

antimicrobial drugs. To address the human health risks surrounding the use of antimicrobial new animal drugs, in 2003, FDA issued Guidance for Industry (GFI) #152, entitled “Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern.”

GFI #152 outlines a qualitative risk assessment methodology as a process for evaluating foodborne antimicrobial resistance concerns related to the use of antimicrobial drugs in food-producing animals. GFI #152 also contains an appendix, commonly referred to as “Appendix A,” in which FDA ranks antimicrobial drugs according to their relative importance to human medicine: “critically important,” “highly important,” or “important.”

The current list of medically important antimicrobial drugs in Appendix A reflects FDA’s thinking at the time of publication, in 2003. It was envisioned at the time of publication of GFI #152 that the Agency would reassess the rankings provided in Appendix A periodically to confirm that the rankings are consistent with contemporary practices and needs. As noted in GFI #152, the development of new antimicrobial drugs for human therapy, the emergence or re-emergence of diseases in humans, and changes in prescribing practices, are some factors that may cause the human medical importance rankings to change over time.

Given the considerable advances in science that have taken place since 2003, new relevant information has become available. In light of those advances and the new information now available, FDA published a notice in the **Federal Register** of October 13, 2020 (85 FR 64481), announcing a public meeting and requesting comments on a concept paper entitled “Potential Approach for Ranking of Antimicrobial Drugs According to Their Importance in Human Medicine: A Risk Management Tool for Antimicrobial New Animal Drugs.”

FDA received more than 60 comment submissions from pharmaceutical companies, academia, organizations, and private citizens on this concept paper. FDA has considered all comments and is issuing this draft guidance document, which contains revised sections in the risk assessment framework, including updated tables and figures, and a revised Appendix A based on new ranking criteria of

antimicrobials according to their importance in human medicine.

This level 1 draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern.” 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 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>.

Dated: December 13, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27415 Filed 12–16–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–4040–0005]

Agency Information Collection Request. 30-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 January 18, 2023.

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 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Sagal Musa, sagal.musa@hhs.gov or (202) 205–2634. When submitting comments or requesting information, please include the document identifier 4040–0005–30D and project title for reference.

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 Collections: Application for Federal Domestic Assistance—Individual.

Type of Collection: Renewal.

OMB No.: 4040–0005.

Abstract: The Application for Federal Assistance—Individual form provides the Federal grant-making agencies an alternative to the Standard Form 424 data set and form. Agencies may use Application for Federal Assistance—Individual form for grant programs not required to collect all the data that is required on the SF–424 core data set and form.

Type of respondent: The Application for Federal Assistance—Individual form is used by organizations to apply for Federal financial assistance in the form of grants. This form is submitted to the Federal grant-making agencies for evaluation and review. This IC expires on January 31, 2023. *Grants.gov* seeks a three-year clearance of these collections.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Application for Federal Assistance— Individual.	Grant Applicants	100	1	1	100
Total		100	1	1	100

Sherrette A. Funn,

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

[FR Doc. 2022-27463 Filed 12-16-22; 8:45 am]

BILLING CODE 4151-AE-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-4040-0020]

Agency Information Collection Request. 30-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 January 18, 2023.

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 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Sagal Musa, sagal.musa@hhs.gov or (202) 205-2634. When submitting comments or requesting information, please include the document identifier 4040-0020-30D and project title for reference.

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 Collections: SF-424 Mandatory Form.

Type of Collection: Renewal.

OMB No.: 4040-0020.

Abstract: The Standard 424 Mandatory form provides the Federal grant-making agencies an alternative to the Standard Form 424 data set and form. Agencies may use SF-424 Mandatory Form for grant programs not required to collect all the data that is required on the SF-424 core data set and form.

Type of respondent: The SF-424 Mandatory form is used by organizations to apply for Federal financial assistance in the form of grants. This form is submitted to the Federal grant-making agencies for evaluation and review. This IC expires on January 31, 2023. *Grants.gov* seeks a three-year clearance of these collections.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
SF424 Mandatory Form	Grant Applicants	5,761	1	1	5,761
Total		5,761	1	1	5,761

Sherrette A. Funn,

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

[FR Doc. 2022-27464 Filed 12-16-22; 8:45 am]

BILLING CODE 4151-AE-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; 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.

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 Center for Advancing Translational Sciences Special

Emphasis Panel; NCATS CTSA Training Grants Review Meeting.

Date: January 25, 2023.

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

Agenda: To review and evaluate grant applications.

Place: National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1037, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Nakia C. Brown, Ph.D., Scientific Review Officer, Office of Grants Management and Scientific Review, National Center for Advancing Translational Sciences, 6701 Democracy Boulevard, Room 1037, Bethesda, MD 20892, 301-827-4905, brownnac@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry