Foreword

When I took the helm of the U.S. Food and Drug Administration’s Center for Veterinary Medicine (CVM) as its seventh director in January 2023, I made a commitment to lead the animal foods and veterinary products program with a vision that embraces an exciting period of innovation. New technologies and a new understanding of biological and chemical processes present tremendous opportunities for advancing human and animal health. What’s more, researchers, scientists, product developers and public health leaders increasingly recognize the interconnectedness of human, animal, and environmental health and are using transdisciplinary One Health approaches to develop new products and technologies that address modern challenges.

The Animal and Veterinary Innovation Agenda (AVIA) presented here details the actions CVM is taking to support development of safe, effective new products, spur innovation, and adopt smart improvements to regulatory pathways for new animal and veterinary products to reach the marketplace. We’re committed to reassessing and modifying CVM’s animal and veterinary product review programs and processes as needed to achieve these goals. The actions laid out in the AVIA will further the agency’s ability to efficiently oversee the diversity of products developed using innovative technologies and facilitate bringing more safe and effective animal health products to the market while protecting human, animal and environmental health.

The time is ripe for an innovation agenda. Veterinary medicine, animal industries, and food production are at an exciting moment where new technologies hold great promise – while global markets, strife, climate change, and increased disease threats mean our food system and animal industries need to become more creative and resilient.

This document is a natural progression of CVM conversations with the other FDA Centers; federal, state, local, and tribal partners; foreign counterparts; the industries we regulate; and the research community about how CVM contributes to maximizing One Health benefits from this era of innovation across a wide range of applications. This will bolster CVM’s ability to contribute to US Government One Health efforts. Today’s AVIA is an initial catalog of CVM’s current and intended actions toward this goal – I intend to further revise, refine, and add to the listed actions as this conversation continues.

I am proud to present CVM’s vision to not just keep pace with, but to elevate CVM’s role in the all-of-government efforts to lead innovation for the animal health, animal agriculture, and food production industries. I am deeply honored to lead the Center at such a pivotal juncture and look forward to the exciting possibilities the future will bring.

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Animal and Veterinary Innovation Agenda

The FDA’s Center for Veterinary Medicine (CVM) is committed to smart, risk-based regulatory approaches that keep pace with technological innovation and support and spur progress in the U.S. animal health, animal food and animal agricultural industries. CVM has a key role as a partner within the FDA, across the federal government, and with external stakeholders in supporting new technologies and approaches that address health needs across human, animal and environmental health sectors.

The world is in a period of rapid change that calls for the evolution of animal and veterinary products: climate change, human encroachment on previously wild environments, international conflict, and global travel and trade have the potential to increase disease transmission, environmental stressors, and pathologic challenges. We and the industries we regulate have access to an array of modern technologies to combat these threats – new technologies that can deliver a more resilient and robust food production system, ensure food-producing animals and their environments are healthier and hardier, and deliver consumers more choices in the foods they eat. These technologies can be used to monitor, prevent, control and treat increasing animal health challenges, such as zoonotic and animal infectious disease threats – leading to healthier animals, communities, and ecosystems.

New technologies and therapeutics – and new adaptations of existing technologies and therapeutics – can also usher in new treatments and tools for veterinary medicine. As veterinary medicine continues to grow and expand, CVM wants to ensure that veterinarians and their clients have reliable access to a wider array of safe and effective animal therapeutics – particularly for unmet needs.

CVM recognizes that human, animal, and environmental health are connected, and that innovative transdisciplinary approaches and technologies hold great potential to address challenges across these sectors. CVM wants to facilitate animal and veterinary product development across the board and see more safe, novel products and products for unmet human and animal needs – such as zootechnical food substances, monoclonal antibody therapies, gene therapies, intentional genomic alterations (IGAs) in animals, cell-based animal foods, and animal cell and tissue-based products – reach the market. To achieve this goal, CVM will work closely with our co-regulators, such as EPA and USDA, where jurisdictions intersect.
CVM is particularly interested in seeing products that address critical animal, human, and societal needs such as:

1. Products to increase the resilience and health of animals, such as products that can help animals be more resilient to heat or other environmental stresses;

2. Products that can increase the efficiency of our food supply, such as zootechnical feed substances that can make feed conversion more efficient and reduce waste byproducts;

3. Products to address unmet veterinary medical needs in major species that create a significant animal health burden, such as new treatments for cancer, cardiac disease, chronic renal failure, and pain control in food animals;

4. Products that address unmet needs in minor species, such as new products for disease threats to fish and small ruminants;

5. Products with novel mechanisms of action or novel technologies where there is a translational benefit to human and animal medicine; and

6. Products to address increasing animal and human disease threats, such as products that can prevent, control, and treat diseases such as African Swine Fever – a current threat to the nation’s pork industry.
Sitting at the intersection of converging science, CVM is uniquely positioned to tap into expertise both in-house, across the FDA and across the government and other sectors. From experts in human genetics and genomics in the FDA’s Center for Biologics Evaluation and Research (CBER) to cellular and biotechnology agriculture experts at the agency’s Human Foods Program (HFP) to world class scientists in the Office of the Chief Scientist (OCS), including the National Center for Toxicologic Research, to subject matter experts at CVM, the FDA’s ability to pool converging scientific expertise via a One Health approach is unparalleled.

This Animal and Veterinary Innovation Agenda (AVIA) delineates CVM’s current and intended future efforts to spur and support these developments in CVM’s regulated product areas and, where needed, adopt approaches to regulation that align the need to protect animals, people and the environment, with helping the regulated industries bring safe products to market that meet the challenges we are facing in animal industries and as a society.

The AVIA builds on FDA’s 2018 Plant and Animal Biotechnology Action Plan by amplifying the successful efforts to encourage biotechnology innovation outlined in that plan and expanding the scope of CVM’s support to advances across the span of relevant science. CVM will publicly track progress on the agenda and solicit public input on future innovation activities and priorities.

CVM has identified four key objectives, each of which is advanced by a variety of actions. Some actions are underway and ongoing, while others could be pursued as resources allow.

**Key Objectives of the Animal and Veterinary Innovation Agenda**

1. Support technologies and products that address high-priority needs
2. Align regulatory pathways to the modern landscape
3. Enhance our One Health workforce for the future of innovation
4. Identify and address gaps specific to new technologies and emerging health threats

CVM will follow publication of the AVIA with additional information and resources expanding on the actions listed here, and with invitations to the public and our partners to participate in refining, expanding, and improving on future iterations of the agenda.
Objective 1: Support technologies and products that address high-priority needs

In 2018, FDA developed the Veterinary Innovation Program (VIP) to assist sponsors and developers of FDA-regulated animal products derived from novel technologies including certain intentional genomic alterations (IGAs) in animals and animal cells, tissues and cell- or tissue-based products (ACTPs) through the review process using established product review timelines. The FDA developed VIP to help developers of these products—typically smaller developers—by providing greater certainty in the regulatory process, encouraging development and research, and supporting an efficient and predictable pathway to market. The FDA is now adding new elements to VIP with the goal of reducing the impact of barriers that come with bringing new types of products to market.

As of July 31, 2023, the FDA had over fifty products enrolled in VIP and this number continues to grow. The products are at different stages of development, with some having completed FDA review (e.g. GalSafe pigs) and some in the early research phase. The FDA’s current regulatory approach reflects the agency’s commitment to ensuring FDA-regulated products undergo a science- and risk-based evaluation by our experts that focuses on product safety in this rapidly developing field.

**Action 1:** Implement VIP Sci-Assist. To further assist innovation in product development, provide tools that address specific product development and regulatory needs and enhance CVM’s regulatory efficiency. For those tools that will assist FDA-regulated product developers, CVM will follow publication of this agenda with targeted outreach to promote awareness, ensure access, and provide education to potential users. These tools include:

- **a. Standardized molecular characterization and evaluation of genome editing.** FDA-funded research in collaboration with the National Institute of Standards and Technology is underway with two primary goals.
  - Generate standardized measurements for characterizing IGAs in cattle and swine that are developed using genome editing. This is a tool that developers and any regulators, including those in other agencies or countries, can use to evaluate whether the genome editing process accomplishes the intended edits, whether there are any off-target edits, and what those off-target edits are, where applicable.
Molecular characterization is the first step in the review process for FDA-regulated IGAs in animals and serves as the basis for hazard identification. This tool eases the burden on developers to evaluate the molecular characterization, creates a standard way of approaching molecular characterization evaluation to facilitate uniformity in the review process and potentially reduces the time CVM needs to evaluate product safety.

- Provide access to suitable comparator or reference materials. This will increase confidence in molecular characterization data by providing well-understood controls to compare against a developer's product.

b. **Validated tests for detecting disease agents in animal donors of ACTPs.** Donor eligibility is a critical part of the ACTP development and approval process. This research aims to provide developers with an important tool to protect the health of humans and animals and facilitate development of these novel biotechnology products. Development of validated test methods will allow CVM reviewers, developers of FDA-regulated products, veterinarians, and the public to have confidence that ACTP donors are free of relevant disease agents and will not transmit disease to humans and animals.

The validated tests developed by the FDA will be shared to allow developers to access them and readily test their ACTP donors. This will ease the burden on developers by facilitating effective screening and FDA review. Currently, CVM has initiated this research as a pilot program.

c. **Computational Power Boosts.** The FDA utilizes unique, advanced computational tools that give us unparalleled ability to analyze complex genomic data.

- **PrecisionFDA** is an advanced web-based platform that offers developers a secure pipeline for transmitting raw next-generation sequencing (NGS) data and other large datasets to the FDA as part of their product submission. PrecisionFDA also includes access to point and click bioinformatics analysis that allows developers to analyze their data using pre-built pipelines without needing to know computer programming or coding, saving them time and money.
High Performance Computing (HPC) allows for rapid processing of large datasets and complex analyses using supercomputers or computer clusters, such as the analysis of NGS data. CVM has access to HPC resources at its sister Center, the Center for Devices and Radiological Health, and is consequently able to perform complex DNA sequencing analysis that allows us to conduct an independent analysis of the developer’s data confirming the characterization of the IGAs, including identify unintended alterations in the genome that would otherwise be difficult to find. This is helpful both to FDA regulators and to developers of FDA-regulated products who may need help in confirming that the alteration they have produced is as intended. For example, upon request, CVM may assist developers with the assessment of sequencing data in support of product characterization, including the identification of unintended alterations that a developer may wish to remove from their production herd.

**Action 2:** Undertake VIP Fast-Step project to identify components of CVM’s VIP review process for which CVM can commit to abbreviated timelines. CVM has different review processes based on the risk questions for a particular product. Products can have differing risks and, therefore, novel products may have data requirements that differ from traditional products. Identifying these components may allow CVM to review specific submissions in a shorter time period. Additionally, routine activities like opening a Veterinary Master File (VMF) to provide notice of the shipment of investigational animals with IGAs, beginning a new study, or opening a new facility require less intensive, and therefore less lengthy review.

**Action 3:** Form an Accelerating the Development of Veterinary and Animal Needs Program (ADVANce Program) designed, in part, based on the success of sister programs at the FDA such as the Accelerating Rare Disease Cures Program and the Oncology Center of Excellence. This program will establish partnerships with the veterinary medical community, universities, and other partners to work with CVM to address the most critical priorities. It is envisioned the program’s activities will include the following:

- Identify and develop proposals to address priority unmet veterinary medical needs;
- Identify and develop proposals to mitigate potential economic, production, or other market barriers; and
- Examine the use of real world and translational data to support novel ways to meet regulatory endpoints and potential changes to regulatory pathways for these products.
**Action 4:** Continue to invest in **data modernization** to re-engineer CVM’s mission-critical business processes and their corresponding IT systems. CVM is working with the Office of Digital Transformation on an enterprise-wide effort to pull data out of locked systems that limit their utility and into a secure data lake environment. The ability to access and manipulate data from various internal and external sources will allow CVM to analyze large data sets to inform on-demand, data-driven decisions, and to more effectively respond to human and animal health emergencies like those that can arise from pandemics, natural disasters, armed conflicts overseas, or domestic human and animal food outbreaks. This initiative includes:

- Streamlining how CVM processes and extracts data from incoming submissions and performs research by reducing redundant or inefficient business processes and leveraging IT solutions that enable CVM to respond at the speed of business;
- Modernizing data storage and applying existing data standards to improve the types and quality of information received;
- Leveraging best-of-class IT solutions that enable CVM to modernize data reporting capabilities to address ongoing and new public health challenges; and
- Remediating any cybersecurity vulnerabilities identified in CVM applications using software and hardware that could result in a release of proprietary data.
Objective 2: Align regulatory pathways to the modern landscape

**Action 1:** Create a CVM Regulatory Modernization Task Force to review and recommend changes to law and policy, such as through changes to regulations and guidance documents, that align with CVM’s commitment to sensible science- and risk-based regulation. Proposed legislative changes to the Federal Food, Drug, and Cosmetic Act (FD&C Act), such as the introduction of new approval paradigms for Zootecnhical Animal Food Substances and biologic products for animals, hold promise to create evaluation and approval pathways that are appropriate for novel FDA-regulated product types.

CVM will continue working with drug sponsors to use the conditional approval pathway, which was expanded in 2018 to incentivize development of drugs for serious or life-threatening conditions or unmet animal or human health needs where a demonstration of effectiveness would require complex or particularly difficult studies. CVM has conditionally approved four drugs under this expanded pathway that are providing veterinarians and pet owners with early access to therapies for epilepsy, heart failure, acute pancreatitis, and anemia associated with chronic kidney disease. The Task Force will conduct a comprehensive review to identify additional policies or changes to existing policies that will modernize CVM’s review processes.

**Action 2:** Work with external stakeholders to identify potential process improvements including exploring ways to increase efficiency in the review process across all of CVM’s portfolio. Some examples include re-examining the process for approving Animal Drug Availability Act feed use combinations, and the feasibility of implementing a process to pause the review of certain submissions, otherwise known as ‘stopping the clock,’ to allow sponsors to provide additional information without extending the allotted time for CVM review. Also, CVM will engage an independent, third-party to conduct a comprehensive assessment of the review of new animal drug applications (NADA) to identify potential improvements, as part of the Animal Drug User Fee Act V program’s objective of expediting the animal drug development process which also includes seeking public input on the findings.
Action 3: Bring clarity to the review process through activities including:

a. Establish a Food Innovation Hub in the Office of Surveillance and Compliance to provide a one stop entry point. CVM has long offered pre-submission conferences to exchange information and ease the application process across the regulated product areas. These early meetings help sponsors design and conduct studies that will provide appropriate data to meet the CVM requirements for approval and provide predictability into the review process. Food additive petitioners and those submitting GRAS notifications are historically less likely to seek a pre-submission conference than New Animal Drug sponsors. A single point of entry with dedicated resources may encourage this sector to seek a pre-submission conference to increase the likelihood that the FDA will have no questions about the product.

b. Further implement a Questions-Based-Review (QBR) process where feasible to provide increased transparency of submission expectations. QBR involves developing and publishing questions that provide a general framework of expected information to be included in submissions to investigational new animal drug (INAD) files, generic investigational new animal drug (JINAD) files, NADA, Abbreviated New Animal Drug Applications (ANADA), Conditional New Animal Drug applications (CNADA), and VMFs. To date, CVM has instituted QBR templates for the CMC technical section and generic protocol and data submissions.

c. Provide developers of innovative products with customized templates for various FDA-regulated animal product application types that prompt them to provide the specific data and information CVM needs to evaluate safety and effectiveness. These templates increase the chances that a product can be reviewed without CVM needing to request additional data or information from the sponsor, reducing review times and helping CVM readily identify pertinent regulatory information for review. Using the provided templates, developers can store information about a product and re-use it across multiple submissions or applications. This saves the developer submission time since they are not re-entering the same information for multiple products and reduces CVM review time by preventing CVM from re-reviewing the same information for multiple submissions.
Objective 3: Enhance our One Health workforce for the future of innovation

**Action 1:** Connect scientific and regulatory experts across FDA on converging science. Animal health, human health, food production, and the environment all stand to benefit from exciting new scientific discoveries and technological capabilities. The FDA is addressing the convergence of these fields through cross-Center scientific working groups of dedicated experts in new and emerging fields hosted by OCS which help CVM and other parts of the agency drive smart, coordinated regulatory approaches to novel products regulated by FDA like those using genome editing. As co-chairs of the FDA’s One Health initiative, CVM and OCS will convene a cross-FDA Genome Editing Regulatory Science Council to increase the leverage of genome editing expertise across the FDA’s human, animal, and plant regulatory programs. This council will bolster the agency’s effort to leverage cross-Center expertise, collaborate with other federal entities, and adopt smart approaches to harnessing the promise of this technology to improve human and animal health.

**Action 2:** Recruit, retain, and continue to develop world class scientific and technical talent. CVM will develop a **Workforce for the Future of Innovation Plan** to catalog the technological and scientific expertise the Center has, and proactively identify the Center’s needs to be prepared for the innovations, One Health challenges, and opportunities of the future. CVM will also convene a **Scientific Recruitment Strike Team** to lead CVM’s strategy when it is necessary to recruit senior, high-impact technical and scientific leadership to address innovation needs, including through utilizing the agency’s agile Title 21 Hiring Authority. CVM will partner with OCS to maximize our ability to recruit and retain the best scientific and technical talent.

**Action 3:** Develop and implement a **FDA One Health Code of Practice**. In conjunction with our agency partners, CVM will develop specific, measurable actions to adapt the Center’s operational practice, risk prioritization, and strategic planning to integrate human, animal, and environmental scientific areas of focus to address complex public health problems. More intentional scientific and regulatory collaboration across disciplines, with other FDA Centers and Offices, with the FDA’s federal and state co-regulators and with other partners will build a more effective workforce, allow for discovery of new opportunities, and minimize hand-off gaps between partners. CVM is dedicated to being a model for leaving behind silos in favor of agile, systems-based approaches.
Objective 4: Identify and address gaps specific to new technologies and emerging health threats

To develop science and methods to refine and improve regulatory pathways and post-market evaluation and response paradigms for existing products and those that have yet to be developed, CVM needs to understand the scope and magnitude of potential human and animal health risks associated with those technologies.

**Action 1:** Form an Innovation Exploration Task Force, which will work across the Center and in collaboration with OCS to develop and implement methods to monitor emerging technologies across sectors, including biomedical products and novel food ingredients for both animals and humans, that can impact CVM’s regulatory work.

CVM will seek input from partners on new technologies and methods that may lead to new kinds of products or new kinds of data about products coming to the FDA for approval. This early awareness can give CVM the lead time to address, from a regulatory science and policy perspective, the utility of CVM’s current pathways or methods for these products. By assessing the risks and opportunities associated with a given emerging technology, CVM will be better positioned to have appropriate regulatory frameworks in place before these products come to CVM for review.

**Action 2:** Undertake research on emerging technologies that will allow CVM to better align its work with the attributes of those technologies. While the listed actions are CVM-initiated, CVM draws on and contributes to expertise in convergent emerging fields across the FDA. The FDA will seek public input on additional endeavors under this project and prioritization of research work. Research currently being conducted at CVM includes:

- **Conduct Genome Editing Technique Research** to evaluate the consistency of genomic editing techniques and address gaps in scientific knowledge in collaboration with the OCS and other scientific experts across the FDA. For example, seek to determine the frequency of and factors that influence unintended alterations (including plasmid integration), the impact of genomic variation in different breeds or strains of animals on editing events, and the reproducibility and reliability of editing and characterization assays.
b. Conduct additional research to generate data to support aspects of the evaluation and approval process that are common across categories of IGA products, such as IGAs in different species, made using different types of edits, and for varied uses, including as a source of organs, tissues, or other medical products to be used in humans or animals. Potential goals include generating data demonstrating the consistency of inherited IGAs across generations, or data comparing the efficiency and risk for unintended alterations when using different editing methodologies (e.g., different delivery methods, nucleases [standard Cas9, high-efficiency versions, TALENs]). CVM has funded and is starting a pilot study comparing the fidelity of multiple nucleases.

Understanding when, why, and how often off-target effects result from genomic alterations may allow developers and CVM to better predict and mitigate the risks from off target effects, facilitating the development of safe and effective products derived from FDA-regulated IGAs and potentially decreasing data requirements for developers of FDA-regulated products with better-understood risks. CVM will strengthen its partnerships with CBER, HFP, and OCS to boost CVM's ability to leverage converging expertise on off-target effects, and to explore how to adapt and evolve regulatory processes and endpoints to manage this potential proportionate to the risk posed by regulated products. CVM recognizes that consumer acceptance and trust of novel products is critical to ensure the benefits of new technologies are realized, making it essential to mitigate the risks of off-target effects in FDA-regulated products.

c. Conduct research to identify characteristics of ACTPs that are critical to potency. Understanding the characteristics and quality attributes that impact potency of ACTPs is key to development and approval of a quality product that consistently produces the intended effect. Potential goals of this research include developing functional bioassays and analytical tests for potency assessment based on the secretome, genome, and proteome of ACTPs from different cell and tissue sources, donors, and processing methods. This research is aimed at facilitating development of appropriate potency assays. This can support development of quality products, facilitate CVM review, and ease the burden on developers of FDA-regulated products for demonstrating comparability through the product lifecycle. CVM is starting a pilot study evaluating the secretome of canine adipose-derived mesenchymal stem cells.
d. **Develop and qualify new alternative methods (NAMs)** that support innovation. As part of the FDA-wide NAMs Program centrally coordinated and managed by OCS, CVM will pursue the establishment of cohesive and comprehensive strategies to advance the development, qualification, and implementation of NAMs for regulatory use. The agency-wide program broadens and complements longstanding work led by the FDA's Centers and Offices, including specific programmatic objectives such as expanding capacity to qualify alternative methods and filling information gaps with applied research to support new policy and guidance development. For CVM, this effort will include identification and prioritization of NAMs based on their potential to ease regulatory approval barriers, and their ability to impact development of products that address unmet veterinary medicine needs. Overall, the program aims to spur the adoption of NAMs for regulatory use that can replace, reduce, and refine animal testing and improve the predictivity of nonclinical testing, thereby streamlining the development of FDA-regulated products and helping make these products more rapidly and efficiently available to the U.S. public and patients while also assuring they are safe, effective, and dependable.

**Action 3**: Conduct and implement a Science Visioning Process. CVM is embarking on a process to develop a clearly defined vision for CVM’s scientific and research functions to deliver upon the goals contained in this innovation agenda and ensure CVM’s scientific expertise can have the greatest impact on animal and human health. CVM expects to be able to announce a new scientific vision in the first quarter of 2024. CVM is conducting this process in collaboration with other scientific offices across the FDA.

**Action 4**: Adopt novel One Health approaches to post-market compliance challenges. For example, CVM will be developing a Chemical Contaminant Playbook to bring clarity to how we can respond to incidents where animals are exposed to potential contaminants, and how CVM will leverage partnerships with co-regulators, academia, the Veterinary Laboratory Investigation and Response Network, and FDA-wide scientific expertise to address these difficult challenges – particularly when they involve contaminants that lack safety data or validated testing methods. CVM will also explore ways we can support co-regulators such as EPA, USDA, tribal organizations, states, and territories in circumstances where these contamination events cross jurisdictions. Working across sectors and with the right partners will ensure human, animal, and ecosystem health are protected.
Action 5: Identify novel approaches and methods to **ensure safety and effectiveness throughout the lifecycle of approved innovative products.** CVM is developing a risk-based approach to assess changes to FDA-approved novel products — such as demonstrating comparability of ACTPs when a new cell line is introduced, changes in monoclonal antibody production, and alterations in gene therapy products — and their potential impact on safety and/or effectiveness, potency assays or other aspects of the products without relying on additional clinical studies. CVM is in the process of identifying tools, establishing criteria to critically evaluate these changes, and exploring novel approaches to assess and determine the impact of the changes on the performance of the product. Establishing methods to assess these changes will increase the ability of CVM regulators to make timely decisions based on a modern assessment of benefits and risks that will encourage investment in technologies that produce effective products. This will help CVM keep products with unacceptable risks off the market, while approving products in a manner that will provide confidence to the veterinarians, end users, and public that the product will perform in a consistent manner.

Action 6: CVM will **leverage expertise and programs across the agency to meet emerging human, animal, and environmental health threats.** CVM will strengthen relationships with the other FDA product Centers and the Chief Medical Officer to take a more proactive stance to monitoring and responding to potential health threats like supply chain disruptions and shortages. Events that create product shortages can impact multiple distribution chains and end user populations, and a coordinated, cross-FDA response can improve efficiency in mitigating negative outcomes.

**Conclusion**

As a science-based public health organization, it is CVM’s responsibility to evolve in the best interest of human and animal health. The actions described will enable the Center to respond to a changing industry and society, and to anticipate coming challenges and maintain agility to meet them. We believe our work to facilitate the development and use of new and emerging innovations will invigorate efforts to find solutions to address some of the most complex One Health challenges our society faces.

Implementation of this agenda will be ongoing, as CVM will be seeking input and revising, refining, and expanding the AVIA. The world will continue to change, and new challenges will keep surfacing. Yet, science will continue to progress and expand our society’s capacity to develop, produce and distribute safe, effective products made using novel technologies in response to emerging and longstanding health challenges. CVM is well positioned to support these innovations and is committed to do so for the protection of human and animal health.