Performance Report to Congress

# Animal Generic Drug User Fee Act

## FY 2025

# Executive Summary

On September 30, 2023, the third reauthorization of the Animal Generic Drug User Fee Act (AGDUFA), referred to as *AGDUFA IV*, was signed into law, providing an additional 5 years (from fiscal year (FY) 2024 to FY 2028) of user fees for the generic new animal drug review program. The AGDUFA IV program includes a comprehensive set of Food and Drug Administration (FDA) review performance goals and commitments designed to improve the timeliness and predictability of the review of abbreviated new animal drug applications (ANADAs) and reactivations, manufacturing supplemental ANADAs and reactivations, and generic investigational new animal drug submissions.

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

## A. Information Included in this Report

This report summarizes FDA's performance results in meeting AGDUFA goals and commitments for FY 2024 and FY 2025. Specifically, it updates and finalizes performance data initially reported in the FY 2024 AGDUFA Performance Report and presents preliminary data on FDA's progress in meeting 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 AGDUFA IV and continued to meet or exceed the 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 (479 of 486) of the FY 2024 cohort submissions. FDA exceeded all (6 of 6) AGDUFA performance goals for the FY 2024 cohort.

[1] www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm.

- Preliminary performance results indicate that FDA met review-time goals for almost all (311 of 319) FY 2025 cohort submissions reviewed and acted on as of September 30, 2025.[2] With 281 additional reviews pending that may yet be completed on time, FDA has the potential to exceed all six AGDUFA performance goals for the FY 2025 cohort.

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.

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## Acronym List

| | |
|---|---|
| **AGDUFA** | Animal Generic Drug User Fee Act |
| **ANADA** | Abbreviated New Animal Drug Application |
| **CVM** | Center for Veterinary Medicine |
| **FDA** | Food and Drug Administration |
| **FD&C Act** | Federal Food, Drug, and Cosmetic Act |
| **FY** | Fiscal Year (October 1 to September 30) |
| **JINAD** | Generic Investigational New Animal Drug |
| **PAI** | Pre-Approval Inspection |

# I. Introduction

The Animal Generic Drug User Fee Act (AGDUFA) 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: (1) a performance report and (2) a financial report. This performance report is the Food and Drug Administration's (FDA's or Agency's) second annual performance report to Congress under the third reauthorization of AGDUFA, referred to as *AGDUFA IV*. Under AGDUFA IV, FDA agreed to meet review performance goals for certain submissions over a 5-year period (fiscal year (FY) 2024 through FY 2028). Further details on FDA's commitments under AGDUFA IV can be found in the AGDUFA IV Performance Goals Letter on FDA's website.[1]

AGDUFA is designed to bring greater predictability in review times for the generic animal drug industry by providing FDA with supplemental funding for the review of generic new animal drug submissions. AGDUFA accelerates the availability of safe and effective generic new animal drug products.

## A. Information Presented in This Report

In any given year, FDA's performance includes reviews of applications and submissions pending from previous fiscal years, along with submissions received during the current fiscal year. This report presents FDA's final performance results for the FY 2024 cohort and presents FDA's preliminary performance results with respect to performance goals for the FY 2025 cohort submissions that were received early enough to be reviewed 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 abbreviated new animal drug applications (ANADAs) and reactivations, supplemental ANADAs and reactivations, generic investigational new animal drug (JINAD) studies, JINAD protocols, and requests to establish a JINAD file when referencing the fiscal year cohort.

- *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. AGDUFA review-time goals range from 60 days to 270 days. An *on-time review* indicates that FDA completed action within the number of calendar days specified by the review-time goal.

[1] https://www.fda.gov/industry/fda-user-fee-programs/animal-generic-drug-user-fee-act-agdufa.
[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.

- *Percent on time* refers to the percentage of reviews where 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 AGDUFA IV performance goals.

- *Performance goal* refers to the percentage of total submissions, agreed to under AGDUFA IV, where FDA is expected to meet the review-time goal for a given type of submission. The AGDUFA IV 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, 270 days), review performance data are usually limited. For those submissions with a shorter review-time goal (for example, 60 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. Please see Table 4.

- When determining performance, FDA-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*). This methodology calculates performance statistics for submissions according to the fiscal year FDA received them, regardless of the year in which FDA ultimately acted on the submissions. A result of this methodology 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 that 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.

**File Types Included in This Report**

- **ANADA** – An ANADA is an abbreviated new animal drug application and includes all reactivations and supplements. This report presents original applications and reactivations, administrative applications, and supplemental applications and reactivations as separate goals.
- **JINAD file** – The JINAD file is the investigational file for generic new animal drugs. The information submitted to the file may be used to support an ANADA. This report presents study submissions, protocols, and requests to establish a JINAD.

**Source:**

https://www.fda.gov/animal-veterinary/development-approval-process/abbreviated-new-animal-drug-applications

# II. AGDUFA 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 AGDUFA application and submission types filed. The individual years that are included in the 5-year average are also referenced below. There are no performance goals associated with workload, but the variations in workload over time can provide context for FDA's performance. The workload count presented in this report for FY 2025 includes all submissions received in FY 2025. For AGDUFA review times, FDA calculates from the original receipt of the application or submission. Workload for four application and submission types showed an increase in FY 2025 from the 5-year average, and one application type showed a decrease. Please see Appendix A for more details on the submission types included in the table below.

**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 Generic Drug Applications and Submissions** | | | | | | | | |
| Original ANADAs and Reactivations | 20 | 10 | 5 | 1 | 24 | 17 | 12 | 42% |
| Administrative ANADAs | 10 | 19 | 15 | 23 | 24 | 14 | 18 | -22% |
| Manufacturing Supplemental ANADAs and Reactivations | 139 | 204 | 303 | 289 | 259 | 278 | 239 | 16% |
| JINAD Studies | 149 | 216 | 164 | 163 | 114 | 178 | 161 | 11% |
| JINAD Protocols | 78 | 52 | 45 | 30 | 45 | 76 | 50 | 52% |
| Initial JINAD Submissions | N/A | N/A | N/A | N/A | 20 | 37 | N/A | N/A |

* The FY 2025 numbers are preliminary and will be updated in the FY 2026 AGDUFA Performance Report.

# III. FY 2024 and FY 2025 AGDUFA Performance Results

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

## A. Final FY 2024 Performance Results

FDA exceeded the 90 percent performance level for all six of the review performance goals for the FY 2024 cohort. Across all submission types, FDA met the review-time goal in 479 of 486 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 AGDUFA performance report. Please see Appendix A for more details on the submission types in the table below and the performance goals.

**Table 2: Final FY 2024 Performance Results**

| Application/Submission Type | Filed | On Time | Overdue | Percent on Time |
|---|---|---|---|---|
| **Animal Generic Drug Applications and Submissions** | | | | |
| 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% |

* The numbers were changed to reflect updates to the data presented in the FY 2024 AGDUFA Performance Report.

## B. Preliminary FY 2025 Performance Results

As of September 30, 2025, preliminary performance data was available for 319 of 600 submissions filed in FY 2025. FDA is currently exceeding performance goals for all six submission types that have at least one submission acted on in FY 2025. Overall, FDA met review-time goals for 311 of 319 submissions acted on. With 281 submissions pending within goal, FDA has the potential to meet or exceed the 90 percent performance goal for all six submission types. Please see Appendix A for more details on the submission types in the table below and the performance goals.

**Table 3: Preliminary FY 2025 Performance Results**

| Application/Submission Type | Filed | On Time | Overdue | Pending Within Goal | Percent on Time |
|---|---|---|---|---|---|
| **Animal Generic Drug Applications and Submissions** | | | | | |
| Original ANADAs and Reactivations | 17 | 6 | 0 | 11 | 100% |
| Administrative ANADAs | 14 | 13 | 0 | 1 | 100% |
| Manufacturing Supplemental ANADAs and Reactivations | 278 | 99 | 4 | 175 | 96% |
| JINAD Studies | 178 | 98 | 3 | 77 | 97% |
| JINAD Protocols | 76 | 64 | 1 | 11 | 98% |
| Initial JINAD Submissions | 37 | 31 | 0 | 6 | 100% |

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 | 1 | 0 | | | |
| Refuse to Review a Submission | 0 | 1 | | | |

# IV. FY 2025 Process Improvements and Major Accomplishments

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

- **Foreign Pre-Approval Inspections (PAIs).** Continuing under AGDUFA IV, 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 ANADA, supplemental ANADA, or JINAD file and may be subject to foreign PAIs for the following fiscal year and 2) a notification 30 days prior to submitting an ANADA, supplemental ANADA, or JINAD file that informs the Agency that the application 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 it took 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 | 1 | 135 |
| 2021 | 0 | N/A |
| 2022 | 5 | 555 |
| 2023 | 6 | 145 |
| 2024 | 9 | 110 |
| 2025 | 8 | 83 |

- **Multiple Data Submissions to the Chemistry, Manufacturing, and Controls Technical Section.** The Agency continued to allow two-phased Chemistry, Manufacturing, and Controls technical section submissions under the JINAD process.

## Appendix A: Progression of AGDUFA Performance Goals

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

| Submission Type | AGDUFA IV Performance Goal: Act on 90 Percent Within (Days) |
|---|---|
| **Original ANADAs and Reactivations** | |
| Original ANADAs | 240 |
| Original ANADA Reactivations | 240 |
| Shortened Review Original ANADA Reactivations | 120 |
| **Administrative ANADAs** | 60 |
| **Manufacturing Supplemental ANADAs and Reactivations** | |
| Manufacturing Supplements and Reactivations (Prior Approval) | 180 |
| Manufacturing Supplements and Reactivations (Changes Being Effected) | 270 |
| **JINAD Study Submissions** | |
| JINAD Data Submissions | 180 |
| JINAD Data Resubmissions | 180 |
| Shortened Review JINAD Data Submissions | 60 |
| **JINAD Protocol Submissions** | 75 |
| **Request to Establish a JINAD File** | 100 |

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

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