In response to recommendations made by FDA in GFI #213,[1] as part of a strategy to address antimicrobial resistance associated with the use of antimicrobial drugs in animal agriculture, sponsors of all NADAs and ANADAs for antimicrobial drugs important to human medicine (medically important antimicrobial drugs) approved for use in or on the feed or in the drinking water of food-producing animals worked with FDA over a 3-year period from 2013 to 2016 to voluntarily withdraw approval of indications that were not considered necessary for ensuring animal health (production indications). In response to FDA recommendations made in GFI #263,[2] sponsors also voluntarily worked with FDA to change the marketing status of all remaining approved uses of such new animal drugs from over-the-counter (OTC) to either by veterinary prescription (Rx) or by veterinary feed directive, as applicable.

In September 2016, FDA announced that it intended to enter the next phase of its efforts to mitigate antimicrobial resistance by focusing on medically important antimicrobials used in animal feed or water that have at least one therapeutic indication without a defined duration of use. In a notice published in the **Federal Register** of September 14, 2016 (81 FR 63187), the Agency requested comments from the public about how to establish appropriately targeted durations of use for therapeutic products within the scope of GFI #213 with no currently defined duration of use. Public feedback received in response to that request for information was taken into consideration during subsequent development of a concept paper released in 2021.

On September 14, 2018, FDA released a 5-year action plan for supporting antimicrobial stewardship in veterinary settings.[3] This plan includes an action item intended ''to ensure that all medically important antimicrobial drugs used in the feed or drinking water of food-producing animals have an appropriately targeted duration of use.''[4]

In a notice published in the **Federal Register** of January 11, 2021 (86 FR 1979), FDA requested comments from the public on a concept paper that outlined a potential framework for how sponsors of NADAs and ANADAs for products containing medically important antimicrobial drugs approved for use in or on the feed of food-producing animals could voluntarily work with FDA to change the approved conditions of use of these drugs to establish appropriately defined durations of use for those indications that currently have an undefined duration of use. The concept paper generated invaluable public comment; FDA considered all information and feedback received on the concept paper as it developed this draft guidance.

This level 1 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 ''Defining Durations of Use for Approved Medically Important Antimicrobial Drugs Fed to Food-Producing Animals.'' 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 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 section 512(n)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(n)(1)) have been approved under OMB control number 0910–0669. The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

III. Electronic Access

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

[1] See GFI #213, ''New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209,'' December 2013. (*https://www.fda.gov/media/83488/download*)

[2] See GFI #263, ''Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available Over-the-Counter,'' June 2021. (*https://www.fda.gov/media/130610/download*)

[3] See FDA's 5-year action plan entitled ''Supporting Antimicrobial Stewardship in Veterinary Settings: Goals for Fiscal Years 2019–2023.'' (*https://www.fda.gov/media/115776/download*)

[4] See Action item 1.1.2 of the 5-year plan.

Dated: September 21, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–20920 Filed 9–25–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0313–60D]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before November 27, 2023.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 264–0041 and *PRA@HHS.GOV.*

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–0313 and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov, PRA@HHS.GOV* or call (202) 264–0041 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: National Blood Collection & Utilization Survey (NBCUS).

Type of Collection: Revision.

OMB No.: 0990–0313 Office of the Assistant Secretary for Health/HHS.

Abstract: The Office of the Assistant Secretary for Health (OASH) is requesting approval for a three-year revised information collection request (ICR) titled ''National Blood Collection & Utilization Survey (NBCUS).'' The NBCUS is a biennial survey that

includes a core of standard questions on blood collection, processing, and utilization practices. Questions on transfusion-transmitted infections, transfusion associated circulatory overload, acute hemolysis, delayed hemolysis, and severe allergic reactions are also included in the survey. The rapidly changing environment in blood supply and demand makes it important to have regular, periodic data describing the state of U.S. blood collections and transfusions for understanding the dynamics of blood safety and availability. In 2023, two sections were removed from the survey related to the impact of the COVID–19 pandemic on the blood supply during the course of 2020.

Survey respondents will consist of blood collection centers and hospitals that perform blood transfusions, except those reporting fewer than 100 inpatient surgeries per year. For the purposes of this ICR, federal burden is only being placed on facilities located within the fifty states and the District of Columbia. The total estimated burden is 5,106 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Transfusing Hospitals	2754	1	1 hour, 46 min	4,865
Hospital Blood Banks	83	1	1 hour, 46 min	147
Community-based blood center	53	1	1 hour, 46 min	94
Total	2,890	.....	.....	5,106

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2023–20865 Filed 9–25–23; 8:45 am]

BILLING CODE 4150–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

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

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: National Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group; Diabetes, Endocrinology and Metabolic Diseases B Study Section Diabetes, Endocrinology and Metabolic Diseases B Study Section.

Date: October 25–27, 2023.

Time: 10:00 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NIDDK Democracy II, Suite 7000A, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Charlene J. Repique, Ph.D., Scientific Review Officer, NIDDK/Scientific Review Branch, National Institutes of Health, 6707 Democracy Blvd., Room 7013, Bethesda, MD 20892, (301) 594–7791, *charlene.repique@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: September 20, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–20753 Filed 9–25–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

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

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: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Genomics Centers for Infectious Diseases (U19 Clinical Trial Not Allowed).

Date: October 24–25, 2023.

Time: 10:00 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F21B, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Maryam Feili-Hariri, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F21B, Rockville, MD 20852, 240–669–5026, *haririmf@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: September 20, 2023.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–20867 Filed 9–25–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as