U.S. FOOD & DRUG ADMINISTRATION

ADUFA Public Meeting Agenda
May 27, 2026
2:00pm – 4:00pm

Time	Description
5 Minutes	Call to Order Ms. Madeline Faunce, Office of Operations, FDA
40 Minutes	FDA Remarks Dr. Timothy Schell, Director, Center for Veterinary Medicine, FDA Dr. Matthew Lucia, Director, Office of New Animal Product Evaluation, Center for Veterinary Medicine, FDA
	Registered Speaker Remarks
8 Minutes	Ms. Martha Scott Poindexter, Animal Health Institute
8 Minutes	Dr. Lindsey Hornickel, American Veterinary Medical Association
8 Minutes	Dr. Kurt Schrader, Former Member of Congress
8 Minutes	Dr. Kathy Simmons, National Cattlemen's Beef Association
8 Minutes	Dr. Michelle Kromm, Food Forward LLC
3 Minutes per speaker	Remarks by the general public
5 Minutes	Wrap-up and closing remarks Ms. Madeline Faunce, Office of Operations, FDA

Timothy C. Schell, Ph.D.

Director, Center for Veterinary Medicine

Food and Drug Administration

Animal Drug User Fee Act (ADUFA)

Public Meeting

May 27, 2026

Matthew Lucia, DVM, Director, Office of New Animal Product Evaluation,
Center for Veterinary Medicine

Agenda

- Reauthorization Cycles
- Benefits of the Animal Drug User Fee Act (ADUFA)
- ADUFA Performance
- Reauthorization Process

Reauthorization Cycles

- The Animal Drug User Fee Act (ADUFA) authorizations cover a 5-year period.
- FDA is currently in ADUFA V, covering fiscal years 2024 through 2028.

Authorization						
ADUFA	I	II	III	IV	V	VI
Fiscal Years	2004-2008	2009-2013	2014-2018	2019-2023	2024-2028	2029-2033

Purpose of the Center for Veterinary Medicine's ADUFA Program

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.

Benefits of ADUFA

- 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
- Facilitate the evaluation of innovative and novel new animal drugs and indications

History: ADUFA I (FY 2004 – FY 2008) Performance

- Eliminated backlog (reduced review times from 600+ days to 180 days)
- Met goal to review 90% of certain submission types within specified time frames
- Created a more predictable, streamlined process
- Exceeded all performance goals

History: ADUFA II (FY 2009 – FY 2013) Performance

- Reduced number of 2nd review cycles with end-review amendments
- Developed electronic submission capability
- Added pre-approval foreign inspection goals
- Increased transparency by participating in 10 public workshops
- Exceeded nearly all performance goals

History: ADUFA III (FY 2014 – 2018) Performance

- Added flexibility to the process by replacing end-review amendments with 2nd cycle shortened review process, including extensive IT enhancements
- Fostered innovation through the early information process; worked to fill the pipeline and increase drug availability
- Added multiple enhancements for chemistry, manufacturing, and controls (CMC) technical section
- Exceeded nearly all performance goals

History: ADUFA IV (FY 2019 – 2023) Performance (1)

- Requires 100% electronic submissions
- Revises the legal status information that appears on products listed on FDA's *Index of Legally Marketed Unapproved New Animal Drugs for Minor Species*
- Requires approved new animal drugs to bear a statement that includes "Approved by FDA" and the new animal drug approval (NADA) number
- Adds new performance goals for pre-submission conferences and tissue residue method trial demonstrations
- Exceeded all performance goals to date

History: ADUFA IV (FY 2019 – 2023) Performance (2)

- **Program Enhancements**
  - Expanded Conditional Approval
  - Investigational Design Guidances
  - Food Additive Petitions
  - Antimicrobial Resistance: Veterinary Oversight
  - US-EU Good Manufacturing Practice Mutual Recognition Agreement (MRA)

Current: ADUFA V Program Enhancements (1)

- Metrics
  - Report annually (Congressional Report):
    - The number of certain filed/submitted sentinel submissions by review division.
    - The average review times, in hours, for protocols without data and INAD study submissions (broken down by technical section) by fiscal year.
  - Report quarterly (FDA-TRACK):
    - INAD protocols without data and for INAD study submissions the number of the following outcomes: favorable, shortened review and non-accepted/non-concurrence.
    - The number of H submissions (information to support a protocol or data submission) submitted by division.
  - Explored potential Agency-reported metrics regarding review time of investigational submissions that lead to approvals by the Agency and response time by industry. (Completed in FY 2025)
  - Third Party Assessment
    - A comprehensive assessment of the process for the review of animal drug applications based on a retrospective analysis of the utilization and effectiveness of the review process and currently available resources and tools used by FDA and industry as established through previous ADUFA authorizations to foster favorable first cycle review outcomes for sentinel submissions. (Completed in early FY 2026)

Current: ADUFA V Program Enhancements (2)

- Mutual Recognition Agreement
  - Expand the existing United States and United Kingdom MRA with respect to animal drugs, including activities prior to and following product approval.
- Meetings
  - New/enhanced processes for qualifying virtual pre-submission conference meeting requests:
    - CVM will issue a response letter (that contains an evaluation of the sponsor's drug development plan and responses to any questions) at least 6 days in advance of the date of the scheduled meeting.
    - CVM will provide the memorandum of conference, should the meeting be held, within 30 days after meeting.
  - FDA will dedicate up to 8 hours once per year for an industry education session in which industry and FDA staff will participate, and it will be open to the public. Presentations will be posted publicly to FDA's "for industry" website in a new "education for industry" section.

Current: ADUFA V Program Enhancements (3)

- Raw Data
  - FDA published P&P 1243.4095 (Review of Raw Data Agreement H Submission for Target Animal Safety Studies) on September 29, 2023.
  - FDA published final GFI #287 (Raw Data for Safety and Effectiveness Studies) on June 5, 2025.
- H Submissions –
  - FDA published P&P 1243.4092 (H Submissions Preceding Meetings and Protocols) on September 29, 2023, to:
    - Clarify timing of a meeting request submission so the meeting occurs at, or in close proximity to, the H submission due date.
    - Clarify timing of a protocol submission in relation to an associated H submission.
    - Clarify the review process for H submissions containing a proposed list of copies of raw data and documents to be submitted with the target animal safety technical section submission.

Current: ADUFA V Program Enhancements (4)

- Chemistry, Manufacturing, and Controls (CMC)
  - FDA published P&P 1243.3028 (Administrative Pathways for Obtaining Additional Chemistry, Manufacturing, and Controls Information) on March 22, 2024.
  - FDA published draft (revised) GFI #227 (“Chemistry, Manufacturing, and Controls (CMC) Technical Section Filing Strategies”) on September 16, 2024.

Current: ADUFA V Program Enhancements (5)

- Exploratory Goals
  - Explored the feasibility of using additional review tools to enhance the efficiency of the animal drug review process, such as implementing a “clock stop” during the review of sentinel submissions. A written analysis and recommendations for the tools was identified. (Completed in FY 2025)
  - Explored the drug residue analytical method trial process and its requirements as they relate to the approval of new animal drugs intended for food producing animals. (Completed in FY 2025)

Current: ADUFA V Program Enhancements (6)

- Exploratory Goals
  - Evaluated the CVM P&P 1243.5730, “Review of 60-day original Animal Drug Availability Act of 1996 (ADAA) feed use combination new animal drug applications (NADAs),” to determine why the process is not being utilized, and to understand how to increase utilization of the process, thereby reducing the review time for eligible ADAA combination drug applications following the approval of a new Type A medicated article. (Completed in FY 2025)
  - Explored the means for CVM to provide feedback on a sponsor’s animal drug development plan more efficiently and effectively for both industry and CVM. (Completed in FY 2025)

ADUFA V Submission Performance Goals (1)

Review and Act on 90% within Goal (Days)

Submission Type	ADUFA I	ADUFA II	ADUFA III	ADUFA IV/V
Original New Animal Drug Applications (NADAs), Applications for Conditional Approval (CNADAs), and Reactivations				
Original NADAs/Reactivations	295	180 + ERAs	180	180
Shortened Review Original NADA Reactivations	n/a	n/a	135	135
ADAA Combinations	n/a	n/a	n/a	60
Administrative NADAs and CNADAs	90	60	60	60
Non-manufacturing Supplemental NADAs and Reactivations				
Non-manufacturing Supplemental NADAs/Reactivations	320	180 + ERAs	180	180
Shortened Review Non-manufacturing Supplemental Reactivations	n/a	n/a	135	135
Manufacturing Supplemental NADAs and Reactivations				
Manufacturing Supplements/Reactivations (Prior Approval)	225	120	120	120
Manufacturing Supplements/Reactivations (Changes Being Effected)	225	120	120	180
Labeling Supplements				
Qualifying Labeling Supplements	n/a	n/a	60	60
Non-qualifying Labeling Supplements	n/a	n/a	180	180

ERA = End Review Amendment (for qualifying submissions)

ADUFA V Submission Performance Goals (2)

Review and Act on 90% within Goal (Days)

Submission Type	ADUFA I	ADUFA II	ADUFA III	ADUFA IV/V
Investigational New Animal Drug (INAD) Study Submissions				
Phased Data Submissions/Resubmissions	320	180 + ERAs	180	180
Phased Data Submissions MFS HC	n/a	n/a	100	100
Shortened Review Phased Data Resubmissions	n/a	n/a	60	60
Phased Data Submissions End Game Categorical Exclusions	n/a	n/a	n/a	60
INAD Protocol Submissions				
Protocol Submissions/Resubmissions	125	50 + ERAs	50	50
Shortened Review Protocol Resubmissions	n/a	n/a	20	20
Presubmission Conference	n/a	n/a	n/a	60
Tissue Residue Method	n/a	n/a	n/a	120

ERA = End Review Amendment (for qualifying submissions)
MFS HC = Microbial Food Safety Hazard Characterization

Final FY 2024 Performance

Review and act on to 90% of submissions within the number of days specified

Submission Type	Filed	On Time	Overdue	Percent on Time
Original NADAs, CNADAs, and Reactivations	6	6	0	100%
Administrative NADAs and CNADAs	11	11	0	100%
Non-manufacturing Supplemental NADAs and Reactivations	4	4	0	100%
Manufacturing Supplemental NADAs and Reactivations	354	339	15	96%
Labeling Supplements	6	6	0	100%
INAD Studies	111	105	6	95%
INAD Study Protocols	93	91	2	98%
Presubmission Conferences	51	51	0	100%
Tissue Residue Method Demonstration	0	0	0	-

ADUFA performance is available on the FDA-TRACK website:
https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-adufa-performance

Preliminary FY 2025 Performance

(as of March 31, 2026)

Review and act on to 90% of submissions within the number of days specified

Submission Type	Filed	On Time	Overdue	Pending Overdue	Percent on Time
Original NADAs, CNADAs, and Reactivations	11	11	0	0	100%
Administrative NADAs and CNADAs	13	13	0	0	100%
Non-manufacturing Supplemental NADAs and Reactivations	3	3	0	0	100%
Manufacturing Supplemental NADAs and Reactivations	331	320	19	2	94%
Labeling Supplements	10	10	0	0	100%
INAD Studies	126	117	5	4	93%
INAD Study Protocols	128	127	1	0	99%
Presubmission Conferences	49	49	0	0	100%
Tissue Residue Method Demonstration	0	0	0	0	-

ADUFA performance is available on the FDA-TRACK website:
https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-adufa-performance

Preliminary FY 2026 Performance

(as of March 31, 2026)

Review and act on to 90% of submissions within the number of days specified

Submission Type	Filed	On Time	Overdue	Pending within Goal	Pending Overdue	Percent on Time
Original NADAs, CNADAs, and Reactivations	2	0	0	2	0	100%
Administrative NADAs and CNADAs	10	7	0	3	0	100%
Non-manufacturing Supplemental NADAs and Reactivations	1	0	0	1	0	100%
Manufacturing Supplemental NADAs and Reactivations	167	13	0	154	0	100%
Labeling Supplements	10	5	0	5	0	100%
INAD Studies	48	3	1	44	1	96%
INAD Study Protocols	79	57	2	20	0	97%
Presubmission Conferences	25	11	0	14	0	100%
Tissue Residue Method Demonstration	0	0	0	0	0	-

ADUFA performance is available on the FDA-TRACK website:
https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-adufa-performance

Reauthorization Process (1)

- 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.
- Obtain public input prior to beginning negotiations with regulated industry.
  - Federal Register notice published on 4/17/2026; docket will remain open until 12/1/2027.
- 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.
  - FR notice published on 4/17/2026 announcing how to sign up; please reach out if you are interested in participating.

Reauthorization Process (2)

- Obtain public review and comment on final recommendations after negotiations with industry.
- Publish the minutes of negotiation meetings on our public website.
- Transmit the recommendations to Congress no later than 1/15/2028.

Questions for Public Comment

1. What is your assessment of the overall performance of the ADUFA program thus far?

2. What aspects of ADUFA should be retained, changed, or discontinued to further strengthen and improve the program?

ADUFA VI: Building on Progress, Advancing Innovation

Modernizing access to animal health innovation for veterinarians, animal owners, and producers

Martha Scott Poindexter

President & CEO, Animal Health Institute (AHI)

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ANIMAL HEALTH INSTITUTE

American Veterinary Medical Association

Animal Drug User Fee Act Public Meeting

Dr. Lindsey Hornickel

Assistant Director, Federal Government Relations

May 27, 2026

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21ST CENTURY ANIMAL HEALTHCARE

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Comments of the National Cattlemen's Beef Association for ADUFA VI Public Meeting



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NCBA

NATIONAL CATTLEMEN'S BEEF ASSOCIATION

CENTER FOR PUBLIC POLICY

Modernizing Animal Health Innovation

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ADUFA PUBLIC MEETING | MAY 2026

Animal Health Is Entering a New Era

- Scientific capability is advancing faster than regulatory frameworks
- The Reagan-Udall report highlights that regulatory infrastructure is struggling to keep pace
- This challenge is especially acute for Minor Use and Minor Species (MUMS)
- Congress has addressed similar(ish) challenges in the human health space via the 21st Cures Act

Impacts

- Inadequate drug availability compromises animal welfare and veterinary care
- Key gaps include analgesics, antiparasitics, anti-infectives, reproductive drugs, and sedatives
- High regulatory costs and limited trial feasibility discourage innovation within the United States
- Result: Unmitigated disease losses creating food security and cost, sustainability, and environmental impacts

Why MUMS Matters

- High regulatory costs and limited trial feasibility discourage innovation
- Small market either based on animal class or narrow application of treatment creates investment disincentive for animal health companies
- Poultry isn't homogenous- egg layers and turkeys often face MUMS-like issues because their market is compared to that of broiler chickens
- Result: Underserved markets and delayed access to animal health tools

Why This Matters for U.S. Competitiveness

- Sponsors avoid markets where pathways are uncertain or economically infeasible
- Small markets are disproportionally affected
- Innovation capacity is increasingly tied to resiliency in our food system which impacts economic sustainability for producers and grocery costs for consumers
- Result: Foreign producers can utilize animal health tools that domestic producers don't have access to, and then export their products into the United States

Specific Recommendation #1: Data package flexibility

- Expand use of real-world evidence and pragmatic data generation
- Allow production datasets, veterinary networks, and longitudinal farm data to support review
- Use adaptive and Bayesian trial designs where traditional pivotal studies are impractical
- Create clear guidance on acceptable fit-for-purpose evidence standards

Specific Recommendation #2: Stop reinventing the wheel

- Leverage trusted foreign regulatory decisions
- Allow conditional approval pathways relying on trusted foreign dossiers
- Use existing foreign approvals and import tolerances to accelerate access
- Explore provisional adoption of foreign residue limits during conditional approval

Specific Recommendation #3: MUMS 2.0 Definitions

- Modernize the definition of 'small numbers' for minor use determinations
- Incorporate disease prevalence, production class, and economic realities
- Recognize that some poultry sectors are commercially small despite large animal populations
- Seek authority to redefine a major species as minor where appropriate

Specific Recommendation #4: MUMS 2.0 Incentives & addressing disincentives

- Strengthen economic incentives and OMUMS capacity
- Extend conditional approval timelines for small markets
- Allow dual labeling and shared manufacturing batches where scientifically justified
- Consider a “front of the line” tag along incentive for pending approvals with a larger market upside
- Expand grants, fee reductions, and public-private partnerships

A pathway to yes

- Producers and veterinarians are willing to take on some risk to have access to tools that support animal health and welfare
- For MUMS populations, modernization determines whether innovation is attempted at all
- 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