Transforming Animal Health

IN THE U.S. FOR THE 21ST CENTURY

JUNE 2025



REAGAN-UDALL
FOUNDATION
FOR THE FDA



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The Reagan-Udall Foundation for the FDA (the Foundation) is an independent 501(c)(3) created by Congress to advance the mission of the FDA to modernize product development, accelerate innovation, and enhance product safety. The Foundation works to advance regulatory science, support development and dissemination of reliable information, and facilitate engagement and information exchange.

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JUNE 2025

To Members of the Animal Health and Veterinary Sector:

At the request of the Food and Drug Administration's Center for Veterinary Medicine (FDA-CVM), the Reagan-Udall Foundation for the FDA convened a panel of experts to conduct an analysis of the U.S. Animal Health and Veterinary Industry. We, the members of this panel, held numerous conversations with experts and invited written submissions by stakeholders. We ultimately found the current laws and regulatory authorities governing animal health and nutrition antiquated and in need of updating. This report is inherently FDA-centric; however, the interconnectedness of the animal health ecosystem will require multiple government agencies and Congress to remedy system flaws.

In 2025, the Administration aspires to return more innovation and jobs to the U.S., while also tackling the rising prices of everyday goods such as the dairy, meat, fish and eggs Americans consume. This report discusses those important and timely issues within the context of animal health, advocating for measures that will make the U.S. economy more efficient and cost effective in producing food and animal products, through the enhancement of animal health and nutrition.

Many of the recommendations in this report are rooted in the economic reality that outdated laws and regulations are constraining the FDA, other regulators, and U.S. industry, particularly in the food-producing and companion animal sectors. These outdated laws and regulations result in cost and time requirements that may lead global companies to abandon product development or choose to seek product approval in foreign countries rather than the U.S., which limits options for U.S.-based veterinarians. For example, U.S. producers of animal protein are at a competitive disadvantage to their foreign counterparts as foreign entities can leverage innovative therapies and feed ingredients unavailable in the U.S. while also exporting the resulting food to American grocery stores. American farmers, pet owners, and veterinarians—and their animals—suffer as a result of these outdated laws.

Modernizing the ecosystem for animal health requires addressing and updating decades-old laws governing animal drugs, devices, and feed. A possible model for reform is the bipartisan legislation known as the 21st Century Cures Act. That Act, initially implemented in 2017, dramatically improved the human medical product innovation environment through modernization of regulations and improving the expertise of medical product regulatory staff. The animal health regulatory process is in urgent need of a similar updating. Recent realignment of resources at FDA provides an excellent opportunity to assess how to best support the animal health industry and veterinary medicine, so that these sectors increase competitiveness and continue to provide necessary tools for American animal owners.

The presence and engagement of animal health experts at the FDA, and their engagement with industry stakeholders, is essential to implementation of the recommendations contained in this report—and, more importantly, to improving animal health and welfare. With the right infrastructure, enhanced authorities and an engaged ecosystem, the Agency's efforts to protect and promote animal health (via food and therapeutics) can thrive. Americans need timelier and more economical drug and feed additive reviews, faster resolution of animal disease outbreaks, and improved antimicrobial stewardship. Efficient and innovative regulation of the $608 billion animal industry, with its 1.5 million jobs, requires intensive efforts. This report outlines where to direct those efforts.

Our work was enhanced by the valuable insights of many external stakeholders, as well as current and former FDA staff. We thank each of them for their time, commitment, and thoughtful participation. Finally, we express our gratitude to the staff of the Foundation for their work and dedicated efforts in facilitating this project.

These recommendations, if implemented, will be beneficial as we enter the next phase for FDA and its animal health responsibilities.

Sincerely,

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Executive Summary

Animals play an important role in people's lives, and the human-animal bond is dynamic and diverse. Some animals are sources of food and income while others provide companionship. Keeping animals healthy is a critical responsibility, supported by multiple stakeholders, including veterinarians, farmers, pet owners, biopharmaceutical companies, and food/feed companies.

The U.S. Food and Drug Administration (FDA), specifically the FDA's Center for Veterinary Medicine (CVM), is responsible for regulating many products for animal health and nutrition. FDA-CVM works closely with its counterpart agencies within the U.S. Department of Agriculture (USDA), such as the Animal and Plant Health Inspection Service (APHIS), the Center for Veterinary Biologics (CVB), and the Food Safety and Inspection Service (FSIS), as well as others within the U.S. government, such as the Environmental Protection Agency (EPA). FDA-CVM's responsibilities (Figure 2) are many and focus on review and regulation of animal drugs, pet food, and animal feed.

New developments in the field of biomedicine, including new genomic and cellular therapies, present tremendous opportunities for their applications to animal health, welfare and food production, as documented in FDA-CVM's Animal and Veterinary Industry Agenda (AVIA), published in 2023. Given these new innovations, as well as the influence of animal health and its impact on the U.S. economy and food prices, FDA-CVM asked the Reagan-Udall Foundation for the FDA (the Foundation) to conduct an analysis of the animal health and veterinary medicine sectors. The goal was to understand where the current pressure points are and to identify areas for improvement, including areas of responsibilities for FDA-CVM. To conduct this analysis, the Foundation recruited a panel of eight outside experts from academia, industry, and professional associations. This Expert Panel thoroughly evaluated the animal health and veterinary medicine ecosystem and proposed a set of recommendations for FDA and other stakeholders, including other Federal agencies.

These recommendations comprise nine areas:

1. New Authorities
2. FDA-CVM Product Oversight and the Review Process, including Animal Drugs, Animal Food, and Biotechnology, Genetic Modification, and Cell-based Therapies
3. Minor Uses & Minor Species
4. One Health
5. Global Competition and Trade Impacts
6. Emergency Preparedness and Emergency Use Authorization
7. Communication and Collaboration Across Key Agencies and Other Stakeholders
8. Enforcement Gaps and Resulting Market Disincentives
9. Workforce Considerations

Individually and/or collectively, implementation of these recommendations would modernize much of the current animal health framework for veterinary therapeutics and animal food/feed ingredients. It also would facilitate innovation and improve efficiency of the animal health regulatory structure. Furthermore, implementing the recommendations would help correct some of the competitive imbalances faced by U.S. animal producers versus their international counterparts.

The recommendations for changes contained in this report will facilitate modernization of the therapeutic regulatory system governing animal health and welfare, and it will further support the veterinary ecosystem in its broadest scope. This report is inherently FDA-centric; however, the interconnectedness of the animal health ecosystem will require multiple government agencies and Congress to remedy system flaws. By taking these actions, the drug and animal food/feed review process in the U.S. will be more efficient, and U.S. animal producers will be more competitive in the global market. Implementation of these recommendations is crucial for ensuring a robust and responsive regulatory framework that safeguards animal health and supports the sustainability of animal welfare and the veterinary ecosystem.

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I. Introduction

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) regulates animal drugs, products, and animal food/feed[1] to protect human and animal health.

Recognizing the interdependence among animal industries, policymakers, and regulators, FDA-CVM requested the Reagan-Udall Foundation for the FDA (the Foundation) to analyze challenges and unmet needs in the animal health, animal food/feed, food-producing animal, and veterinary industries. In response, the Foundation assembled an Expert Panel to coordinate a comprehensive study of the U.S. animal health and veterinary industries. The Panel identified key challenges and unmet needs and formulated recommendations to overcome existing barriers within the animal health ecosystem. Various information-gathering methods were employed, including roundtable discussions, conversations with FDA-CVM staff, and public comment. The Panel sought input from a diverse range of stakeholders, including representatives from federal, state, and local government agencies, non-governmental organizations, pharmaceutical and animal food industries, and end-users of FDA-regulated products—such as farmers, ranchers, companion animal owners, zoo operators, and veterinarians.

Their analysis also examined how the animal health sectors align with the One Health[2] approach, which seeks to ensure a holistic perspective on the interconnectedness of animal, human, and environmental health. The Panel presents these findings to help the FDA identify areas where regulatory approaches should evolve to accommodate emerging innovations.[3]

The insights gained from this initiative highlight developments that have the potential to benefit the entire animal health and welfare, veterinary, and public health ecosystem.

1 Food/feed, when used throughout this document, refers to nourishment in its various forms provided to animals.

2 U.S. Food and Drug Administration. Cross-cutting Topics: One Health Initiative. www.FDA.gov. Published 2022. Accessed April 2, 2025. https://www.fda.gov/science-research/focus-areas-regulatory-science-report/cross-cutting-topics-one-health-initiative.

3 This report was prepared prior to the March 2025 reorganization announcement.

II. Background

The mission of FDA-CVM is to protect animal and human health throughout the United States.[4] This is achieved through various regulatory authorities, as shown in Figure 1. FDA-CVM functions as a smaller-scale counterpart to other FDA Centers that oversee human products, focusing on regulations related to animals. Consequently, it must stay aligned with the rapid advancements in animal drugs, products, devices, and foods. FDA-CVM is also responsible for ensuring the safety of these products across multiple species, each with its unique conditions and requirements (Figure 2). FDA-CVM launched the Animal and Veterinary Innovation Agenda (AVIA) in 2023 to ensure regulatory processes keep pace with technological advancements in animal health, veterinary medicine, and animal agriculture.[5] The agenda focuses on fostering innovation, streamlining regulatory pathways, and ensuring access to safe and effective animal health products. It aims to build systems that are agile, resilient, and capable of addressing both long-standing challenges, such as endemic diseases, and emerging threats, including novel pathogens or biosecurity risks.

AVIA also intends to ensure that a diverse range of safe and effective animal health products remain available to the animal industry, veterinarians, owners, and caretakers.

4 Center for Veterinary Medicine. CVM Vision and Mission. www.FDA.gov. Published 2023. Accessed February 9, 2025. https://www.fda.gov/about-fda/center-veterinary-medicine/cvm-vision-and-mission.

5 Center for Veterinary Medicine. *Animal and Veterinary Innovation Agenda*. www.FDA.gov. Published September 2023. Accessed February 10, 2025. https://www.fda.gov/animal-veterinary/products/animal-and-veterinary-innovation-agenda.

FIGURE 1. TIMELINE OF KEY FDA-CVM REGULATORY AUTHORITIES[6] AND DOCUMENTS[7,8,9]

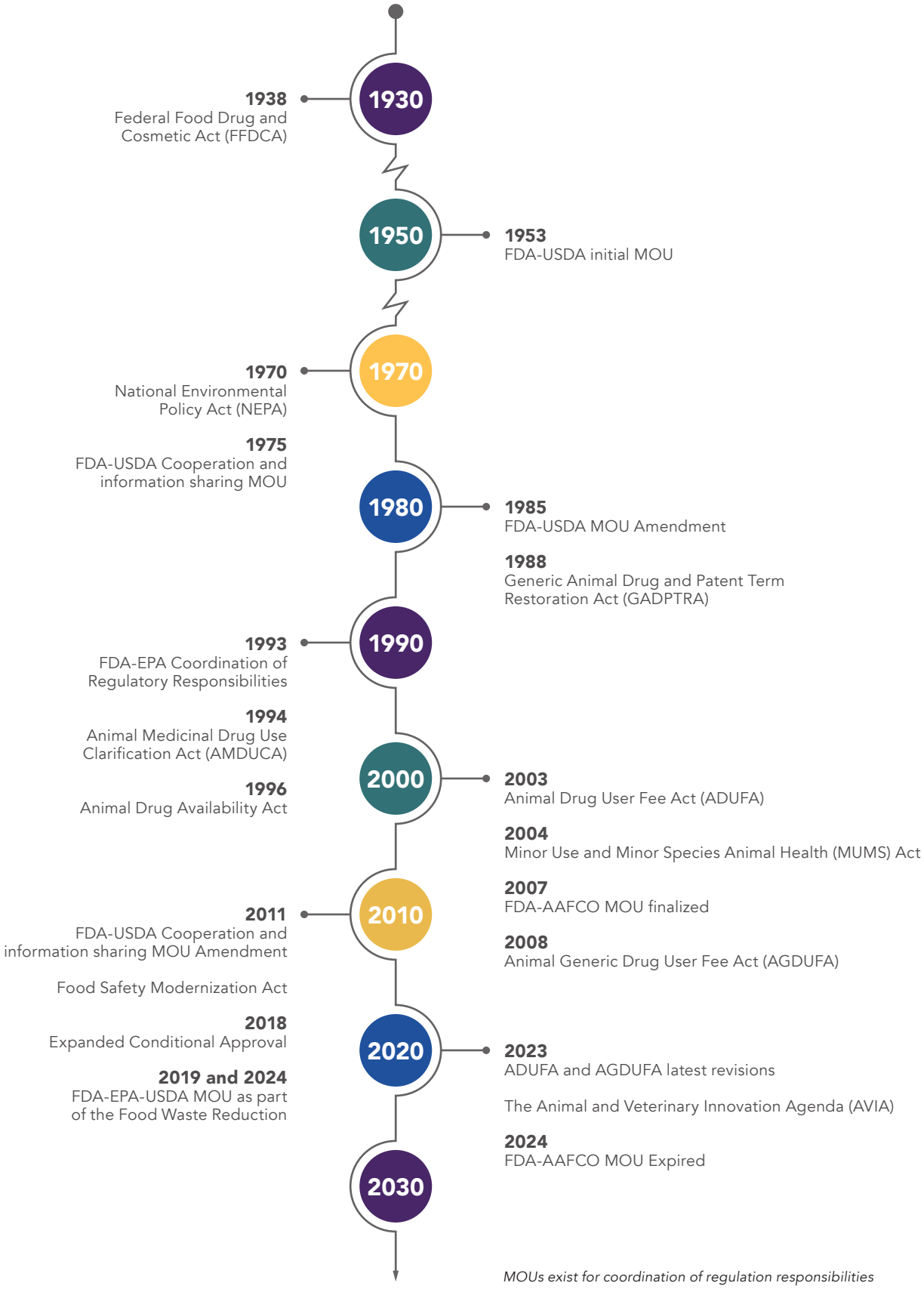
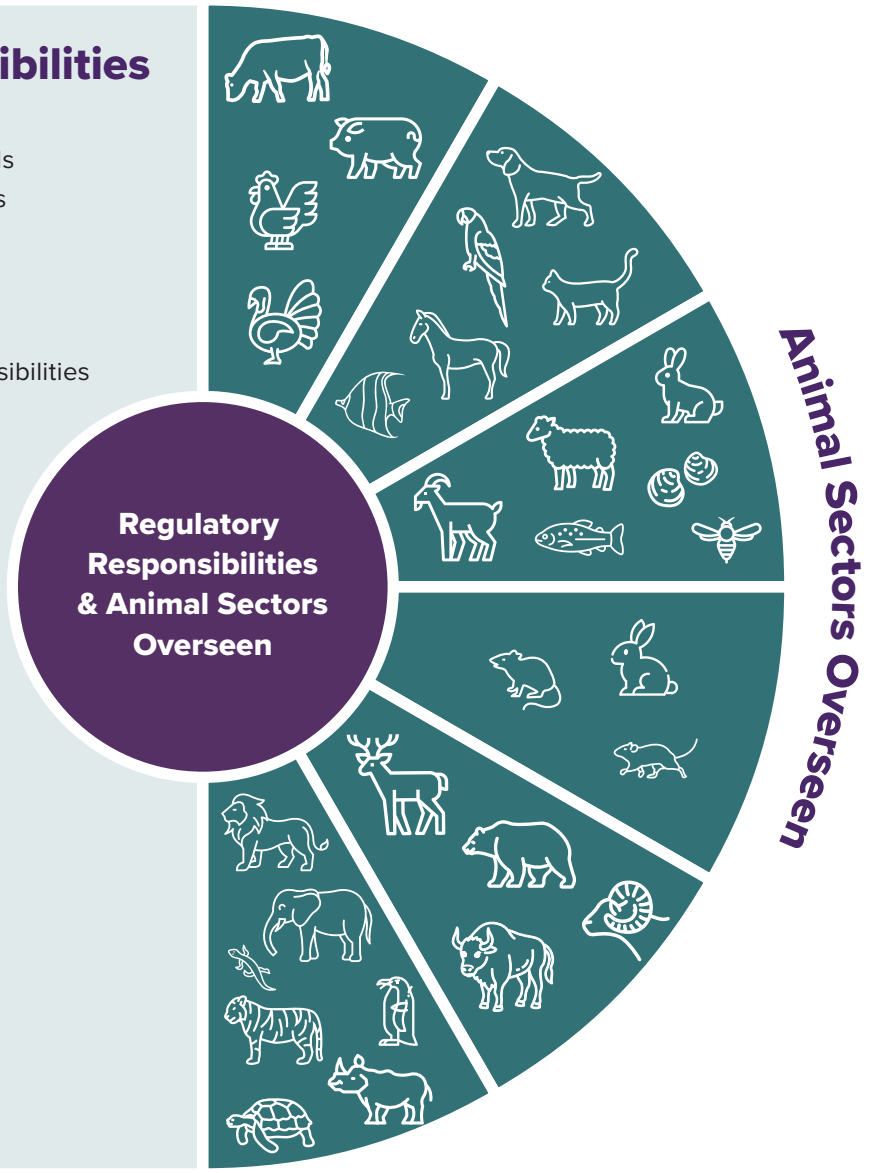


FIGURE 2. FDA-CVM REGULATORY RESPONSIBILITIES AND VARIED SPECIES THAT RELY ON CVM REGULATED PRODUCTS

Regulatory Responsibilities

- Pre-Market Animal Drug Approvals
  - Safety & effectiveness reviews
  - Companion animal drugs
  - Livestock medication safety
  - Manufacturing inspections
- Post-Market Animal Drug Responsibilities
  - Veterinary drug labeling and compliance
  - Drug residue monitoring
  - Post-market surveillance
  - Minor use/minor species guidance
  - Antibiotic use oversight
- Animal Feed and pet food regulation
- Animal Devices (post-market authority only)
- Aquaculture medicine
- Biotechnology and gene editing
- Research for regulatory decisions
- Veterinary research support



Facilities Registered with FDA-CVM (all figures approximate)

- 51,800 animal food facilities domestically.
- 19,000 global (foreign) animal food facilities
- 2,952 animal device firms
- 700 GMP domestic and foreign drug facilities
- Numerous unapproved drug manufacturers including compounding pharmacy facilities not following CVM GFI #256*

* Center for Veterinary Medicine. CVM GFI #256 – Compounding Animal Drugs from Bulk Drug Substances. www.FDA.gov. Published August 10, 2022. Accessed April 15, 2025. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-256-compounding-animal-drugs-bulk-drug-substances.

Two regulatory pathways exist for the approval of new products as outlined by the 1996 Animal Drug Availability Act (ADAA)[10] amendment to the Federal Food, Drug, and Cosmetic Act (FFDCA): 1) approval as a drug,[11] (Appendix G) or 2) approval as a food or feed additive[12] (Appendix H).

The Food Safety Modernization Act (FSMA)[13] expanded FDA's authority and responsibilities in ensuring the safety of animal food. FSMA expanded FDA-CVM's regulatory oversight by making preventive food safety measures mandatory, increasing inspection expectations, and strengthening compliance enforcement for the animal food industry. The FDA must ensure that domestic and international animal food producers meet high safety standards, reducing risks for animals and humans in the food supply chain.

Numerous U.S. agencies and regulatory bodies govern animal health, veterinary practice, animal feeds, and food for companion animals (Figure 3). These agencies and organizations help maintain a safe and healthy environment for animals, support the veterinary industry, and ensure that the animal food/feed industry adheres to strict safety and quality standards. Products under the purview of each authority are listed in Table 1. This comprehensive regulatory landscape secures safety and quality across animal health and related industries, and it sets the stage for a cooperative approach that bridges the gaps between animal, human, and environmental health.

The One Health[14] strategy is an integrated, unifying approach that recognizes the interconnectedness of animal, human, and environmental health. It emphasizes collaboration across multiple disciplines—including veterinary medicine, human medicine, agricultural production, environmental science, and public policy—to address health challenges and develop solutions for shared health concerns.

Regulatory actions have a significant impact on the financial stability and overall well-being of the animal health industry, affecting the health and welfare of all animals. Furthermore, prioritizing and enhancing research investments across the ecosystem will positively impact animal health.

The animal health industry generates a cumulative economic benefit of $608.1 billion, which includes 1.5 million jobs contributing $74.5 billion in wages, while maintaining the health of approximately 10 billion companion and food-producing animals nationwide.[15]

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6 Center for Veterinary Medicine. Guidance & Regulations. www.FDA.gov. Published April 14, 2023. Accessed April 2, 2025. https://www.fda.gov/animal-veterinary/guidance-regulations.

7 MOUs exist for coordination of regulation responsibilities.

8 U.S. Food and Drug Administration. Domestic MOUs. www.FDA.gov. Published 2024. Accessed April 2, 2025. https://www.fda.gov/about-fda/fda-memoranda-understanding/domestic-mous.

9 Center for Veterinary Medicine. *Animal and Veterinary Innovation Agenda*. www.FDA.gov. Published September 2023. Accessed February 10, 2025. https://www.fda.gov/animal-veterinary/products/animal-and-veterinary-innovation-agenda.

10 The Animal Drug Availability Act (H.R. 2508). Center for Veterinary Medicine. Animal Drug Availability Act of 1996. www.FDA.gov. Published April 22, 2022. Accessed February 9, 2025. https://www.fda.gov/animal-veterinary/guidance-regulations/animal-drug-availability-act-1996.

11 FFDCA defines the term "drugs" to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." (See Section 201(g)(1)(B) & (C) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321(g)(1)(B) & (C)].).

12 Provision of the ADAA that defines how drugs can be used in animal feed; feed additives are regulated under the FFDCA as products affecting animal nutrition but not intended to treat, cure, or prevent disease.

13 U.S. Food and Drug Administration. Food Safety Modernization Act (FSMA). www.FDA.gov. Published May 2, 2024. Accessed April 2, 2025. https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma.

14 U.S. Food and Drug Administration. Cross-cutting Topics: One Health Initiative. www.FDA.gov. Published 2022. Accessed April 2, 2025. https://www.fda.gov/science-research/focus-areas-regulatory-science-report/cross-cutting-topics-one-health-initiative.

15 Pham ND, Donovan M. The Economic and Social Contributions of the Animal Health Industry. ndpanalytics.com. Published December 2022. Accessed February 10, 2025. https://ndpanalytics.com/the-economic-and-social-impact-of-the-animal-health-industry/.

TABLE 1. PRODUCT OVERSIGHT[16,17]

PRODUCT	AUTHORITY
Drugs/Pharmaceuticals	FDA-CVM, DEA (controlled substances)
Nutritional products[18]	FDA-CVM
Vaccines	USDA-CVB
Diagnostics	USDA-CVB
Animal devices	FDA-CVM
Cell and tissue-based products, including intentional genomic alterations (FDA-CVM only)	FDA-CVM or USDA-CVB depending on the primary mechanism of action
Ectoparasitics	FDA-CVM, EPA (topical products)

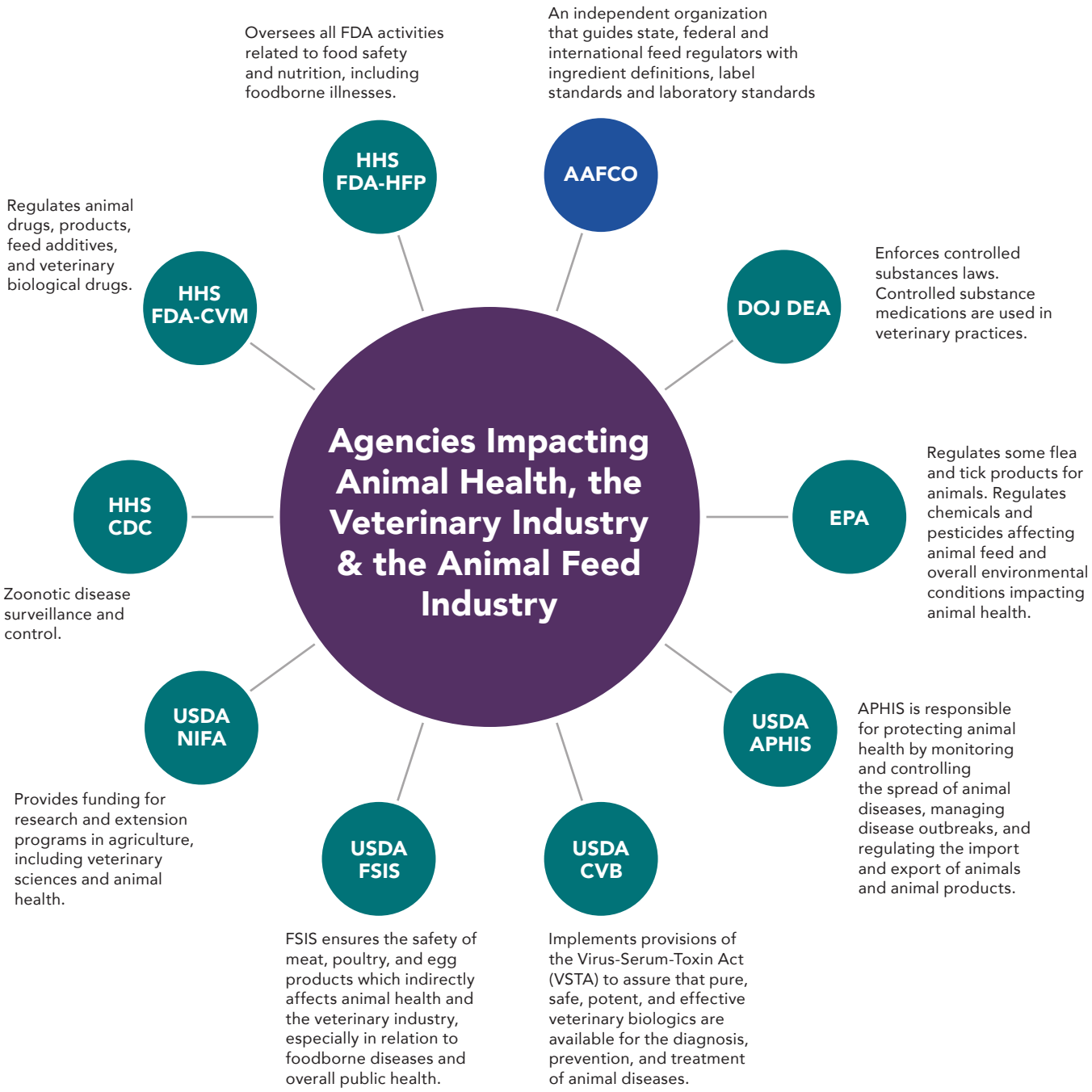
* See glossary (Appendix B) for abbreviations and definitions.

16 U.S. Department of Agriculture, U.S. Food and Drug Administration, Environmental Protection Agency. About the Coordinated Framework. Unified Website for Biotechnology Regulation. Published 2017. Accessed April 2, 2025. https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/about.

17 U.S. Food and Drug Administration. FDA's Role in Protecting Animal Health. www.FDA.gov. Published June 5, 2024. Accessed April 2, 2025. https://www.fda.gov/animal-veterinary/animal-health-literacy/fdas-role-protecting-animal-health.

18 Association of American Feed Control Officials (AAFCO), not a federal agency, also plays a role in regulating animal feed at the state level.

FIGURE 3. AGENCIES IMPACTING THE ANIMAL HEALTH ECOSYSTEM[19,20]



* See glossary (Appendix B) for abbreviations and definitions

The Panel considered numerous issues throughout the project. This report focuses on the challenges encountered by individuals working within the animal ecosystem, as identified by various stakeholders and prioritized by the Expert Panel.

19 U.S. Food and Drug Administration. FDA's Role in Protecting Animal Health. www.FDA.gov. Published June 5, 2024. Accessed April 2, 2025. https://www.fda.gov/animal-veterinary/animal-health-literacy/fdas-role-protecting-animal-health.

20 U.S. Department of Agriculture. Animals. www.usda.gov. Published February 3, 2025. Accessed April 2, 2025. https://www.usda.gov/animals.

III. Recommendations

A. AUTHORITIES: DEFINING ANIMAL DRUGS AND ANIMAL FOOD

The FDA lacks the necessary flexibility needed to keep pace with innovation and modernization in the animal health industry. Regulatory frameworks should not hinder innovation, but instead encourage, facilitate, and support industry advancements that address current needs in animal agriculture and veterinary medicine. To address this, the FDA requires updated authorities, oversight tools, and legislative changes to reform the regulatory frameworks under which it operates.

Observations & Challenges

FDA-CVM currently reviews two classes of products: drugs and food.[21] Current review pathways are limited to those depicted in Appendices G and H. The ADAA reflected the veterinary and regulatory environment at the time it was enacted. However, almost 30 years later, the ADAA lacks the flexibility and frameworks needed to keep pace with innovation and modernization of the animal health industry. Issues such as antimicrobial resistance, gene editing, and emerging diseases require updated oversight tools and legislation that modify the regulatory frameworks under which FDA operates. Products emerging from advancements in biotechnology and nutrition, particularly those that support nutrition as a form of medicine, do not easily conform to these two classifications.

Further, the two existing classifications have some overlap that limits innovation. Current law defines animal drugs as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals."[22] As currently interpreted, this definition limits FDA's options to classify some substances as food ingredients rather than as drugs, diminishing the potential role of food in animal health.

Recommendations

1. The U.S. Congress should modernize the regulatory pathways for animal health products, via a "21st Century Cures Act" approach, to create clearer, more efficient, and more flexible pathways to encourage the introduction of innovative products while ensuring safety for both animals and humans. Features of this legislation should include dynamic pathways that address:
   - Minor Use/Minor Species (MUMS) modernization
   - Biotechnology (e.g., gene-editing, cellular therapies)
   - Food additives and zootechnical animal food substances (ZAFS)
   - Consideration of regulatory data and approvals from nations with trusted regulatory systems
2. Congress should provide FDA more flexibility to interpret the definitions of a drug and food, allowing more products to be regulated as animal food ingredients rather than as drugs. Legislation should create new categories of food additives to keep pace with scientific advancements.

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21 FDA-CVM also regulates an additional class of product—animal devices—but only has postmarket authority. FDA-CVM does not have pre-market review authority over animal devices.

22 Section 201(g)(1)(B) & (C) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321(g)(1)(B) & (C)].

Discussion

The 21st Century Cures Act[23] was a seminal piece of legislation that sought to overhaul human drug development in the United States. Addressing a number of critical topics, the Act was designed to help accelerate medical product development and bring new innovations to patients faster and more efficiently. Legislation with similar approach and intent is needed to overhaul how animal health and food products are regulated by the FDA. The FFDCA currently defines drugs using the same criteria for both human and animal use, leading to a rigid interpretation that overlooks the fundamental differences between human and animal therapeutics, as well as the development of innovative products that influence animal physiology without being intended for disease treatment. The FDA requires greater regulatory flexibility in distinguishing between drugs and food for animals, allowing more products to be classified as animal food ingredients instead of drugs.

The existing distinction between drugs and animal food ingredients stifles innovation. The current definition of an animal drug includes certain animal food ingredients, forcing the FDA to classify some ingredients as new animal drugs, while other countries have regulatory authorities that allow greater flexibility in categorizing products as food ingredients.

Consequently, when companies realize that the FDA will evaluate their novel food ingredient as a drug, many opt out of the FDA drug review process due to its lengthy, complex, and costly nature and only seek approvals in other countries. As a result, animals and animal producers in the U.S. do not benefit from innovations that are readily available to their counterparts in other countries. This in turn reduces economic opportunities for U.S.-based producers.

Until new pathways are established by Congress, FDA should continue to exercise the most flexibility possible within its current authority, adopting a more progressive approach to classify new products as food ingredients. Furthermore, new authorities, as discussed in this section, would greatly expand available flexibilities.

B. FDA-CVM PRODUCT OVERSIGHT AND THE REVIEW PROCESS

ANIMAL DRUGS & OVERALL PRODUCT DEVELOPMENT
Observations & Challenges

Many animal sectors have been battling the same diseases for years, and in some cases, decades, without significant advances in prevention or treatment options. This situation is particularly concerning in the realm of food-producing animals.

The drug review process for new veterinary medications has been described as out-of-date, onerous, very slow, unpredictable, overly risk-averse, and expensive. Some stakeholders perceive FDA's processes as slower and less predictable compared to other global regulators. However, there are also examples of FDA approvals that have been given first. The Panel recognizes that current review pathways are ripe for modernization, which would speed innovation and economic progress, as well as improve animal health in the 21st century.

Although not a requirement, at times FDA will recommend the submission of raw data for study protocol concurrence, which is routinely interpreted as compelling submission. Technically, the raw data must be collected and available and submitted only upon request. The collection of raw data is unique to the FDA and

23 U.S. Food and Drug Administration. 21st Century Cures Act. www.FDA.gov. Published 2020. Accessed April 2, 2025. https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/21st-century-cures-act.

is resource-intensive for both the sponsor and FDA. While helping to provide the agency with information supporting sound regulatory review, the FDA's expectations for raw data availability—encompassing study related materials (e.g., emails, handwritten documents, and temperature logs)—results in substantial administrative overhead for sponsors. For companies seeking product approval in multiple countries or jurisdictions, repackaging the data adds time and cost to meet different regulatory requirements. In contrast, other global regulators typically rely on aggregated data, requesting raw data only on a selective basis. This option of submitting aggregated data could provide regulatory flexibility in the U.S. Recent FDA-CVM guidance[24] permits companies to suggest which raw data to submit, which is helpful. Further, manufacturers report that high costs, prolonged timelines, and regulatory unpredictability disproportionately affect smaller companies, restricting their capacity to compete and invest in new technologies.

Stakeholders noted there are opportunities for the FDA to adjust the level of acceptable risk in the approval process. FDA-CVM's mission requires risk-based decision making, which is complicated by the breadth of animal species within their scope. The difference in species can lead to varying data needs resulting in perceived unpredictability of the review process. As noted above, from the industry perspective, FDA-CVM frequently asks for more data, particularly concerning risk, rendering a perception that the process is "risk-averse" rather than "risk-based." FDA and stakeholders should explore ways to establish acceptable levels of risk: particularly in areas like minor species or unmet needs, where balancing safety and effectiveness should be the ultimate goal.

Significant concern has also been expressed regarding the perceived lack of ongoing communication between FDA and the veterinary profession, animal sector organizations, and allied industries, especially around alignment of product development priorities. While CVM regularly communicates with veterinary, animal sector, and industry partners, the different animal sectors vary greatly in their approaches to coordination and organization within their own stakeholder communities. One advantage of increased communication would be to explore further areas of unmet needs. At present, product development and stakeholder discussions are disproportionately (and somewhat logically) focused on regulated products applicable to major species which are seen as more economically viable in the U.S., rather than addressing the needs of veterinarians for the enhancement of animal health and welfare. As a result, certain species are being overlooked because of limited return on investment. The high cost of bringing a product tailored for minor species to market, when combined with limited anticipated revenues, often fails to interest drug developers. This creates gaps in therapeutic options for less commercially attractive species (See Appendix F: Animal Health Threats). More dialogue between FDA, the veterinary sector and the biopharmaceutical industry could help address issues raised such as certain species or diseases being overlooked or having insufficient prioritization across the system.

"...[we] need to reevaluate the approval process for a number of the regulated [products], whether that's a feed additive or drug or what have you, that FDA has purview over. Time to getting those to market is critically important..." "...being able to turn around tools that will help us with the health and welfare of our animals is really, really important."

—Stakeholder

24 Guidance # 287 – Raw Data for Safety and Effectiveness Studies. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-287-raw-data-safety-and-effectiveness-studies.

Recommendations

3. FDA should implement a structured risk-benefit assessment framework in the new animal drug review process. This framework should facilitate flexibility, balance considerations of benefits and risks, be consistent and systematic in regulatory decision-making approaches, and establish clear communication pathways for revealing benefits and risks associated with new animal drugs.
4. FDA should provide clear thresholds for achieving protocol concurrence and well-defined endpoints required for efficacy and safety evaluations to improve predictability in the drug approval process.
5. FDA should reduce data burden requirements by more consistently allowing the submission of aggregate, rather than raw, data.
6. FDA should implement a "Stop-the-Clock" program modeled after the European Union (EU) approach that allows drug sponsors to address deficiencies identified in technical section submissions mid-cycle without restarting the review timeline.
7. FDA should track and report on additional outcome-driven metrics—such as first-cycle reviews, total review time per technical section, and amendment frequency—to more meaningfully assess the efficiency of the drug review process. FDA should use these metrics to establish a baseline, assess trends over time, and evaluate impacts of process optimization efforts.
8. FDA should explore mechanisms to utilize small ad hoc panels of nonagency experts who can provide additional perspectives and expertise, and resolve complex or contentious issues, during the review process.
9. FDA should increase its utilization of mathematical modeling and simulation approaches, such as physiologically based pharmacokinetic (PBPK) and population pharmacokinetic (PopPK) models, to streamline FDA approvals of veterinary drugs.
10. FDA should improve the functionality of the adverse event database for animal drugs and devices.

Discussion

The U.S. review process for animal drugs, including cell and gene therapies, is perceived as lengthy and unpredictable, which results in significant economic consequences and hinders the introduction of innovative products to the U.S. market. This perception may deter some U.S. and global companies because of high costs and regulatory uncertainty. Components of the review process (e.g., risk aversion, challenges with attaining protocol concurrence, data requirements, length of time to approval) add significant overhead costs and time investments for the sponsor. The FDA and Congress should pursue regulatory and statutory changes that allow streamlining of data requirements; however, this should not deter FDA from using as much discretion as possible under its current regulatory authorities to accept aggregate data. The current process disproportionately burdens smaller companies, which struggle to compete and invest in advancing new technologies under the existing system.

Improving predictability in regulatory timelines, alleviating burdens associated with routine edits, and implementing provisional approvals could significantly accelerate innovation while upholding safety standards.

RISK-BENEFIT ASSESSMENT FRAMEWORK. In creating a new animal drug review process with a structured risk-benefit assessment framework, FDA-CVM could draw from 14 Section 905 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Public Law 112–144), which is used by the FDA Center for

Drug Evaluation and Research (CDER) to evaluate human drug safety. This risk-benefit assessment framework should recognize, however, that safety risks are different between animal and human medicine.[25] Such a framework is needed for all animal drug products and could be initiated by FDA or mandated by Congress.

REVIEW PROCESSES. Slow approvals hinder veterinarians' access to new therapies, and U.S. farmers often suffer production or mortality losses because of the unavailability of treatments accessible elsewhere. This not only undermines economic viability but also increases risk of zoonotic disease transmission and poses risks to global health and food security under One Health principles.

To enhance decision-making, the FDA should use external expert panels, similar to those employed by CDER and the Center for Devices and Radiological Health (CDRH), incorporating diverse perspectives from clinicians and researchers outside the federal government.[26] This program enhances FDA's ability to make timely, informed decisions by supplementing internal knowledge with external perspectives, especially in rapidly evolving or highly specialized fields.

The purpose of the "Stop-the-Clock" program, modeled after the EU process,[27] is to reduce delays in approvals related to iterative review cycles, particularly for key technical sections, and to increase first-cycle review approvals. This initiative should become a routine aspect of the review process rather than being used as a discretionary tool.

Outcome-based metrics, such as first-cycle review rates, review duration by technical section, and amendment frequency, should be used to benchmark performance and guide improvement. These metrics need not be tied to the Animal Drug User Fee Act (ADUFA) but should inform broader efforts to optimize the review system.

REVIEW PRIORITIES. Investment in animal health products often follows profitability, not need—especially for minor species—leaving therapeutic gaps unaddressed (Appendix F). Without systemic reform and appropriate incentives, companies will remain hesitant to pursue U.S. approval for promising technologies.

There is opportunity for increased communication between the FDA and the veterinary profession, animal sector organizations, and allied industries, particularly regarding the alignment of priorities. Current engagement skews toward sponsors of economically viable products, which overlooks vital input from veterinarians and producers. Establishing regular dialogue with these groups is essential to ensure that the FDA remains informed about the immediate needs of different animal sectors. This communication will help identify therapeutic gaps that impact animal health and well-being, as well as economic productivity.

MODELING AND SIMULATION. Computational models offer promising alternatives to animal studies and can support the expansion of label claims. For example, models could facilitate the inclusion of small ruminant species on a product label originally approved for cattle, or justify updating dosage recommendations for older products where original doses are no longer effective—such as penicillin formulations used in dairy cattle.

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25 14 Section 905 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Public Law 112-144), amends section 505(d) of the FD&C Act by requiring FDA to: implement a structured risk-benefit assessment framework in the new drug approval process to facilitate the balanced consideration of benefits and risks, a consistent and systematic approach to the discussion and regulatory decision-making, and the communication of the benefits and risks of new drugs.

26 Center for Devices and Radiological Health. Network of Experts Program: Connecting the FDA with External Expertise. www.FDA.gov. Published October 14, 2022. Accessed April 15, 2025. https://www.fda.gov/about-fda/center-devices-and-radiological-health/network-experts-program-connecting-fda-external-expertise.

27 European Medicines Agency. The Evaluation of medicines, step-by-step | European Medicines Agency. www.ema.europa.eu. Published July 31, 2024. Accessed April 2, 2025. https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/evaluation-medicines-step-step.

Physiologically based pharmacokinetic (PBPK) and population pharmacokinetic (PopPK) models are well supported in human drug regulation by the FDA, EPA, European Medicines Agency (EMA), World Health Organization (WHO) and Organisation for Economic Co-operation and Development (OECD), yet veterinary specific guidance remains lacking.[28,29,30,31,32,33,34]

In veterinary medicine, PBPK models have proven useful for predicting pharmacokinetics and estimating extralabel drug withdrawal times across various species. These models can potentially supplement—or even replace—studies traditionally required to support label modifications. However, regulatory guidance on the use of PBPK and other pharmacometric models in veterinary species is currently lacking. To align veterinary regulatory science with advancements in human medicine, the FDA should increase the adoption of mathematical modeling approaches—particularly PBPK—and take the lead in developing guidance on the design, validation, and application of these models in veterinary contexts. In addition, the FDA should continue to explore and support the integration of artificial intelligence (AI) to enhance animal health and welfare.[35] As computational and data-driven tools continue to evolve, their integration into regulatory science could improve efficiency, reduce the need for live animal testing, and promote evidence-based decisions that benefit both animals and public health.

DATABASES. Roundtable participants appreciated access to the adverse event database for animal drugs and devices but expressed significant frustration with its usability. They noted that the platform is difficult to navigate—especially for users without coding experience—and emphasized the need for a more intuitive, searchable interface. Functionality is also needed to allow users to easily search Animal Drugs@FDA by species.

ANIMAL FOOD
Observations & Challenges

The animal health industry is seeking innovative animal food/feed solutions to enhance animal health. However, current definitions create challenges in regulating these innovative products. Zootechnical animal food substances (ZAFS), for example, affect the structure or function of an animal through a means other than nutrition. This category of food ingredients positively impacts animal health and performance by acting within the gastrointestinal tract. These substances differ from traditional drugs and potentially necessitate a distinct

28 European Medicines Agency (EMA). *Committee for Medicinal Products for Human Use (CHMP) Guideline on the Reporting of Physiologically Based Pharmacokinetic (PBPK) Modelling and Simulation*. EMA; 2018. Accessed April 15, 2025. https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-reporting-physiologically-based-pharmacokinetic-pbpk-modelling-and-simulation_en.pdf.

29 Center for Drug Evaluation and Research (CDER). Physiologically Based Pharmacokinetic Analyses—Format and Content Guidance for Industry. www.FDA.gov. Published January 26, 2021. Accessed April 15, 2025. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/physiologically-based-pharmacokinetic-analyses-format-and-content-guidance-industry.

30 Center for Drug Evaluation and Research (CDER). The Use of Physiologically Based Pharmacokinetic Analysess—Biopharmaceutics Applications for Oral Drug Product Development, Manufacturing Changes, and Controls. www.FDA.gov. Published September 30, 2020. Accessed April 15, 2025. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-physiologically-based-pharmacokinetic-analyses-biopharmaceutics-applications-oral-drug-product.

31 Center for Drug Evaluation and Research (CDER). Population Pharmacokinetics. www.fda.gov. Published February 3, 2022. Accessed April 15, 2025. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/population-pharmacokinetics.

32 Environmental Protection Agency. Approaches for the Application of Physiologically Based Pharmacokinetic (PBPK) Models and Supporting Data in Risk Assessment (Final Report) | Science Inventory | US EPA. www.EPA.gov. Published 2017. Accessed April 15, 2025. https://cfpub.epa.gov/si/si_public_record_Report.cfm?Lab=NCEA&dirEntryID=157668.

33 WHO, 2010. Characterization and application of physiologically based pharmacokinetic models in risk assessment. World Health Organization, IPCS harmonization project document no. 9. Available at: https://www.who.int/publications/i/item/9789241500906.

34 OECD, 2021. Guidance document on the characterisation, validation and reporting of Physiologically Based Kinetic (PBK) models for regulatory purposes. and Organisation for Economic Co-operation and Development. Available at: https://www.oecd.org/en/publications/guidance-document-on-the-characterisation-validation-and-reporting-of-physiologically-based-kinetic-pbk-models-for-regulatory-purposes_d0de241f-en.html.

35 U.S. Food and Drug Administration. Considerations for the Use of Artificial Intelligence. www.fda.gov. Published January 2025. Accessed April 18, 2025. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-use-artificial-intelligence-support-regulatory-decision-making-drug-and-biological.

regulatory pathway. Current animal food regulations, however, limit companies' claims to basic attributes of taste, aroma and nutritive value of the food, and they prohibit "health-related claims." Health claims, such as those attributed to ZAFS, would trigger classification as a drug.

Food/feed can impact animal health and performance through nutritional or other additive ingredients. Under FDA's current regulatory approach based on statute, case law and policy, companies that manufacture animal food/feed are prohibited from making performance and certain health-related claims. Such claims would trigger classification as a drug.

Further, U.S. regulatory approaches for animal food/feed ingredients differ significantly from major U.S. trading partners (Appendix H). The FDA faces challenges in adapting its current frameworks to accommodate non-nutritive enhancements for food/feed additives that are intended to improve animal performance (e.g., weight gain, food/feed conversion), and claims related to behavioral changes, stress reduction, or welfare improvements in animals. According to current U.S. law and regulation, these claims often require the ingredient to be evaluated as a drug, which is a complicated, expensive, and time-consuming process that serves as a disincentive for sponsors seeking regulatory approval of their product in the United States. Often, these same non-nutritive ingredients can be approved in other countries or jurisdictions in significantly less time and at a lower overall cost to the sponsor.

For example, environmental claims for food/feed ingredients, such as those related to methane reduction or improving sustainability in livestock production, often face regulatory challenges because of the lack of a dedicated functional category for such claims. The absence of a defined category for "non-nutritive" additives within U.S. regulations limit innovative products from reaching the U.S. market. In the EU, Canada, Australia, and New Zealand, environmental benefit claims are typically incorporated within existing food/feed additive frameworks rather than being subject to drug-level regulatory scrutiny. This approach enables animal producers in those countries to adopt innovative products more readily. Notably, these foreign producers are permitted to export their animal products to the United States. As a result, any regulatory protections stemming from the more stringent U.S. requirements apply only to users of domestically produced animal products—placing U.S. producers at a competitive disadvantage compared to their foreign counterparts.

For products that more clearly fall under the definition of food/feed, manufacturers have three pathways for food/feed ingredient reviews in the United States (Appendix H). However, these review processes can take several years to complete, and manufacturers often face uncertainty about which pathway is most appropriate for their product. Additional factors, such as publication of efficacy data in peer-reviewed journals, and the need for species-specific data, further contribute to delays in bringing new ingredients to market.

Recognizing these challenges, the FDA has taken steps to improve its processes by encouraging pre-submission consultations and, in August 2024, issued a request for comments to gather input on potential process improvements.[36] These efforts are a positive step toward clarifying regulatory expectations and identifying opportunities to enhance the efficiency and predictability of the review system.

When considering animal food and feed ingredients, it is essential to account for the broader regulatory landscape, which extends beyond federal oversight to include varying state-level requirements. Many states mandate their own premarket label reviews, requiring manufacturers to submit separate regulatory packages across multiple jurisdictions. These requirements are not standardized, resulting in a fragmented and

36 Department of Health and Human Services, U.S. Food and Drug Administration. Pre-Market Animal Food Ingredient Review Programs; Request for Comments. www.federalregister.gov. Published August 9, 2024. Accessed April 2, 2025. https://www.federalregister.gov/documents/2024/08/09/2024-17779/pre-market-animal-food-ingredient-review-programs-request-for-comments.

inconsistent patchwork of state-level reviews and differing acceptance criteria for animal food/feed ingredients. The lack of harmonization creates a complex, resource-intensive regulatory environment that slows innovation and discourages manufacturers from bringing new products to market efficiently.

Recommendations

11 FDA should expedite ongoing efforts to clarify the most appropriate review pathways for various types of ingredients and streamline processes, where possible, to minimize delays in introducing new ingredients. New regulatory pathways are needed to accommodate zootechnical animal food substances (ZAFS) that affect the structure or function of an animal through a means other than nutrition and that will allow manufacturers to claim health and other benefits of these food/feed formulations. (see also Recommendation 1.)

12 FDA should secure the necessary expertise to review novel food ingredients (e.g., cell-cultured meat and insect-based proteins) and provide clear guidance on review requirements.

13 Congress and the states should work to harmonize the current patchwork of state requirements for labeling and ingredient safety reviews, with an ultimate goal of establishing a uniform federal framework for these activities.

14 FDA should continue to participate in and encourage global harmonization efforts to improve the efficiency of food/feed ingredient development and regulation. FDA should also maintain collaboration with international bodies such as Codex Alimentarius and the World Organisation for Animal Health (WOAH) to participate in the development of harmonized standards for food/feed ingredients.

Discussion

Feed ingredient and pet food companies currently invest millions of dollars in research on food ingredients for animals. They publish results in peer-reviewed journals and present their findings at scientific conferences. Yet, current laws restrict what claims they can make about their findings. For example, instead of acknowledging the biological effects of their products, some companies are limited to vague statements that their products "support normal immune function," even when their research shows specific systemic impacts on inflammatory cytokines. This restriction on labeling disincentivizes investment in cutting-edge nutritional science, preventing innovative products from reaching the market.

New regulatory pathways are needed to deem ZAFS and similar products as food ingredients distinct from drugs.[37] Current regulations create significant challenges for innovating and commercializing functional nutrition products for both production and companion animals. A key concern is that innovations, such as ZAFS, are treated under the same regulatory framework as drugs, creating challenges for manufacturers. Without regulatory approval, they cannot communicate legitimate benefits of feed ingredients and functional pet foods to animal owners. Further, such food/feed ingredients regulated as drugs will require additional labeling appropriate for drugs rather than food. This in turn can be confusing to purchasers, such as pet owners and farmers. In addition, the National Research Council guidelines on nutrient requirements of dogs and cats haven't been updated since 2006,[38] and therefore do not include ZAFS or other innovative products that may benefit companion animals.

37 FDA FY 2025 Legislative Agenda. Supporting Innovation: Regulate Certain Articles as Zootechnical Animal Food Substances. https://www.fda.gov/media/176924/download.

38 "Summary." National Research Council. 2006. Nutrient Requirements of Dogs and Cats. Washington, DC: The National Academies Press.

If nutrition is to advance as a health tool, companies must be able to make claims that go beyond basic descriptors, such as taste, aroma, and nutrient content. Looking forward, the microbiome is the next frontier in animal health, providing new methods to manage disease, inflammation, and stress through targeted nutrition. However, regulatory paradigms must shift to allow discussions on enabling scientifically supported claims while ensuring appropriate oversight.

As new innovations are developed, it is also essential for the FDA to advance its expertise in new ingredients such as cell-cultured proteins and insect-based proteins. The FDA should seek to hire additional staff and provide learning opportunities to existing staff on the production techniques and safety considerations for new ingredients. As industry adopts these new technologies, it will also be important for the FDA to provide additional guidance to industry on how to safely produce foods with these innovations and highlight any different review information or pathways that may be needed to effectively regulate use.

BIOTECHNOLOGY, GENETIC MODIFICATION AND CELL-BASED THERAPIES

Observations & Challenges

Biotechnologies, genetic modification, and cell-based therapies have the potential to further improve animal health and food/feed production. Advances in precision breeding are creating new opportunities to enhance disease resistance, improve sustainability, and increase efficiency in food production.

In general, there is confusion regarding the jurisdiction and responsible lead agency for regulating biotechnology, genetic engineering, and novel immune-related therapeutic products impacting different organisms. Some sponsors convey there is confusion and difficulty identifying the primary responsible agency (FDA, USDA, or EPA). The public lacks awareness of key agency collaborations despite initiatives such as a recent announcement published on the EPA website.[39]

Recommendations

15 Congress should work with FDA to develop fit-for-purpose pathways for biotechnology products.

16 FDA should coordinate with USDA and EPA to provide a clearer entry point for developers of biotechnology products. Reviewing agencies should seek feedback from developers who have navigated or are currently navigating the biotechnology review process to ensure that the entry point is clear, and the process is working effectively.

Discussion

Significant regulatory complexities surrounding biotechnological innovation, particularly for gene-edited animals, may be alleviated by creation of a dynamic, interagency development and review pathway that goes beyond the regulation of genetically modified microorganisms.[40]

39 United States Environmental Protection Agency. EPA, FDA, and USDA Release Tool to Help Biotechnology Developers Navigate Regulatory Landscape | US EPA. www.EPA.gov. Published October 2, 2024. Accessed March 30, 2025. https://www.epa.gov/pesticides/epa-fda-and-usda-release-tool-help-biotechnology-developers-navigate-regulatory.

40 U.S. Environmental Protection Agency, U.S. Food and Drug Administration, U.S. Department of Agriculture. Unified Website for Biotechnology Regulation. Unified Website for Biotechnology Regulation | Animal and Plant Health Inspection Service. Published 2024. Accessed March 30, 2025. https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/home.

Along with regulatory hurdles, infrastructure limitations slow progress. Computational power constraints, including limited access to high-performance computing resources, such as the USDA's Ceres cluster, hinder researchers from effectively analyzing complex genetic data. Similarly, alternative testing models—such as organoids and *in vitro* systems that could reduce reliance on live animal testing—lack clear regulatory validation pathways, preventing their widespread adoption despite their potential to improve efficiency and address ethical considerations in biotechnology research.

Without consistent guidelines, improved communication and better access to critical resources, biotechnology developers will continue to face delays, compliance burdens, and uncertainty, ultimately slowing the advancement of promising technologies in animal health and genetics.

FDA-CVM's Veterinary Innovation Program (VIP), although resource intensive for the FDA, enables developers to engage in more frequent and informal communication with the Agency, facilitating progress that benefits both parties. The VIP program stands out as a model for communication and product evaluation across all pathways under FDA oversight.

C. MINOR USE/MINOR SPECIES (MUMS)

Observations & Challenges

The Minor Use and Minor Species (MUMS) Animal Health Act of 2004 was designed to incentivize the development of drugs in two situations: 1) for minor species (e.g., fish, small ruminants, game birds, honeybees), and 2) for uncommon diseases ("minor use") in major species, such as treating rare conditions in cattle, horses, or dogs.[41] While the legislation has facilitated some progress, the existing incentive programs require updates to better align with current sector needs and ensure practical solutions for drug availability and approval challenges. Additionally, the definition of minor use is too narrow and unclear and requires revision.

The aquaculture industry, small ruminants, bees, and other sectors face significant challenges due to limited drug availability, which is exacerbated by their smaller market representation and lack of economies of scale. The dearth of financial viability in developing treatments for these species worsens the problem, making it difficult for producers to access essential medications and creating challenges for animal welfare and food production. A targeted regulatory framework that supports these sectors despite poor market incentives is necessary to ensure continued innovation, access to treatment, and industry sustainability.

In addition, review timelines for minor species' drugs are subject to ADUFA statutory settings, which may not align with the life cycles of some minor food animal species, such as honeybees which live 42 days. For example, under ADUFA, FDA-CVM can take up to 50 days for protocol review and 180 days for the review of data submissions for all animal drugs and innovative technologies. This creates challenges for timely intervention of emerging diseases, as discussed in Section F (Emergency Preparedness and Emergency Use Authority). A more responsive and flexible regulatory approach is needed to accommodate sector-specific timelines and unique requirements.

Generally, there are far greater economic incentives for the animal drug industry to seek approval for label claims applicable to major species only. The lack of return on investment for seeking approval for additional label claims for minor food animal species or for minor uses in major species is a deterrent for sponsors. As

41 Minor Use and Minor Species Animal Health Act of 2004, Pub. L. No. 108-282, 118 Stat. 891 (2004). Available at: https://www.govinfo.gov/link/plaw/108/public/282.

a result, minor food animal species are not optimally treated, leading to downstream economic losses for producers of those food animals and animal welfare issues such as unnecessary pain and suffering. The incremental expense of approving drugs for the minor food animal species market is burdensome and costly for the drug sponsor, considering the marginal economic return. In general, producers of minor food-producing species in other countries have access to more drugs and therapies, putting U.S. producers at a disadvantage in a competitive global marketplace.

Another option available to veterinarians is extralabel use -- the use of a drug approved for one animal species (e.g., a major species such as cattle) to treat another animal species not listed on the drug label. However, veterinarians have some limitations surrounding extralabel drug use. For example, if an animal drug is used extralabel by a veterinarian to treat a minor food animal species, e.g., a sheep or goat, and there is no established tolerance for that species or matrix, there is a requirement that no drug residues can be detected. This in turn results in a substantially extended withdrawal interval, especially given the increased sensitivities of analytical methods. To ameliorate this situation, changes to the Animal Medicinal Drug Use Clarification Act (AMDUCA) and/or MUMS legislation that protects human health while making extralabel drug use more economical for minor food animal producers would be beneficial.

"There are more than 100 species of fish that are cultured in the USA, most of which are not represented in any therapeutic drug claims whatsoever. Without extralabel flexibility, many fish would suffer and die unnecessarily from readily treatable diseases."

—Stakeholder

In contrast, foreign producers of the same minor food animal species can export products to the U.S. where the animals have been treated with the same medications approved in their home markets. By not being required to test for drug residue, they can export product at a lower cost than U.S. producers. While only trace amounts of drug residues are allowed in imported product, the inspection rate of imported animal-derived food products intended for human consumption is low.[42] As a result, U.S. producers are at a competitive disadvantage in the domestic market. To partially ameliorate these disparities, Congress should amend AMDUCA and/or the MUMS legislation to permit the use of related species tolerances or Maximum Residue Limits (MRLs) for minor food animal species.

"The current approach to drug review for minor food-producing species yields an uneven playing field for U.S. producers versus international producers, who are allowed to use a broader array of drugs and then import those animals [products] to the United States."

—Stakeholder

Recommendations

17 FDA should restructure the Office of Minor Use and Minor Species (OMUMs) to bring the drug review and approval process for minor species under its jurisdiction.

18 FDA should establish a means for accepting data packages that have been prepared for and accepted by equivalent global regulator review processes. (see also Recommendation 17.)

19 Congress should amend AMDUCA and/or MUMS legislation to allow for the use of related species

42 U.S. Government Accountability Office (GAO). (2025, January 8). Food Safety: FDA Should Strengthen Inspection Efforts to Protect the U.S. Food Supply [GAO-25-107571].

tolerances or maximum residue limits (MRLs) in establishing withdrawal intervals for minor food animal species products following extralabel drug use. (See also Section E. Global Competition and Trade Impacts.)

20 Congress should amend the definition of minor use in major species to ensure that products are brought to market for animal sectors in need. (See also Section E. Global Competition and Trade Impacts.)

21 Congress should provide sustainable multiyear funding for the Food Animal Residue Avoidance Databank (FARAD) to maintain vital food safety services.

Discussion

FDA should consider restructuring the Office of Minor Use and Minor Species (OMUMS) to ensure that the drug review and approval process for minor species falls under its jurisdiction. To address the unique challenges of developing drugs for minor species, OMUMS should take the lead in all product approvals for minor species. Additionally, greater labeling flexibility is essential to alleviate regulatory burdens and prevent the need for entirely new drug approvals for minor modifications.

It is vital to consider the needs of food-producing industries when conducting drug reviews for minor food-producing species. This includes enabling U.S. producers of minor food animals to get their animal products to market and compete against importers who have access to effective and approved drugs to treat their animals, which has created an uneven playing field for U.S. producers.

Strengthening federal agency collaboration by enhancing communication between the FDA, USDA, and EPA is crucial to effectively address ongoing and future threats to minor species. Clarifying agency jurisdictions and responsibilities will help eliminate regulatory uncertainties and streamline decision-making processes.

FDA should adopt a more proactive approach to engaging with a wide range of stakeholders, ensuring that product development aligns with veterinary needs rather than solely focusing on economic viability of the biopharmaceutical industry. Hosting regular FDA-led meetings, similar to USDA animal sector meetings,[43] can facilitate ongoing dialogue and proactive engagement with more stakeholders. These meetings would provide a structured platform for industry input, helping FDA better understand sector-specific challenges and priorities. As FDA is a regulatory body with limitations on who it can meet, meetings could be enhanced by FDA partnering with other agencies or entities to facilitate actionable outcomes.

The Food Animal Residue Avoidance Databank (FARAD),[44] funded by USDA's National Institute of Food and Agriculture, remains a critical resource for minor species and extralabel drug use guidance. Securing consistent multiyear funding and reliable Congressional appropriation is vital to ensure continued access for veterinarians to essential services. Ensuring sustained financial support for programs like FARAD is crucial for maintaining industry compliance, ensuring food safety, and facilitating effective veterinary decision making. Congress should expand the FARAD program's authorization (original authorization in 1998; P.L. 105–185) in the Farm Bill to include multiyear funding and increase funding levels to be consistent with inflation, in order to maintain vital food safety services for veterinarians, animal agriculture, and the American consumer.

43 For example, similar to the USDA Agricultural Marketing Service (AMS) stakeholder meetings around Mandatory Price reporting. https://www.ams.usda.gov/rules-regulations/mmr/lmr/2024-stakeholder-meetings.

44 Food Animal Residue Avoidance Databank. Funding Status | FARAD. Farad.org. Published 2018. Accessed April 15, 2025. http://www.farad.org/funding.html.

D. ONE HEALTH

Observations & Challenges

One Health is a collaborative, transdisciplinary, and multisector approach that acknowledges the interconnectedness of human, animal, and environmental health. It operates across local, regional, national, and global levels to address complex health challenges. Key focus areas include zoonotic diseases, antimicrobial resistance, and other issues that affect both animal welfare and public health.

Despite its importance, investment in One Health prevention strategies has often been deprioritized. In the face of emerging zoonotic threats, the emphasis must shift from reactive responses to proactive preparedness. Limited funding should be strategically directed toward preventive measures—rather than only being deployed once risks escalate into acute human health crises.

One critical area where proactive preparedness is urgently needed is antimicrobial resistance (AMR), a growing One Health challenge that demands more than just monitoring antimicrobial use.

While antimicrobial-sales data provides valuable insight into prescribing trends, relying solely on sales data offers an incomplete understanding of the broader use and resistance landscape. There are relatively few programs that actively track AMR in a comprehensive and coordinated manner. The U.S. government currently utilizes the National Antimicrobial Resistance Monitoring Systems (NARMS). However, NARMS is limited to human clinical samples, animal slaughter samples, and retail meat samples. NARMS does not currently capture use data. Without more complete resistance surveillance, we lack critical context to assess whether changes in use are actually influencing resistance patterns in pathogens of concern. Emphasizing use data alone risks misdirected policies—particularly if reductions in antimicrobial use become the primary metric of success. For example, in parts of Europe, efforts to reduce antimicrobial use in food animals have sometimes proceeded without adequately considering the consequences for animal health or the actual relationship between use patterns and resistance trends in human pathogens. To avoid these pitfalls, it is essential that use data be interpreted alongside robust resistance monitoring to ensure balanced, science-based decision-making.

Recommendations:

22 Congress, HHS, USDA, and EPA should increase investments and proportionally allocate funds to prepare for and respond to current and emerging zoonotic diseases.

23 The FDA should continue its focus on embracing new data tools and mechanisms to accurately estimate antibiotic usage in all animal sectors and explore additional approaches to accurately capture stewardship practices. The FDA should partner with companion animal stakeholders to promote antimicrobial stewardship in the companion animal sector, and recognize the need for tailored messaging.

Discussion

The One Health approach, which considers all sectors where antimicrobials are used—including human, animal, and environmental domains—is essential for understanding whether and how antibiotic use contributes to resistance. Monitoring antibiotic use in food-producing animals, using appropriate and standardized metrics, can help reveal trends across species, commodity groups, geographic regions, and time. This data-driven approach supports more effective antimicrobial stewardship of medically important drugs.

Antimicrobial stewardship aims to preserve the effectiveness of antibiotics for both animals and humans, not to eliminate their use entirely. Responsible stewardship involves collecting and analyzing antimicrobial-use data across all animal sectors. This is a critical first step toward understanding the complex dynamics between use and resistance. Stewardship efforts must account for species-specific needs and treatment contexts while prioritizing the proactive containment of zoonotic pathogens in animal populations to reduce the risk of spillover and future pandemics.

While livestock production has been the primary focus of federal antimicrobial stewardship initiatives, there is a growing need to expand these efforts to the companion animal sector, as household pets live in close proximity to humans. Enhanced education for veterinary professionals and pet owners, alongside tools such as digital dashboards that track and visualize prescribing patterns, can improve awareness and promote more judicious antibiotic use.

The FDA should build partnerships to advance stewardship in the companion animal space and strengthen data collection and reporting—similar to the progress made with food-animal producers.[45] This will ensure a more comprehensive and balanced stewardship strategy across all animal sectors.

E. GLOBAL COMPETITION AND TRADE IMPACTS

Observations & Challenges

Regulatory delays identified in earlier sections of this report adversely impact U.S. animal food producers operating in both domestic and global markets. Drugs and food/feed additives available in other countries but not in the U.S. highlight the regulatory gaps that place U.S. producers at an economic disadvantage. Many animal drug sponsors, whether U.S.-based or foreign-based, refrain from pursuing animal drug or feed additive approval in the U.S. because of the burdensome regulatory process, additional costs beyond research and development, and the inconsistent acceptance of foreign studies and real-world evidence. When those sponsors do not pursue U.S. approval, U.S. animal food producers do not have access to those innovations.

The lack of access to essential drugs, food/feed additives, or vaccines adversely affects U.S. competitiveness in the global animal marketplace. Additionally, inconsistent standards for residue presence and testing of domestic versus imported animal food products further complicate the landscape (see also Section C: MUMS Observations and Challenges).

The COVID-19 pandemic exposed vulnerabilities in the supply chain, particularly the significant reliance on non-U.S. manufacturers for active pharmaceutical ingredients (APIs). This reliance has highlighted the risks associated with securing essential nutrients, vitamins, and APIs from a single country or manufacturer.

45 U.S. Food and Drug Administration. FDA Releases 2023 Antimicrobial for Food-Producing Animals Sales Data. www.FDA.gov. Published 2024. Accessed April 2, 2025. https://www.fda.gov/animal-veterinary/cvm-updates/fda-releases-annual-summary-sales-and-distribution-antimicrobials-2023-use-food-producing-animals.

Recommendations:

24 FDA should allow the use of foreign studies and aggregate data to support the approval of products under FDA oversight, as applicable. Reduce data burden requirements by allowing the submission of aggregate data rather than raw data (see also Section B. Animal Drugs and Overall Product Development, Recommendation 5). Explore the possibility of allowing sponsors to submit foreign dossiers for review and approval from jurisdictions with which FDA has harmonization agreements.

25 FDA should address the inequalities between imported and domestic animal products with respect to residue limits.

26 To improve the availability of products, industry and regulators should collaborate to conduct thorough risk assessments of supply chains for feed ingredients and pharmaceutical manufacturing. These assessments should highlight the key areas where greater domestic manufacturing will make the U.S. more resilient during future disruptive events and include a plan for mitigating vulnerable areas. A goal should be to develop a mechanism for real-time reporting of supply chain issues and convey those issues to relevant sectors.

Discussion

The existing review framework for animal drugs and food/feed additives places U.S. food animal producers at a disadvantage in the global marketplace.

A harmonized regulatory approach—incorporating reciprocity agreements and mutual recognition of global regulatory outcomes—could streamline the review process while upholding high safety standards. The FDA can facilitate broader market access, reduce regulatory delays and promote innovation by allowing the use of foreign studies and data for safety and efficacy assessments, supplemented by U.S.-based validation when necessary. Additionally, the submission of aggregate data, as practiced in other countries, can further alleviate the regulatory burden associated with seeking product approval in the U.S. and may help minimize discrepancies in product availability across different countries.

Implementing a reciprocity framework with other nations, where U.S. regulatory agencies recognize legal drugs and label claims based on studies that have already been completed and accepted by an international agency with which reciprocity has been established, would be beneficial. Given the concerns regarding the availability of drugs for minor species and the existence of approved products in countries with robust regulatory systems, these products represent an ideal area for piloting this new procedure.

The FDA should conduct comprehensive and routine risk assessments of supply chains for food/feed ingredients and pharmaceutical manufacturing. These assessments should identify key areas where increased domestic manufacturing can enhance U.S. resilience to future disruptive events. Furthermore, alternative strategies should be explored to maintain animal health and production efficiency when critical products are unavailable, thereby reducing dependence on single-source suppliers. To build a more resilient supply chain, Congress should empower the FDA with the authority and funding necessary to monitor ingredient shortages in real time and implement proactive measures to avert disruptions.

As noted in Section C, Minor Uses/Minor Species, importers of minor food species' products are able to ship products to the U.S. that have been treated with drugs approved in their home countries, often without undergoing residue testing. These imported products can enter the U.S. market at a lower cost than those

produced domestically. Although trace levels of drug residues are permitted in these imports, the inspection rate for imported animal food remains low.[46]

This disparity in regulations, as illustrated by the benzocaine example, leaves U.S. producers at a competitive disadvantage in the domestic retail market. Congress should consider amending AMDUCA or the MUMS legislation to permit the use of related species tolerances or Maximum Residue Limits (MRLs) for minor food animal species.

Benzocaine is a local anesthetic commonly used in aquaculture to sedate fish during handling and procedures. Its use and the regulation of its residues in fish intended for human consumption differ between domestically produced and imported fish in the U.S.

Benzocaine is not approved by the FDA for use in fish intended for human consumption within the United States. Consequently, there is no established tolerance for benzocaine residues in domestically produced fish, effectively resulting in a zero-tolerance policy. This means that any detectable residue of benzocaine in domestic fish renders the product adulterated under the FFDCA.

For imported fish, the FDA has established an import tolerance for benzocaine residues of 50 parts per billion (ppb) in the muscle with adhering skin of Atlantic salmon and rainbow trout.* This allows for the legal importation of these fish species treated with benzocaine, provided the residue levels do not exceed this limit.

**Freedom of Information Summary for Benzocaine Import Tolerance*.; 2018. Accessed April 1, 2025. https://www.fda.gov/media/113329/download.

F. EMERGENCY PREPAREDNESS AND EMERGENCY USE AUTHORIZATION (EUA)

Observations & Challenges

The threat of emerging infectious and zoonotic diseases among animals is ever present. The current cross-sectoral outbreak of highly pathogenic avian influenza (HPAI) among dairy cattle, poultry, and wildlife is just one example where the tools to diagnose, treat, and prevent the spread of disease are inadequate. The current process for detecting and responding to emerging animal diseases is too slow and arduous to effectively address new diseases as they emerge. This slow response has significant economic and human health implications for disease spread, control of mutations, and trade. Non-native diseases impact not only domestic production systems but also carry implications for export markets that persist long after the disease has been brought under control.

Clearer Emergency Use Authorization (EUA) guidelines for animal drugs that treat both major and minor species are needed that provide legal access to drugs, vaccines, and diagnostics approved in other countries.

46 U.S. Government Accountability Office (GAO). (2025, January 8). Food Safety: FDA Should Strengthen Inspection Efforts to Protect the U.S. Food Supply [GAO-25-107571].

Recommendations:

27 HHS should streamline, clarify, and expedite EUA and Public Health Emergency declaration processes in its application to animals.

28 In emergencies, FDA should explore applicability of enforcement discretion to allow veterinarians access to drugs, vaccines, and diagnostics that are already approved in other countries.

Discussion

To effectively respond to emerging health crises, FDA and other regulatory agencies must enhance coordination and transparency in the EUA process. This includes establishing tiered emergency use levels to address immediate, upcoming, and temporary needs, such as critical drug shortages. The key is to try to mitigate the spread of the emerging threat before the pathogen crosses into additional species and/or creates major economic losses for the animal agriculture sector.

A credible, centralized, science-driven coordinator is essential to streamline crisis response efforts among Federal, state and local agencies, ensuring that resources are mobilized efficiently before bureaucratic delays and miscommunication hinder action. Beyond addressing immediate threats, a proactive strategy for disease tracking and early intervention is crucial. Veterinary professionals need real-time data to monitor trends and respond swiftly to outbreaks.

U.S. producers do not have quick access to drugs currently available in other countries to treat diseases that are currently present in those countries and emerging in the United States. For example, in the event where a bacterial pathogen emerges on fish farms in the U.S., for which no approved drug treatment exists, quick access to foreign-approved antimicrobials or an autogenous vaccine could prevent a high mortality event.

G. COMMUNICATION AND COLLABORATION ACROSS KEY AGENCIES AND OTHER STAKEHOLDERS

Observations & Challenges

Navigating the animal health ecosystem is complex due to the involvement of multiple federal and state regulatory agencies, each with overlapping and sometimes unclear jurisdictions. The delineation of regulatory responsibilities is often ambiguous, making it difficult to determine which agency oversees specific products or issues. Coordination and collaboration among agencies are not always transparent, and their interactions with stakeholders lack clarity. Additionally, inconsistent terminology and product classifications further complicate regulation. Communication across agencies and sectors remains opaque, with insufficient regular information sharing to ensure a cohesive regulatory approach.

Overlapping and indistinct oversight, along with a fragmented regulatory structure among key regulatory agencies (e.g., FDA, USDA, EPA, etc.), obfuscates the agency responsible for oversight, particularly when addressing emerging diseases, risks to animal health and well-being and threats to economic stability.

Standards and terminology are not consistent across agencies and other entities that impact animal health and veterinary practice. For example, varying uses of the phrases "animal food," "animal feed," and "animal feed additives" cause confusion regarding when and how to apply these terms.

Recommendations:

29 FDA, USDA, and EPA should establish a standing regulatory interagency working group that meets frequently to identify and address discrepancies in agency terminology and processes that cause stakeholder confusion regarding product approval and enforcement. These agencies should publish key regulatory interagency meeting schedules and summaries of information of public importance that are easily accessible to interested parties.

30 FDA and other regulators should use well-defined and standardized terminology in agency communications. Terminology should be consistent with that used throughout the animal health ecosystem (e.g., in veterinary practice, research, publications, food safety, and the pharmaceutical and food/feed industries).

31 FDA, the veterinary profession, animal sector organizations, industry sponsors, and allied industries should engage in frequent conversations to stay current with threats affecting these parties, to identify gaps in therapy, and to address concerns in real time.

Discussion

The observations and challenges presented underscore the need for greater regulatory alignment, improved interagency communication, and a more nuanced framework for evaluating animal health products.

Broadening the scope of regular communication beyond drug sponsors would enable an active dialogue with animal sectors and veterinarians, keeping the FDA up to date with both the immediate needs and forward-looking concerns of the various animal sectors and identifying where gaps in therapy affect the health and well-being of animals.

H. ENFORCEMENT GAPS AND RESULTING MARKET DISINCENTIVES

Observations & Challenges

In the U.S., animal drugs are evaluated and approved for use in specific species as listed on the product label. However, most approved drugs have not been tested, formulated, or authorized for all animal species that might receive benefit. One approach to bridging this gap is through pharmacy drug compounding.

Compounded medications play a role in addressing unmet animal health needs—particularly when commercially available drugs do not exist in appropriate doses or dosage forms for minor species, wildlife, zoo, or laboratory animals. While CVM has not authorized compounding to address a shortage of FDA-approved products (as stated in GFI 256), stakeholders report the need to use compounding as a critical alternative to meet unmet needs and address drug shortages, helping to prevent treatment disruptions and maintain access to essential therapies.

FDA Guidance for Industry (GFI) #256 provides direction for “compounding animal drugs from bulk drug substances for use in nonfood-producing animals, as antidotes in food-producing animals, or as sedatives or anesthetics in free-ranging wildlife under limited circumstances when no other medically appropriate treatment options exist.”[47] The FDA recognizes the necessity of compounding in certain circumstances and has established enforcement discretion policies accordingly.

47 Center for Veterinary Medicine. CVM GFI #256 – Compounding Animal Drugs from Bulk Drug Substances. www.FDA.gov. Published August 10, 2022. Accessed April 15, 2025. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-256-compounding-animal-drugs-bulk-drug-substances.

Compounding outside of these parameters is problematic. The presence of unapproved and illegally compounded products creates disincentives for sponsors to pursue the animal drug approval process. When enforcement against unapproved products or illegally compounded drugs is minimal, the problem is further exacerbated. The relative availability of and ease of access to illegally compounded products allows for far broader use. In addition, the relative lack of enforcement against compounding with bulk drug substances outside of the parameters of Agency Guidance[48,49] exacerbates market disincentives.

Further, inconsistencies in state regulations and policies regarding compounded drugs and how these policies differ from federal policies create a logistical and legal challenge for the animal industry and veterinarians.

Recommendations:

32 FDA should identify pathways to ensure the availability of safe and efficacious FDA-reviewed products for animal sectors that predominately or solely rely on compounded products.

33 FDA should enforce its stated priorities for compounded drugs and update and clarify its priorities for unapproved drugs.

Discussion

The FDA should explore strategies to support animal sectors that depend heavily on compounded veterinary medications, particularly in cases where compounding is the only viable option for effective treatment or anesthesia. It is essential to address these needs in a way that safeguards animal welfare while also ensuring the availability of safe and effective veterinary products—especially during periods of drug shortages or supply chain disruptions.

Per FDA-CVM GFI #256, "FDA will make enforcement decisions on a case-by-case basis, recognizing that it needs to make the best use of limited Agency resources."[50] How these enforcement decisions are made is not transparent and enforcement priorities, though outlined in the guidance, do not appear to be systematically managed.

The lack of enforcement for illegally compounded and unapproved products creates unfair market competition, undermining the viability of FDA-compliant products and creating disincentives to new drug and food/feed additive development. Oversight of animal drug compounding and enforcement of federal requirements should be strengthened, for animal health, to assure a level playing field, and to ensure quality products for animal health. Without stronger regulatory oversight and enforcement, the innovation agenda suffers, as companies are less inclined to invest in new drug development when they must compete against unregulated products that bypass approval requirements. Addressing this issue is crucial to maintaining a fair and science-driven marketplace that fosters innovation while ensuring that safety and efficacy standards are upheld.

48 Ibid.

49 Center for Veterinary Medicine. Animal Drug Compounding. www.FDA.gov. Published May 1, 2023. Accessed April 15, 2025. https://www.fda.gov/animal-veterinary/unapproved-animal-drugs/animal-drug-compounding.

50 Ibid.

I. WORKFORCE CONSIDERATIONS

Observations & Challenges

As mentioned in Section II. Background, FDA-CVM is responsible for a wide array of animal species and has a broad mandate (See Figure 2). Inevitably, gaps in subject matter expertise exist within FDA-CVM. Concerns were raised in various roundtables regarding the expertise of FDA-CVM staff in reviewing drug submissions that fall outside their core knowledge or experience. Stakeholders provided examples of FDA-CVM reviewers' comments and questions that suggested a lack of familiarity with specific animal sectors, particularly when assessing products intended for minor species.

Across the nation, experts working in various animal sectors expressed concerns regarding finding or hiring veterinarians. Issues include a skewed distribution of veterinarians and veterinary practices serving major and minor food-producing species and in different regions of the United States. Additionally, fewer lifestyle amenities, a more challenging work-life balance, insufficient community or mentorship, and lower salaries were cited as reasons why rural areas, in particular, struggle to attract veterinarians. Similar challenges have been expressed for other fields that are part of the animal health ecosystem, such as animal handlers, farm workers, pharmacists, and veterinary technicians.

Concerns were also expressed regarding the hiring and retention of veterinarians across animal sectors. For example, fewer veterinary school graduates are opting for careers working with food-producing animals. Retention of those already in the veterinary sector is also challenging. Veterinary professionals experience fast-paced, unpredictable workloads, juggling various responsibilities and the myriad needs of the animals they see, and experiencing repeated exposure to emotionally intense animal health situations. This can lead to poor mental health and high burnout rates. Along with high attrition, the lack of qualified veterinarians poses a threat to the industry's ability to maintain health standards and manage disease threats. Shortages in skilled labor resulting from reduced approval rates for work visas, an aging workforce, and rising labor demands in animal health and production were also mentioned as exacerbating workforce challenges across the industry.

Recommendations:

34 To the extent possible, the FDA should utilize the agile hiring authorities and salary flexibility of the 21st Century Cures Act to increase efficiency and decrease timelines from application to hire and to attract highly qualified professionals.

35 FDA should build expertise by leveraging opportunities for field exposure in collaboration with industry, educational institutions, and the various animal sectors.

36 Congress should invest in the veterinary workforce in two ways: 1) strengthen the Veterinary Medicine Loan Repayment Program (VMLRP)[51] by increasing funds, increasing funding per person, and making the VMLRP debt relief payments tax-free, and 2) increase funding for Cooperative Extension programs and the National Institute of Food and Agriculture (NIFA) grant funding[52] focused on training in animal handling, husbandry, and biosecurity to address workforce needs.

37 FDA should join other animal health stakeholders in efforts to improve recruiting, training, and retaining individuals to maintain workforce health and sustainability in animal health.

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51 https://www.nifa.usda.gov/grants/programs/veterinary-medicine-loan-repayment-program.

52 USDA National Institute of Food and Agriculture. Cooperative Extension System. www.nifa.usda.gov. Published January 29, 2025. Accessed March 30, 2025. https://www.nifa.usda.gov/about-nifa/how-we-work/extension/cooperative-extension-system.

38 States should harmonize veterinarian and veterinary technician licensing reciprocity as a way to address workforce issues. States should also harmonize regulations related to telemedicine.

Discussion

FDA-CVM should consider implementing a program similar to FDA's Center for Devices and Radiological Health's (CDRH) Experiential Learning Program (ELP)[53] to increase field experience and close knowledge gaps among FDA-CVM staff and reviewers. This program provides CDRH staff with exposure to modern research, development and manufacturing in the medical device industry. Similarly, a program based in FDA-CVM would expose product reviewers to the working conditions of those in the field who would apply these products. Modeled on patient listening sessions held by other FDA centers, the FDA could schedule virtual listening sessions with animal producers, farmers, practicing veterinarians, pet owners, and others to learn more about their needs and the conditions seen in the field.

The veterinary workforce has continued to evolve in response to the changing demands of the U.S. animal industry. Increased spending in the companion animal space has drawn veterinarians into the field, away from traditional large animal and specialty roles.[54,55] The VMLRP is designed to incentivize qualified veterinarians to work in high-priority areas, but requires additional support. A thoughtful and multifaceted approach to the workforce is required to address these concerns and form sustainable environments to attract veterinarians and associated personnel long-term.

Student debt remains a top concern for new veterinary graduates, which affects both rural settings and animal sectors with smaller markets. This limits the pathways for advancement and practice ownership. A growing number of new veterinarians report degree-related debt of more than $300,000.[56] Communities and trade associations will need to work together to provide awareness of opportunities and incentives available to attract necessary talent to these fields and locations in addition to enhanced government support for rural programs and research. In addition, work among states to harmonize licensing reciprocity and telemedicine requirements could help improve access to care.

53 Center for Devices and Radiological Health. CRDH Experiential Learning Program (ELP). U.S. Food and Drug Administration www.fda.gov. Published 2024. Accessed March 30, 2025. https://www.fda.gov/science-research/fda-stem-outreach-education-and-engagement/cdrhs-experiential-learning-program-elp.

54 Federal Reserve Bank of St. Louis. Personal Consumption expenditures: Pets, Pet products, and Related Services. Stlouisfed.org. Published 2023. Accessed April 15, 2025. https://fred.stlouisfed.org/series/DPETRC1A027NBEA.

55 AVMA. (2025). Economic State of the Veterinary Profession. AVMA.

56 Ibid.

IV. Conclusion

This report outlines recommendations for changes that can be made by FDA, Congress, and other stakeholders to facilitate modernization of the regulatory system governing the animal health and welfare and veterinary ecosystem. The Panel's recommendations provide a broad range of potential actions to improve the drug and animal food/feed review process and enhance the economic viability of U.S. animal producers in the global market. Numerous threats to animal health exist and are emerging for which there are inadequate preventive measures and effective treatments (Appendix F). Implementation of these recommendations is crucial for ensuring a robust and responsive regulatory framework that safeguards animal health and supports the sustainability of the entire animal health and welfare and veterinary ecosystem.

Appendix A: Recommendations

Authorities: Defining Animal Drugs and Animal Food

1. The U.S. Congress should modernize the regulatory pathways for animal health products, via a "21st Century Cures Act" approach, to create clearer, more efficient, and more flexible pathways to encourage the introduction of innovative products while ensuring safety for both animals and humans. Features of this legislation should include dynamic pathways that address:
   - Minor Use/Minor Species (MUMS) modernization
   - Biotechnology (e.g., gene-editing, cellular therapies)
   - Food additives and zootechnical animal food substances (ZAFS)
   - Consideration of regulatory data and approvals from nations with trusted regulatory systems
2. Congress should provide FDA more flexibility to interpret the definitions of a drug and food, allowing more products to be regulated as animal food ingredients rather than as drugs. Legislation should create new categories of food additives to keep pace with scientific advancements.

FDA-CVM Product Oversight and the Review Process

ANIMAL DRUGS & OVERALL PRODUCT DEVELOPMENT

3. FDA should implement a structured risk-benefit assessment framework in the new animal drug review process. This framework should facilitate flexibility, balance considerations of benefits and risks, be consistent and systematic in regulatory decision-making approaches, and establish clear communication pathways for revealing benefits and risks associated with new animal drugs.
4. FDA should provide clear thresholds for achieving protocol concurrence and well-defined endpoints required for efficacy and safety evaluations to improve predictability in the drug approval process.
5. FDA should reduce data burden requirements by more consistently allowing the submission of aggregate, rather than raw, data.
6. FDA should implement a "Stop-the-Clock" program modeled after the European Union (EU) approach that allows drug sponsors to address deficiencies identified in technical section submissions mid-cycle without restarting the review timeline.
7. FDA should track and report on additional outcome-driven metrics—such as first-cycle reviews, total review time per technical section, and amendment frequency—to more meaningfully assess the efficiency of the drug review process. FDA should use these metrics to establish a baseline, assess trends over time, and evaluate impacts of process optimization efforts.
8. FDA should explore mechanisms to utilize small ad hoc panels of nonagency experts who can provide additional perspectives and expertise, and resolve complex or contentious issues, during the review process.
9. FDA should increase its utilization of mathematical modeling and simulation approaches, such as physiologically based pharmacokinetic (PBPK) and population pharmacokinetic (PopPK) models, to streamline FDA approvals of veterinary drugs.
10. FDA should improve the functionality of the adverse event database for animal drugs and devices.

ANIMAL FOOD

11 FDA should expedite ongoing efforts to clarify the most appropriate review pathways for various types of ingredients and streamline processes, where possible, to minimize delays in introducing new ingredients. New regulatory pathways are needed to accommodate zootechnical animal food substances (ZAFS) that affect the structure or function of an animal through a means other than nutrition and that will allow manufacturers to claim health and other benefits of these food/feed formulations. (see also Recommendation 1.)

12 FDA should secure the necessary expertise to review novel food ingredients (e.g., cell-cultured meat and insect-based proteins) and provide clear guidance on review requirements.

13 Congress and the states should work to harmonize the current patchwork of state requirements for labeling and ingredient safety reviews, with an ultimate goal of establishing a uniform federal framework for these activities.

14 FDA should continue to participate in and encourage global harmonization efforts to improve the efficiency of food/feed ingredient development and regulation. FDA should also maintain collaboration with international bodies such as Codex Alimentarius and the World Organisation for Animal Health (WOAH) to participate in the development of harmonized standards for food/feed ingredients.

BIOTECHNOLOGY, GENETIC MODIFICATION AND CELL-BASED THERAPIES

15 Congress should work with FDA to develop fit-for-purpose pathways for biotechnology products.

16 FDA should coordinate with USDA and EPA to provide a clearer entry point for developers of biotechnology products. Reviewing agencies should seek feedback from developers who have navigated or are currently navigating the biotechnology review process to ensure that the entry point is clear, and the process is working effectively.

Minor Use/Minor Species (MUMS)

17 FDA should restructure the Office of Minor Use and Minor Species (OMUMs) to bring the drug review and approval process for minor species under its jurisdiction.

18 FDA should establish a means for accepting data packages that have been prepared for and accepted by equivalent global regulator review processes. (see also Recommendation 17.)

19 Congress should amend AMDUCA and/or MUMS legislation to allow for the use of related species tolerances or maximum residue limits (MRLs) in establishing withdrawal intervals for minor food animal species products following extra-label drug use. (See also Section E. Global Competition and Trade Impacts.)

20 Congress should amend the definition of minor use in major species to ensure that products are brought to market for animal sectors in need. (See also Section E. Global Competition and Trade Impacts.)

21 Congress should provide sustainable multiyear funding for the Food Animal Residue Avoidance Databank (FARAD) to maintain vital food safety services.

One Health

22 Congress, HHS, USDA, and EPA should increase investments and proportionally allocate funds to prepare for and respond to current and emerging zoonotic diseases.

23 The FDA should continue its focus on embracing new data tools and mechanisms to accurately estimate antibiotic usage in all animal sectors and explore additional approaches to accurately capture stewardship practices. The FDA should partner with companion animal stakeholders to promote antimicrobial stewardship in the companion animal sector, and recognize the need for tailored messaging.

Global Competition and Trade Impacts

24 The FDA should allow the use of foreign studies and aggregate data to support the approval of products under FDA oversight, as applicable. Reduce data burden requirements by allowing the submission of aggregate data rather than raw data (see also Section B. Animal Drugs and Overall Product Development, Recommendation 5). Explore the possibility of allowing sponsors to submit foreign dossiers for review and approval from jurisdictions with which FDA has harmonization agreements.

25 FDA should address the inequalities between imported and domestic animal products with respect to residue limits.

26 To improve the availability of products, industry and regulators should collaborate to conduct thorough risk assessments of supply chains for feed ingredients and pharmaceutical manufacturing. These assessments should highlight the key areas where greater domestic manufacturing will make the U.S. more resilient during future disruptive events and include a plan for mitigating vulnerable areas. A goal should be to develop a mechanism for real-time reporting of supply chain issues and convey those issues to relevant sectors.

Emergency Preparedness, Emergency Use Authorization (EUA) and One Health

27 HHS should streamline, clarify, and expedite EUA and Public Health Emergency declaration processes in its application to animals.

28 In emergencies, FDA should explore applicability of enforcement discretion to allow veterinarians access to drugs, vaccines, and diagnostics that are already approved in other countries.

Communication and Collaboration Across Key Agencies and Other Stakeholders

29 FDA, USDA, and EPA should establish a standing regulatory interagency working group that meets frequently to identify and address discrepancies in agency terminology and processes that cause stakeholder confusion regarding product approval and enforcement. These agencies should publish key regulatory interagency meeting schedules and summaries of information of public importance that are easily accessible to interested parties.

30 FDA and other regulators should use well-defined and standardized terminology in agency communications. Terminology should be consistent with that used throughout the animal health ecosystem (e.g., in veterinary practice, research, publications, food safety, and the pharmaceutical and food/feed industries).

31 FDA, the veterinary profession, animal sector organizations, industry sponsors, and allied industries should engage in frequent conversations to stay current with threats affecting these parties, to identify gaps in therapy, and to address concerns in real time.

Enforcement Gaps and Resulting Market Disincentives

32 FDA should identify pathways to ensure the availability of safe and efficacious FDA-reviewed products for animal sectors that predominately or solely rely on compounded products.

33 FDA should enforce its stated priorities for compounded drugs and update and clarify its priorities for unapproved drugs.

Workforce Considerations

34 To the extent possible, the FDA should utilize the agile hiring authorities and salary flexibility of the 21st Century Cures Act to increase efficiency and decrease timelines from application to hire and to attract highly qualified professionals.

35 FDA should build expertise by leveraging opportunities for field exposure in collaboration with industry, educational institutions, and the various animal sectors.

36 Congress should invest in the veterinary workforce in two ways: 1) strengthen the Veterinary Medicine Loan Repayment Program (VMLRP)[57] by increasing funds, increasing funding per person, and making the VMLRP debt relief payments tax-free, and 2) increase funding for Cooperative Extension programs and the National Institute of Food and Agriculture (NIFA) grant funding[58] focused on training in animal handling, husbandry, and biosecurity to address workforce needs.

37 FDA should join other animal health stakeholders in efforts to improve recruiting, training, and retaining individuals to maintain workforce health and sustainability in animal health.

38 States should harmonize veterinarian and veterinary technician licensing reciprocity as a way to address workforce issues. States should also harmonize regulations related to telemedicine.

57 https://www.nifa.usda.gov/grants/programs/veterinary-medicine-loan-repayment-program.

58 USDA National Institute of Food and Agriculture. Cooperative Extension System. www.nifa.usda.gov. Published January 29, 2025. Accessed March 30, 2025. https://www.nifa.usda.gov/about-nifa/how-we-work/extension/cooperative-extension-system.

Appendix B: Glossary

TERM	ABBREVIATION	DEFINITION
Abbreviated New Animal Drug Application	ANADA	Process for the approval of generic copies of new animal drug products that have been previously approved and shown to be safe and effective
Active Pharmaceutical Ingredients	APIs	Key substances in medicines that produce the therapeutic effect
Additives		Substances added to animal feed to improve nutrition, health, or performance without treating, curing, or preventing disease
American Feed Industry Association	AFIA	Represents the interest of the U.S. animal food industry and its suppliers and advocates for legislative changes like the Innovative FEED Act
American Veterinary Medical Association	AVMA	Veterinary professional association
Animal and Plant Health Inspection Service	APHIS	Agency of the USDA which protects the health and value of American agriculture and natural resources
Animal and Veterinary Innovation Agenda	AVIA	CVM agenda for modernizing its approach to evaluating and supporting creating innovative animal and veterinary products
Animal Cell- or Tissue-Based Products	ACTPs	Articles containing, consisting of or derived from cells or tissues that are intended for administration to an animal recipient
Animal Drug Availability Act	ADAA	Federal legislation signed into law in 1996
Animal Drug User Fee Act	ADUFA	Authorizes FDA to collect fees for certain animal drug applications
Animal Medicinal Drug Use Clarification Act	AMDUCA	Permits veterinarians to prescribe extralabel uses of certain approved animal and human drugs under certain conditions
Animal Welfare or Well-being Claims		Claims focused on structure or function changes that support an animal's comfort, behavior, or overall quality of life such as improving coat or skin condition
Antibiotic Stewardship		Approach to optimize the use of antibiotics, improve outcomes, reduce antibiotic resistance, and protect public health
Antimicrobial Resistance	AMR	Pathogens no longer respond to antimicrobial medications
Association of American Feed Control Officials	AAFCO	Works on feed ingredient definitions and model regulations in the United States
Australian Pesticides and Veterinary Medicines Authority	APVMA	Oversees safety, efficacy, and environmental impacts of feed additives in Australia
Avian Metapneumovirus	aMPV	Viral infection of poultry
Biosecurity		Management practices designed to prevent the introduction, delivery, and spread of disease pathogens that can adversely affect livestock, crops, environments, and people

TERM	ABBREVIATION	DEFINITION
Canadian Food Inspection Agency	CFIA	Regulates feed ingredients and claims in Canada
Center for Biologics Evaluation and Research	CBER	FDA biologic product center
Center for Devices and Radiological Health	CDRH	FDA human medical product center
Center for Drug Evaluation and Research	CDER	FDA human medical product center
Center for Veterinary Biologics	CVB	The Veterinary Biologics Program implements the provisions of the Virus-Serum-Toxin Act (VSTA) to assure that pure, safe, potent, and effective veterinary biologics are available for the diagnosis, prevention, and treatment of animal diseases
Center for Veterinary Medicine	CVM	FDA center
Centers for Disease Control and Prevention	CDC	Federal agency
Chronic Wasting Disease	CWD	A fatal neurological disease that affects cervids
Codex Alimentarius		A global body developing food safety and quality standards, including for animal feed additives
Department of Health and Human Services	HHS	An executive department of the U.S. federal government
Directive 2001/82/EC		European Union legislation governing veterinary medicinal products, including animal drugs
Distributor		Any person who distributes a medicated feed containing a VFD drug to another person
Dossier		A collection of data submitted to regulatory authorities for evaluating the safety, efficacy, and quality of products
Drug Enforcement Administration	DEA	Federal agency
Emergency Use Authorization	EUA	Allows FDA to help strengthen the nation's public health protections
Environmental Claims		Claims related to sustainability, such as methane reduction, often triggering specific regulatory pathways
Environmental Protection Agency	EPA	Federal agency
European Commission	EC	Responsible for granting final approval of feed additives and veterinary drugs in the European Union
European Food Safety Authority	EFSA	Conducts scientific evaluations for feed additives and environmental claims in the European Union
European Medicines Agency	EMA	Regulates animal drugs in the European Union

TERM	ABBREVIATION	DEFINITION
Experiential Learning Program	ELP	CDRH program to help close knowledge gaps in emerging and innovative technology
Extralabel Use		The use of a veterinary drug in a manner that is not in accordance with the approved labeling. Veterinarians may prescribe extralabel use of drugs to treat an animal or a disease that is not on the approved label
Federal Food, Drug, and Cosmetic Act	FFDCA	Regulatory legislation signed into law in 1938
Feed Additive		There is no universally standardized definition of an animal feed additive. However, according to the European Union under Regulation (EC) No 1831/2003, a feed additive is defined as: "Substances, micro-organisms, or preparations, other than feed material and premixes, which are intentionally added to animal feed or water" to perform particular functions, such as improving feed quality, animal health, environmental consequences of animal production,or animal performance.
Food Additive		Defined in the U.S. FDA's FFDCA (21 U.S.C. § 201(s)), as any substance whose intended use results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use); if such substance is not GRAS or sanctioned prior to 1958 or otherwise excluded from the definition of food additives
Food Additive Petition		A submission process to gain FDA approval for new animal food additives
Food/Feed		Food/feed, when used throughout this document, refers to nourishment in its various forms provided to animals
Food and Drug Administration (U.S.)	FDA	Regulates feed additives and animal drugs under the Federal Food, Drug, and Cosmetic Act (FFDCA)
Food and Drug Administration Safety and Innovation Act	FDASIA	Regulatory legislation signed into law in 2012
Food Animal Residue Avoidance Databank	FARAD	A national program that serves as the primary source for scientifically-based recommendations regarding safe withdrawal intervals of drugs and chemicals in food-producing animals
Food Safety Modernization Act	FSMA	Regulatory legislation signed into law in 2011
Functional Feed Additives		Additives providing benefits beyond basic nutrition, like environmental or welfare improvements
Generally Recognized As Safe	GRAS	A regulatory category allowing certain feed ingredients to bypass premarket approval if deemed safe
Harmonization		Efforts to align regulatory standards across different jurisdictions for feed additives or animal drugs

TERM	ABBREVIATION	DEFINITION
Health Canada (VDD)	VDD	Veterinary Drugs Directorate. Oversees animal drug safety, efficacy and quality in Canada
Health Claims		Claims focused on structure or function changes that maintain or improve the animal's natural functions such as promoting gut health
Highly pathogenic avian influenza	HPAI	A contagious and lethal strain of bird flu
International Cooperation for the Convergence of Technical Requirements for the Assessment of Feed Ingredients	ICCF	Collaborates with international feed regulators and industry associations to develop and establish common technical guidance for the assessment of feed ingredients
International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products	VICH	Focuses on harmonizing veterinary drug standards in the European Union, Japan and the United States
International Cooperation on Veterinary Medicines	ICVMP	Promotes harmonization of veterinary medicine regulations globally
International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use	ICH	Sets guidelines for human drugs
Investigational New Animal Drug	INAD	A drug intended for use in animals that is under investigation to determine its safety and effectiveness
Major Species		FDA regulatory classification; includes horses, cattle, pigs, dogs, cats, chickens and turkeys
Maximum Residue Limits	MRLs	The highest level of residue legally tolerated in or on food/feed
Minor Species		FDA regulatory classification; includes all animals that are not one of the major species
Minor Use Drugs		Drugs intended for use in major species for diseases that occur infrequently or in limited geographic areas
Minor Use/Minor Species	MUMS	See above definitions
National Institute of Food and Agriculture	NIFA	Federal institute
New Animal Drug Application	NADA	A U.S. regulatory process for approving animal drugs
New Zealand Ministry for Primary Industries	NZMPI	Oversees feed additives and veterinary drug approvals
NRSP7	NRSP7	A national agricultural program for minor use animal drugs
Office of Minor Use and Minor Species	OMUMS	Office within CVM

TERM	ABBREVIATION	DEFINITION
One Health		An interdisciplinary approach that recognizes the interconnectedness of human, animal, and environmental health
Ostreid Herpesvirus 1	OsHV-1	Disease in shellfish
Performance Claims		Claims focusing on structure or function changes that improve physiological functions such as growth, feed efficiency, or production
Pharmacokinetics	PK	The study of how substances are absorbed, distributed, metabolized, and excreted
Physiologically Based PK	PBPK	A mathematical modeling technique to simulate and predict PK
Population PK	PopPK	The study of variability in PK within a patient population receiving clinically relevant doses of a drug
Porcine Reproductive and Respiratory Syndrome	PRRS	A viral disease in swine
Regulation (EC) No. 1831/2003		Governs feed additives in the European Union, including functional groups like environmental additives
Residue Monitoring		Postmarket surveillance process to ensure feed additives and drugs do not leave harmful residues in animal products
Sustainability Claims		Environmental claims focusing on outcomes like methane reduction or climate impact mitigation
Timeframes		Review durations for regulatory approvals, varying by jurisdiction and product complexity
U.S. Department of Agriculture	USDA	An executive department of the U.S. federal government
Veterinary Feed Directive	VFD	An authorization written by a licensed veterinarian that allows animal feed intended for a specific population of animals to contain certain antibiotics
Veterinary Feed Directive Drug	VFD Drug	A drug intended for use in or on animal feed, which is limited to use under the professional supervision of a licensed veterinarian
Veterinary Innovation Program	VIP	The goal of the VIP is to facilitate advancements in development of innovative animal products by providing greater certainty in the regulatory process, encouraging development and research, and supporting an efficient and predictable pathway to market for ACTPs and intentional genomic alterations (IGAs) in animals
Veterinary Medicine Loan Repayment Program	VMLRP	Authorized by the National Veterinary Medical Services Act (NVMSA) to offset student debt
World Organisation for Animal Health	OIE/WOAH	Develops global guidelines for animal health, including antimicrobial resistance
Zootechnical Animal Food Substances	ZAFS	Substances added to animal feed that affect the animal's gastrointestinal tract, with the goal of influencing digestion, reducing pathogens, or altering animal performance

Appendix C: Methodology

Expert Panel

Expert Panel members (listed) were identified based on their expertise (See also Appendix D).

Lisa Tell, DVM, DACZM, DABVP (Avian)
Caitlin Boon, PhD
Sathya Chinnadurai, DVM, MS, DACZM, DACVAA, DACAW
Virginia Fajt, DVM, PhD, ACVCP
Randall Gnatt, JD
Michelle Kromm, DVM, MPH, MAM, DACPV
Katelyn McCullock, MS
Kurt Schrader, DVM

The Panel examined significant challenges and unmet needs within the animal health ecosystem, drawing on valuable insights gathered from both roundtable participants and public feedback. Focus areas included:

1. Identification of regulatory and other barriers impeding progress, innovation, or veterinary medicine;
2. How to modernize regulatory approaches that incentivize innovation across animal sectors, especially in minor food animal species, as well as the use of biotechnology; and
3. Health challenges within animal sectors, especially those without effective prevention or treatment or those requiring multifaceted, interdisciplinary solutions.

Contributors were asked to pinpoint aspects of their sector functioning effectively and where challenges existed. They also shared their views on potential opportunities for change or improvement and obstacles that might impede progress.

From this input, the Panel developed actionable recommendations, allowing agencies and organizations affecting the animal health ecosystem to assist the development of new or modified regulatory approaches. These efforts would be aimed at better meeting the needs of and support innovations in the modern animal health ecosystem. By developing recommendations directed at modernizing timely regulatory processes and reducing barriers to progress, the Panel aims to position the FDA and associated agencies to better adapt to the evolving landscape of medicine, biotechnology, and veterinary science, ensuring a future that supports animal health advancements while upholding essential safety standards.

Virtual Roundtables

To support the Expert Panel's work, it conducted a series of roundtables to discuss topics related to the veterinary industry, animal health, and animal feed. The roundtables were focused, invitation-only discussions and included experts in various fields.

Roundtables and Presentations:

1. Beef and Dairy Cattle Roundtable, September 25, 2024
2. Aquaculture Roundtable, October 23, 2024
3. Swine Roundtable, November 6, 2024
4. Animal Drug Company Discussions, November 20, 2024
5. Poultry Roundtable, December 4, 2024
6. Wildlife, Zoo, & Lab Animals Roundtable, December 18, 2024
7. Minor Food Species Roundtable, January 22, 2025
8. Biotechnology Discussions, February 5, 2025
9. Companion Animals Roundtable, February 26, 2025
10. Equine Roundtable, March 5, 2025

Conversations with FDA-CVM Staff

The Expert Panel also engaged with FDA-CVM leadership and subject matter experts to better understand the Agency's structure and processes. To encourage candor from stakeholders, FDA-CVM staff did not participate in the roundtables.

Information Gathering Portal

The Animal Health Portal allowed interested parties to comment on unmet needs within the animal and veterinary industries. The Panel welcomed input from end users of FDA's regulated products (farmers, ranchers, owners of companion animals), veterinarians, and people working in or associated with zoos, animal food and drug industries, public health organizations, non-governmental groups, and other U.S., state, or local government agencies. All comments remained confidential and were not shared with the public. The portal remained open from September 16, 2024, through December 31, 2024, and received 164 public comments associated with 13 prespecified sectors of expertise. Comments were analyzed and key themes were identified.

Appendix D: Report Contributors and Foundation Staff

Lisa Tell, DVM, DACZM, DABVP (Avian), School of Veterinary Medicine, UC Davis, (Chair)

Dr. Tell is a Distinguished Professor of Medicine and Epidemiology at the University of CA, Davis. She is board certified in avian and zoological medicine and was a practicing veterinarian (National Zoological Park and UC Davis Veterinary Medical Teaching Hospital) from 1991-2006. In 2006, Dr. Tell became the Director for the Western Region of the Food Animal Residue Avoidance Databank and Minor Use/Minor Species Animal Drug (2006–2012) Programs. Her research focuses on veterinary pharmacology, with an emphasis on drug residue depletion and mitigating drug residues in animal derived food products destined for human consumption.

Caitlin Boon, PhD, Mars, Inc., Senior Director for Health & Nutrition Policy at Mars

Dr. Boon leads policy engagement on health, food safety and nutrition issues across the portfolio, which includes major pet food brands as well as veterinary diagnostic and hospital facilities. With a PhD in food science and an undergraduate degree in Poultry Science, Dr. Boon brings a wealth of knowledge in public health and food safety to her role. In addition, she has past experience as a regulator, working on scientific and policy matters relating to food safety, nutrition, and veterinary medicine for nearly a dozen years at FDA.

Virginia Fajt, DVM, PhD, ACVCP, Texas A&M University, Clinical Professor at Texas A&M University in the Department of Veterinary Physiology and Pharmacology.

Dr. Fajt holds a DVM and a PhD in Veterinary Physiology and is board certified in veterinary clinical pharmacology. Dr. Fajt has collaborated with clinical faculty, microbiologists, epidemiologists and librarians to study drug disposition and other aspects of clinical drug use in various major and minor species of animals.

Randall Gnatt, JD, Elanco, Associate General Counsel at Elanco

Mr. Gnatt focusing on legal, regulatory, and policy issues involving animal health products. He navigates the complex regulatory landscape, facilitating the approval and compliance of innovative animal health products that enhance the well-being of animals globally. In addition, Gnatt has extensive experience as a regulator, working for more than 10 years on legal, compliance, and policy matters within FDA's Center for Veterinary Medicine.

Michelle Kromm, DVM, MPH, MAM, DACPV, Food Forward LLC

Dr. Kromm is the Principal at Food Forward LLC, a consulting practice focused on improving the resiliency of the food system through risk mitigation and management. She is a board-certified poultry veterinarian with more than 15 years of experience in food safety, emergency disease response, and antimicrobial stewardship. Dr. Kromm received her DVM from Iowa State University, her MPH from the University of Iowa, and her MAM

from the University of Georgia. She previously held leadership roles at Jennie-O Turkey Store, including Vice President of Animal Health and Welfare at Hormel Foods. Dr. Kromm is recognized for her expertise in engaging with diverse stakeholders to enhance animal health and welfare outcomes.

Katelyn McCullock, MS, American Veterinary Medical Association, Chief Economist at the American Veterinary Medical Association (AVMA).

She provides in-depth economic analysis and insights to support the veterinary profession. With a background in agricultural economics, McCullock helps guide policy and business decisions within the field of veterinary medicine. Her work involves evaluating economic trends, conducting market research, and providing financial guidance to ensure the sustainability and growth of veterinary practices.

Kurt Schrader, DVM, Williams and Jensen

Dr. Kurt Schrader is a former U.S. Congressman and currently a lobbyist at Williams and Jensen. With a background in veterinary medicine and a long career in public service, Dr. Schrader now focuses on influencing policy and advocating for agricultural and veterinary issues. His experience as a veterinarian and legislator allows him to provide valuable insights into the development of policies that support the veterinary community and the agricultural sector.

Foundation Staff

Eynat Amir, MA, LMSW

Amar Bhat, PhD

Hannah Gray

Carolyn Hiller, MBA

Angela Hoth, PharmD, MPH

Jessica Palfreyman

Susan C. Winckler, RPh, Esq.

Appendix E: Roundtable and Discussion Participants

Samantha E Allen
Glen W. Almond
Jose Angulo
Melanie Archer
Edward B. Arnett
Dorothy Bailey
Stephanie Batliner
Sebastian Belle
Cheryl Greenacre
Derek Bickhart
Lynne Boxer
Roselle Busch
Kenneth Cain
Abbey Canon
Michael Capel
Charlie Culpepper
Lindy Chiaia
Tristan Colonius
Walter E Cook
Constance Cullman
Rachel Cumberbatch
Brinda A. Dass
Gigi Davidson
Mark L. Drew
Anna Dunaway
Beth Ellikidis
Laura Epstein
William T. Flynn
David Foley
Tracey Forfa
Heather Fowler
Carlos A. González
John W. Hallberg
Gareth Harris
Denise L. B. Heard
Marc Hulin
Rob Hunter
Ashley Johnson
J.J. Jones
Jamie Jonker
Nicole Juba
Terry Ryan Kane
Margo Karriker Reeves
Jerry Klein
Matthew A. Lucia
Alison C. Manchester
Eric Martin
Molly McAllister
Amber McCoig
Suzanne Young McComb
John Metzer
Adam Moyer
Amy Omer
Kenneth Opengart
Randy Peach
Michael R. Pedersen
Gerardo Perez-Camargo
Ashley Peterson
Sara Place
Paul J. Plummer
Kent M. Reed
David Reim
Nilima Renukdas
Sarah Reuss
Joan Dean Rowe
Pamela L Ruegg
Tammy Sadek
Erica Sanko
Timothy Schell
Kathy Simmons
Randall S. Singer
Scott Snyder
Montserrat Torremorell
Linnea Tracy
Jesse Trushenski
Kurt Venator
Mark Walton
Cindy Wolf

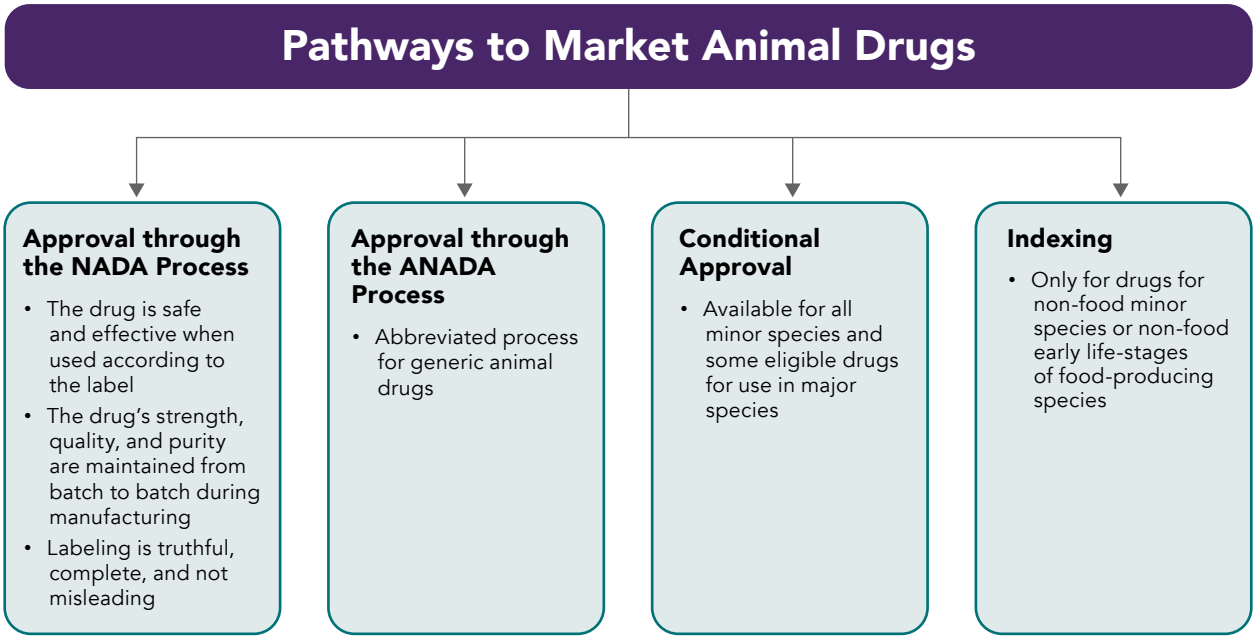
Appendix F: Animal Health Threats

Selected Animal Health Threats Described by Roundtable Participants

Aquaculture	• *Ostreid herpesvirus 1* (OsHV-1) in shellfish • Exotic viral pathogens • Mixed pathogen disease events • Parasites
Beef & Dairy Cattle	• Highly pathogenic avian influenza (HPAI) • Asian longhorned tick • *Theileria orientalis* • Gastrointestinal parasite resistance
Companion Animals	• Bacterial infections and antimicrobial resistance
Equine	• Herpes, neurologic herpes • Ectoparasitic and tick-borne diseases • Lameness due to laminitis, chronic arthritis, etc.
Honey Bees	• Varroa mites
Laboratory Animals	• Adequate pain control
Poultry	• HPAI • Avian Metapneumovirus (aMPV) • Parasitic infections e.g., *histomoniasis* (blackhead disease) in turkeys, *Dermanyssus gallinae* (poultry red mite)
Sheep & Goats	• Anthelmintic-resistant parasites • *Coxiella* • Foot rot and foot scald (*Dichelobacter nodosus*, *Fusobacterium necrophorum*) • Bacterial and lentiviral mastitis • *Campylobacter jejuni* abortions
Swine	• African Swine Fever (ASF) • Porcine Reproductive and Respiratory Syndrome (PRRS)
Wildlife	• HPAI in wild birds • Chronic wasting disease (CWD) in ruminant species • Bighorn sheep pneumonia • Fungal diseases
Zoo Animals	• Herpesvirus in elephants • Aspergillosis in penguins

Appendix G: Drug Approval Pathways

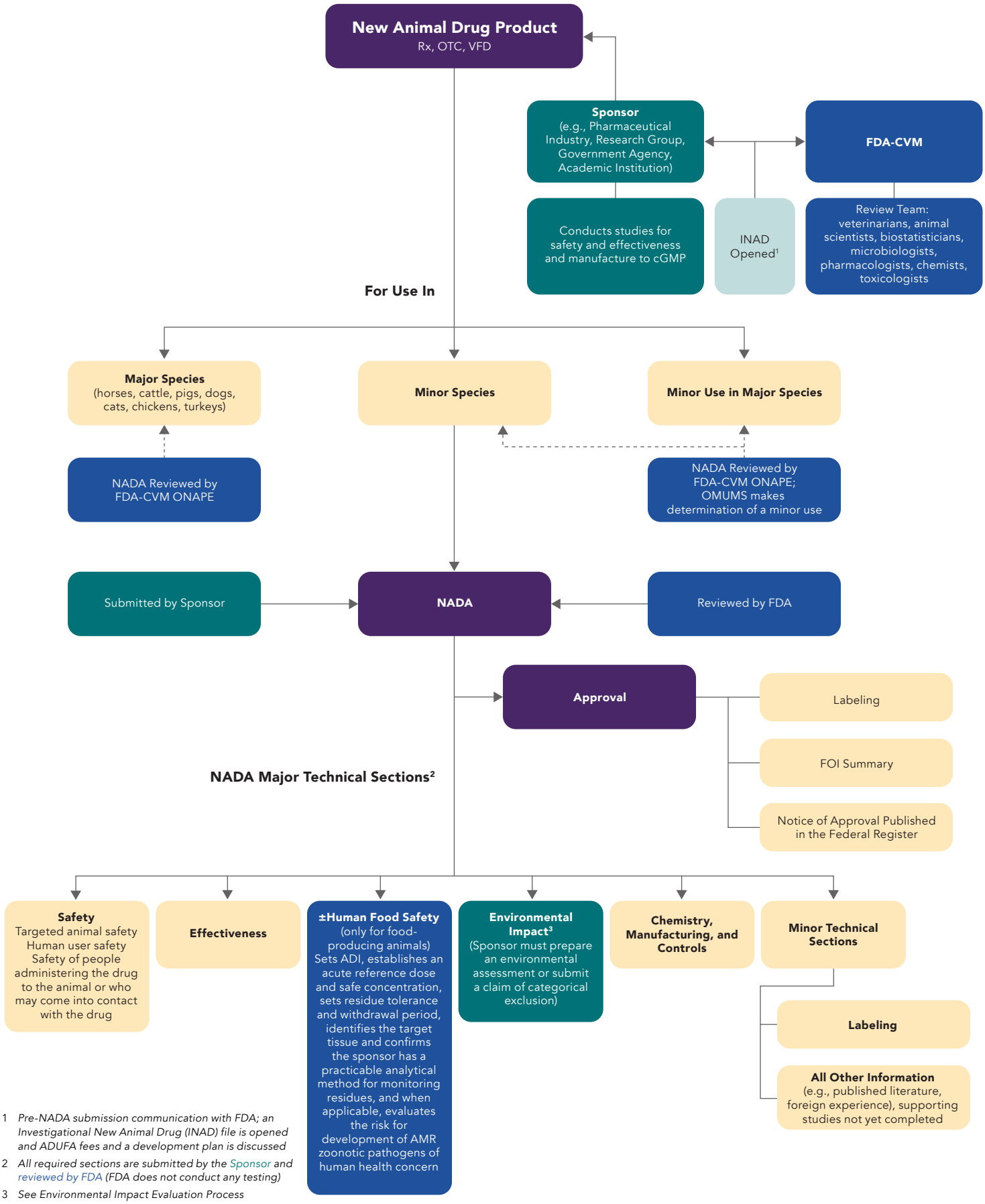
Pathways[59,60]



59 https://www.fda.gov/animal-veterinary/animal-health-literacy/idea-marketplace-journey-animal-drug-through-approval-process.

60 https://www.fda.gov/animal-veterinary/minor-useminor-species/drug-indexing.

New Animal Drug Product Pathway[61,62,63,64]

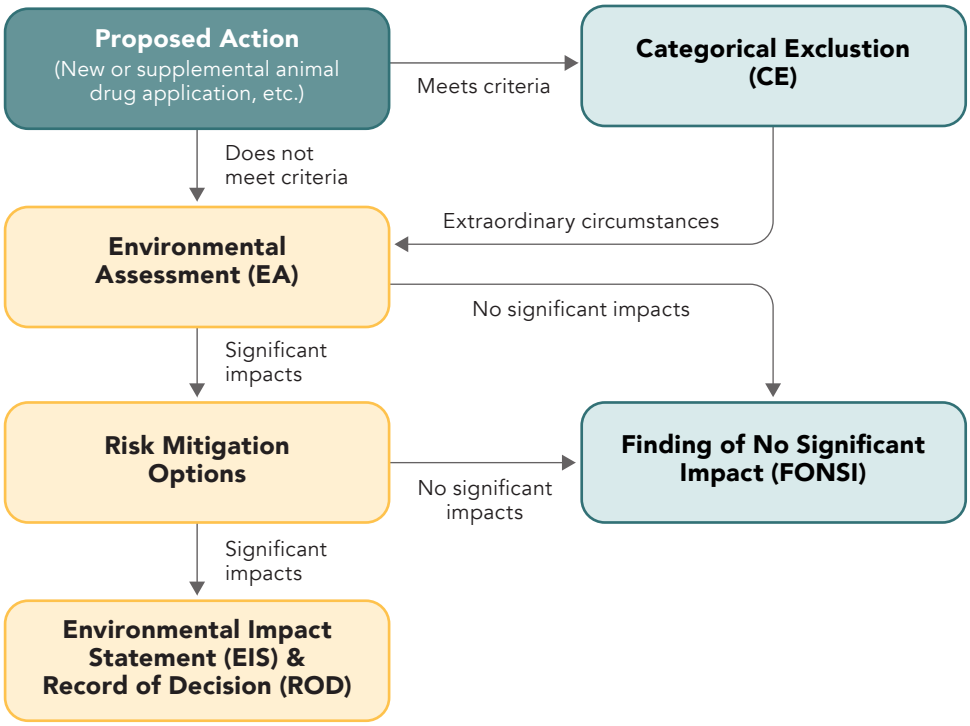


1 *Pre-NADA submission communication with FDA; an Investigational New Animal Drug (INAD) file is opened and ADUFA fees and a development plan is discussed*

2 *All required sections are submitted by the Sponsor and reviewed by FDA (FDA does not conduct any testing)*

3 *See Environmental Impact Evaluation Process*

Environmental Impact Evaluation Process



61 https://www.fda.gov/animal-veterinary/animal-health-literacy/idea-marketplace-journey-animal-drug-through-approval-process.

62 https://www.fda.gov/animal-veterinary/development-approval-process/environmental-impact-considerations.

63 https://www.fda.gov/animal-veterinary/approved-animal-drug-products-green-book/freedom-information-foi-summaries-approved-and-conditionally-approved-animal-drugs.

64 https://www.fda.gov/animal-veterinary/development-approval-process/minor-useminor-species.

Appendix H: Analysis of Regulatory Frameworks for Animal Feed Additives[65] and Animal Drugs

This analysis provides comparison of regulatory frameworks in the U.S, European Union (EU), Australia, New Zealand, and Canada for animal feed additives and veterinary drugs. It includes assessments of premarket and postmarket requirements, harmonization efforts, and areas of excellence and opportunity.

Scope & Summary of Assessment

SCOPE OF THE ANALYSIS

This analysis provides a comparative evaluation of regulatory frameworks for animal feed additives and veterinary drugs across the U.S, EU, Australia, New Zealand, and Canada. It examines pre-market approval processes, postmarket compliance requirements, and claims validation pathways, while also exploring efforts toward harmonization in regulatory practices. Additionally, it highlights key areas of excellence in scientific evaluation and innovation and identifies opportunities for improvement, particularly in streamlining processes and addressing environmental and other efficacy claims.

SUMMARY OF OUTCOMES

The assessment reveals significant divergence in regulatory approaches for animal feed additives and veterinary drugs across the evaluated jurisdictions. The EU demonstrates strong integration of environmental claims through defined functional categories, while Canada and Australia offer relatively streamlined approval pathways for feed additives with non-therapeutic benefits.

The U.S., with its robust scientific standards, faces challenges in adapting its frameworks to accommodate modern innovations, particularly for functional additives and sustainability claims. Efforts at global harmonization, such as VICH guidelines, have achieved greater alignment in drug regulations across various countries. Similarly, initiatives aimed at harmonizing technical requirements and assessments for feed ingredients have been undertaken by organizations like the ICCF. However, regulatory frameworks and definitions are not consistently applied across all countries, and progress remains limited, particularly concerning animal feed additives. Overall, opportunities exist to improve flexibility, efficiency, and alignment, especially for the U.S. system, which could benefit from legislative reforms and expanded functional categories.

Comparative Analysis of Animal Feed Additive Regulatory Frameworks

Table H1 provides an overview of regulatory governance specific to animal feed additives. Please note that this is specific to animal feed additives and presumes livestock relevance, i.e., food-producing animals. Some

65 For the purposes of this analysis, the term “animal feed additive” and/or “animal feed ingredient” includes “food additives” as defined by U.S. FDA (Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 201 (s)) as well as products administered to animals in feed that are regulated as drugs in the U.S. (Type A medicated articles) but alternatively regulated as “animal feed additives” in other countries. This would include animal foods with claims of zootechnical effects.

markets may have shorter pathways for non-food animals (e.g., pets, ornamental fish) that do not require human food safety consideration.

In the U.S., human and animal food additives are regulated under the FFDCA and are defined as any substance whose intended use results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food. According to FDA's interpretation, if products administered through animal feed have claims beyond nutritive value or having a technical effect on the feed itself, such as enhancing growth or changing the digestive process or microbiome of animals, it is to be evaluated as an animal drug rather than a feed additive. This regulatory approach creates a two-track system for animal ingredient reviews: products are classified as either food additives or drugs. As a result, many products that are regulated as feed additives in other countries must undergo the FDA's more stringent New Animal Drug approval process if their intended use or claims suggest effects beyond nutrition. This distinction presents challenges for international alignment and approval of animal feed additives in the United States.

Table H2 highlights the difference in the treatment of animal product claims, showing the frequency with which the U.S. system triggers the New Animal Drug Application (NADA) process in circumstances that would not trigger drug applications in other countries.

TABLE H1: COMPARATIVE SUMMARY OF ANIMAL FEED INGREDIENT REGULATION GOVERNANCE

ASPECT	UNITED STATES	EUROPEAN UNION	CANADA	AUSTRALIA	NEW ZEALAND
Approval Process	Regulated by FDA-CVM. Pathways include Food Additive Petition, GRAS notification or self determination of GRAS. (FDA) Note: AAFCO, an independent organization, has a complementary scientific review process for animal food ingredients.	Governed by Regulation (EC) No. 1831/2003. EFSA conducts scientific evaluations; the European Commission grants final approval. (EFSA)	Regulated by CFIA. Feed ingredients must be approved and listed in the Canadian Feed Ingredients Table. (CFIA)	APVMA oversees approvals, focusing on safety, efficacy and environmental impact. (APVMA)	Regulated by NZMPI, which evaluates safety, efficacy and environmental impacts. (MPI)
Dossier Submission & Review Timeframes	Timeframes vary depending on complexity and comprehensiveness of data/method; reviews can take years. (FDA)	EFSA scientific opinions take ~6 months; final approval by the Commission may take longer. (EFSA)	Timeframes depend on complexity; processes are relatively streamlined. (CFIA)	Review timeframes vary based on additive complexity. (APVMA)	Similar timeframes to Australia but coordinated with local needs. (MPI)

ASPECT	UNITED STATES	EUROPEAN UNION	CANADA	AUSTRALIA	NEW ZEALAND
Postmarket Requirements	Includes residue monitoring and compliance audits. (FDA)	EU member states conduct postmarket monitoring; compliance is enforced at the national level. (EFSA)	Ongoing compliance monitoring by CFIA; periodic reassessments may occur. (CFIA)	APVMA requires ongoing monitoring, including environmental impact assessments. (APVMA)	NZMPI mandates postmarket surveillance similar to APVMA. (MPI)
Fees	No fees for food additive submissions. (FDA)	Fees required for dossier evaluation; rates depend on the additive and complexity. (EFSA)	Fees are charged for evaluation and registration. (CFIA)	Fees required for assessments; rates vary by submission complexity. (APVMA)	Fees are structured similarly to Australia. (MPI)
Claims & Validation	Claims are evaluated based on safety and achievement of the intended physical or technical effect (such as emulsifiers and preservatives). Must comply with NEPA and must be scientifically substantiated during FDA review. Limited for feed. (FDA).	EFSA evaluates scientific validity of claims; political factors may influence final approvals. (EFSA) (Additional Regulation Promulgation Table in Section 7)	Health/ environmental claims require rigorous validation. (CFIA)	Claims are evaluated based on safety, efficacy and environmental impacts by APVMA. (APVMA)	Claims follow similar evaluation processes as Australia. (MPI)

TABLE H2: COMPARISON PRACTICES FOR CLAIMS RELATED TO ADDITIVES AND DRUGS

TYPE OF CLAIM	UNITED STATES	EUROPEAN UNION	CANADA	AUSTRALIA	NEW ZEALAND
Sustainability/ Environmental Claims	Typically considered a drug if affecting methane emissions or other environmental outcomes or are intended to affect the structure or any function of the animal's body other than by providing nutritive value. (FDA)	Treated as environmental additives under feed additive regulations. (EFSA)	Assessed as feed ingredients with environmental claims under CFIA. (CFIA)	Regulated as feed additives with integrated environmental reviews. (APVMA)	Similar to Australia; regulated under NZMPI with environmental considerations. (MPI)
Performance Claims	Triggers drug categorization, requiring NADA. (FDA)	Handled under feed additive categories like zootechnical additives. (EFSA)	Evaluated as feed ingredients without requiring drug-level scrutiny. (CFIA)	Performance-related claims remain under feed additive regulation. (APVMA)	Similar to Australia; treated as feed additives under NZMPI. (MPI)
Health Claims	Health claims may be permitted for animal food additives if they are narrowly limited to structure/ function claims based on nutritive value; cannot make claims to treat or prevent disease. (FDA)	Health claims are permitted for feed additives unless they claim to treat/prevent disease. (EFSA)	Health-related feed ingredients are assessed by CFIA. (CFIA)	Health-promoting claims are evaluated as feed additives unless therapeutic. (APVMA)	Similar to Australia. (MPI)
Animal Welfare or Well-being Claims	May require drug-level scrutiny if they alter animal behavior. (FDA)	Welfare claims are generally allowed under feed additive regulations. (EFSA)	Treated as feed ingredients under CFIA unless therapeutic. (CFIA)	Welfare-related additives are regulated similarly to other feed additives. (APVMA)	Same as Australia. (MPI)

Environmental and Sustainability Claims

U.S: Environmental claims for animal food additives, such as methane reduction or improving sustainability in livestock production, often face regulatory challenges because of the lack of a dedicated functional category for such claims. In the U.S., these products frequently fall under the NADA process, as FDA views them as altering the "structure or function" of the animal in a manner not directly linked to the CVM definition/interpretation of nutritive value. This pathway, designed for production and therapeutic drugs, is lengthy, costly and ill-suited

for nontherapeutic additives with environmental benefits. Current regulatory frameworks, interpretations, and policies lack the flexibility to accommodate claims related to environmental outcomes without triggering drug-level scrutiny, timing, and cost. The absence of a defined category for "environmental additives" within U.S. animal food additive regulations limits innovation and delays the market entry of sustainable technologies.

Other Jurisdictions: In the EU, Canada, Australia and New Zealand, environmental claims are often integrated into existing animal feed additive frameworks, as they are not allowed or interpreted to be animal drug claims and, thus, avoid drug-level scrutiny. For example, in the EU, additives with environmental benefits, such as methane reduction, are categorized as "environmental additives" under Regulation (EC) No. 1831/2003, simplifying the approval process while ensuring safety and efficacy. Canada, Australia and New Zealand similarly regulate these claims within their feed additive systems, allowing for faster approval and encouraging innovation in sustainability. These approaches highlight the potential for more streamlined processes that balance safety with the urgent need for environmentally beneficial solutions in animal agriculture.

Performance Claims

U.S: Animal food additives that make performance or efficacy claims (such as structure function that would not be considered animal drugs by other authorities) face similar challenges as claims related to environmental outcomes. For example, if an additive is intended to improve animal production and performance such as weight gain or feed conversion, the additive may fall under the category of a drug rather than an animal food additive. Non-nutritive animal food, with such claims must navigate the NADA process even though these claims often do not involve therapeutic benefits. Current legislative interpretation applied by CVM does not provide a clear or efficient pathway for approving non-nutritive additives with performance-enhancing claims. Much of this is dependent on the agency's interpretation of what characteristics of a substance would allow it to be considered "nutritive" for animals. A legislative proposal, the Innovative FEED Act, seeks to address this gap. For example, it would allow some non-nutritive animal food additives intended to affect the structure of the animal's body by altering its microbiome to be regulated as food additives rather than requiring them to undergo the NADA process.

Other Jurisdictions: In the EU, Canada, Australia and New Zealand, non-nutritive additives with production or production claims are typically regulated as feed additives, not drugs, provided they do not claim to treat or prevent disease since these jurisdictions do not allow production claims on animal drugs. For example, in the EU, additives promoting weight gain are classified as zootechnical additives, a functional group under Regulation (EC) No. 1831/2003.

Animal Health

U.S: General health-related claims for animal feed additives (e.g., improving gut health, but not preventing or curing disease) are often considered drug claims, even if they are intended for non-therapeutic purposes. The FDA's interpretation of animal drug claims on substances excluded from "nutritive" qualification, limits the ability of manufacturers to market substances with such benefits unless they undergo the NADA process. This likely requires legislative changes for FDA to change regulatory practice or a less-restrictive interpretation of the statute as applied by FDA.

Other Jurisdictions: In the EU, Canada, and Australia/New Zealand, health-related claims are often handled within the feed additive framework, provided they do not cross into therapeutic territory. For example, the CFIA evaluates health-related claims for animal feed ingredients as part of its Feed Ingredient Registration Program, using a simpler and faster process than NADA but still requiring efficacy data.

Other Non-Nutritive Benefits

U.S: Claims related to behavioral changes, stress reduction, or improved well-being for animals face similar regulatory ambiguities in the U.S. These types of claims are considered drug claims because: (1) they affect animal "structure or function," and (2) non-nutritive animal food does not qualify for the "other than food" parenthetical in the FFDCA's drug definition (section 201(g)(1)(C)).

Other Jurisdictions: These claims are often recognized under specific functional groups or categories for feed additives in other jurisdictions.

Table H3 expands on the Environmental Claims example highlighting the conflict created when animal agriculture environmental goals or mandates might use animal feed-use cases, but regulatory frameworks are not in place for applicable evaluation. FDA recently bridged the gap between product categories by using its discretion within the confines of the legislative definitions governing its regulatory categorization in its review of Bovaer®.[66]

TABLE H3: APPROACHES TO PRODUCTS WITH DISTINCT PATHWAYS FOR *SUSTAINABILITY* CLAIMS

JURISDICTION	CATEGORIZATION	APPROVAL PATHWAY	ADVANTAGES
European Union	Treated as a feed additive (functional group: environmental additives).	Governed by Regulation (EC) No. 1831/2003. Assessed by EFSA for safety and efficacy; approved by the European Commission.	**Flexibility for Innovation:** Feed additives with environmental benefits are explicitly recognized and have a defined approval process.
Canada	Categorized as a feed ingredient with environmental claims.	Regulated by CFIA as part of the Feed Ingredient Registration Program. Requires validation of safety, efficacy, and sustainability claims.	**Streamlined Process:** Feed additives with environmental claims face a shorter, less burdensome pathway.
Australia	Treated as a feed additive under specific categories.	Regulated by APVMA. Requires safety and efficacy data, with consideration for environmental impacts.	**Integrated Review:** APVMA accommodates environmental claims under its existing feed additive framework.
New Zealand	Treated similarly to Australia as a feed additive.	Regulated by NZMPI. Requires proof of efficacy, safety, and environmental benefits.	**Aligned Approach:** NZMPI coordinates approvals with Australia to ensure harmonized regulatory outcomes.

66 Elanco. Elanco Announces FDA Has Completed Review of Bovaer®, First-in-Class Methane-Reducing Feed Ingredient, for U.S. Dairy Industry. www.elanco.com. Published May 28, 2024. Accessed March 29, 2025. https://www.elanco.com/en-us/insights/elanco-announces-fda-has-completed-review-of-bovaer-first-in-class-methane-reducing-feed-ingredient-for-u-s-dairy-industry.

NB: Unlike the EU, Canada, and Australia/New Zealand, the U.S. does not have a functional category for environmental additives within its animal food additive framework. Therefore, in the U.S., what is considered "non-nutritive" methane-reducing animal food products must undergo the NADA process, which is not optimized for products that do not prevent or treat diseases.

Comparative Analysis of Animal Drug Regulatory Frameworks

Animal Drug Regulatory Governance in all countries, with the exception of the EU, allows technical regulatory bodies to assess and determine regulatory permissibility. In the EU, EMA or EFSA conduct scientific assessments—and the European Commission grants final regulatory allowance. The EU system allows for precautionary and political approaches to intercede in final determination in a manner that is different from the other countries that are assessed here (Table H5).

In the U.S. (FFDCA Section 201(g)) an animal drug is defined, in part, as: Any "articles recognized in the official U.S. Pharmacopoeia, official Homeopathic Pharmacopoeia of the U.S., or official National Formulary that is intended for use in animals." Any "article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in animals." Any "articles (other than food) intended to affect the structure or function of the body of animals" or "any component of such articles."

This definition captures much of the intended use that is permitted in animal food additives and additive related claims. Therefore, the FDA is assessing ingredients as new animal drugs that are not considered/allowed to be animal drugs in other countries. This lack of harmonization increases the workload of FDA and impacts what claims innovators make on their products due to lengthiness, complexity and cost of NADA. Innovators might try to justify products through other pathways such as self-concluded GRAS that may be inappropriately applied, or labels with claims that do not reflect true intended use. There is also a differential impact on cross-border trade as it complicates labeling and other regulatory requirements related to functional claims, animal feed guidance and approvals, as well as animal drug harmonization.

Table H4 also highlights the difference among countries related to timeframes. Timeframes are impacted by a variety of factors, beginning with the incongruous definitions but also including agency interpretations of local regulations. Harmonization agreements between countries on animal drugs along with the sharing of data could lessen burden and timeframes. All countries have similar postmarket review processes for animal drugs. However, with the FDA applying enforcement discretion to animal drugs classified as feed, there can be confusion among states and users regarding the product's status and the associated requirements.

TABLE H4: COMPARATIVE SUMMARY OF ANIMAL DRUG REGULATION GOVERNANCE

ASPECT	UNITED STATES	EUROPEAN UNION	CANADA	AUSTRALIA	NEW ZEALAND
Approval Process	Regulated by FDA (CVM) through New Animal Drug Applications (NADA) for, among other things, safety, and efficacy. (FDA)	Regulated by EMA under Directive 2001/82/EC; EMA evaluates data; the European Commission grants approval. (EMA)	Regulated by Health Canada (VDD); submissions must prove safety, efficacy, and quality. (Health Canada)	Regulated by APVMA for safety, efficacy, and environmental impact. (APVMA)	Regulated by NZMPI, focusing on safety, efficacy, and environmental data. (MPI)
Dossier Submission & Review Timeframes	Phased review of technical submissions with extensive communication. Technical section evaluations. Lengthy time-frames for entire administrative process; can average up to 6–8 years. (FDA)	EMA technical section evaluations typically take ~1 year; Review is not phased, and all technical sections must be complete upon submission. Final approval by the Commission may take longer. (EMA)	Timeframes are shorter if joint reviews are conducted with the US or EU. (Health Canada)	Timeframes depend on drug complexity; often lengthy due to data validation needs. (APVMA)	Similar timeframes to Australia; local context is considered. (MPI)
Postmarket Requirements	Includes adverse event reporting and residue monitoring. (FDA)	EMA collaborates with national authorities for pharmacovigi-lance; EU member states monitor compli-ance. (EMA)	VDD mandates pharmacovigi-lance and periodic reas-sessments. (Health Canada)	APVMA enforces postmarket pharmacovigi-lance and residue monitor-ing. (APVMA)	NZMPI enforces compliance audits and adverse event reporting. (MPI)
Fees	Application fees apply based on product type. (FDA)	Fees vary based on the drug's intended use and complexity. (EMA)	Fees are charged for submission and review. (Health Canada)	Fees required for all submissions; rates depend on the scope and complexity. (APVMA)	Fees are similar to Australia but adjusted for local regulatory needs. (MPI)
Claims & Validation	Safety and efficacy claims must be substantiated with robust data. (FDA)	EMA validates claims scientifically; sustainability claims are increasingly prioritized. (EMA)	Claims require strong evidence for safety and efficacy; sustainability claims are evaluated separately. (Health Canada)	Efficacy and safety claims undergo rigorous evaluation, including environmental considerations. (APVMA)	Claims are validated similarly to Australia, with additional local assessments for environmental impact. (MPI)

Assessment and Maximum Residue Limit (MRL) setting comparison

The EU uses a multispecies approach when establishing MRLs for veterinary medicinal products that appears to be more flexible than FDA's approach at this time. The EU allows for the extrapolation of MRLs from one species to others under *certain conditions*, streamlining the regulatory process and potentially benefiting multiple species without necessitating separate residue studies for each. The U.S. takes a more cautious approach unless there is evidence of very strong similarity in metabolism and tissue distribution.

EU's Multispecies MRL Approach:

1. **Extrapolation Principles:**
   - The EU's Committee for Medicinal Products for Veterinary Use (CVMP) considers the possibility of extrapolating MRLs to additional species and foodstuffs during the evaluation process, even if not explicitly requested by applicants. Commission Regulation (EU) 2017/880, outlines the principles and minimum criteria for such extrapolations.[67]
2. **Application to Minor Species:**
   - For minor species (e.g., rabbits, goats, horses), where conducting comprehensive residue studies may be impractical, CVMP assesses whether data from major species can be *appropriately* applied to these minor species, considering factors like metabolic similarities and consumption patterns.
3. **Scientific Justification:**
   - Extrapolations are based on scientific assessments, ensuring that the MRLs remain protective of consumer health. CVMP evaluates the pharmacokinetic and residue depletion data to determine the validity of applying existing MRLs across species.

Harmonization

Harmonized approaches to regulatory approvals related to scientific data, animal and human safety, and evidence-based claims are generally considered positive for global public health and the facilitation of trade, and innovation. Consistency allows broader market access that may reduce risks such as antimicrobial resistance, zoonotic disease, and environmental and food safety concerns. Animal drugs are traditionally more harmonized than animal feed additives.

ANIMAL DRUG/MEDICINE HARMONIZATION:

Animal Medicines are generally more harmonized across countries but due to the categorization differentiation and diversity of data requirements, there is room for continuous improvement. Much of this effort is through the International Conference on Veterinary Microbiology and Pathology (ICVMP) as well as the Global Harmonization Task Force (GHTF) with approvals often mirroring the processes for human drugs, which have well-established international harmonization frameworks (e.g., ICH guidelines). FDA is a founding member of VICH which harmonizes technical requirements for veterinary drug safety, efficacy, and quality between the U.S., EU, Japan, and other member countries.

ANIMAL FEED ADDITIVE HARMONIZATION:

Harmonization in animal feed additives is more challenging due to **complexity**.

67 Maximum residue limits (MRL) | European Medicines Agency (EMA).

Feed additives include a broad range of substances (e.g., vitamins, enzymes, probiotics, minerals, and amino acids), which vary in how they are classified and their use cases from jurisdiction to jurisdiction. For example, some countries classify certain additives as feed ingredients, while others treat them as medicated products, creating regulatory divergence.

While the World Organisation for Animal Health (WOAH, formerly known as OIE) addresses drug-related issues, there is no equivalent global body dedicated to harmonizing feed additive regulations. Regional entities like the European Food Safety Authority (EFSA), and the FDA follow different protocols for assessing safety, efficacy, and environmental impact. Animal Feed additives are also very closely tied to local agricultural practices, and countries often prioritize national interests or trade competitiveness over international alignment.

While Codex Alimentarius has developed some guidelines for feed additives, such as MRLs for contaminants in feed, the scope of harmonization is narrower compared to veterinary drugs because the focus is primarily on food safety. That said, Codex is working on feed-related guidelines and has done a great deal of work in antimicrobial resistance. Adopting a multispecies MRL approach in the U.S. that is similar to the EU, could be an opportunity for regulatory efficiency, resource optimization, and enhanced animal health. Today it is done in limited circumstances, particularly when related to animals for food production. Unlike the EU there is not formalized guidance for species extrapolation and it is not common in regulatory permissibility implementation as it is in the EU.

International Cooperation for the Convergence of Technical Requirements for the Assessment of Feed Ingredients (ICCF) aims to establish guidance for assessing feed ingredients. They currently have an expert working group developing a guidance document on the assessment of feed ingredients with technical effects. However, ICCF does not explicitly define animal feed additives or address the lack of uniformity between feed additive regulations.

Additional Information

Some countries' or markets' regulations are promulgated by the agencies conducting the assessments themselves as technical experts. In others there are distinct policy bodies that finalize the regulations.

TABLE H5: DIFFERENTIATION OF REGULATORY AUTHORITY RESPONSIBILITIES WITHIN THE SAME/DIFFERENT BODIES

JURISDICTION	REGULATORY AUTHORITY	SCIENTIFIC REVIEW	POLICY/FINAL APPROVAL
United States	FDA (CVM)	Same agency conducts scientific review.	Same agency grants final approval.
European Union	EFSA (Feed), EMA (Drugs)	EFSA or EMA conduct scientific reviews.	European Commission makes final approval decisions.
Canada	CFIA (Feed), Health Canada (VDD) (Drugs)	Scientific review conducted by CFIA or VDD.	Same agency grants final approval.
Australia	APVMA	APVMA performs scientific evaluations.	APVMA grants approvals.
New Zealand	NZMPI	NZMPI conducts evaluations.	NZMPI grants final approval.

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