Animal Generic Drug User Fee Act (AGDUFA)

May 26, 2026

Public Meeting Transcript

00:00:17 Ms. Faunce: Okay, everyone, welcome. We're going to start the meeting promptly at 11:03, just giving people time to get into the meeting. Thank you. Again, for those just joining, we're going to start at 11:03. Thank you. Okay. It's 11:03, so we'll get started.

00:02:59 Good morning. I'd like to welcome you all to the Animal Generic Drug User Fee Act 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 AGDUFA program. Your comments will help us strengthen and improve our future program.

00:03:25 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 Generic Animal Drugs director, Dr. Julie Bailey. This will be followed by an Open Comment Period and we look forward to hearing from you.

00:03:46 Registered speakers for this session, Dr. Lindsey Hornickel from the American Veterinary Medical Association will be the first to provide remarks. Following completion of Dr. Hornickel's remarks, we will open public comment to all registered attendees. 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 that you would like to speak. We will then ask you to unmute your microphone, state your name, affiliation, and then provide your comments.

00:04:19 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're entered into the record. Please be aware the FDA is in listening mode during this meeting. We will not be answering any questions or responding to statements posed today.

00:04:39 This meeting is being recorded and that recording along with a written transcript will be posted on fda.gov on our Animal Generic Drug User Fee page. You'll 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 AGDUFA program.

00:05:05 Dr. Schell: Thank you, Madeline, and thank you all for being here today. This meeting kicks off the effort to reauthorize the Animal Generic Drug User Fee Act, otherwise known as AGDUFA. There will be a separate

meeting this afternoon focused on the Animal Drug User Fee Act, ADUFA, for pioneer products. We welcome your participation and input throughout the reauthorization process.

00:05:28 Your input helps to shape the future of our user fee programs and animal health. The additional resources provided by user fees are relied on by CVM and industry to advance our shared goal of protecting and promoting human and animal health.

00:05:44 Generic animal drugs play a vital role in this effort by offering affordable alternatives to brand name products and fostering marketplace competition that lowers prices across the board. Through the upcoming negotiations, we'll establish the next user fee cycle's performance goals and enhancements to modernize how we approach generic animal drug review and bring products to the market.

00:06:09 Since the start of AGDUFA IV in fiscal year 2024, we've approved 15 first generics. Some of these are copies of brand name products that were the sole approved treatment options for decades. The cost of many of these treatments have risen throughout their marketing periods. When end users find treatment costs prohibitive, they may forgo care for their animals altogether or turn to unapproved alternatives of questionable safety, efficacy, and quality.

00:06:40 By introducing market competition through the approval of generic animal drugs, FDA expects to reduce costs and expand consumer access to products that meet our standards for safety and effectiveness. Another key priority is supporting the America First initiative. More information on a pilot program for incentives for domestic manufacturing will be coming in the next few months. Stay tuned for those.

00:07:07 In our current cycle of AGDUFA IV, CVM has had numerous accomplishments. Thanks to the stability provided by user-fee funding, we completed various efforts to enhance generic animal drug approval in addition to those we committed to in the goals letter. We will discuss those in detail in the next presentation, but I want to highlight a few of those accomplishments now.

00:07:29 CVM updated and published a number of guidances for industry to clarify various aspects of the generic animal drug review process. We significantly revised the question-based review template sponsors use to submit generic investigational drug manufacturing technical sections. The focus is to collect only essential information per risk-based review principles. The ultimate goal is reducing the number of cycles before CVM accepts submissions to support drug approval.

00:08:01 We also implemented internal process updates and training to ensure reviewers apply risk-based review concepts and remove regulatory burdens

for drug manufacturing. We collaborated with industry to attend mock bioequivalent studies. This benefits both CVM and industry by improving the design and evaluation of bioequivalent studies, leading to fewer issues during the review process and reducing the risk of enrolling animals in unsuccessful studies.

00:08:31 We made significant progress in developing tools to evaluate in vitro bioequivalence data for non-systemically absorbed drugs based on formulation sameness and physiochemical sameness. Our goal is to establish alternatives to animal terminal studies and ethically questionable studies. Ultimately, this will give us, the generic industry, a viable path to pursue certain drugs, such as intramammary products for which there are currently no approved generics.

00:09:01 In 2025, HHS issued the first declaration allowing FDA to use emergency use authorizations for animal drug products to treat or prevent infestations caused by New World screwworm. CVM has been working with animal drug sponsors to identify products, including generic products, that could be approved or authorized for this use. We greatly appreciate the industry cooperation to make FDA reviewed products available to livestock producers and pet owners in the event of a New World screwworm incursion.

00:09:35 Finally, FDA continues to be a voting member of the United States Pharmacopeia Convention and we have a voice in resolutions that will drive the next five-years work of USP. Our participation is critical because USP's work, especially monograph development, can have implications for both pioneer and generic drug approvals. These achievements highlight what a fully resourced AGDUFA program can accomplish.

00:10:03 I'd like to note that during our recent reduction in staffing, coupled with continued increase in generic animal drug submissions that has placed us a significant strain on our ability to maintain our current level of performance. We're optimistic that we'll be able to return to our previous staffing levels and that using user fees will continue to support our important work.

00:10:24 As stated earlier, our common goal is protecting and promoting human and animal health, particularly through advancing affordability, drug availability, and supporting America First initiatives. The AGDUFA program provides us with necessary resources for timely and efficient evaluation of generic animal drug submissions. The program supports FDA's responsibility to protect human and animal health by ensuring animal drugs are safe and effective, and products from food-producing animals are safe for human consumption.

00:10:55 The reauthorization process is an opportunity to reflect on the program's successes and to look ahead to program improvements and innovations. Thank you for your interest and involvement in this important process. I'll now turn it over to Dr. Julie Bailey, the director of CVM's Office of Generic

Animal Drugs to present the history and current performance of the AGDUFA program. Julie.

00:11:19 Dr. Bailey: Thank you. And good morning. As Dr. Schell mentioned, I'm Julie Bailey, director of the Center for Veterinary Medicine's Office of Generic Animal Drugs and I'll be presenting on the Animal Generic Drug User Fee Act, also known as AGDUFA. Next slide.

00:11:41 Here's a quick overview of the major topics I'm going to cover. I'll review the basic structure of the AGDUFA program and its reauthorization cycles. Then I'll highlight program benefits and accomplishments, including performance under the previous authorizations of AGDUFA. I'll also give you an overview of some of the process improvements we've initiated in this current AGDUFA cycle, some of which Dr. Schell touched on in his introductory remarks. These have enhanced the predictability of the generic animal drug review process and are helping the animal drug industry to increase access to more affordable generic equivalents for animal drugs. Then I'll close with an overview of the reauthorization process. Next slide.

00:12:25 All FDA's user fee programs run for a five-year period. Congress first authorized AGDUFA in fiscal years 2009 through 2013. We're currently in AGDUFA IV and the next reauthorization, if enacted, would be AGDUFA V from 2029 to 2033. Next slide.

00:12:50 The overarching purpose of the AGDUFA 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.

00:13:13 The user fee program assists CVM in accomplishing its mission by helping to provide more predictable timelines to evaluate generic new animal drug submissions, facilitate the review of generic animal drugs to better meet the therapeutic needs of animals, and facilitate the review of generic animal drugs used in food animal production to improve both human and animal health. Next slide.

00:13:37 Performance is one of the main goals of the AGDUFA program. As you can see, we've dramatically improved our performance over the course of AGDUFA's history. In the first authorization of AGDUFA, we eliminated our backlog and significantly reduced our review times from an average of more than 700 days to the target 270 days. And in AGDUFA II, we added flexibility, installed IT enhancements, and improved our review process for the bioequivalent section of the application that's so important to ensure generic animal drugs act the same way their pioneer counterparts do. Next slide.

00:14:17 In AGDUFA III, we continue to reduce performance goal review times for all submission types, and required 100% electronic submission. We also required approved generic animal drugs to bear a statement that includes "Approved by FDA" and the abbreviated new animal drug application number. In AGDUFA III, we exceeded all performance goals. Next slide.

00:14:41 In AGDUFA IV, we enhance transparency by formalizing the bioequivalence technical section meeting process and creating dosage form specific template letters to use when a JINAD is opened by a sponsor. In AGDUFA IV, we continue to explore the US-EU Mutual Recognition Agreement and future MRAs with additional countries. We also enacted the US-UK MRA to reduce costly and redundant GMP surveillance inspections.

00:15:10 The authorization also added a request to open a JINAD file as a sentinel submission with a performance goal to act on 90% of original JINAD file requests within 100 days after the submission date. And so far, we've exceeded all of our performance goals. Next slide.

00:15:30 I'll now transition to talking about the performance goals that are associated with AGDUFA. I know there is a lot of information in the table, but as a reminder, the presentation will be available at fda.gov along with the recording and a written transcript when available.

00:15:45 These performance goals help us to provide predictability as they define the timeframes for review of the different submission types. In order to track AGDUFA's success, we monitor the timely review of key submission types known as sentinel submissions. This slide provides the review times in days for abbreviated new animal drug applications and generic investigational new animal drug submissions, and shows the evolution of the review timeframes in almost all cases reduced for the first three cycles with the addition of the request to open a JINAD file in the current cycle. Next slide.

00:16:24 The next three slides show the performance metrics for the first three fiscal years of the current authorization. This information is outlined annually in a public report to Congress and is also updated quarterly on the FDA-TRACK website. This slide shows the performance data for fiscal year 2024 in which we exceeded all performance goals for the six submission types, meaning we responded within the review dates specified more than 90% of the time. Next slide.

00:16:54 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 the performance goals for the six submission types, meaning we responded within the review days specified more than 90% of the time. Because we are continuing to review and act on fiscal year 2025 submissions, there is an additional column in this table called Pending within Goal. Next slide.

00:17:23 This slide shows preliminary performance data for submissions filed in the first two quarters of the current fiscal year from October 1st, 2025 until March 31st, 2026. So far, for the submissions we've completed, we are exceeding all performance goals for the six submission types, meaning we responded within the review days specified more than 90% of the time. Next slide.

00:17:49 Now, I'll speak to the various steps for the upcoming reauthorization process between now and 2028. First, we 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 obtain public input prior to beginning negotiations with regulated industry. There is a Federal Register notice published on April 17th, 2026 and the docket will remain open until December 1st, 2027.

00:18:26 We'll hold discussions with stakeholders, including representatives of veterinary, patient, and consumer advocacy groups to continue discussions of the reviews on the reauthorization and their suggestions for changes at least once every four months during negotiations. There is an FR notice published on May 11th, 2026 announcing how to sign up. So, please reach out if you want to participate. We'll publish the meetings of negotiating-- The negotiation minutes-- Minutes of negotiation meetings on our public website, obtain public review and comment on final recommendations after negotiations with industry. And finally, we'll transmit the recommendations to Congress no later than January 15th, 2028. Next slide.

00:19:12 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 are requesting feedback from today's attendees on two questions. What is your assessment of the overall performance of the AGDUFA program thus far? And what aspects of AGDUFA should be retained, changed, or discontinued to further strengthen and improve the program? Thank you.

00:19:43 Ms. Faunce: Thank you, Dr. Bailey. So, now we will proceed with the Open Public Comment Period of the meeting. Please remember to speak clearly and directly into your microphone for purposes of transcription and for the attendees. Our registered speaker today is Dr. Lindsey Hornickle, assistant director of Federal Government Relations at the American Veterinary Medical Association. Dr. Hornickle, if you could try to unmute your mic, or if not, we'll get your audio working.

00:20:17 Dr. Hornickle: I am unmuted. Are you able to hear me?

00:20:19 Ms. Faunce: Yes, we can hear you. Thank you.

00:20:20 Dr. Hornickle: Okay, perfect. Right. Good morning. I am Dr. Lindsey Hornickle, assistant director in the Federal Government Relations Division of the American Veterinary Medical Association. The AVMA, with more than 111,000 member veterinarians, is committed to protecting animal health and welfare, public health, and a safe food supply. Informed by our members' unique scientific training and expertise the AVMA serves as a trusted leader to protect, promote, and advance a veterinary profession that meets the needs of society.

00:20:57 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 these challenges. 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.

00:21:31 The FDA's diligent and expedited review of these 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.

00:21:56 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 in 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.

00:22:21 Expanding access to more safe, effective, and appropriately regulated animal drugs is essential to ensuring veterinarians have the tools they need to support animal welfare and food safety. AVMA supports user fees for generic animal drug applications when those fees continue to improve the progress the FDA CVM has made in improving efficiency, predictability, and timeliness of its reviews. Importantly, the costs associated with FDA approved animal drugs are ultimately borne by our clients.

00:22:58 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 FDA-approved generic animal drugs can determine whether treatment is feasible for clients. Animal owners depend on generic products that meet rigorous standards for safety, effectiveness, and quality while remaining reasonably affordable.

Veterinarians therefore need access to a safe and effective generic product review process that is as efficient and cost effective as possible.

00:23:36 Approval of generic animal drugs is critical to maintaining reliable access to essential medications. Veterinarians regularly encounter situations in which a pioneer drug becomes commercially unavailable, limiting treatment options and disrupting patient care. Recent supply chain instability has further underscored the importance of maintaining multiple dependable sources for essential animal drugs. In these circumstances, access to FDA approved generic products for which bioequivalence has been demonstrated and that are manufactured in compliance with CGMP standards is far preferable to relying on compounded alternatives.

00:24:16 Expanding the availability of FDA approved generic animal drugs would also encourage greater manufacturer participation in the market by signaling that investment in generic development is both viable and valuable. Increased competition can help stabilize supply, strengthen market resilience and reduce cost for manufacturers and animal owners alike.

00:24:41 If the AGDUFA legislation will serve as a vehicle for changes to regulatory pathways, 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. Building on FDA CVM's progress in the generic animal drug review process, the AVMA may suggest several additional steps to further advance AGDUFA's goal of accelerating access to generic animal drugs.

00:25:13 First, where appropriate, the AVMA encourages FDA CVM to consider adopting regulatory approaches used by comparable agencies and other developed countries that have successfully streamlined reviews and expedited market access for generic animal drug products.

00:25:30 Second, the AVMA encourages FDA CVM to prioritize review of active pharmaceutical ingredients for which no animal drug currently exists. Focusing resources on expanding the range of available generic products would better address the unmet veterinary needs, improve market resilience, and maximize the benefit of the review process.

00:25:53 Finally, the AVMA encourages a generic animal drug user fee structure that incentivizes product development for minor uses and minor species. While some products may serve markets large enough to support multiple generic approvals, many products intended for smaller or specialty markets remain unavailable or underserved.

00:26:14 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 populations, or less common conditions where therapeutic options are already limited.

00:26:40 In closing, the AVMA appreciates FDA CVM's commitment to continue efforts to improve the generic animal drug review process and supports user fees as an important mechanism for expediting access to safe, effective, and affordable generic animal drugs. A modernized and responsive AGDUFA program will expand treatment options, help control costs, and maintain rigorous standards for safety, efficacy, and quality.

00:27:09 The AVMA remains committed to working collaboratively with the FDA and other stakeholders to ensure current and future iterations of AGDUFA 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 feedback to FDA today.

00:27:35 Ms. Faunce: Thank you, Dr. Hornickle, for your comments. 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 that you would like to speak. If you would like to type your entire comment into the chat, I will read it aloud so it is 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.

00:28:05 So, do we have anybody that's raising their hand? I do not see any comments. Just give it a minute before we close. Oh, I see one. Stephanie Batliner, did you want to come off mute?

00:28:33 Ms. Batliner: Hi, hello. I'm Stephanie Batliner, chairperson of Generic Animal Drug Alliance and also VP Regulatory Affairs and R&D for Bimeda Incorporated. Generic Animal Drug Alliance plans to submit more formal and longer comments to this public meeting and to the docket that is established for such, but we did not-- As the duration given for registering to be a speaker today was quite short, we did not take the opportunity to prepare full written comments.

00:29:13 We do look forward to the discussions around how we can enhance AGDUFA V. We recognize some of the meaningful progress that was made in AGDUFA IV. However, we still believe there's much work to do to help foster a competitive and vibrant generic animal drug industry. Thank you.

00:29:39 Ms. Faunce: Thank you. We look forward to receiving your future comments as well. Anyone else have a comment? I look at the chat. Okay, so there is no comment. So, I will read this out loud.

00:29:54 Similar to practices adopted by CDER, could CVM consider taking measures to enhance the first cycle approval rate of CMC submissions and where

feasible publish performance metrics from past reviews? Such transparency would not only highlight areas of improvement but also provide valuable insight to sponsors in aligning their submissions with regulatory expectations. Any more comments? Okay.

00:30:38 Okay, I do not see any more comments. Okay. Since I see no other comments, this officially closes the Open Public Comment Period and I would like to offer a few closing remarks.

00:30:56 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 value your comments. So, what's next?

00:31:07 Congress has outlined an interactive and transparent process for us to follow. As Dr. Bailey covered in her 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 us all to stay involved in the process.

00:31:28 First, we will schedule stakeholder meetings during the AGDUFA negotiations to provide an opportunity for stakeholders to provide input in developing recommendations for the next AGDUFA reauthorization. If you would like to participate in these meetings and if not yet register, please email at AGDUFAReauth@fda.hhs.gov. In order to participate, you do need to sign up in advance. Please register by June 1st, 2026.

00:32:03 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 negotiation and any resolutions.

00:31:18 Third, we will keep the AGDUFA public comment docket open through 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.

00:32:35 Lastly, once an agreement on AGDUFA has been reached, the following steps will occur. First, we will publish the negotiated recommendations in a federal register notice and provide 30 days for a written comment. Second, we will hold another public meeting to present views on those recommendations. Third, after consideration of public comments, we may revise the recommendations as necessary.

00:33:00 We must transmit the AGDUFA package to Congress no later than January 15th, 2028. 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. This officially closes our public meeting.

[End of the recording.]