Animal Drug User Fee Act (ADUFA)

May 27, 2026

Public Meeting Transcript

00:00:18 Ms. Faunce: Good afternoon. We will begin promptly at 2:03 p.m. We're just waiting for everyone to get into the meeting. Thank you.

00:01:08 Again, for those just joining, I'll start at 2:03 p.m.

00:02:51 Dr. Kromm, that'll be fine. I'll share your slides for you. Thank you.

00:02:55 Dr. Kromm: Thank you.

00:03:04 Ms. Faunce: Okay, it's 2:03 p.m. Good afternoon, everyone. I'd like to welcome you all to the Animal Drug User Fee Public Meeting. I now call this meeting to order. My name is Madeline Faunce. I'm a branch chief in FDA's Office of Operations and I will be your moderator for today's meeting. We are meeting today to receive your comments on the ADUFA program. Your comments will--

00:03:30 Ms. Miller: Can you still hear me? Oh.

00:03:32 Ms. Faunce: If you can mute, please. Thank you. Your comments will help us strengthen and improve our future program. Today's meeting will be structured as follows. First, CVM will provide remarks from our center director, Dr. Timothy Schell. Then, we will hear a review of the program to date from our Office of New Animal Drug Evaluation director, Dr. Matthew Lucia. This will be followed by an Open Comment Period and we look forward to hearing from you. Registered speakers for this session will be the first to provide their remarks. Following completion of their remarks, we will open public comment to all registered attendees.

00:04:10 There will be two ways to provide your comments. First, you may use the "raise hand" feature in the toolbar at the top of your screen to indicate you would like to speak. We will then ask you to unmute your microphone, state your name and affiliation, and then provide your comments. The second option will be to type your comments in the chat box. Please identify your name, affiliation, and then provide your statement. I will read those statements aloud so they are entered into the record.

00:04:37 Please be aware that FDA is in listening mode during this meeting. We will not be answering questions or responding to statements posed today. This meeting is being recorded and that recording, along with a written transcript, will be posted on fda.gov on our Animal Drug User Fee page. You will also be able to find today's presentation

there. At this point, I'm going to turn it over to Dr. Schell, director of our Center for Veterinary Medicine to provide remarks about the ADUFA program.

00:05:08 Dr. Schell: Thank you, Madeline. I'm pleased to welcome you all today to the virtual public meeting on reauthorizing the Animal Drug User Fee Act or ADUFA. I encourage active participation today so that we can gather your input. Your engagement throughout this reauthorization process is critical to our shared goal of promoting and protecting human and animal health. It's been a challenging year for CVM, but the Center has demonstrated tremendous resilience during this period and we continue to meet our user fee goals.

00:05:41 Today's discussion will primarily focus on performance under the ADUFA program, but I'd like to briefly touch on a couple of other additional areas. Antimicrobial resistance. In February 2026, CVM published Guidance for Industry 273, which aims to phase out undefined long-term use of medically-important antibiotics and food-producing animal feed. This initiative is part of a broader long-term strategy to combat AMR by ensuring these drugs are used only as long as necessary to treat, control, or prevent specific diseases. We are currently actively engaged with industry on implementing the goals outlined in this guidance.

00:06:17 New World screwworm. CVM is working with animal drug sponsors to identify potential products to approve or otherwise authorize for the prevention or treatment of New World screwworm myiasis. This is the first-ever use of the emergency use authorization authority to address an emerging animal health threat. Through collaboration with industry, we've made 11 products available for use for New World screwworms should we have an incursion. These products cover a range of species.

00:06:52 The ADUFA program is fundamentally about ensuring FDA has resources to review new animal drugs for safety and effectiveness while giving industry the predictability it needs to invest in drug development. User fees are the mechanism that makes this possible. Across all five authorization cycles, FDA has consistently raised the bar, not simply maintained the status quo. Each cycle introduced meaningful progress improvements from eliminating massive review backlogs in the early years to embracing electronic submissions, international cooperation, and innovation-focused pathways.

00:07:32 The program has a strong history of meeting or exceeding performance commitments with on-time review rates frequently at or near 100% across nearly all submission categories. Rather than overhauling the fundamentals, ADUFA V has focused on refinement, including expanding the mutual recognition agreement framework, extending cooperation to activities both before and after product approval, reducing duplicative regulatory work across borders. presubmission conferences were

significantly enhanced with FDA now committing to issue a response letter evaluating the sponsor's drug development plan at least six days before the scheduled meeting and delivering a memorandum of conference within 30 days after, making the process more structured and productive for both parties.

00:07:32 ADUFA V introduced an annual industry education session of up to eight hours open to the public, with presentations posted on FDA's website in a dedicated "education for industry" section to improve transparency and sponsored preparedness. Continuing to increase transparency, FDA agreed to publish the new performance metrics both quarterly on FDA-TRACK and annually in the performance report to Congress.

00:08:50 FDA formalized its approach to raw data review by publishing updated internal policies and issuing final Guidance 287 on raw data requirements for safety and effectiveness studies, giving sponsors clear and more predictable expectations. Updated H submission policies clarified the timing and process for submissions that precede meetings and protocols, reducing procedural ambiguity and helping sponsors plan development timelines more effectively.

00:09:20 FDA published a new CMC policy and revised draft guidance on filing strategies, giving sponsors clear direction on how to structure chemistry, manufacturing, and controls information to improve first-cycle review outcomes. FDA completed multiple exploratory analyses during a ADUFA V covering review efficiency tools like clock stops, drug residue method trials, underutilized ADAA combination drug pathways, sponsor feedback mechanisms, and new program metrics. These all lay important groundwork for future program improvements.

00:09:56 At the midpoint of ADUFA V reauthorization period, the program's core function has yielded significant results. 58 new animal drug products were approved, including 10 new chemical entities, which are among the most complex submissions that the program evaluates. This reflects a high scientific rigor and efficiency. Five products were conditionally approved, demonstrating the program's ability to utilize flexible regulatory pathways. Three of these are tied to the New World screwworm response. Eight emergency use authorizations were issued also in response to the New World screwworm threat. Ten risk reviews were explicitly granted or updated. A risk review is an FDA evaluation of scientific data determining that certain animal genomic alterations or cell-based products are low risk permitting marketing without formal premarket approval.

00:09:56 FDA is committed to transparency throughout the ADUFA VI reauthorization process, including publishing meeting minutes, seeking broad public and stakeholder consultation, and transmitting recommendations to Congress in early 2028. Our common goal remains promoting and protecting human and animal health. The

ADUFA program gives CVM the resources to evaluate new animal drug submissions efficiently and in a timely manner, ensuring drugs are safe and effective and that food from treated animals is safe for human consumption.

00:11:27 This reauthorization process is an opportunity to reflect on successes and look ahead to improvements and innovations. I look forward to hearing your comments today and throughout the reauthorization process. Thank you for your interest and involvement in this process. Now, I'd like to turn it over to Dr. Matt Lucia. He's the director of our CVM's Office of New Product Evaluation. He's here to present on behalf of FDA on the ADUFA program. Matt?

00:11:55 Dr. Lucia: Thanks, Tim. Good afternoon. I'm Dr. Matt Lucia, the director of the Center for Veterinary Medicine's Office of New Animal Product Evaluation and I'll be presenting on the Animal Drug User Fee Act, also known as ADUFA. Next slide, please.

00:12:15 Here's a quick overview of the major topics I'm going to be covering. I'll review the basic structure of the ADUFA program and its reauthorization cycles. Then, I'll highlight program benefits and accomplishments including performance under the previous authorizations of ADUFA. I'll also give you an overview of some of the process improvements we've initiated in this current ADUFA cycle. These have enhanced the predictability of the new animal drug review process and are helping the animal drug industry to innovate and bring novel products or new indications to existing products to market. Then I'll close with an overview of the reauthorization process. Next slide, please.

00:13:06 All FDA's user fee programs run for a five-year period. Congress first authorized ADUFA for fiscal years 2004 to 2008. You can see the next reauthorizations in the table on the slide. ADUFA II, ADUFA III, ADUFA IV, and ADUFA V, which is our current one. ADUFA VI, if enacted, would be the next reauthorization from 2029 to 2033. Next slide, please.

00:13:40 The overarching purpose of the ADUFA program is to support CVM's mission of protecting human and animal health. To support FDA's responsibilities to ensure new animal drug products are safe and effective for animals and ensure the safety of food from treated animals, Congress authorized the FDA to collect user fees. Next slide, please. The user fee program assists CVM in accomplishing its mission by helping to provide more predictable timelines to evaluate new animal drug submissions, facilitate the review of animal drugs to better meet the therapeutic needs of animals, facilitate the review of drugs used in food animal production to improve both human and animal health, and to facilitate the evaluation of innovative and novel new animal drugs and indications. Next slide, please.

00:14:36 Performance is one of the main goals of the ADUFA program. As you can see, we've dramatically improved our performance over the course of ADUFA's history. In ADUFA I, our biggest achievements were eliminating our review backlog and reducing our review timeframes from an average of more than 600 days to 180 days. Next slide, please. In ADUFA II, we developed our electronic submissions capability and increased our transparency with more stakeholder outreach. Next slide, please. In ADUFA III, we added flexibility in several processes, enhanced our IT support, improved business processes, and worked to fill the pipeline and increased drug availability. Next slide, please.

00:15:34 ADUFA IV required 100% electronic submissions. The ADUFA IV authorization also required the revision of labeling on index drugs for minor uses in minor species. By the end of the user fee term, these products had to include their minor species index file number. The reauthorization also required some labeling changes by the end of the performance period to address misbranded drugs by requiring that all marketed new animal drugs bear the statement "Approved by FDA" and the new animal drug approval number. Additionally, the authorization provided for new performance goals for our presubmission conferences and tissue residue method trial demonstrations, and we exceeded all of our performance goals. Next slide, please.

00:16:24 There are also several additional program enhancements added to the ADUFA IV reauthorization. Expanded conditional approval. Conditional approval is an approval pathway under which a sponsor can make the drug available by providing the drug is safe and showing a reasonable expectation of effectiveness. Before the ADUFA IV reauthorization, conditional approval was only available to minor species or for minor uses in major species, but the expanded conditional approval authority incentivizes development of new animal drugs for serious or life-threatening conditions or unmet animal or human health needs that require particularly difficult studies to demonstrate effectiveness. Antimicrobial drugs aren't allowed to use the expanded conditional approval pathway. We published a Guidance for Industry, GFI 261, in which we clarified the criteria for determining a drug's eligibility for expanded conditional approval pathway by providing definitions for key terms, like "serious or life-threatening disease or condition," "unmet animal or human health need," and "complex or particularly difficult study or studies."

00:17:38 Investigational design guidances. After gathering input from stakeholders, CVM published four guidances intended to assist sponsors in incorporating complex adaptive and other novel investigation designs, data from foreign countries, real-world evidence, biomarkers, and surrogate endpoints into protocols and study designs.

00:18:01 Food additive petitions. Also, we were required to address some areas of our animal food ingredient premarket review program, which included a guidance to address

presubmission considerations for food additive petitions and generally recognized as safe, or GRAS, notices. The final guidance describes the type of information stakeholders should include in consultations with FDA, including recommendations for investigational food additive files, use of foreign data, circumstances when we recommend submitting study protocols, and an explanation of our review process and best practices for communicating with us along the way.

00:18:46 Antimicrobial resistance. In June of 2021, FDA released final GFI 263 to explain our recommended process for sponsors to voluntarily bring under the oversight of licensed veterinarians any remaining approved animal drugs containing antimicrobials of human medical importance. The process for doing this would involve changing the approved marketing status from "over the counter" to "prescription."

00:19:15 US-EU Mutual Recognition Agreement. ADUFA IV also directed us to implement the US-EU Good Manufacturing Practice Inspection Mutual Recognition Agreement. In May 2023, the FDA and the European Union published the amended sectoral annex for pharmaceutical good manufacturing practices expanding the mutual recognition agreement to include animal drugs. This followed the EU's May 2023 recognition that the FDA is capable of conducting GMP inspections at a level equivalent to that of the European Union. I'll speak more about the MRA shortly and how it has progressed under the ADUFA V authorization. Next slide, please.

00:20:06 FDA's goal for the ADUFA V reauthorization was to promote and protect human and animal health by having the capacity to meet performance goals and continuing to invest in program improvements using a lifecycle approach by ensuring a predictable review process through sustained revenue. This is the authorization we're currently under. We agreed to report certain new programmatic metrics. These metrics provide additional transparency to stakeholders on the success of the program. Some are reported quarterly on the FDA-TRACK website and others are reported annually in the ADUFA V performance report to Congress.

00:20:48 We agreed to create a working group to explore potential additional metrics for the review time of investigational submissions that lead to approvals by the Agency and response time by industry. And like third party assessments agreed to and executed under ADUFA, FDA and the animal health industry agreed to and participated in a comprehensive assessment of the process for the review of animal drug applications that included consultation with both FDA and industry. The FDA engaged an independent third party to conduct the assessment of first cycle reviews as they pertain to the ADUFA program's objective of expediting the animal drug development process and the review of new and supplemental animal drug applications and investigational animal drug submissions. A public meeting was held in October '25 where the findings of the assessment were presented. Next slide, please.

00:21:51 In ADUFA V, we expanded the ADUFA IV exploration of the US-EU MRA. To date, the FDA has determined that 25 EU member state inspectorates are capable and is actively assessing the remaining two to achieve full implementation. The FDA has also established MRAs covering animal drugs with Switzerland and the United Kingdom, which are demonstrating clear benefits. These agreements allow FDA to rely on GMP inspectional information from MRA partners in lieu of completing our own inspection, providing greater efficiencies and allowing the United States to focus resources on higher public health risks around the globe. We also enhanced our presubmission conference process by incorporating a new virtual meeting option that allows industry to receive feedback from CVM on their product development plans faster.

00:22:47 And to provide helpful information to external stakeholders on the animal drug approval process, FDA has been conducting an industry education conference once a year that is open to the public. These are intended to be similar to the regulatory education for industry workshops held by CDER and CBER. Two sessions have already been conducted in 2024 and 2025, and the third session, which I would encourage anyone to sign up for when that is made available, is scheduled for July 7th, 2026. FDA and industry work together to choose topics for these conferences and presentations are then posted publicly to FDA's "for industry" website. Next slide, please.

00:23:38 To increase transparency-- One back. Thank you. To increase transparency and regulatory predictability for drug sponsors, FDA agreed to publish a series of documents on topics important to the animal drug industry. We published a guidance for industry on our expectations for submitting raw data in safety and effectiveness data submissions. We also published a policy and procedures document to clarify the timing of meeting requests and protocol submissions when supportive data is submitted in advance and to clarify the review process when a sponsor submits a proposed list of what raw data, they intend to include in their target animal safety technical section. Next slide, please.

00:24:30 And again, to increase transparency and regulatory predictability for drug sponsors, FDA agreed to publish additional externally-facing documents that enable stakeholders to navigate the CMC process more efficiently. The first was a policy and procedure manual for CMC reviewers to clarify when reviewers should request amendments, use shortened review time, or classify submissions as incomplete and describe what administrative actions are appropriate when good manufacturing practice status or pending preapproval inspection is the only comment remaining for a CMC technical section. The second was we revised Guidance for Industry 227, which is the two-phased chemistry manufacturing and controls technical sections to define

situations for which parallel submission of phased data submissions would be allowed. Next slide, please.

00:25:29 We also agreed to form working groups with industry to explore several potential program enhancements. Specifically, we explored additional tools to enhance the efficiency of the review process, such as implementing a clock stop feature during review of sentinel submissions. We explored the drug residue analytical method trial process for drugs intended for food producing animals, and these groups continue to work on the tactical application of the recommendations that were completed at the end of fiscal year 2025. Next slide, please. Additionally, we formed working groups that evaluated the current policy and procedure manual on Animal Drug Availability Act drug combinations to learn why the process is not used frequently and understand how we might increase utilization to reduce the review time for these products, and explored how CVM could more efficiently provide feedback to sponsors on their drug development plan in a way that works best for both industry and CVM. We are implementing those things we can from the exploratory working groups in ADUFA V and otherwise they will inform our ADUFA VI discussions. Next slide, please. Thank you.

00:26:5 I'll now transition to talking about the performance goals that are associated with ADUFA V. I know there's a lot of information in the table, but as a reminder, the presentation will be available at fd.gov along with the recording and a written transcript when available. These performance goals help us to provide predictability as they define the timeframes for review of the different submission types. In order to track ADUFA success, we monitor the timely review of key submission types known as sentinel submissions. This slide provides the review times in days for new animal drug applications—or NADAs—and shows the evolution of the timeframes often reduced from one authorization to the next. It also shows the different types of submissions where we've monitored in each authorization and how that is increased from ADUFA I to ADUFA V. Next slide, please.

00:27:52 The submission goals on this slide are for investigational new animal drug files known as INADs, presubmission conferences, and tissue residue methods. These also reflect the evolution of timeframes for these submission types from one authorization to the next. This includes the different INAD submission types we monitor, which is increased from ADUFA I to ADUFA V. Next slide, please.

00:28:19 The next three slides show the performance metrics for the three fiscal years of the current authorization. This information is outlined annually in a public report to Congress and is now also available on the FDA-TRACK website. This slide shows the performance data for fiscal year 2024 and which we exceeded all performance goals

for the nine submission types, which means we responded within the review day specified greater than 90% of the time. Next slide, please.

00:28:54 We are continuing to review and act on submissions received during fiscal year 2025, which ended on September 30th, 2025. So far, we are exceeding all performance goals for the nine submission types, which means we responded within the review days specified greater than 90% of the time. Because we're continuing to review and act on submissions from fiscal year 2025, there's an additional column in this table, "pending overdue", in relation to the previous table for fiscal year 2024. There are currently six pending overdue submissions from fiscal year 2025. Next slide, please.

00:29:35 This slide shows preliminary fiscal year 2026 performance data, which is the current fiscal year. The number of filed submissions represents those filed or submitted between October 1st, 2025 and the end of the second quarter of March 31st, 2026. And the table reflects those that have been completed and those that are still under review. So far for the submissions we finalized, we are exceeding all performance goals for the nine submission types, which means we responded within the review day specified greater than 90% of the time. Next slide, please.

00:30:16 Now, I'll speak to the various steps for the upcoming reauthorization process between now and 2028. We'll consult with the Senate HELP and House Energy and Commerce committees, scientific and academic experts, veterinary professionals, representatives of patient and consumer advocacy groups, and regulated industry. We'll obtain public input prior to beginning negotiations with regulated industry. The Federal Register notice was published on April 17th, 2026 that included a link to a docket that will remain open until December 1st, 2027. We'll hold discussions with stakeholders, including representatives of veterinary, patient, and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes at least once every four months during negotiations. The FR Notice, which was published on April 17th, announced how to sign up, and please reach out if you are interested in participating. Next slide please.

00:31:28 We will obtain public review and comment on final recommendations after negotiations with industry, and we will publish the minutes of negotiation meetings on our public website before transmitting the recommendations to Congress no later than January 15th, 2028.

00:31:48 Next slide, please. I will conclude my presentation by reminding you why we are holding this public meeting today. As was published in the Federal Register notice, we would like to request feedback from today's attendees on two questions. What is your assessment of the overall performance of the ADUFA program thus far? And what

aspects of ADUFA should be retained, changed, or discontinued to further strengthen and improve the program? Thank you very much.

00:32:25 Ms. Faunce: Thank you, Dr. Lucia. Now we would like to proceed with the Open Public Comment period of this meeting. Please remember to speak clearly and directly into your microphone for purposes of transcription and for the attendees. Our first registered speaker today is Martha Scott Poindexter, president and CEO of the Animal Health Institute. Ms. Poindexter, if you could do an audio check for us, please.

00:32:53 Ms. Poindexter: Hello.

00:32:55 Ms. Faunce: I can hear you. Thank you.

00:32:57 Ms. Poindexter: Great. Thank you for the opportunity to comment today on the future of the Animal Drug User Fee Act. My name is Martha Scott Poindexter and I am the president and CEO of the Animal Health Institute. AHI is the trade association representing companies that make animal health products, including medicines, diagnostics, and vaccines that help keep American animals, both pets and livestock, healthy. Like many Americans, I also see the importance of animal health innovation personally. My dog Boomer is my treasured companion and I know firsthand how important it is that veterinarians have timely access to safe and effective tools. The same principle applies across animal health for pets, livestock, producers, veterinarians, and the families and communities that depend on healthy animals.

00:33:55 Before turning to ADUFA VI, I want to acknowledge what has been a challenging year for CVM. Even with significant demands on the Center and while continuing to meet its ADUFA timelines, FDA and CVM have gone above and beyond in their proactive approach to New World screwworm. In the face of these challenges, CVM recorded a record number of approvals in fiscal year 2025. At the same time, data shows that workload is going up-- Is going down, excuse me, highlighting an opportunity for FDA and industry to work together to spur innovation and increase access to animal health products.

00:34:37 As we begin this reauthorization process, AHI wants to approach ADUFA VI in a spirit of collaboration. We value the important work CVM does and believe the most productive path forward is one grounded in practical problem solving to achieve our shared commitment to a strong animal health system. The ADUFA process has built an important foundation by providing capacity and predictability. Looking to the future, the question is, how can we build on this foundation and improve the animal drug review process? ADUFA VI comes at an important moment. As described by the Reagan-Udall Foundation report, there's an urgent need to modernize the animal health framework to harness the immense potential of new products and technologies. We have a significant opportunity to pursue reforms to improve the timeliness and

predictability of animal health drug review and advance the United States as the leading environment for animal health innovation. The New World screwworm response provides a strong model to help move needed tools forward while maintaining appropriate rigor. The same spirit should help guide ADUFA VI.

00:36:00 To capitalize on this opportunity, AHI is focused on three priorities for ADUFA VI: speed, innovation, and harmonization. With speed, we seek to bring new drugs to veterinarians, American families, and food producers faster and more efficiently. This means taking a holistic view of the full drug development review process and identifying where FDA and industry can better work together to achieve alignment and obtain the data needed to have confidence that new animal drugs are safe and effective. With innovation, we seek to ensure that the United States is the strongest and most attractive environment for animal health research, development, and launch, especially for cutting-edge products. American families, veterinarians, farmers, and ranchers should have unmatched access to animal health innovation and our regulatory framework should reflect that goal. By harmonization, we mean identifying where high quality foreign submissions, trusted regulatory experience, and aligned international standards can support efficient science-based review. Animal health development is increasingly global and alignment can reduce costly duplication.

00:37:25 We can translate these goals into concrete progress by focusing on practical opportunities that include implementing lessons learned from approaches that have demonstrated promise, like the New World screwworm response; aligning review expectations and processes with the benefits and risk of the products in question to maximize the public health benefit from limited resources; and finally, developing better metrics to facilitate a common understanding of the review process and to inform continuous improvement. We also believe ADUFA is just one part of the animal drug framework. Full modernization will require Congress to act, particularly where additional reforms, incentives, pathways, new authorities, or emergency use tools may be needed. AHI is committed to being a constructive partner in the modernization effort and we look forward to working with Congress, CVM, and other stakeholders on complimentary efforts to support long-term innovation and access.

00:38:36 In closing, ADUFA VI is an opportunity to build on a strong foundation and work together toward a review process that supports timely access, innovation, and U.S. leadership in animal health. If we approach this process with a shared commitment to practical problem solving, we can build a modernized approach, one that benefits CVM, sponsors, veterinarians, pet owners, farmers, ranchers, and most importantly, the animals that we care for. Thank you for the opportunity to comment.

00:39:16 Ms. Faunce: Thank you, Ms. Poindexter. Our next speaker today is Dr. Lindsay Hornickel, assistant director of Federal Government Relations at the American

Veterinary Medical Association. Dr. Hornickle, if you could do an audio check for us, please.

00:39:31 Dr. Hornickel: Yes. Can you hear me?

00:39:32 Ms. Faunce: Yep, I can hear you. Thank you.

00:39:34 Dr. Hornickel: Perfect. Thank you. Good afternoon. I am Dr. Lindsay Hornickel, assistant director in the Federal Government Relations Division of the American Veterinary Medical Association. The AVMA, with more than 111,000 members of veterinarians, is committed to protecting animal health and welfare, public health, and a safe food supply. The AVMA appreciates the FDA Center for Veterinary Medicine's continued collaboration with the veterinary profession to address unmet needs for the animals under our care, as well as its work with the regulated industry to identify innovative and practical solutions to those challenges.

00:40:13 A recent example of the successful collaboration is the availability of tools veterinarians can now use to respond to New World screwworm under the Department of Health and Human Services' Emergency Use Authorization Declaration and Conditional Approvals. The FDA's diligent and expedited review of animal products for the treatment and prevention of New World screwworm has provided veterinarians with timely access to critical tools needed to protect animal health, animal welfare, and public health. This example demonstrates the value of innovative and flexible regulatory approaches as significant unmet needs remain in veterinary medicine.

00:40:53 Veterinarians face unique medical and regulatory challenges in caring for animals across a wide range of species, diseases, and uses while working with significantly fewer FDA-approved products than are available for human medicine. In food producing animals, veterinarians must comply with stringent safeguards designed to prevent violative drug residues and protect the nation's food supply. Expanding access for more safe, effective, and appropriately-regulated animal drugs is essential to ensuring veterinarians have the tools they need to support animal health, animal welfare, and food safety.

00:41:17 The AVMA supports user fees for new animal drug applications when those fees continue to improve the progress FDA CVM has made in efficiency, predictability, and timeliness of its reviews. Importantly, the costs associated with FDA-approved animal drugs are ultimately borne by our clients. Unlike human medicine, where third party payers often absorb a substantial portion of healthcare costs, veterinary medicine continues to rely heavily on out- of-pocket payment. As a result, access to affordable animal drugs can determine whether treatment is feasible for clients. Animal owners depend on products that meet rigorous standards for safety, effectiveness, and quality while remaining reasonably affordable. Veterinarians therefore need access to safe and

effective products through a review process that is as efficient and cost effective as possible.

00:42:23 AVMA encourages FDA CVM to continue working with the regulated industry to streamline and modernize the review process. We want the United States to be the market of choice for the development and approval of new and innovative animal drugs. Improvements in review efficiency, predictability, and timeliness can attract investment from drug sponsors, expand the availability of therapeutic tools, and ultimately improve animal health and welfare. Importantly, these efforts should support not only high volume blockbuster products, but also therapies intended for minor uses and minor species.

00:43:00 In 2025, the Reagan-Udall Foundation issued recommendations to CVM that included modernizing regulatory pathways and providing greater regulatory flexibility. If the ADUFA legislation will serve as a vehicle for these changes, the AVMA requests a high degree of transparency during the negotiations to allow the veterinary profession time to understand the proposals and contribute meaningfully to the discussion.

00:43:27 Building on FDA CVM's progress, the AVMA suggests several steps to further advance ADUFA's goals of accelerating access to new animal drugs. First, where appropriate, FDA CVM should continue the consideration of regulatory approaches used by comparable agencies and other developed countries that have successfully streamlined reviews and expedited market access for animal drugs. Second, support the conditional approval pathway and encourage further evaluation of how this mechanism can be better utilized to provide veterinarians with timely access to needed products, including appropriate regulatory flexibility for the extra label use of conditionally approved drugs. Finally, the AVMA encourages the animal drug user fee structure and-- Encourages an animal user drug fee structure that incentivizes product development for minor uses and minor species.

00:44:24 While some products may serve markets large enough to support multiple approvals, many products intended for smaller or specialty markets remain unavailable or underserved. Without a user fee structure that accounts for market size and commercial viability, sponsors may be discouraged from pursuing products that are critically important to veterinary medicine but offer limited financial return. This disproportionately affects veterinarians treating minor species, niche animal populations, or less common conditions where therapeutic options are already limited.

00:44:56 In closing, the AVMA appreciates FDA CBM's commitment to continue efforts to improve the animal drug review process and supports user fees as an important mechanism for expediting access to safe, effective, and affordable animal drugs. A modernized and responsive ADUFA program will expand treatment options, help

control costs, and maintain rigorous standards for safety, efficacy, and quality. AVMA remains committed to working collaboratively with the FDA and other stakeholders to ensure current and future iterations of ADUFA effectively support veterinary medicine, animal health and welfare, and public health interests, including those tied to a safe and secure food supply. Thank you for the opportunity to provide comments today.

00:45:47 Ms. Faunce: Thank you, Dr. Hornickel. Next, we welcome former member of Congress, Dr. Kurt Schrader. Dr. Schrader, if you could unmute your mic and do a sound check for us, please.

00:45:58 Dr. Schrader: Yes. Can you guys hear me now?

00:46:00 Ms. Faunce: Yes, I could hear you. Thank you.

00:46:03 Dr. Schrader: Excellent, Madeline. Thank you. My name's Kurt Schrader. I'm a former seven-term member of the United States Congress. I've been practicing large and small animal veterinarian for over 30 years. Very excited about the upcoming ADUFA VI reauthorization and kudos to CVM for all the work it's been doing. My remarks will piggyback a lot of what Dr. Lucia said and our two other presenters, because I think there are good current initiatives going on and maybe some others that I've personally helped develop as a member of the Reagan-Udall Foundation work. I think it's an extraordinarily unique time to enact some of these sweeping reforms. Everyone seems to be in violent agreement that things can be improved. Kudos to the Agency for stepping up and authorizing the Reagan-Udall Foundation process with the expert panels. The administration is looking for increased efficiencies in the different agencies and processes to help businesses and people in America get ahead of some of our competitors overseas.

00:47:13 I had that privilege of sitting on that panel being one of the eight expert panel members. It was held under the auspices of well-known Reagan-Udall group and we had meetings over a six-month period, from September 24 to about April of 2025. We heard from hundreds of different people. We had representation from large animal groups, small animal groups, companion animal groups, minor species, wildlife, zoo, lab people, folks in the biotech industry, folks in the pharmaceutical-- Animal health pharmaceutical industry also. The goal was to basically identify unmet needs and challenges that they were facing in their respective spheres of interest that CVM could address possibly. There are many common themes revolving around modernizing, as we've heard, our animal health regulatory structure, accelerating the drug review process and limiting costs so we can be competitive. Improving our global competitiveness is a big deal and frankly, dealing with the inadequate access—as Dr. Hornickel just alluded to—for minor species of animals.

00:48:30 Well, this group, we were able to identify 38 very specific recommendations, some of which we've already seen CVM pick up and run with, which is really exciting. There are others that could be picked up and run with too. Some will take a lot more work than others. Some will require congressional approval with some key statutory changes, but I don't think that's a bridge too far. I think animal health is a unifying spirit, and sometimes a divisive Congress. Every time I was there, food safety was paramount, Pet Night was paramount. People really cared about improving the health and welfare of our four-footed friends to make sure that we all benefited at the end of the day.

00:49:15 What I find exciting is that CVM stepped up here again to look at what they've been doing, realizing that a 20th century process grown up after World War II doesn't really fit the paradigm of drug and product innovation we're now seeing here in the 21st century.

00:49:33 That's exciting. That gives us an opportunity and we've already heard from Dr. Lucia about some of the things that they can actually do now that they haven't been able to do in the past as a result of some of the initiatives. Biotech stuff, currently their approvals are done pretty much on an ad hoc basis without much of a regulatory framework that individuals and industry can rely on. There is an area of products anomaly referred to as zootechnical that fall somewhere between drug approval process and food approval process. Those are the only two criteria, regulatory structures we have currently, that CVM has currently, by which to regulate these new products. These products perhaps could be somewhere in between. There needs to be a new regulatory structure. And as we've heard, the minor use, minor species current framework is hopelessly out of date and not working at all for those in the minor species and minor use areas.

00:50:32 The FDA CVM, I think, can make big strides within its own authority too; they don't have to have congressional approval for everything. One of the big things was adopting a structured risk-benefit assessment framework, so that the work would-- The return on investment, the return on inquiry, would depend a lot on the degree of risk that was out there. We would rely more on aggregate data, not just the raw data that was referred to earlier, but on aggregate data that is done oftentimes on our peer countries around the world. Using that stop-the-clock—that came up in our meetings also. Kudos to CVM for working on that, or starting to work on that. And I think we should be thinking in terms of allowing other clinical studies from peer trusted countries that are out there. And the harmonization is really important, not just internationally, but among states—to the extent we can—to make sure we're all using the same nomenclature, make sure that we're all using the same standards so that the consumer as well as the industry person can figure out what is actually expected of them at the end of the day.

00:51:40 I think there's a great opportunity for collaboration here. Some of the meetings we're currently having are very good, but it became clear in the course of our hearings on the expert panel that more is needed. Not just to put out what is going on at CVM, but also to take input. What are some of the current unmet needs? What are the threats that these different animal groups are hearing about right now, that veterinarians out in the field are having to try and deal with right now? The EU authorization that we're working with the screwworm, that's huge. We need to expand that and make that more accessible, more understandable, and more apparent to folks out there that need to be in the loop on these processes.

00:52:30 I mean, we saw during COVID how important food safety was, particularly in our own country, when trade was scarce and it was tough to get things done. We saw in the companion animal realm how our four-footed friends became virtually life-support folks for people isolated at home in many, many cases. And we have an opportunity to improve and help these processes like I haven't seen in my 14 years in the United States Congress.

00:53:05 It's a great opportunity. The turnaround time for a lot of our animal health industry partners is very quick. We've seen that even potentially dealing with avian flu and some of the stuff that's out there. It's an area of bipartisan, nonpartisan agreement. The administration is really interested in improving processes out there. In the Center for Veterinary Medicine, man, you stepped up and want to step up even more. I think this is a very exciting time. We should not let this go. This is a blueprint to make things happen for our animal health kingdom. Thank you.

00:53:45 Ms. Faunce: Thank you, Dr. Schrader. Now we will hear from Dr. Kathy Simmons, chief veterinarian from the National Cattlemen's Beef Association. Dr. Simmons, if you could do an audio check for us, please.

00:53:59 Dr. Simmons: Hello, Madeline. Can you hear me?

00:54:01 Ms. Faunce: Yeah, I can hear you. Thank you.

00:54:03 Dr. Simmons: Good afternoon. I'm Dr. Kathy Simmons, chief veterinarian at the National Cattlemen's Beef Association. The National Cattlemen's Beef Association appreciates the opportunity to offer public comments to the Food and Drug Administration during the Animal Drug User Fee Act public meeting. NCBA is the oldest and largest national trade association representing cattle producers in the United States. Our members are firmly committed to ensuring the health and wellbeing of the cattle under their care and to producing high-quality, safe, and wholesome beef.

00:54:37 Food safety begins at the farm level, where protecting the health of animals contributes to the safety of meat and milk for consumers. While livestock producers have adopted extensive systems and techniques to prevent animal disease outbreaks,

veterinary drugs remain a vital tool in the management of animal health. An effective and efficient animal drug approval process is essential both to the health and wellbeing of animals and to overall public health.

00:55:03 Cattle producers rely on a rigorous, predictable, and science-based new animal drug review process at FDA's Center for Veterinary Medicine to approve new animal drugs for sale in this country. New animal drugs are needed to protect against emerging animal disease threats. For this reason, the new animal drug regulatory approval process should not carry excessive financial or regulatory burdens that might stifle future drug innovation and development. A swift reauthorization of ADUFA provides the necessary assurance to animal health stakeholders for a stable and predictable drug review process, provides veterinarians and livestock producers with the tools that they need to keep animals healthy, and benefits consumers through increased food safety and improved public health.

00:55:51 NCBA appreciates the work of CVM to promote research and development into new animal drugs that can close therapeutic gaps in veterinary medicine while at the same time focusing attention on new innovations. Despite a recently challenging work environment at the Agency, CVM has been able to balance the need to meet ADUFA timelines with new work to prepare for the threat of a foreign animal disease.

00:56:15 The recent work of CVM to utilize conditional approval and emergency use authorization to approve veterinary drugs to treat and control New World screwworm myiasis illustrates the success of rapid collaboration between CVM and stakeholders as well as the value of available process and authorities to provide timely access to much needed treatments for animal disease preparedness.

00:56:42 Emergency use authorization was available for New World screwworm for animals due to the possibility of an associated public health emergency. We would like to see emergency use authorization expanded to apply to animal health emergency use. The response for approvals for drugs to prevent and treat New World screwworm myiasis illustrates that when CVM has access to the right flexible regulatory tools, the ability exists to move necessary products forward for approval quickly while maintaining the required standards for drug review. As appropriate, the alignment with trusted international regulatory partners and global harmonization could facilitate timely drug approvals and lead to greater access to much needed products.

00:57:27 The U.S. cattle industry is currently facing the advancing problem of the invasive longhorned tick that transmits the protozoan parasite *Theileria orientalis* Ikeda genotype, causing bovine infectious anemia. Recovered animals are persistently infected. Currently, there is no approved treatment or vaccine against *Theileria orientalis* Ikeda in the United States. Access to effective treatment options not

available in the United States could be beneficial for controlling and treating emerging animal diseases.

00:58:01 The Reagan-Udall Foundation for the FDA published a report in June 2025 titled *Transforming Animal Health in the United States for the 21st Century*, which identified that FDA lacked the necessary flexibility needed to keep pace with innovation and modernization in the animal health industry. Regulatory frameworks should support industry advancements that address current needs in animal agriculture and veterinary medicine. FDA CVM should look for opportunities to adjust the level of acceptable risk in the drug approval process to further explore areas of unmet needs.

00:58:37 The ADUFA process will continue to be successful and sustainable by ensuring that the funds received through user fees are effectively utilized to focus on increased efficiency for the drug approval process, streamline new animal drug review systems, increased regulatory predictability, and continued attention to ensuring the safety and effectiveness of all new animal drug approvals.

00:59:02 NCBA encourages FDA CVM to strive for continued improvement for the ADUFA program to increase the number of available drugs to assist veterinarians, farmers, and ranchers in caring for their animals. Thank you for your consideration of our comments today.

00:59:25 Ms. Faunce: Thank you, Dr. Simmons. For our final registered speaker, we have Dr. Michelle Kromm from Food Forward LLC. Dr. Kromm, if you could unmute your mic and do a sound check for us, please.

00:59:39 Dr. Kromm: Good afternoon, Madeline. Can you hear me?

00:59:41 Ms. Faunce: I can hear you. Yeah, I can hear you. Thank you.

00:59:43 Dr. Kromm: Perfect. Good afternoon, everyone. I'm Michelle Kromm. I'm a turkey veterinarian, but I am going to—maybe attempt to—summarize the first part of today's comments. Having also served on the expert panel with Dr. Schrader and having participated in AVMA's round table that they hosted exploring what is next for MUMS. So, that is where my comments will focus on. Next slide, please.

01:00:21 So, as we've gathered already, and all kind of know just innately, scientif-- Scientific capability, excuse me, is advancing faster than regulatory frameworks. And as we've also mentioned already, the Reagan-Udall report highlights that regulatory infrastructure is struggling to keep pace. This challenge is especially acute for minor use and minor species, and I'll talk about that here in a little bit. And Congress has addressed similar-ish issues in the human health space via the 21st Century Cures Act. Next slide, please.

01:01:01 So, there's some very tangible impacts that relate to that first reigning slide, many of which we've already discussed. So, inadequate drug availability, which compromises animal health and welfare, as well as the ability for veterinarians to care for the animals that they need to. Key gaps include analgesics, antiparasitics, anti-infectives, reproductive drugs, and sedatives, and that's some information, again, generated by the Reagan-Udall report. High regulatory costs and limited trial feasibilities often discourage innovation within the United States. And really the result is unmitigated disease losses which have the impact of creating food insecurity and costs issues, sustainability challenges, as well as environmental impacts. Next slide, please.

01:02:01 More specifically for MUMS, high regulatory costs and limited trial feasibility especially discourage innovation for any diseases or markets that might qualify under the current definition of MUMS. And that narrow treatment creates an investment disincentive for animal health companies. As a turkey veterinarian, I think it's important to point out that poultry—although we use the term generally—isn't a homogenous group. And egg layers and turkeys often face MUMS-like issues because their market relatively-- Is small, relatively, compared to that of broiler chickens. So, the result is underserved markets, even those not currently defined under MUMS, have issues and delays with accessing animal health tools that we really do need. Next slide, please.

01:03:03 So, if we actually take a step back and think about what the measurable, or maybe more tangible, impacts of limited tools and limited just investment in this space, we really can talk about a couple different things. So, sponsors avoid markets where pathways are uncertain or economically infeasible. Small markets like MUMS's markets are disproportionately affected. Innovation capacity is increasingly tied to resiliency in our food system—and I think Dr. Simmons's examples of New World screwworms are great call-outs for those impacts—which can impact economic sustainability for producers and ultimately impact grocery costs for consumers. So, some of the results here, for example, our foreign producers can utilize health tools that domestic producers don't have access to, but then we turn around and they export those products into the United States. And again, that was an issue that was identified in the Reagan-Udall report as well. Next slide, please.

01:04:18 So, diving into some more specific honey-dos related to considerations for this next ADUFA funding cycle. The first one is around data package flexibility. And again, we've already heard some of these opportunities to maybe improve or become more flexible with the types of data CVM would accept. For example, allowing production datasets, veterinary networks, and longitudinal farm data to support reviews; expanded use of real-world evidence and pragmatic data generation. As veterinarians and producers, often we bear the brunt of the lack of tools in our toolbox. So, let us

participate in generating the data that's needed to help put more tools in our toolbox. Next slide, please.

01:05:18 Recommendation number two is around not reinventing the wheel. So, leveraging trusted foreign regulatory decisions, allowing conditional approval pathways that rely on trusted foreign dossiers, using existing foreign approvals and import tolerances to accelerate product access and approval, and exploring provisional adoption of foreign residue limits during the conditional approval. So again, getting at this idea of level-setting what U.S. producers have access to versus some of our foreign counterparts. Next slide, please.

01:06:05 Specifically related to MUMS, which I'll address on this slide and the next one, the modernized definition of small numbers, we need-- Excuse me. We need to modernize the definition of small numbers for minor use determinations. And in order to do that, we should incorporate information around disease prevalence, production class, and really the economic realities, whether that is the impact of disease on specific animal populations or the economic realities of getting certain products to market to address those diseases. Recognize that some poultry sectors are commercially small despite a large number of animals in that population. Again, examples of being the commercial table egg layer industry or the commercial turkey industry. And seeking authority to redefine a major species as minor where it's appropriate. Next slide, please.

01:07:08 In order to try to continue to update MUMS, there are some things that could be beneficial when addressing incentives and disincentives: strengthening economic incentives and the capacity of the OMUMS office; extend conditional approval timelines for small markets; allowing dual labeling and shared manufacturing batches where it's scientifically valid and justified; consider a "front of the line" tag along incentive for pending approvals with a larger market upside. So, for example, bringing a drug to market that could address a MUMS's disease and also maybe bringing a dog or cat approval towards the front of the line as an incentive to get some of these MUMS's needs addressed more quickly. And of course, expanding grants, fee reductions, and private-public partnerships. Next slide, please.

01:08:15 So, in general, my request as a production veterinarian is to figure out how we can collaborate through CVM, through the animal health industry, and through the industries that rely on you folks to get us the tools we need to support animal health and welfare. For MUMS populations specifically, modernization determines whether or not innovation is attempted at all, and we all can imagine what the impacts of that are and some of us are living that in our daily lives. And collaboration across stakeholders, including the Agency, animal health companies, veterinarians, and producers, is critical to ensure regulatory systems will evolve fast enough to support

the speed of innovation. And that concludes my comments. Thank you for your consideration.

01:09:11 Ms. Faunce: So, thank you, Dr. Kromm. This concludes the presentation from our registered speakers. At this time, we invite any additional comments from our registered attendees. If you would like to provide comments, please use the "raise hand" feature or type in the chat to indicate you would like to speak. If you would like to type your entire comment into the chat, I will read it aloud so it's entered into the record. Please remember that FDA is in listening mode during this meeting and will not be answering questions or responding to statements posed today. Okay. So, the first person I see on my screen with their hand raised, Steven Roach.

01:09:57 Mr. Roach: Yeah. Hello. I'm Steve Roach. I'm the Safe and Healthy Food Program director of Food Animal Concerns Trust, and FACT appreciates the opportunity to provide some brief comments on the Animal Drug User Fees Act reauthorization. And I would want to point out that I did register to make comments on April 24th when I sent an email, so I'm not sure exactly what went wrong there.

01:10:22 Food Animal Concerns Trust is a nonprofit organization that believes in transforming our food systems so that all food producing animals will be raised in a humane and healthy manner and everyone will have access to safe and responsibly produced food. We do this by supporting humane pasture-based farmers, promoting policies that make food from animals safe and healthy to eat, and helping consumers make informed food choices. This is the fifth round of ADUFA reauthorization that FACT has participated in representing the interests of consumers and farmers.

01:10:56 Congress has consistently required the FDA to consult with representatives of patient and consumer advocacy groups. FACT is once again doing our part and we ask that FDA take this consultation seriously and not solely as proforma. In terms of the overall performance of the program, FACT has consistently argued that a user fee program such as ADUFA is an inappropriate way to fund the work of a regulatory agent like the FDA because it provides regulated industry undue influence over Agency priority setting. And we can see that where there's been so much discussion today about the need for speed and innovation in drug approvals, but there is no similar feeling—at least I get from the agent—on the need to address some of the problems that result from the drug approvals.

01:11:46 And two cases are-- I can give us, like, in terms of antibiotic resistance. The FDA has not updated its medically important list for over 20 years. Similarly, with Carbidox, a known carcinogen, FDA has known for over 20 years that there were problems with the data used to set up the required regulatory method for detecting residues. So, we have this real need for speed when it comes to drug approvals, it's what everyone's

talking about. But there seems to be no concern for actually protecting public health and speed in that sector.

01:12:22 While FACT believes there are better alternatives to feed programs for funding the FDA's work, we accept that this current system is in place. In 2008, Congress acknowledged that postmarket drug safety is within the scope of ADUFA by including Section 105, which directs FDA to collect and report antibiotic cells and distribution data from drug sponsors. While we recognize the limitations of the Section 105 data, we believe that this part of ADUFA has provided valuable information about antibiotic use in food producing animals and has played a critical role in the public policy debate around antibiotic use on farm.

01:13:00 It is through the ADUFA Section 105 data that we know that FDA action resulted in a significant reduction in antibiotic use in food animal production in 2017. Section 105 data also show that antibiotic cells increased by a record amount in 2024. There is also the basis for showing that the amount of antibiotics needed to raise a pig or cow has increased by 40% and 30% respectively compared to 2017. Antibiotic-resistant infections driven by antibiotic overviews continue to be a major challenge to health care in both humans and animals. And a recent study found that almost 20% of resistant urinary tract infections in humans are linked to animal agriculture, along with hundreds of thousands of resistant Salmonella and Campylobacter infections.

01:13:49 FACT asks that FDA includes steps to manage the postmarket safety of antibiotic drugs as part of the current reauthorization of ADUFA. Specifically, we ask that the Agency look at prohibiting use when no illness has been diagnosed, prohibit continuous use of antibiotics, setting sector-specific reduction targets and collecting data on how antibiotics are used on farm. FACT will follow up with more detailed written comments. Thank you.

01:14:20 Ms. Faunce: Thanks for your comment. The next I see on my screen is Phillip Kaufman.

01:14:26 Mr. Kaufman: Hello, can you hear me? Hello?

01:14:31 Ms. Faunce: Can you try again? Sorry.

01:14:33 Mr. Kaufman: Alright.

01:14:35 Ms. Faunce: Yeah, I can hear you. Thank you.

01:14:36 Mr. Kaufman: Can you hear me now?

01:14:37 Ms. Faunce: Yeah, you sound a little far away but I can hear you.

01:14:42 Mr. Kaufman: Hello?

01:14:44 Ms. Faunce: We can hear you.

01:14:46 Mr. Kaufman: Hello? Hello?

01:14:49 Ms. Faunce: Hello? You must not be able to hear us. We can hear you. Okay. We will come back to Phillip. Next up, Ashley Johnson.

01:15:11 Dr. Johnson: Hi, good afternoon. Can you hear me okay?

01:15:15 Ms. Faunce: Yep, I can hear you. Thanks.

01:15:17 Dr. Johnson: Perfect. Thank you very much. I'm Dr. Ashley Johnson, the director of Food Policy at the National Pork Producers Council. NPPC is the global voice for the U.S. pork industry and consists of 42 affiliated state organizations representing America's 60,000+ pork producers who supply a demonstratively safe, wholesome, and nutritious product appreciated on American and international tables.

01:15:41 Our producers rely on animal drugs to help promote animal health as well as human health. The Animal Drug User Fee Act is an integral part of reviewing new animal drugs in a timely manner without compromising quality review. MPPC supports a clean reauthorization of the agreement as negotiated with drug sponsors and stakeholders. The intention of the ADUFA is to streamline the review process of animal drugs and better meet the needs of animals. MPPC, though, also encourages the FDA to continue to facilitate the evaluation of innovative and novel animal drugs, especially in food animal production.

01:16:18 There are multiple unmet needs for food animals, especially in the swine sector, such as analgesics, antibiotics, and novel antimicrobials, especially those that can be administered at a population level and not just for the individual animal. As a swine veterinarian myself, I've seen firsthand the barriers that veterinarians and producers have due to the gaps in approved innovative products, and the needs that we must have for these different animal drugs.

01:16:48 ADUFA is a valuable program that can be enhanced with focusing on the need for more innovation in animal health products to meet these unmet needs that will continue to promote and protect human and animal health. Thank you.

01:17:03 Ms. Faunce: Thank you. Next up, I have Roselle Busch.

01:17:09 Dr. Busch: Good afternoon. Can you hear me?

01:17:11 Ms. Faunce: Yes, I can hear you.

01:17:12 Dr. Busch: Great. Thank you for the opportunity to speak today. My name is Dr. Rosie Bush and I'm here on behalf of the American Sheep Industry Association as co-

chair of the Animal Health Committee representing more than 100,000 sheep producers across the United States.

01:17:26 Sheep producers, veterinarians, industry, and the Center for Veterinary Medicine all share the same goal: healthy animals and a safe, affordable food supply. We appreciate CVM's continued engagement and the work being done under ADUFA. However, access to animal health tools remains a serious challenge for the sheep industry. Sheep producers have extremely limited access to safe and effective products, particularly for parasite control. New drug development has largely stalled because the cost and complexity of the approval process discourage investment in what is already a relatively small market. Timely access to animal health tools is essential for animal welfare, producer viability, and a resilient food supply.

01:18:07 The U.S. is falling behind trusted international partners, including Australia, New Zealand, Canada, and the European Union, where producers have access to significantly more treatment options. This places American producers at a competitive disadvantage.

01:18:21 ADUFA reauthorization is an important opportunity, but maintaining the status quo is not enough. We encourage FDA to build on what is working while advancing practical science-based flexibility in the review process. The New World screwworm response demonstrated that when CVM has the tools and flexibility to act quickly, meaningful progress can happen. We also encourage greater use of existing pathways like conditional approvals, increased alignment with trusted international partners, established science-based tolerance limits for legal extra label drug use, and continued efforts to reduce unnecessary barriers to innovation. User fees should support a more efficient and streamlined system, not create additional disincentives for developing products for minor species like sheep.

01:19:08 Getting this right means healthier animals, lower costs for producers, improved productivity, and a resilient, secure food supply. Thank you for your time and consideration.

01:19:18 Ms. Faunce: Thank you. Okay. Next on my screen I see is Maggie Baldwin. Maggie, can you unmute your mic?

01:19:32 Ms. Baldwin: How's that?

01:19:33 Ms. Faunce: Yep, I can hear you. Thanks.

01:19:35 Ms. Baldwin: Great. Thank you. My name is Maggie Baldwin. I'm the state veterinarian and director of the Animal Health Division at the Colorado Department of Agriculture. I currently serve as the vice president of the National Assembly of State Animal Health Officials. I appreciate the opportunity to provide brief comments today.

Some of my comments are a bit repetitive from previous speakers, so I'll try to shorten them a little bit.

01:19:54 The CVM provides an important support to ensure healthy animals in a safe, affordable food supply in the U.S. Access to safe, effective animal health tools is essential to animal welfare farm productivity and food safety. These tools are also vital to the health and welfare of companion animals. We look forward to continuing to work with CVM as partners to improve the animal drug framework. We appreciate CVM's work and willingness to collaborate on solutions. This helps ensure that producers, veterinarians, and pet owners have timely access to the necessary tools to keep animals healthy.

01:20:28 We greatly appreciate the close collaboration with CVM on the new and emerging issue of the New World screwworm. They've collaborated with state animal health officials and ensured faster access to necessary tools in an emergency situation. As we've recently seen expanding foreign animal disease incidents like New World screwworm and highly pathogenic avian influenza spillover into dairy cattle, I encourage the CVM to continue to adopt rapid-response models to ensure that we have necessary tools available for regulatory response.

01:20:56 Lastly, as a SAHO who also recently participated in a Reagan-Udall roundtable on cross-sectoral relationships, I understand the value and work that has gone into those third-party reports. I encourage the CVM to continue to adopt recommendations from these reports, including the 2025 report entitled *Transforming Animal Health in the U.S. for the 21st Century*. We look forward to continuing to work with the FDA CVM in supporting the next iteration of ADUFA and continuing to meet the growing needs in animal health and regulatory medicine. I appreciate your time and thank you.

01:21:30 Ms. Faunce: Thank you. Next up is Leah Wilkinson.

01:21:36 Ms. Wilkinson: Good afternoon. Can you hear me okay?

01:21:38 Ms. Faunce: Yes, I can hear you.

01:21:40 Ms. Wilkinson: All right. Thank you. I'm Leah Wilkinson, chief policy officer for the American Feed Industry Association. AFIA is a trade association representing the entire animal food industry with almost 600 member companies who manufacture feed, pet food, the ingredients that we use, the pharmaceuticals that we use, and then the equipment that is used to make all of our feed and pet food products.

01:22:06 So, I'm here today to talk about how we need workable regulatory review processes for animal food ingredients and those animal drugs that we use to manufacture the feed products and pet foods our customers need and desire to keep their animals healthy, productive, and safe. These review processes, whether it be for a new feed

ingredient or an animal drug, need streamlining, as you've heard today from several others, and AFIA supports that. They need to be efficient and they need to also allow for innovation.

01:22:42 And right now, the U.S., I think, we're lacking in that department. Right? We are falling behind the rest of the world. So, we need to have more tools to be able to give our livestock, poultry, aquaculture, equine, and our companion animals, whether they be for nutrition or for treating diseases and viruses.

01:23:05 The ADUFA reauthorization process provides us that opportunity to implement some of the recommendations, either in CVM's own innovation agenda or—that's been also referenced several times—in the Reagan-Udall report. The AFIA would especially like CVM to request authority that would be provided in the Innovative FEED Act that's being currently considered in Congress as part of the legislative package if that act does not pass on its own before ADUFA would move forward for consideration. And if Congress won't give that new authority, then we continue to urge the Center to find ways to bring these new innovative products to market using other policy options.

01:23:54 We also think the ADUFA process could be used to improve the availability of drugs that fall under the minor use and minor species designation and make some improvements there. We at AFIA support the effort to update the MUMS Act and CVM's processes under this to make those products more available. So, thank you for the opportunity to provide some comments today. We look forward to continuing to participate in the ADUFA reauthorization process.

01:24:23 Ms. Faunce: Thank you for your comment. Next, I have Logan Moss. Logan, can you do a soundcheck for us?

01:24:30 Mr. Loss: Can you hear me?

01:24:32 Ms. Faunce: Yes, I can hear you.

01:24:34 Mr. Loss: Terrific. Well, good afternoon and thank you for the opportunity to provide some brief comments here today. My name's Logan Moss and I serve as associate director of Public Policy at the National Association of State Departments of Agriculture. NASDA represents the commissioner, secretaries and directors of State Departments of Ag in all 50 states and four U.S. territories. Our members support farmers, ranchers, and food systems through regulatory oversight, market development, animal and plant health programs, among numerous other activities.

01:25:01 Animal health is the core responsibility of State Departments of Agriculture. SDA serves as the lead regulatory authority for animal health in 45 states, and even in the states where that authority is outside of our members' offices, our members work

closely with our counterparts in the state government to prevent, detect, and respond to foreign animal diseases.

01:25:19 We want to thank FDA Center for Veterinary Medicine for its recent work in supporting response efforts related to New World screwworm. [We have] heard a lot about that today. Screwworm is a top concern for our members and their stakeholders, and we appreciate CVM's efforts to move quickly on emergency use authorizations and conditional approvals needed to support veterinarians, producers, and SAHOs, who will be the first responders should we have a domestic detection of New World screwworm.

01:25:46 This work really highlights why ADUFA remains so important. Foreign animal diseases don't wait. State responders need a regulatory system that can move with urgency while maintaining scientific rigor and public confidence. ADUFA helps provide the staffing capacity and predictability necessary for CVM to evaluate and make available critical animal health tools for emerging threats like screwworm. We support additional streamlining within the ADUFA process.

01:26:13 ADUFA is important not only during emergency response situations, but also for ensuring producers and veterinarians continue to have access to innovative health products that support food security and resiliency in the livestock sector.

01:26:24 As discussions move forward on ADUFA VI, NASDA encourages continued focus on maintaining a fast, strong, and science-based review process that gives producers, veterinarians, and SAHOs timely access to the tools they need when they need them. We appreciate the opportunity to participate today and look forward to continued engagement with FDA, Congress, and the stakeholders on this call throughout the ADUFA VI process. Thank you again for the time to speak.

01:26:52 Ms. Faunce: Thank you. Next, I have Dale Nellor. Dale, can you do an audio check for us?

01:26:59 Mr. Nellor: Yes. Good afternoon. Can you hear me?

01:27:01 Ms. Faunce: Yes, I can hear you. Thank you.

01:27:03 Mr. Nellor: Perfect. Well, good afternoon. My name is Dale Nellor and I'm here representing the National Turkey Federation. Our members consist of U.S. turkey producers, processors, and allied companies that support the industry.

01:27:16 U.S. turkey producers have a limited selection of animal health products compared to other livestock species. That is largely because turkey represents a smaller market, which can limited [sic] investment in the research, development, and regulatory approval of turkey-specific products. However, a smaller market does not mean there are less significant animal health issues. The turkey industry faces a wide range of

bacterial, viral, and parasitic threats. These can often only be addressed by management practices, biosecurity measures, and off-label use of products where permitted. Without effective tools, however, turkey producers continue to face substantial losses and ongoing challenges protecting flock health. NTF provided feedback during the development of recent reports by the GAO and the Reagan-Udall Foundation that offer suggestions to address unmet needs.

01:28:10 The turkey industry feels that it is imperative that partners challenge ourselves to explore how recommendations such as international alignment of regulatory standards and alternatives for data sources and submission formats could be implemented. NTF supports practical science-based flexibility. It is essential that regulatory pathways effectively address unmet animal health needs while implementing a risk-benefit assessment framework. While maintaining rigorous standards, CVM should apply flexibility where appropriate by fully utilizing existing authorities such as conditional approvals and the MUMS program, and evaluate how these tools can be strengthened to better incentivize innovation. Blackhead disease is a clear example. In 2018, FDA designated the treatment for blackhead disease in turkeys as a minor use in a major species. This designation was recognition that blackhead represents a significant unmet health need within a relatively small market. However, while the designation was intended to encourage research and facilitate product development through incentives and streamlined pathways, nearly a decade later, there is still no viable treatment in the marketplace.

01:29:24 NTF believes the MUMS process is a positive acknowledgement of issues such as this one. However, due to its limited success in delivering practical solutions, the process may need to be reevaluated to better translate that recognition of needs into tangible outcomes. Turkey producers need more tools in their toolbox to prevent and treat disease, protect flock health, and maintain productivity. A risk-based science-driven approach can help prioritize resources and accelerate access to needed products without compromising safety or efficacy.

01:29:59 And finally, FDA's response to New World screwworm serves as a strong example of successful collaboration between CVM and industry stakeholders to address an emergency and animal health threat. NTF encourages FDA to explore how it can expand on this model and how a similar risk-versus-benefit framework could be applied more broadly in other circumstances, especially for devastating diseases affecting smaller sectors like the turkey industry where limited treatment options and urgent response needs may warrant additional regulatory flexibility.

01:30:34 We appreciate the work FDA has done so far and we look forward to continuing the dialogue throughout this process to better address animal health needs. Thank you for the opportunity to provide comments today.

01:30:48 Ms. Faunce: Thank you. Next, I have Callie Willingham.

01:30:56 Dr. Willingham: Hello. Can you hear me?

01:30:58 Ms. Faunce: Yes, I can hear you.

01:30:59 Dr. Willingham: Hi, I'm Dr. Callie Willingham. I'm the current president of the American Association of Bovine Practitioners. We'd like to thank FDA for allowing us to have this comment period for the reauthorization of ADUFA. The AABP is an international association of veterinarians, veterinary technicians and veterinary students with a mission to provide support, continuing education and advocacy for current and future veterinary professionals and the cattle they serve. The vision of AABP is to serve society as leaders in cattle health, welfare, and productivity.

01:31:33 AABP supports ADUFA and the reauthorization of ADUFA to ensure a robust new animal drug review process. ADUFA is an important component of ensuring that cattle veterinarians and producers have access to medications for cattle health, welfare, and productivity. It is our assessment that the overall performance of ADUFA is adequate. However, measures should be taken to improve the efficiency of drug approvals and the supply of medications within the market.

01:32:03 Our AABP members have expressed concerns with continual drug availability shortages and disruptions in supply. There are multiple instances over the past several years of disruptions in supply including lidocaine, epinephrine, Folltropin, penicillin, ceftiofur, ampicillin, and oxytocin-- Oxytetracycline. Pardon me. These drugs are critical for treating a variety of important diseases in cattle. When one antimicrobial becomes available, it can often lead to shortages of another antimicrobial due to increased purchases of the available product. This creates a continual cycle of shortages and creates challenges for veterinarians, and also for producers who are attempting to follow the treatment protocols provided by their veterinarian of record.

01:32:49 AABP has engaged with FDA CVM on this subject and one barrier identified to addressing shortage issues is the lack of mandatory reporting by drug manufacturers. For human medications, companies are required to notify FDA of a potential drug shortage ever since the enactment of the Food and Drug Administration Safety and Modernization Act of 2012.

01:33:11 In 2020, the CARES Act enhanced the FDA's ability to identify, prevent, and mitigate possible shortages of human drugs by expanding the notification requirement. AABP strongly encourages FDA to consider similar requirements in ADUFA for animal drug manufacturers. This could include notification at least six months in advance or as soon as practicable thereafter of a permanent discontinuance in the manufacture of products and interruption in the manufacture of such products as likely to lead to a

meaningful disruption and supply of those products in the United States, a permanent discontinuance in the manufacture of active pharmaceutical ingredients for such products, and interruption in the manufacture of API for such products is likely to lead to a meaningful disruption in the supply of the API for those products. In addition, a notification of drug shortage communicating the estimated time to alleviate the shortage.

01:34:13 The AABP appreciates the opportunity to provide these comments and is willing to engage with FDA on assisting with necessary steps to reporting drug shortages and maintaining a robust and safe supply of critical drugs to protect cattle health, welfare, and productivity. Thank you.

01:34:30 Ms. Faunce: Thank you. Okay. Next, we'll go back to Phillip Kaufman. Philip, are you ready to comment?

01:34:37 Mr. Kaufman: Yes. Are you able to hear me?

01:34:39 Ms. Faunce: Yes, I can hear you.

01:34:40 Mr. Kaufman: All right. Thank you. Thank you for the opportunity to comment today on the future of ADUFA, on the reauthorization. My name is Phillip Kaufman and I'm a professor and the head of the Department of Entomology at Texas A&M University. I also serve as the chair of the Texas A&M AgriLife New World screwworm task force and am a researcher in the field of livestock pest management.

01:35:04 My career has been focused on the development of new pest management tools for producers to use to control livestock pests and has included many studies providing data to support product registrations with FDA. Texas A&M AgriLife is a Texas state agency representing agricultural research and extension interests, which includes animal health products such as medicines, drugs, vaccines, and diagnostics that help keep American livestock and companion animals healthy. Our enterprise exceeds 400 research oriented faculty at multiple Texas institutions and we are a global leader in animal agriculture.

01:35:46 Texas has the largest beef kettle herd in the U.S. and leads, or nearly leads, in many other animal industry categories. A recent concern has been the reemergence of the New World screwworm, Cochliomyia hominivorax, a pest which you've heard considerable comments on today. We once eradicated this pest, but it has escaped its quarantine in Panama and now sits about 60 miles south of the U.S. border with Mexico.

01:36:13 It is the actions of the FDA and other federal agencies who have worked tirelessly with our industry and clientele partners to ensure that we have the best and safest products

available to protect our multi-billion dollar animal agriculture industry that I will address here.

01:36:33 Animal health is largely driven by the availability of safe and effective compounds developed and marketed by industry under the watchful auspices of the FDA to ensure that these products are efficacious and safe. One of the tenants of animal pest control drug development has been the strict requirement of the geographic location of where product efficacy testing has occurred, whether that be in the U.S. or at an international location.

01:37:00 However, as we've recently learned with the New World screwworm, there are limitations to this requirement that must be taken into consideration. Typically, for animal drugs to be sold in the U.S., product registration required that efficacy testing occur with the pest in the U.S. For many pests, this is not a challenge as they readily occur in the U.S., which is why we seek these registrations. However, for New World screwworm, that fly was eradicated from the U.S. with the last wild-transmitted cases prior to eradication occurring in 1982, long before entire classes of pesticides and drugs were discovered.

01:37:40 Many of these products were registered by the industry in Latin American countries where New World screwworm was endemic. U.S.-based testing limitation severely restricted FDA's ability to register products with New World screwworm on the label, as no U.S.-based testing against the fly had been done as it was an impossibility given New World screwworm is considered a foreign animal disease pest and was not permitted to be in the U.S., even for experimental testing. Thus, this prevented the critical on-animal testing required for efficacy.

01:38:17 Once the loss of New World screwworm containment was fully recognized, CVM through ADUFA addressed this by facilitating the FDA and other agency partners capacity to lower these barriers and bring many products to market using the conditional approval or emergency use authorization protocols, which maintained the long practice safety processes while adhering to the needed guardrails of a proper review.

01:38:51 It was recognized that if a product was efficacious against New World screwworm in Latin America, it would be just as likely to work on New World screwworm should that fly population reach the U.S., particularly because that was the source of the flies that escaped quarantine. To accomplish this, FDA utilized the emergency use authorization process, which has proven especially effective in bringing several products to our stakeholders in a way that protects the integrity of our food safety requirements and health of our livestock and companion animals.

01:39:27 We support the reauthorization of ADUFA and encourage the continued efforts to streamline processes while maintaining the integrity of the process. Although highly unfortunate, the New World screwworm outbreak has demonstrated the importance of CVM and ADUFA, as well as how the government can be rapidly responsive to clientele needs. Thank you for your time.

01:39:59 Ms. Faunce: Okay. Thank you so much for all your comments. Is there anyone else that would like to provide a public comment? If so, one last opportunity to use the raise your hand feature or put a comment in the chat box. Okay. Since I see no other comments, this officially closes the Open Public Comment Period and I will now offer a few closing remarks.

01:40:38 Thank you everyone for your important feedback as we enter this next phase of the process. Your support for this program is very much appreciated and we've appreciated it-- And we value your comments. So, what's next?

01:40:50 Congress has outlined an interactive and transparent process for us to follow, as Dr. Lucia covered in his presentation. Over the next few months, we will begin negotiations with industry. Although the negotiations themselves will not be public, there will be several touchpoints that provide opportunities for all of us to stay involved in the process.

01:41:11 First, we will schedule stakeholder meetings during the ADUFA negotiations to provide an opportunity for stakeholders to provide input in developing recommendations for the next ADUFA reauthorization. If you would like to participate in these meetings and have not yet registered, please email ADUFAReauth@fda.hhs.gov. In order to participate, you do need to sign up in advance, so please register by June 1st, 2026.

01:41:45 Second, we will publish the minutes of each negotiation session with regulated industry on the FDA website. These minutes will summarize substantial proposals, significant controversies, differences of opinion during negotiations and any resolutions.

11:42:03 Third, we will keep the ADUFA public comment docket open throughout the entire process for additional comments you may wish to share with us. We will also provide a 30-day period after this meeting to obtain written comments from the public and those comments will be published on FDA's website.

01:42:22 Lastly, once an agreement on ADUFA has been reached, the following steps will occur. First, we will publish the negotiated recommendations in a Federal Register notice and provide a 30-day period for written comment. Second, we will hold another public meeting to present views on these recommendations. Third, after consideration

of public comments, we may revise the recommendations as necessary. We must transmit the ADUFA package to Congress no later than January 15th, 2028.

01:42:55 I again want to express our sincere thanks to all of you for participating in this public process and for sharing your comments, whether today or afterwards through the docket. You may go to www.regulations.gov to submit additional comments. Thank you so much, everyone, and this officially closes our public meeting.

[End of the recording.]