Performance Report to Congress

Animal Drug User Fee Act

FY 2025

Executive Summary

On September 30, 2023, the fourth reauthorization of the Animal Drug User Fee Act (ADUFA), referred to as *ADUFA V*, was signed into law extending the ADUFA program for an additional 5 years (from fiscal year (FY) 2024 through FY 2028). ADUFA V includes a comprehensive set of the Food and Drug Administration's (FDA's) review performance goals and commitments designed to improve the timeliness and predictability of its review of new animal drug applications (NADAs) and reactivations, supplemental NADAs and reactivations, and some investigational new animal drug submissions.

More information on the history of ADUFA is available on FDA's ADUFA website.[1]

A. Information Included in This Report

This report summarizes FDA's performance results in meeting its ADUFA goals and commitments for FY 2024 and FY 2025. Specifically, it updates and finalizes performance data initially reported in the FY 2024 ADUFA Performance Report and presents preliminary data on FDA's progress in meeting its FY 2025 review goals, implementation activities, and accomplishments.

Due to staff departures and technical issues with the reporting system used for calculating performance data, FDA has official information through September 7, 2025, rather than September 30, 2025. FDA anticipates finalizing FY 2025 performance data using the restored reporting system in the FY 2026 performance report.

B. Review Performance

FDA met or exceeded the expectations of the review performance goals in the first year of ADUFA V (i.e., FY 2024) and continued to meet or exceed expectations of the review performance goals for FY 2025. Key activities and accomplishments during FY 2025 included the following:

- FDA met review-time goals for almost all (613 of 636) of the FY 2024 cohort submissions. FDA exceeded all eight ADUFA performance goals for the FY 2024 cohort for which FDA received submissions.
- Preliminary performance results indicate that FDA met review-time goals for almost all (434 of 445) of the FY 2025 cohort submissions reviewed and acted on

[1] www.fda.gov/industry/fda-user-fee-programs/animal-drug-user-fee-act-adufa.

as of September 30, 2025.[2] With 238 additional reviews pending that may yet be completed on time, FDA has the potential to meet or exceed the eight ADUFA performance goals for the FY 2025 cohort for which FDA received submissions.

Please see Appendix A for more details on the submission types and related performance goals.

[2] Due to staff departures and technical issues with the reporting system used for calculating performance data, FDA has official information through September 7, 2025, rather than September 30, 2025. FDA anticipates finalizing FY 2025 performance data using the restored reporting system in the FY 2026 performance report.

Table of Contents

Acronym List

ADAA	Animal Drug Availability Act
ADUFA	Animal Drug User Fee Act
AHI	Animal Health Institute
CMC	Chemistry, Manufacturing, and Controls
CNADA	Conditional New Animal Drug Application
CVM	Center for Veterinary Medicine
EU	European Union
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
FY	Fiscal Year (October 1 to September 30)
GFI	Guidance for Industry
GMP	Good Manufacturing Practice
INAD	Investigational New Animal Drug
MFS HC	Microbial Food Safety Hazard Characterization
MRA	Mutual Recognition Agreement
NADA	New Animal Drug Application
PAI	Pre-Approval Inspection
P&P	Program Policy and Procedures Manual Guide
TAS	Target Animal Safety

I. Introduction

The Animal Drug User Fee Act (ADUFA) requires the Secretary of Health and Human Services to submit the following two annual reports to the Committee on Health, Education, Labor, and Pensions of the Senate, and to the Committee on Energy and Commerce of the House of Representatives for each fiscal year (FY) in which fees are collected: (1) a performance report and (2) a financial report. This report is the Food and Drug Administration's (FDA's or Agency's) second annual performance report to Congress under the fourth reauthorization of ADUFA, referred to as *ADUFA V*. Under ADUFA V, FDA agreed to meet performance goals over 5 years (from FY 2024 through FY 2028) for certain submissions. Further details on FDA's commitments under ADUFA V can be found in the ADUFA V Performance Goals Letter on FDA's website.[1]

By providing FDA with supplemental funding for the review of new animal drug submissions, ADUFA was designed to provide greater predictability in review times for the animal drug industry and to accelerate the availability of safe and effective new animal products.

A. Information Presented in This Report

In any given year, FDA's performance includes its review of applications and submissions pending from previous fiscal years along with submissions received during the current fiscal year. This report provides FDA's final performance results for the FY 2024 cohort submissions and presents FDA's preliminary performance results for the FY 2025 cohort submissions that were received early enough to be reviewed and acted on, or due for review, by September 30, 2025.[2] The definitions below apply to the information provided in the FY 2025 report:

- The term *submission* is used to refer to new and conditional new animal drug applications (NADAs and CNADAs, respectively) and reactivations, supplemental NADAs and reactivations, investigational new animal drug (INAD) studies, and INAD protocols.

- *Review-time goal* is the targeted time period, identified in number of calendar days, within which individual submissions are to be acted on by FDA. ADUFA review-time goals range from 20 days to 180 days. FDA calculates ADUFA review times by the date of the original receipt of the application or submission. An *on-time review* indicates that FDA completed an action within the number of

[1] https://www.fda.gov/industry/fda-user-fee-programs/animal-drug-user-fee-act-adufa.
[2] Due to staff departures and technical issues with the reporting system used for calculating performance data, FDA has official information through September 7, 2025, rather than September 30, 2025. FDA anticipates finalizing FY 2025 performance data using the restored reporting system in the FY 2026 performance report.

calendar days specified by the review-time goal.

- *Percent on time* refers to the percentage of reviews for which FDA met a review-time goal for a given type of submission. FDA's percent on time for a given type of submission is used to determine whether FDA met or exceeded the ADUFA performance goals.

- *Performance goal* refers to the percentage of total submissions, agreed to under ADUFA, for which FDA is expected to meet the review-time goal for a given type of submission. The ADUFA performance goals call for FDA to meet the review-time goals 90 percent of the time for the defined fiscal year cohort.

  For submission types with a longer review-time goal (for example, 180 days), review performance data are usually limited at the time the performance report is prepared. For submission types with a shorter review-time goal (for example, 50 days), review performance data for submissions received early in the fiscal year are available at the time the report is prepared and thus the report may provide an early indicator of review performance.

  Performance goal tables indicate the total number of submissions filed, as well as whether the submission was reviewed on time, was overdue, or is still pending and not past its due date. Submissions that FDA refused to file or refused to review, as well as reviews that were stopped at the request of the sponsor, are not included in the statistics used to measure performance. However, beginning in FY 2024, FDA is reporting the numbers and types of refusals in its performance reports. (See Table 4.)

  When determining performance, FDA's calculated percentages are rounded to the nearest whole number, up to 99 percent. Percentages above 99 percent, but below 100 percent, are rounded down to 99 percent.

- The performance statistics in this report are based on submissions received during a fiscal year, known as a *receipt cohort*. The performance statistics for submissions were calculated according to the fiscal year FDA received them, regardless of the year in which FDA ultimately acted on the submissions. A result of this approach is that the statistics shown for a particular fiscal year may change from one report to the next. As more submissions are completed, the statistics for the year of receipt are adjusted to reflect the new completions. Therefore, until all submissions in a cohort are acted on or have passed the due date, whichever comes first, only a preliminary performance assessment is provided for that fiscal year cohort.

- The term *labeling supplement* is understood to mean a supplemental application for certain labeling changes as described in 21 CFR 514.8(c)(2)(i)(A) and (D) that require approval of a supplemental application prior to distribution of the drug made using the change.

File Types Included in This Report

- **NADA** – A new animal drug application (NADA) includes all amendments and supplements. This report presents original applications and reactivations, administrative applications, and supplemental applications and reactivations as separate goals.
- **INAD** – Under an investigational new animal drug (INAD) file, sponsors may submit data intended to support an application for new animal drug approval. This report presents studies and protocols.
- **CNADA –** An approved application for conditional approval of a new animal drug (CNADA) allows a sponsor to legally market a new animal drug after fulfilling the requirements for conditional approval and while it pursues full approval. This report includes CNADAs as a type of new animal drug application.

Sources:

- NADA: www.fda.gov/animal-veterinary/guidance-industry/new-animal-drug-application-guidances
- INAD: www.fda.gov/animalveterinary/guidancecomplianceenforcement/guidanceforindustry/ucm123818.htm
- CNADA: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-261-eligibility-criteria-expanded-conditional-approval-new-animal-drugs

II. ADUFA Review Workload

A. Review Workload: FY 2020 to FY 2025

In the table below, preliminary review workload numbers from FY 2025 are compared to the previous 5-year averages for all ADUFA application and submission types filed. The workload counts presented for FY 2025 include all submissions received in FY 2025. The individual fiscal years that are included in the 5-year average are also referenced below. There are no performance goals associated with the workload, but the variations over time in the workload can provide context for FDA's review performance. In FY 2025, the workload for two application and submission types showed an increase from the 5-year average, and seven application and submission types decreased.

Table 1: Review Workload for Applications and Submissions

Application/Submission Type	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025 (#)	FY 20 to FY 24 5-Year Average	FY 25 Compared to 5-Year Average
Animal Drug Applications and Submissions								
Original NADAs, CNADAs, and Reactivations *	9	4	5	2	6	11	5	120%
Administrative NADAs and CNADAs	11	7	11	13	11	13	11	18%
Non-manufacturing Supplemental NADAs and Reactivations	3	7	1	4	4	3	4	-25%
Manufacturing Supplemental NADAs and Reactivations †	423	389	294	317	354	340	355	-4%
Labeling Supplements ‡	23	19	57	36	6	10	28	-64%
INAD Study Submissions §	160	170	138	156	111	128	147	-13%
INAD Protocol Submissions ¶	259	158	173	125	93	128	162	-21%
Presubmission Conferences	84	73	47	30	51	50	57	-12%
Tissue Residue Method Demonstration	1	2	1	0	0	0	1	-100%

* Original NADAs, CNADAs, and Reactivations *include Animal Drug Availability Act (ADAA) combination medicated feeds applications.*
† Manufacturing Supplemental NADAs and Reactivations *include Prior Approval Supplements and Supplement-Changes Being Effected in 30 Days.*
‡ Labeling Supplements totals *include qualifying and non-qualifying submissions.* (See Appendix A.)
§ INAD Study Submissions *include categorical exclusions.*

¶ INAD Protocol Submissions without data.
# The FY 2025 numbers are preliminary and will be finalized in the FY 2026 ADUFA Performance Report.

III. FY 2024 and FY 2025 ADUFA Performance Results

The tables that follow present FDA's review performance results for the FY 2024 and FY 2025 ADUFA cohort submissions.

A. Final FY 2024 Performance Results

FDA exceeded the 90 percent performance level for all eight of the submission types for which submissions were received for the FY 2024 cohort. Across all submission types, FDA met the review-time goal for 613 of the 636 submissions. The entire FY 2024 cohort has closed; therefore, there are no pending submissions. The performance data presented here have been updated from the preliminary performance information reported in the FY 2024 ADUFA performance report. Please see Appendix A for more details on the submission types presented in the table below and on the ADUFA V performance goals.

Table 2: Final FY 2024 Performance Results

Application/Submission Type	Filed	On Time	Overdue	Percent on Time
Animal Drug Applications and Submissions				
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 Study Submissions **	111	105	6	95%
INAD Protocol Submissions **	93	91	2	98%
Presubmission Conferences **	51	51	0	100%
Tissue Residue Method Demonstration *	0	N/A	N/A	N/A

* No performance can be calculated since there were no submissions of this type.
** The numbers were changed to reflect updates to the data presented in the FY 2024 ADUFA Performance Report.

B. Preliminary FY 2025 Performance Results

As of September 30, 2025, preliminary performance data was available for 445 of 683 submissions filed in FY 2025. FDA is currently exceeding performance goals for the eight submission types that have at least one submission acted on in FY 2025. Overall, FDA met review-time goals for 434 of 445 submissions acted on. With 238 submissions pending within the goal, FDA has the potential to meet or exceed the 90 percent performance level for all eight of the submission types for which submissions were received in FY 2025. Please see Appendix A for more detail on the submission types in the table below and the ADUFA V performance goals.

Table 3: Preliminary FY 2025 Performance Results

Application/Submission Type	Filed	On Time	Overdue	Pending Within Goal	Percent on Time
Animal Drug Applications and Submissions					
Original NADAs, CNADAs, and Reactivations	11	4	0	7	100%
Administrative NADAs and CNADAs	13	11	0	2	100%
Non-manufacturing Supplemental NADAs and Reactivations	3	1	0	2	100%
Manufacturing Supplemental NADAs and Reactivations	340	184	5	151	97%
Labeling Supplements	10	8	0	2	100%
INAD Study Submissions	128	77	4	47	95%
INAD Protocol Submissions	128	112	1	15	99%
Presubmission Conferences	50	37	1	12	97%
Tissue Residue Method Demonstration *	0	N/A	N/A	N/A	N/A

* No performance can be calculated since there were no submissions of this type.

A decision to refuse to file an application, or to refuse to review a submission, results in the application or submission not being included in the receipt cohort for that fiscal year, which means they are not included in the user fee goal. The numbers of refusals per fiscal year are shown in the table below.

Table 4: Refusals to File an Application or to Review a Submission

Decision Type	FY 2024	FY 2025	FY 2026	FY 2027	FY 2028
Number of Decisions					
Refuse to File an Application	4	0			
Refuse to Review a Submission	3	1			

IV. FY 2025 Process Improvements and Major Accomplishments

Under ADUFA V, FDA committed to a variety of process improvements. FDA agreed to continue to enhance and further improve the review process via the following goals and procedures:

A. Foreign Inspections.

1. Pre-Approval Inspections (PAIs). Continuing under ADUFA V, to improve the timeliness and predictability of foreign PAIs, the regulated industry may voluntarily submit, 1) at the beginning of the calendar year, a list of foreign manufacturing facilities that are specified in an NADA, a CNADA, a supplemental NADA, or an INAD submission and may be subject to foreign PAIs for the following fiscal year and 2) a notification 30 days prior to submitting an NADA, a CNADA, a supplemental NADA, or an INAD submission that informs the Agency that the application/submission includes a foreign manufacturing facility.

Accomplishment: In FY 2025, the average time to complete a PAI improved. The table below shows the number of foreign PAIs conducted and the average time to complete a PAI during each fiscal year.

Table 5: Number of Foreign PAIs and Average Time to Complete PAIs

Fiscal Year	Number of Foreign PAIs Conducted	Average Time to Completion (in Days)
2020	5	130
2021	1	159
2022	2	456
2023	11	186
2024	8	109
2025	9	81

2. Foreign Good Manufacturing Practice (GMP) Inspections. The Agency commits to working to implement and maintain the United States and European Union (EU), and the United States and United Kingdom, GMP mutual recognition agreements (MRAs) and future MRAs with respect to animal drug products subject to review. The Agency agreed that beginning in FY 2024 it would report quarterly in FDA-TRACK the percentage of PAI risk decisions that relied at least in part on information from inspections recognized under an MRA with a foreign regulatory authority.

Accomplishment: The Center for Veterinary Medicine (CVM) worked collaboratively with FDA's Office of Global Policy and Strategy and Office of Inspections and Investigations to enact an MRA with the European Union to support surveillance inspections of veterinary drug manufacturers. The U.S.- EU MRA scope expansion for veterinary products was implemented to include Czech Republic, Cyprus, Italy, Romania, and Slovakia in FY 2025, in addition to Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Netherlands, Poland, Portugal, Slovenia, Spain, and Sweden. FDA has developed a potential solution for concluding capability assessments with the two remaining regulatory authorities, Malta and Croatia, and is negotiating the path forward with the European Commission. Previously, two separate MRAs between the United States and the United Kingdom and the United States and Switzerland were implemented for both human and animal drugs; these MRAs have been in use to support surveillance inspections. For more information, please see https://www.fda.gov/international-programs/international-arrangements/mutual-recognition-agreements-mra.

B. Meetings.

1. Presubmission conferences held virtually. Beginning on October 1, 2023, FDA agreed to provide written responses to sponsor questions at least 6 days prior to virtual presubmission conferences and to provide a memorandum of conference within 30 days after virtual presubmission conferences. For non-virtual presubmission conferences, FDA agreed to provide a memo of conference within 45 days.

Accomplishment: In FY 2025, FDA received a total of nine requests for presubmission conferences to be held virtually. These were through early response letter requests. Eight of the requests have been completed and one is still pending. All eight completed requests received a written response at least 6 days prior to the presubmission conference. Of the eight completed, four meetings were held, and four were cancelled by the sponsor because the written responses answered its questions.

2. Stakeholder engagement. FDA agreed to hold three meetings per year with Animal Health Institute (AHI) members, including a sub-meeting with CVM leadership. One meeting per year will include a public educational session for the drug industry and will be recorded for posting on FDA's website.

Accomplishment: FDA held three meetings with AHI members on issues of mutual concern, including the planning for and conducting of a day-long educational session on the new animal drug approval process on July 15, 2025. The session was attended by over 533 registrants from 14 countries both in-person and virtually. FDA worked with AHI members to develop the agenda for the session to ensure the topics were relevant and applicable to meet stakeholder needs.

C. H submissions.

1. Supporting information for presubmission conferences and INAD protocols without data submissions. FDA agreed that by October 1, 2023, it would publish a Program Policy and Procedures Manual Guide (P&P) for CVM reviewers on H submissions related to presubmission conferences and the timing and scheduling of related meeting requests. Also by October 1, 2023, FDA agreed to publish a P&P for CVM reviewers on the timing of protocol submissions in relation to H submissions to support the protocol.

Accomplishment: FDA published P&P 1243.4092 (H Submissions Preceding Meetings and Protocols) on September 29, 2023.

2. Dosage characterization. The Agency clarified that dosage characterization is part of the effectiveness technical section of the INAD file. The Agency and regulated industry agreed that if information about dosage is integral to the review of a protocol, it should be provided early to inform the review.

Accomplishment: The Agency continued to implement the dosage characterization process.

3. Raw data submission expectations. FDA agreed that by October 1, 2023, it would publish a P&P for CVM reviewers on sponsors' proposed lists of copies of raw data and documents supporting target animal safety (TAS) protocols without data submission. FDA also agreed that by October 1, 2024, it would publish a draft guidance for industry (GFI) on raw data submission expectations for non-clinical studies conducted under Good Laboratory Practice requirements and clinical studies conducted under Good Clinical Practice requirements.

Accomplishment: 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.

4. eSubmitter and H submissions for raw data. FDA agreed that by October 1, 2023, it would launch an eSubmitter template for TAS protocols, provided that industry had provided timely feedback to further FDA's work on the template. FDA may also develop an eSubmitter template for effectiveness protocol submissions and invite industry feedback.

Accomplishment: FDA deployed the H submission for the raw data eSubmitter template for TAS studies on October 2, 2023.

D. Exploration with industry.

1. ADAA combination medicated feeds. FDA and industry agreed to explore why the ADAA combination medicated feed review process outlined in P&P 1243.5730 is not being utilized. The exploration will be completed by October 1, 2025. FDA may revise the P&P based on the outcome of the exploration.

2. Residue method trial. FDA agreed to explore, in concert with affected parties including the animal health industry, 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. The exploration was to be completed by October 1, 2025.

3. Sentinel submission clock stop. FDA agreed to explore, in concert with industry, the feasibility of using additional review tools to enhance the efficiency of the animal drug review process. The exploration was to be completed by September 30, 2025.

4. Feedback on product development plans. FDA agreed to explore, in concert with affected parties including the animal health industry, means for the Agency to provide feedback on a sponsor's animal drug development plan more efficiently and effectively for both industry and FDA. This exploration was to be completed by October 1, 2025.

Accomplishment: FDA established the above four working groups in conjunction with regulated industry. All four working groups completed their explorations by the specified due dates.

E. Other, Including Metrics

1. Chemistry, Manufacturing, and Controls (CMC). FDA agreed that by September 30, 2024, it would publish a P&P for CMC reviewers to clarify when reviewers should request amendments, use shortened review time, or classify submissions as incomplete. In addition, this P&P will describe what administrative actions are appropriate when GMP status (or pending PAI) is the only comment remaining for a CMC technical section. Further, FDA agreed that

by September 30, 2024, it would revise GFI #227 ("Two-Phased Chemistry, Manufacturing, and Controls (CMC) Technical Sections") to define situations for which parallel submission of phased data submissions would be allowed.

Accomplishment: 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.

2. Metrics: Time in Agency/Time in Industry. FDA agreed that beginning in FY 2024, it would, in concert with industry, explore potential Agency-reported metrics regarding the review time of investigational submissions that lead to approvals by the Agency and response time by industry.

Accomplishment: FDA established this working group in conjunction with regulated industry. The working group concluded its meetings on September 17, 2025.

3. Metrics: Favorable Outcomes. FDA agreed to report quarterly in FDA-TRACK, beginning in the second quarter of FY 2024, for INAD protocols without data and for INAD study submissions, the number of the following outcomes: (1) favorable, (2) non-concurrence/non-accepted with shortened review offered, and (3) non-concurrence/non-accepted and shortened review not offered.

Accomplishment: FDA began publishing outcomes metrics quarterly on FDA-TRACK [4] in January 2024.

4. Metrics: INAD H Submissions Submitted at Division Level. FDA agreed that beginning in the second quarter of FY 2024, FDA will report quarterly in FDA-TRACK the number of H submissions submitted to the Office of New Animal Drug Evaluation by division.

Accomplishment: FDA began publishing INAD H submissions submitted at the division level quarterly on FDA-TRACK[5] in January 2024.

5. Metrics: Average Review Times in Hours. FDA agreed that beginning in FY 2024, it would include in the performance report the average review times, in hours, for protocols without data and for INAD study submissions (broken down by technical section) by fiscal year. The FY 2024 metric data are different from last year's FY 2024 ADUFA Performance Report since the data have been

[4] https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-animal-drug-user-fee-act-animal-favorable-outcomes-inad-protocols-and-data-submissions
[5] https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-animal-drug-user-fee-act-performance-inad-h-submissions-submitted-division-level

updated and finalized. FY 2025 metric data reported are preliminary. The following two tables report this information.

Table 6: Average Review Times in Hours for INAD Protocols without Data by Fiscal Year

Technical Section	FY 2024	FY 2025	FY 2026	FY 2027	FY 2028
Average Review Time in Hours for INAD Protocols without Data by Fiscal Year					
Effectiveness	101	98			
Target Animal Safety	83	97			
Manufacturing Chemistry	33	45			
Human Food Safety	59	59			
Environmental Impact *	N/A	81			

* FY 2024 Environmental Impact data reflect a correction to the preliminary data presented in the FY 2024 ADUFA performance report.

Table 7: Average Review Times in Hours for INAD Study Submissions by Fiscal Year*

Technical Section	FY 2024	FY 2025	FY 2026	FY 2027	FY 2028
Average Review Time in Hours for INAD Study Submissions by Fiscal Year					
Effectiveness	550	458			
Target Animal Safety	455	589			
Manufacturing Chemistry	257	209			
Human Food Safety	211	206			
Environmental Impact	107	143			

* FY 2024 data reflect updates to the preliminary data presented in the FY 2024 ADUFA performance report.

6. Metrics: Sentinel Submissions Filed/Submitted at Division Level. FDA agreed that beginning in FY 2024, it would include in the performance report the number of certain filed/submitted sentinel submissions by review division. The following table reports this information. A key to the review division abbreviations follows Table 8.

Table 8: Number of Filed/Submitted Sentinel Submissions by Review Division*

Sentinel Submission	Review Division	FY 2024	FY 2025	FY 2026	FY 2027	FY 2028
Sentinel Submissions Filed/Submitted by Division Level						
Original NADAs, CNADAs and reactivations	DCAD	0	4			
	DFAD	6	7			
Administrative NADAs and CNADAs	DB	0	1			
	DCAD	6	10			
	DFAD	5	2			
Non-manufacturing supplemental NADAs and reactivations	DCAD	4	3			
Labeling supplements	DCAD	2	3			
	DFAD	3	7			
INAD study submissions	DB	4	5			
	DCAD	33	46			
	DFAD	20	14			
	DHFS	11	18			
	DMT	22	22			
	DSBS	21	23			
INAD study protocols without data submissions	DB	3	0			
	DCAD	49	42			
	DFAD	10	17			
	DHFS	7	15			
	DMT	24	41			
	DSBS	0	13			
Presubmission conferences	DB	0	2			
	DBISM	37	26			
	DCAD	4	10			
	DFAD	3	5			
	DHFS	6	2			
	DMT	0	4			
	DSBS	1	1			

* FY 2024 data reflect updates to the preliminary data presented in the FY 2024 ADUFA performance report.

Key To Review Division Abbreviations Used in Table 8

DB	Division of Biotechnology
DBISM	Division of Business Information Science and Management
DCAD	Division of Companion Animal Drugs
DFAD	Divison of Food Animal Drugs
DHFS	Division of Human Food Safety
DMT	Division of Manufacturing Technologies
DSBS	Division of Statistical and Biological Sciences

Appendix A: Progression of ADUFA Performance Goals

The table in this appendix shows the current ADUFA V (FY 2024 to FY 2028) goals.

Submission Type	ADUFA V Performance Goal: Act on 90 Percent Within (Days)
Original NADAs and Reactivations	
Original NADAs and Reactivations	180
Shortened Review Original NADA Reactivations	135
ADAA Combinations	60
Administrative NADAs	60
Non-Manufacturing Supplemental NADAs and Reactivations	
Non-Manufacturing Supplement NADAs	180
Non-Manufacturing Supplemental Reactivations	180
Shortened Review Non-Manufacturing Supplemental Reactivations	135
Manufacturing Supplemental NADAs and Reactivations	
Manufacturing Supplements and Reactivations (Prior Approval)	120
Manufacturing Supplements and Reactivations (Changes Being Effected)	180
Labeling Supplements	
Qualifying Labeling Supplements	60
Non-Qualifying Labeling Supplements	180
INAD Study Submissions	
Phased Data Submissions	180
Phased Data Resubmissions	180
Phased Data Submissions Microbial Food Safety Hazard Characterization (MFS HC)	100
Shortened Review Phased Data Resubmissions	60

Submission Type	ADUFA V Performance Goal: Act on 90 Percent Within (Days)
Phased Data Submissions End Game Categorical Exclusions	60
INAD Protocol Submissions	
Protocol Submissions	50
Protocol Resubmissions	50
Shortened Review Protocol Resubmissions	20
Presubmission Conference	60
Tissue Residue Method	120

This report was prepared by FDA's Performance Management Staff in collaboration with FDA's Center for Veterinary Medicine. For information on obtaining additional copies, please contact:

Performance Management Staff
Office of Operations
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

This report is available on FDA's website at https://www.fda.gov/fdatrack.

U.S. FOOD & DRUG ADMINISTRATION