DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5538]

National Antimicrobial Resistance Monitoring System 2026–2030 Strategic Plan; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is soliciting comments from the public regarding the National Antimicrobial Resistance Monitoring System (NARMS) 2026–2030 Strategic Plan. Comments received will help inform the development of a draft 2026–2030 Strategic Plan, to be discussed at a public meeting in spring 2025. Specific questions and information requests are included in this notice to help guide input from interested parties.

DATES: Submit either electronic or written comments by March 26, 2025.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 26, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the FDA–N–2024–5538 for ''National Antimicrobial Resistance Monitoring System 2026–2030 Strategic Plan; Request for Comments.'' Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit 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.

FOR FURTHER INFORMATION CONTACT: Heather Tate, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–5454, *heather.tate@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Antimicrobial resistance (AMR) has been ranked by the World Health Organization as a top global health challenge. Reducing human exposure to antimicrobial resistant microorganisms and their resistance determinants is key to reducing the burden of antimicrobial resistant infections. Food is a potential source of human exposure. An antimicrobial resistance monitoring system is required to track resistance among different population groups and in different settings over time, detect new resistance types, reveal the underlying determinants of resistance in different microorganisms, and measure the effectiveness of interventions.

NARMS was established in 1996 as a collaborative public health surveillance program comprised of State and local public health departments and universities, FDA, the Centers for Disease Control and Prevention (CDC), and the U.S. Department of Agriculture (USDA). The overall purpose of this national program is to monitor trends in antimicrobial resistance among enteric (intestinal) bacteria from people (CDC), retail meats (FDA), and food animals at the time of slaughter (USDA) in the United States; disseminate timely information on antimicrobial resistance to promote interventions that reduce resistance among foodborne bacteria; conduct research to better understand the emergence, persistence, and spread of antimicrobial resistance; provide timely antimicrobial resistance data for outbreak investigations; and provide data that assist FDA in making decisions related to the approval of safe and effective antimicrobial drugs for animals.

On August 18, 2020, FDA, CDC, and USDA released the NARMS Strategic Plan 2021–2025, listing the program's

strategic goals and objectives, as well as its challenges and opportunities. A central theme of the 2021–2025 NARMS Strategic Plan is One Health, which is a collaborative, multisectoral, and transdisciplinary approach to health—working at the local, regional, national, and global levels—with the goal of achieving optimal health outcomes by recognizing the interconnection between people, animals, plants, and their shared environment. In accord with the principles of One Health, NARMS has collaborated with FDA's Veterinary Laboratory Investigation and Response Network (Vet-LIRN), with USDA's Animal and Plant Health Inspection Service (APHIS), and with the U.S. Environmental Protection Agency (EPA) to test for various pathogens.

NARMS is now seeking input from interested parties for its 2026–2030 Strategic Plan. The feedback received will help inform the development of a draft 2026–2030 NARMS Strategic Plan, to be discussed at a public meeting to be held in spring 2025.

II. Questions for Consideration

We seek input on the following questions:

1. How do you use NARMS human, animal, and retail data? Do you use other sources of AMR data for your program?
2. Are you using these data for risk management activities, including implementation of mitigation and prevention strategies?
3. What aspects of the NARMS data do you find most useful and why?
4. Is there additional AMR information that you would want NARMS to collect that is not currently being collected? Alternatively, are there any current aspects of NARMS that could or should be discontinued and, if so, why?
5. Considering that One Health is an approach that recognizes that the health of people is closely connected to the health of animals and our shared environment, what approaches could NARMS use to conduct monitoring within the One Health framework?
6. What data-sharing capacities are available for interested parties to collaborate with NARMS more effectively?
7. What type of NARMS analyses, data visualization, and/or reporting do you think are needed to demonstrate whether there are changes in AMR as a result of antimicrobial stewardship and animal management practices?
8. What research do you think is needed to demonstrate whether there are changes in AMR as a result of antimicrobial stewardship and animal management practices?
9. If not covered under the above questions, specifically include at least one item that you think should be considered in the development of the 2026–2030 NARMS Strategic Plan.

Dated: January 2, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–00342 Filed 1–8–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0026]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product; CRENESSITY (crinecerfont)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that CRENESSITY (crinecerfont), approved on December 13, 2024, manufactured by Neurocrine Biosciences, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1394.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that CRENESSITY (crinecerfont), manufactured by Neurocrine Biosciences, Inc., meets the criteria for a priority review voucher. CRENESSITY (crinecerfont) is indicated for the treatment to glucocorticoid replacement to control androgens in adults and pediatric patients 4 years of age and older with classic congenital adrenal hyperplasia.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about CRENESSITY (crinecerfont), go to the ''*Drugs@FDA*'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: January 3, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–00340 Filed 1–8–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5829]

Advisory Committee; Antimicrobial Drugs Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the renewal of the Antimicrobial Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Antimicrobial Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the October 7, 2026, expiration date.

DATES: Authority for the Antimicrobial Drugs Advisory Committee will expire on October 7, 2026, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Yvette Waples, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, *AMDAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Antimicrobial Drugs