SUPPORTING ANTIMICROBIAL STEWARDSHIP IN VETERINARY SETTINGS

Goals for Fiscal Years 2024-2028:
Key Phase 3 and Phase 4 Actions

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September 2023

FDA U.S. FOOD & DRUG ADMINISTRATION

Introduction

Since antimicrobials were developed 80 years ago, their widespread use in human and veterinary medicine has had tremendous benefits in fighting disease. An unwelcome side effect of antimicrobial use is the evolution of bacteria that are resistant to these medicines in both people and animals. The FDA, Center for Veterinary Medicine (CVM) has long been committed to antimicrobial stewardship in animals in order to help preserve the effectiveness of antimicrobial drugs and slow the development of antimicrobial[1] resistance. This includes the principles that medically important antimicrobial drugs (antimicrobial drugs used to treat human infections) should only be used in animals when necessary to treat, control, or prevent disease. In addition, when such use is necessary, medically important antimicrobials should be used under the oversight of a licensed veterinarian.

Judicious use is defined as the optimal selection, dosage, and duration of antimicrobial treatment that results in the best clinical outcome for the treatment or prevention of infection, with minimal toxicity to the patient and minimal impact on subsequent resistance.[2] In 2021, US farmers raised approximately 9.6 billion chickens, 216 million turkeys, 2.2 million sheep and goats, 77 million hogs and pigs, and 93 million cattle.[3] Sometimes these animals get sick and need antimicrobials. They often receive the same types of antimicrobials used to treat human bacterial illnesses. CVM recognizes that farmers, ranchers, veterinarians, and other animal caretakers need to have access to antimicrobials for ensuring animal health and that vigilant attention to the principles of judicious use is necessary to safeguard the use of antimicrobial products for the future.

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[1] Antimicrobial: For the purposes of this document, refers broadly to drugs with activity against a variety of microorganisms including bacteria, viruses, fungi, and parasites. Antimicrobial drugs that have specific activity against bacteria are referred to as antibacterial or antibiotic drugs. The broader term "antimicrobial," is used in this document and includes reference to drugs with activity against bacteria including antibacterials and antibiotics.

[2] "The search for good antimicrobial stewardship." JT Comm J Qual Improv. 2001. 27(8): 403-404.

[3] USDA. National Agricultural Statistics Service. Agricultural Statistics. US Government Printing Office, Washington DC 20402. See: http://www.nass.usda.gov/.

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Background

FDA's CVM has a long history[4] of supporting antimicrobial stewardship in animals that began in the 1980s and continues today. To provide a transparent roadmap for stakeholders, in 2018 CVM published a multi-phase action plan titled, "Supporting Antimicrobial Stewardship in Veterinary Settings." This action plan was executed in fiscal years[5] 2019-2023 in two phases. Phase 1 activities were initiated between fiscal years 2019 and 2021. Phase 2 actions were initiated between fiscal years 2022 and 2023. All activities in the action plan are organized under three goals.

CVM's 3 Goals for Supporting Stewardship in Veterinary Settings

1 ALIGN

Align antimicrobial drug product use with the principles of antimicrobial stewardship

2 FOSTER

Foster stewardship of antimicrobials in veterinary settings

3 ENHANCE

Enhance monitoring of antimicrobial resistance and antimicrobial drug use in animals

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4   Timeline of FDA Action on Antimicrobial Resistance, accessed May 3, 2023
5   The federal government's fiscal year covers the period from October 1 through September 30.

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Key Accomplishments

Successful collaborations between CVM and stakeholders have led to important changes that support judicious use of medically important antimicrobials in animals. Recent contributions can be summarized by a few general themes.

Revised safety assessment process[6]
In 2003, FDA-CVM revised its pre-approval review of animal antimicrobials by establishing a qualitative risk assessment approach to evaluate antimicrobial resistance concerns as part of its drug approval process and developed criteria for ranking the importance of antimicrobials approved for use in human medicine for risk assessment. FDA has incorporated these processes into its safety evaluation and only considers these drugs to be safe when there is reasonable certainty of no harm to human health from their intended use in animals.

In 2023, FDA published a proposed new ranking criteria for determining the degree of importance in human medicine of antimicrobial drug classes and applied that criteria to revise the ranking of antimicrobial drug classes.[7] Once FDA finalizes this revised document, FDA expects to reassess the rankings periodically to align with current science and clinical practices in human medicine.

Judicious use policies
Judicious use of antimicrobial drugs is an approach to maximize the therapeutic effects of antimicrobial drugs for their intended uses while minimizing selection pressure for antimicrobial resistant microorganisms. Judicious use approaches are considered to be an integral part of sound veterinary practice and animal husbandry. We described below a few examples of CVM's recent policies aimed to promote the judicious use of antimicrobials in animals.

In 1997, CVM placed extra-label prohibitions on the use of glycopeptides and fluoroquinolones in food animals. In 2005, FDA withdrew the approval of fluoroquinolones for use in poultry, and in 2016 placed extra-label restrictions on certain cephalosporins. CVM collaborated with animal drug sponsors to eliminate production uses of medically important antimicrobials used in the feed or in water of food-producing animals[8] (e.g., to promote weight gain or to enhance feed efficiency) and bring the use of such products under veterinary oversight.[9] This policy took effect in January 2017 and resulted in a 33% drop in antimicrobial drugs sales approved for use in animals between 2016 and 2017. Since that time, the antimicrobial sales volume has remained at reduced levels.[10] Lastly, by coordinating with animal drug sponsors, in 2023, CVM brought the remaining over-the-counter uses of medically important antimicrobials under veterinary oversight.[11]

Education/outreach activities
CVM has been actively involved in educational initiatives that promote the judicious use of antimicrobials in animals, including through its collaborative work with academic partners and other institutions, including through funding various cooperative agreements. Most recently, the University of Pennsylvania used CVM funding to 1) publish a comprehensive website for education on carbapenem-resistant Enterobacterales (CRE) outlining how to identify, plan for, and respond to CRE outbreaks, and 2) develop veterinary teaching tools to teach

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6   GFI #152, "Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern," accessed August 17, 2023.
7   FDA Proposes Revisions to Guidance on Evaluating Safety of Antimicrobial Animal Drugs Based on Their Importance in Human Medicine, accessed May 3, 2023.
8   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," accessed January 5, 2023.
9   Veterinary Feed Directive Final Rule, accessed March 29, 2023.
10 2021 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals, accessed January 5, 2023.
11 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," accessed January 5, 2023.

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veterinary students how to appropriately choose antibiotics. Also, Kansas State University and the University of Missouri created resistant bacteria education handouts to attach to laboratory reports to help clients and veterinarians understand the results and next steps. Additional materials are being developed at other veterinary institutions to promote judicious antimicrobial use, including antimicrobial use guidelines, fact sheets, formal continuing education (CE) presentations, educational videos for owners and veterinarians, and competency-based learning modules for school curricula. CVM has also developed a multi-media outreach campaign[12] for stakeholders impacted by GFI #263, including 10 online deliverables and targeted outreach through social media and radio ads.

Research

CVM research scientists have played a leading role in uncovering the genetics of resistance, characterizing the strain types carrying resistance in different animal populations, measuring the evolutionary relatedness of foodborne pathogens, examining the impact of antimicrobial use on the development of resistance in treated animals, developing global standards for laboratory susceptibility testing methods, and conducting some of the first large studies showing how genomics could be used to track resistance in foodborne bacteria. This team is currently developing metagenomics and machine learning algorithms to characterize complex biological samples for the presence of resistance genes and bacteria.

Collect antimicrobial use (AMU) and sales information

The judicious use of antimicrobials requires reliable information on which drugs are used in animals, how much, and why. Historically, FDA has required that companies report bulk annual sales of active ingredient estimated by animal species for medically important antimicrobials. These data are published online annually by CVM in detailed reports. Sales and distribution data can provide some information regarding the types of products in circulation and the quantities sold, but it provides limited context to evaluate why a particular product is used. This makes sales data an imperfect indicator of actual drug use.

To help address this, CVM has been actively engaged in identifying processes to acquire AMU information in animals. From 2016 to 2021, CVM funded two grants to evaluate new mechanisms for AMU data collection in food-producing animals.[13] Additionally, since 2020, CVM funded two grants for the collection of data on AMU in companion animals.[14]

In 2021, CVM began a collaboration with the Reagan Udall Foundation for the FDA to explore the feasibility of a public-private partnership to sustain national AMU monitoring.[15] This ongoing work aims to generate actual AMU information to address the data gaps resulting from reliance on drug sales volume alone.

[12] FDA Antimicrobial Stewardship in Animals: Stakeholder Resources, accessed May 3, 2023.

[13] Information gathered from these cooperative agreements can be found in the November 2020 special issue of Zoonoses and Public Health and FDA-CVM's report on Antimicrobial Use and Resistance in Animal Agriculture in the United States 2016 – 2019, accessed August 17, 2023.

[14] FDA Funded Grants and Contracts Related to Antimicrobial Use and Resistance in Animals, accessed August 17, 2023.

[15] Exploring the Potential for a Public-Private Partnership to Support the Tracking and Monitoring of Antimicrobial Use in Food-Producing Animals, accessed August 17, 2023._

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Improved antimicrobial resistance (AMR) information

Through the expansion of scope and the adoption of next generation DNA sequencing technology, the National Antimicrobial Resistance Monitoring System (NARMS) has been improved to provide comprehensive data on AMR from food animals (chicken, turkey, cattle and swine), retail meats, and human clinical cases of illness. Beginning in 2017, AMR data from clinical animal cases were collected by the Veterinary Laboratory Investigation and Response Network (Vet-LIRN) and included with the NARMS report. In recent years, NARMS has conducted small pilot studies to collect data from minor food animal species (catfish, goat, lamb, sheep, and veal), and retail seafood (salmon, tilapia, and shrimp). The program is also working in collaboration with other Federal agencies (including the US Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Centers for Disease Control and Prevention (CDC)) to conduct studies to explore possible approaches for incorporating environmental sampling into routine monitoring. NARMS continues to expand its sampling to new commodities and sources, all with the aim of building the most comprehensive One Health monitoring program of its kind.

For additional information on accomplishments during Phase 1 see: Progress Made on CVM's 5-Year Plan for Supporting Antimicrobial Stewardship in Veterinary Settings Phase 1.

To help measure the success of actions identified in the initial 5-year plan, CVM established performance measure on FDA Track. For additional information on specific projects see: FDA-TRACK: Progress on FDA's Support of Antimicrobial Stewardship in Veterinary Settings.

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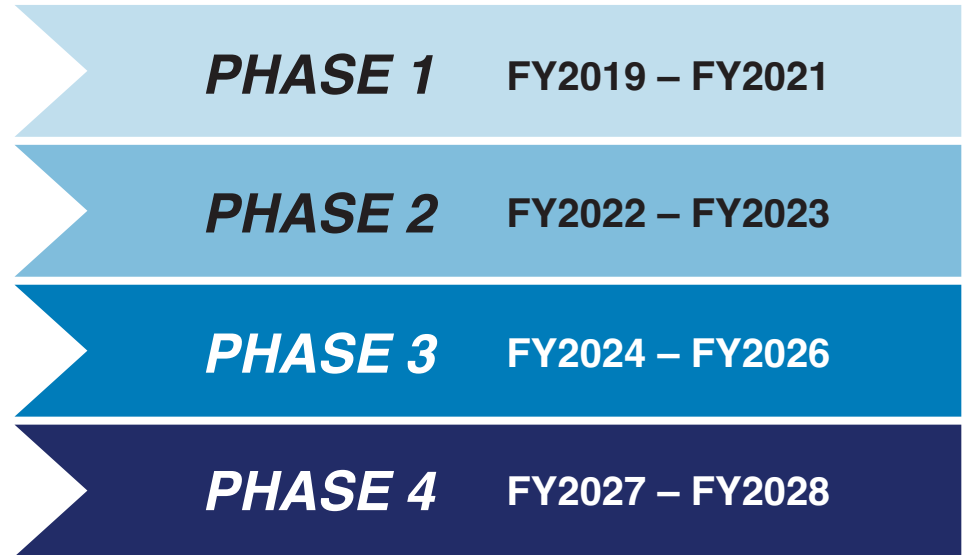
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Next steps to Support Antimicrobial Stewardship in Veterinary Settings during FY 2024 – 2028 (Phase 3 and 4)

Previous efforts are propelling CVM's AMR Strategy forward and CVM is now introducing Phase 3 and 4 actions intended for FY 2024 - 2028.

While a great deal of work was accomplished during Phase 1 and 2 under the initial 5-year plan, those time periods were targets for initiating work and did not necessarily represent the timeline for when actions would be completed.

Key activities planned for Phases 3 and 4 include those that represent a continuation of activities under CVM's initial 5-year plan in FY 2019-2023. Subject to the availability of adequate resources, CVM plans to complete the actions outlined in Phase 3 and 4 over the next five fiscal years. Phase 3 actions are meant to be completed by the end of FY 2026, and Phase 4 actions are meant to be completed by the end of FY 2028. CVM intends to engage stakeholders and the public as we develop and implement the strategies to address individual actions identified.

For continuity, actions included below are organized under the same overarching goals and objectives, and continues the numbering format from the 2019-2023 5-year plan.

PHASE 1	FY2019 – FY2021
PHASE 2	FY2022 – FY2023
PHASE 3	FY2024 – FY2026
PHASE 4	FY2027 – FY2028

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GOAL 1: ALIGN ANTIMICROBIAL DRUG PRODUCT USE WITH THE PRINCIPLES OF ANTIMICROBIAL STEWARDSHIP

Under Goal 1, CVM strives to collaborate with stakeholders to consider the use conditions for approved medically important antimicrobial drug products in animals, develop and implement strategies for ensuring that such products align with antimicrobial stewardship principles, and enhance processes to support new product development.

Objective 1.1: Revise, as necessary, the use conditions for approved, medically important antimicrobials in food-producing animals

It is CVM's role to ensure that antimicrobial drug products are aligned with the principles of antimicrobial stewardship. Under the 2019-2023 plan, CVM published several documents to guide stakeholders to revise the use conditions for a subset of products. This included issuing a final Guidance for Industry (GFI) #263 to bring all dosage forms of medically important antimicrobial drugs approved for use in food-producing animals under the oversight of a licensed veterinarian.

In addition, CVM published a list of medically important antimicrobial drugs administered in the feed of food-producing animals that are approved for indications that lack a defined duration of use, and a concept paper, "Potential Approach for Defining Durations of Use for Medically Important Antimicrobial Drugs Intended for Use in or On Feed" to obtain early input on how animal drug sponsors could voluntarily make changes to the approved conditions of use for certain medically important antimicrobial drugs to establish a defined duration of use for those indications that currently lack a defined duration of use.

Throughout the next 5 years, CVM plans to continue developing and then implement a specific strategy for ensuring that all medically important antimicrobial drugs used in food-producing animals are labeled with a conclusive duration of use.

	Objective 1.1: Revise, as necessary, the use conditions for approved medically important antimicrobials in food-producing animals		
Item	**Action**	**Phase**	**Predecessor**
1.1.7	Finalize guidance to define durations of use for approved medically important antimicrobial drugs fed to food-producing animals.	3	2019-2023 action plan, items 1.1.2 and 1.1.6
1.1.8	Work with affected drug sponsors to voluntarily align their products during implementation of policy that would define durations of use for approved medically important antimicrobial drugs fed to food-producing animals	4	2019-2023 action plan, items 1.1.2 and 1.1.6

Objective 1.2: Develop and implement a strategy for promoting antimicrobial stewardship in companion animals

Under the 2019-2023 plan, CVM made progress toward developing a strategy to promote antimicrobial stewardship in companion animals. CVM issued a request for information to gain insight about the use of antimicrobial drugs in companion animals. CVM through the

implementation of GFI #263 ensured that all dosage forms of medically important antimicrobials for use in companion animals are now under the oversight of a licensed veterinarian.

In the next 5-year plan, using the knowledge gained through the public comment process, CVM plans to continue pursuing a strategy for promoting antimicrobial stewardship in companion animals.

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Objective 1.2: Develop and implement a strategy for promoting antimicrobial stewardship in companion animals			
Item	**Action**	**Phase**	**Predecessor**
1.2.4	Publish CVM's strategy for promoting antimicrobial stewardship in companion animals.	3	2019-2023 action plan, item 1.2.3.

Objective 1.3: Enhance processes to support new product development

To enhance processes to support new product development, as part of the 2019-2023 action plan, CVM led Action 3.3 Group of the Transatlantic Task Force on Antimicrobial Resistance (formerly Action 3.7) to discuss the challenges related to authorization of novel veterinary therapies presented as alternatives to antimicrobials.

In addition, to ensure there is an effective process for assessing antimicrobial resistance concerns as part of the FDA's animal drug approval process, CVM

published draft revised GFI 152, "Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern." The guidance is a tool for assessing the risk of AMR in people that could result from the use of a medically important antimicrobial drug in food-producing animals. The main updates to the guidance include updated ranking criteria for determining the degree of medical importance of antimicrobial drug classes, and a revised ranking of antimicrobial drug classes based on the newly updated ranking criteria (Appendix A).

Objective 1.3: Enhance processes to support new product development			
Item	**Action**	**Phase**	**Predecessor**
1.3.3	Collaborate with stakeholders and international counterparts to encourage the development of alternatives to traditional antimicrobials[16], which may include new regulatory approaches to assessing alternatives to traditional antimicrobial drugs that could spur innovation.	3	2019- 2023 action plan, item 1.3.2
1.3.4	Finalize revised Appendix A of GFI #152 to update the list of medically important antimicrobials.	3	2019- 2023 action plan, item 1.3.1

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[16] Traditional antimicrobial: a drug that is of the same class as, or is known to have a similar mechanism of action to, any drug (regardless of medical importance) listed in Appendix A of GFI #152, "Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern."

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GOAL 2: FOSTER ANTIMICROBIAL STEWARDSHIP IN VETERINARY SETTINGS

To support CVM's mission to safeguard human and animal health, Goal 2 of this plan is aimed at enhancing outreach and education by providing information on antimicrobial stewardship, strengthening CVM compliance programs related to antimicrobial stewardship, and continuing international collaboration in veterinary settings.

Objective 2.1: Support outreach and education by providing information on antimicrobial stewardship

During the 2019-2023 action plan, CVM's focus was on educating affected stakeholders on new Veterinary Feed Directive (VFD) requirements as part of the VFD final rule, and on label changes brought forth by the implementation of GFI #263.

To aid in those efforts, CVM awarded an education and outreach contract to develop information on antimicrobial resistance highlighting the importance of stewardship and veterinary involvement, funded a jointly[17] sponsored conference focused on judicious use and stewardship in dairy cattle, and through collaborations with Vet-LIRN, supported multiple stewardship related grants with Kansas State University, Cornell University, The Ohio State University, and University of Pennsylvania.

Education and outreach are essential for ensuring stakeholder cohesion and accuracy of information on this complex topic. As such, CVM plans to continue providing resources to our stakeholders in the next 5-year plan and beyond.

Objective 2.1: Support outreach and education by providing information on antimicrobial stewardship			
Item	**Action**	**Phase**	**Predecessor**
2.1.4	Continue to support academic institutions and collaborate with federal partners to develop and share educational materials that emphasizes the importance of antimicrobial stewardship in animals.	4	2019-2023 action plan, item 2.1.2

Objective 2.2: Strengthen CVM compliance program activities to support antimicrobial stewardship

Under the previous 5-year plan, CVM expanded its comprehensive VFD compliance strategy to integrate a VFD component into the Drug Residue Inspection Program, first as a pilot alongside drug residue inspections, and then permanently as part of CVM's Comprehensive Animal Food Inspection Program. CVM also began and continues to publish VFD inspection numbers and classifications annually to the FDA-TRACK web site. VFD data on the site currently goes through FY 2022. Since CVM

began conducting VFD inspections (2016), CVM has found 95% of inspected stakeholders in compliance with the VFD rule. This high compliance rate indicates veterinarian involvement in the judicious use of VFD feeds and serves as a signal that education and outreach have been successful.

To continue strengthen antimicrobial stewardship, it is important also to focus compliance activities on ensuring that medically important antimicrobial products are being appropriately marketed (i.e., that marketed products are approved, conditionally approved, or indexed).

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[17] Washington State University and California Department of Food and Agriculture were the collaborators.

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Objective 2.2: Strengthen CVM compliance program activities to support antimicrobial stewardship			
Item	**Action**	**Phase**	**Predecessor**
2.2.4	Continue to address the inappropriate marketing of antimicrobial drugs (e.g., illegal marketing of unapproved animal drugs containing medically important antimicrobials).	3	2019-2023 action plan, item 2.2.3
2.2.5	Collaborate with partners to characterize diseases that are significant drivers for antimicrobial use in animal production settings and identify alternative practices that help reduce reliance on such drugs while addressing animal health needs.	3	2020-2025 NARMS Strategic Plan (SP), objective 4.3

Objective 2.3: Support international outreach and collaboration to foster antimicrobial stewardship in veterinary settings

Given that antimicrobial resistance poses a worldwide animal and public health challenge, it is critical that CVM continue to engage international partners as policies related to antimicrobial stewardship are developed and implemented in the international arena.

Over the past five years, CVM has supported international collaborations in numerous ways. A few highlights include providing technical assistance to FDA's Europe (EU) Office to discuss new EU veterinary medicine regulations, participating in drafting and coordination of agency clearance for a World Organisation for Animal Health One Health Article (published in several languages), participating extensively in Transatlantic Taskforce on Antimicrobial Resistance (TATFAR), and playing a leadership role in the Codex Task Force on AMR to develop a guideline on integrated surveillance of AMR for member countries to utilize for establishing priorities for surveillance along the food chain.

Objective 2.3: Support international outreach and collaboration to foster antimicrobial stewardship in veterinary settings			
Item	**Action**	**Phase**	**Predecessor**
2.3.3	Continue to engage with international organizations to combat antibiotic resistance within a One Health framework.	4	2020-2025 NARMS SP, objective 3.3 and National Action Plan (NAP) to Combat Antibiotic-Resistant Bacteria CARB, action 5.1.2

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GOAL 3: ENHANCE MONITORING OF ANTIMICROBIAL RESISTANCE AND ANTIMICROBIAL DRUG USE IN ANIMALS

To achieve Goal 3, CVM intends to facilitate the development and implementation of a sustainable system for collecting data on AMU, enhance the collection and analysis of antimicrobial resistance data, and improve timely data sharing, analysis, and reporting.

Objective 3.1: Collect and analyze data on antimicrobial drug use in animals

Collecting and analyzing data on antimicrobial drug use in animals remains a critical gap to understand the emergence of antimicrobial resistance and its potential relationship to use of antimicrobials in animals. To bridge this gap, over the past five years CVM pursued multiple strategies to help stimulate the development of AMU data collection efforts in food animals and in companion animals. For example, CVM funded two cooperative agreements for collecting and reporting AMU data in the four major food-producing species. These pilot projects are also developing methodologies to inform development of

long-term antimicrobial use data collection strategies and have published a series of papers in 2020 describing the first few years of data collection (in one issue of the journal, Zoonoses and Public Health). In addition, FDA funds two ongoing cooperative agreements that are piloting AMU data collection methodologies within companion animal veterinary settings. There have been many additional publications resulting from the work of these grantees, all of which are listed on CVM's grants/contracts page.

Most recently, CVM collaborated with the Reagan-Udall Foundation to evaluate the feasibility of developing and maintaining a system to collect and report AMU data in the United States. This work resulted in the publication of a report, "Potential framework for establishing a public-private partnership (PPP) to collect and analyze antimicrobial use (AMU) data from food-producing animals" which outlines the first proposal for how FDA could help establish this new subset of data and will be leveraged in the future to further develop a strategy for collecting AMU data in animals.

Objective 3.1: Collect and analyze data on antimicrobial drug use in animals			
Item	**Action**	**Phase**	**Predecessor**
3.1.4	Develop a long-term strategy for implementing a framework for collecting antimicrobial use data in animals.	3	2019-2023 action plan, item 3.1.3
3.1.5	Complete pilot projects initiated in 2020 that are piloting antimicrobial use data collection methodologies for companion animal veterinary practices.	3	2019-2023 action plan, items 1.2.1 and 3.1.1

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Objective 3.2: Enhance the collection and analysis of antimicrobial resistance data

During the 2019 – 2023 action plan, to enhance the collection and analysis of antimicrobial resistance data, CVM expanded NARMS to characterize resistance in bacteria from additional animal species and commodities where medically important antimicrobials are used. This included the addition of seafood (shrimp, salmon, tilapia) to NARMS and launching a veal pilot study. Results are included in the 2020 NARMS Report.

CVM also worked to improve the understanding of antimicrobial resistance using advanced genomic technologies and bioinformatics for research and surveillance. Whole genome sequencing was leveraged for all isolates of Salmonella and Campylobacter, and most E. coli recovered in the program. Metagenomic[18] studies also were done using 1) animal samples collected by the Food Safety and Inspection Service, 2) environmental waters, in collaboration with EPA, to evaluate antimicrobial resistance in the environment, and 3) for seafood, poultry, pork, and beef to gain a more complete picture of antimicrobial resistance in these commodities.

Advancements made through the FDA-NARMS program have been fundamental to tracking antimicrobial resistance trends. These contributions aid in the pre-approval evaluation of new animal antibiotics, can identify emerging resistance hazards, and can measure interventions aimed at limiting resistance. Looking to FY 2024-2028, CVM intends to continue advancing these initiatives and is seeking opportunities to further utilize resistance data to protect public health.

Objective 3.2: Enhance the collection and analysis of antimicrobial resistance data			
Item	**Action**	**Phase**	**Predecessor**
3.2.6	Complete pilot national survey of surface waters to establish baseline AMR data in aquatic ecosystems within the United States.	3	2020-2025 NARMS SP, objective 1.2
3.2.7	Prioritize laboratory testing for antibiotic resistance (e.g., number of isolates accompanied by test results, number of different specimen sources, specimen types collected) to ensure timely release of resistance data.	4	2020-2025 NAP CARB, action 2.1.1
3.2.8	Enhance Vet-LIRN routine resistance monitoring in select pathogens causing illness in food-producing and companion animals.	4	2020-2025 NARMS SP, objective 1.1 and 2019-2023 action plan, item 3.2.4
3.2.9	Complete an evaluation of the results from the pilot national survey of surface waters and provide an opportunity for stakeholder input on possible approaches for incorporating environmental sampling into the NARMS program.	4	2020-2025 NARMS SP, objective 1.2
3.2.10	Explore AMR testing strategies for animal food.	4	2020-2025 NARMS SP, objective 1.3
3.2.11	Employ genomic and computational technologies to better understand the evolution and spread of resistance among foodborne pathogens.	4	2020-2025 NARMS SP, objectives 2.1, 2.2, 2.3., 2.4 and 2019-2023 action plan, item 3.3.2

[18] Metagenomics refers to methods to determine the total sequence of all DNA present in a complex biological sample. This allows for a comprehensive view of resistance genes in a sample without being limited to cultivatable organisms.

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Objective 3.3: Increase data sharing and reporting to aid in the monitoring of antimicrobial drug use practices and resistance

To achieve this important objective, CVM published a comprehensive report that integrates and analyzes available information about antimicrobial use and resistance in animal agriculture. CVM also increased avenues for data sharing by publishing an interactive summary of biomass-adjusted sales and distribution data in food-producing animals, reported antimicrobial sensitivity profiles based on genomic sequencing following NARMS research, led state and university laboratories that participate in FDA-NARMS to submit genomic data directly to the National Center for Biotechnology Information (NCBI) which accelerated the pace data is able to be shared, and through the use of NARMS-Now updated antimicrobial sensitivity profiles weekly based on genomic sequencing of strains submitted to NCBI.

Not only is data capture and its analysis valuable, CVM is also committed to providing a public platform for such resources. CVM recently created two webpages to empower end users to access this information: 1) FDA Reports & Data Dashboards: Veterinary Antimicrobial Drug Sales, Use, and Resistance and 2) FDA Funded Grants and Contracts Related to Antimicrobial Use and Resistance in Animals. Using these pages, individuals can glean insights into AMR-related reports generated by CVM and also have access to published literature resulting from numerous grants CVM has initiated and will continue to support throughout the next 5-year plan.

Objective 3.3: Increase data sharing and reporting to aid in the monitoring of antimicrobial drug use practices and resistance			
Item	**Action**	**Phase**	**Predecessor**
3.3.5	Improve online data dashboards for timely reporting of microbiological data related to antimicrobial resistance.	3	2020-2025 NARMS SP, objective 3.1
3.3.6	Increase published reports and dashboards on antimicrobial use in animals.	4	2020-2025 NAP CARB, action 2.4.2 and 2019-2023 action plan, item 3.3.4
3.3.7	Increase the number of isolates, panels, and data available and relevant publications in the scientific literature.	4	2020-2025 NAP CARB, action 2.2.1 and 2020-2025 NARMS SP, Goal 1

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Conclusion

The nature of the antimicrobial resistance threat requires that public health officials, medical professionals, pharmaceutical companies, and agriculture industries collaborate to ensure that effective antimicrobials are available in the future for human and animal use. While real progress has been made, continued vigilance and technological advancements are still needed. CVM remains committed to working collaboratively with interested stakeholders as we continue our efforts to mitigate the development of antimicrobial resistance and protect human and animal health.

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