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.