination to address the burden of diseases and disorders that disproportionately impact the health of minority populations. One of the major goals of the office is to build and sustain a pipeline of researchers from underrepresented populations in the biomedical, behavioral, clinical, and social sciences, with a focus on NIDDK mission areas. The office accomplishes this goal by administering a variety of programs and initiatives to recruit high school through post-doctoral educational level individuals into OMHRC research training and mentor programs: The Short-Term Research Experience Program to Unlock Potential (STEP–UP), the Diversity Summer Research Training Program (DSRTP) for Undergraduate Students, and Network of Minority Health Research Investigators (NMRI), the NIH/National Medical Association (NMA) Academic Career Fellow Travel Awards, and the NIDDK/National Hispanic Medical Association (NHMA) Academic Career Fellow Travel Awards.

Identification of participants to matriculate into the program and initiatives comes from applications and related forms hosted through the NIDDK website. The proposed information collection activity is necessary in order to determine the eligibility and quality of potential awardees for traineeship in these programs.

OMB approval is requested for three (3) years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1,651.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Attachment 1: Short-Term Research Experience Program to Unlock Potential (STEP–UP) Application	600	1	1	600
Attachment 2: STEP–UP Student Feedback Form	175	1	15/60	44
Attachment 3: STEP–UP Participant Survey Form	2,200	1	5/60	183
Attachment 4: Diversity Summer Research Training Program (DSRTP) Feedback Form	14	1	30/60	7
Attachment 5: Network of Minority Health Research Investigators (NMRI) Enrollment Form	200	1	15/60	50
Attachment 6: NMRI Evaluation Form	120	1	30/60	60
Attachment 7: NMRI Survey Form	800	1	30/60	400
Attachment 8: NMRI Mentor-Mentee Agreement Form	100	1	30/60	50
Attachment 9: NIH/National Medical Association (NMA) Academic Career Fellow Travel Awards Application	200	1	20/60	67
Attachment 10: NIH/NMA Feedback Form	40	1	30/60	20
Attachment 11: NIH/NMA Academic Career Development Workshop Contact Information and Feedback Form	1,000	1	5/60	83
Attachment 12: NIH/National Hispanic Medical Association (NHMA) Academic Career Fellow Travel Awards Application	200	1	20/60	67
Attachment 13: NIH/NHMA Feedback Form	40	1	30/60	20
Total	.....	5689	.....	1651

Dated: March 7, 2023.

Melbourne L. Bull Jr.,

NIDDK Project Clearance Liaison, Office of Management Policy Analysis, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health.

[FR Doc. 2023–05085 Filed 3–10–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting of the National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel.

The meetings 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