U.S. FOOD & DRUG ADMINISTRATION

AGDUFA Public Meeting Agenda
May 27, 2026
11:00am – 1:00pm

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. Julie Bailey, Director, Office of Generic Animal Drugs, Center for Veterinary Medicine, FDA
8 Minutes	Registered Speaker Remarks Dr. Lindsey Hornickel, American Veterinary Medical Association
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 Generic Drug User Fee Act (AGDUFA)

Public Meeting

May 27, 2026

Julie Bailey, Ph.D., Director, Office of Generic Animal Drugs,
Center for Veterinary Medicine

Agenda

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

Reauthorization Cycles

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

Authorization					
AGDUFA	I	II	III	IV	V
Fiscal Years	2009-2013	2014-2018	2019-2023	2024-2028	2029-2033

Purpose of the Center for Veterinary Medicine's AGDUFA Program

To support FDA's responsibilities to ensure generic 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 AGDUFA

- 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
- Facilitate the review of generic animal drugs used in food animal production to improve both human and animal health

History: AGDUFA Performance

- **AGDUFA I (FY 2009 – FY 2013)**
  - Eliminated backlog (reduced review time from 700+ days to 270 days)
  - Met goal to review 90% of certain submission types within specified time frames
  - Created a more predictable, streamlined process
  - Exceeded nearly all performance goals

- **AGDUFA II (FY 2014 – FY 2018)**
  - Added flexibility to the process with 2nd cycle shortened review process, including extensive IT enhancements
  - Added multiple enhancements for Chemistry, Manufacturing, and Controls (CMC) technical section
  - Developed electronic submission capability
  - Added pre-approval foreign inspection goal
  - Developed question-based-review for bioequivalence
  - Exceeded all performance goals

History: AGDUFA Performance (cont.)

- **AGDUFA III (FY 2019 – FY 2023)**
  - Reduced performance goal review times for all submission types
  - Required 100% electronic submission
  - Required approved generic animal drugs to bear a statement that includes "Approved by FDA" and the abbreviated new animal drug application (ANADA) number
  - Exceeded all performance goals

Current: AGDUFA IV Performance

- **AGDUFA IV (FY 2024 – FY 2028)**
  - Enhances transparency by formalizing the Bioequivalence Technical Section (BETS) meeting process
  - Enhances transparency by creating dosage form-specific template letters to use when a generic investigational new animal drug (JINAD) file is opened by a sponsor
  - Explores US-EU Mutual Recognition Agreement (MRA) and future MRAs with additional countries, and enacts US-UK MRA to reduce costly and redundant GMP surveillance inspections
  - Adds JINAD A-0000 (request to open a JINAD file) as sentinel submission with a performance goal to review and act on 90% of original JINAD file requests within 100 days after submission date
  - Exceeding all performance goals to date

Current: AGDUFA IV Submission Performance Goals

Review and Act on 90% within Goal (Days)

Submission Type	AGDUFA I	AGDUFA II	AGDUFA III	AGDUFA IV
Original Abbreviated New Animal Drug Applications (ANADAs) and Reactivations				
Original ANADAs / Reactivations	700	270	240	240
Shortened Review Original ANADAs Reactivations	n/a	190	120	120
Administrative ANADAs	120	100	60	60
Manufacturing Supplemental ANADAs and Reactivations				
Manufacturing Supplements and Reactivations (Prior Approval)	600	270	180	180
Manufacturing Supplements and Reactivations (Changes Being Effected)	600	270	270	270
Generic Investigational New Animal Drug (JINAD) Study Submissions				
JINAD Data Submissions / Resubmissions	700	270	180	180
Shortened Review JINAD Data submissions	n/a	90	60	60
JINAD Protocol Submissions	400	100	75	75
Request to Establish a JINAD File	n/a	n/a	n/a	100

Final FY 2024 Performance

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

Submission Type	Filed	On Time	Overdue	Percent on Time
Original ANADAs and Reactivations	24	24	0	100%
Administrative ANADAs	24	24	0	100%
Manufacturing Supplemental ANADAs and Reactivations	259	256	3	99%
JINAD Studies	114	110	4	96%
JINAD Protocols	45	45	0	100%
Initial JINAD Submissions	20	20	0	100%

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

Preliminary FY 2025 Performance

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

Submission Type	Filed	On Time	Overdue	Pending within Goal	Percent on Time
Original ANADAs and Reactivations	14	13	0	1	100%
Administrative ANADAs	14	14	0	0	100%
Manufacturing Supplemental ANADAs and Reactivations	267	229	9	29	96%
JINAD Studies	178	173	5	0	97%
JINAD Protocols	76	75	1	0	99%
Initial JINAD Submissions	37	37	0	0	100%

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

Preliminary FY 2026 Performance (Q1-Q2)

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

Submission Type	Filed	On Time	Overdue	Pending within Goal	Percent on Time
Original ANADAs and Reactivations	13	1	0	12	100%
Administrative ANADAs	13	12	0	1	100%
Manufacturing Supplemental ANADAs and Reactivations	116	2	0	114	100%
JINAD Studies	105	14	0	91	100%
JINAD Protocols	42	24	0	18	100%
Initial JINAD Submissions	29	10	0	19	100%

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

Reauthorization Process

- 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 want to participate.
- Publish the minutes of negotiation meetings on our public website.
- Obtain public review and comment on final recommendations after negotiations with industry.
- 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 AGDUFA program thus far?

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

American Veterinary Medical Association

Animal Generic Drug User Fee Act Public Meeting

Dr. Lindsey Hornickel

Assistant Director, Federal Government Relations

May 27, 2026

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