Performance Report to Congress

Animal Generic Drug User Fee Act

FY 2023

Executive Summary

On August 14, 2018, the second reauthorization of the Animal Generic Drug User Fee Act (AGDUFA), referred to as *AGDUFA III*, was signed into law, providing an additional 5 years (from fiscal year (FY) 2019 to FY 2023) of user fees for the generic new animal drug review program. The AGDUFA III 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. The reauthorization also dramatically reduces review time goals across all submission types.

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 2022 and FY 2023. Specifically, it updates and finalizes performance data initially reported in the FY 2022 AGDUFA Performance Report and presents preliminary data on FDA's progress in meeting FY 2023 review goals, implementation activities, and accomplishments.

B. Review Performance

FDA met or exceeded the expectations of the review performance goals in the first 4 years of AGDUFA III and continued to meet or exceed the expectations of the review performance goals for FY 2023. Key activities and accomplishments during FY 2023 included the following:

- FDA met review-time goals for almost all (522 of 532) of the FY 2022 cohort submissions. FDA exceeded all (5 of 5) AGDUFA performance goals for the FY 2022 cohort. Please see Appendix A for more details on the submission types and related performance goals.

- Preliminary performance results indicate that FDA met review-time goals for almost all (239 of 243) FY 2023 cohort submissions reviewed and acted on as of September 30, 2023. With 273 additional reviews pending that may yet be completed on time, FDA has the potential to exceed all five AGDUFA

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

performance goals for the FY 2023 cohort. Please see Appendix A for more details on the submission types and related performance goals.

Table of Contents

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) fifth annual performance report to Congress under the second reauthorization of AGDUFA, referred to as *AGDUFA III*. Under AGDUFA III, FDA agreed to meet review performance goals for certain submissions over a 5-year period (fiscal year (FY) 2019 through FY 2023). Further details on FDA's commitments under AGDUFA III can be found in the AGDUFA III Performance Goals Letter on FDA's website.[2]

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 2022 cohort and presents FDA's preliminary performance results with respect to performance goals for the FY 2023 cohort submissions that were received early enough to be reviewed or due for review by September 30, 2023. The definitions below apply to the information provided in the FY 2023 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, and JINAD protocols 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.

- *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

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

of submission is used to determine whether FDA met or exceeded the AGDUFA III performance goals.

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

- 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.

- 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.

- The workload count presented in this report for FY 2023 includes all submissions received in FY 2023. For AGDUFA review times, FDA calculates from the original receipt of the application or submission.

- 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.

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 generic investigational new animal drug file (JINAD) is the investigational file for generic animal drugs. The information submitted to the file may be used to support an ANADA. This report presents study submissions and protocols.

Source:

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

II. AGDUFA Review Workload

A. Review Workload: FY 2018 to FY 2023

In the table below, preliminary review workload numbers from FY 2023 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. Workload for two application and submission types showed an increase in FY 2023 from the 5-year average and three application and submission types showed a decrease. Please see Appendix A for more details on the submission types included in the table below.

Review Workload for Applications and Submissions

Application/ Submission Type	FY 18	FY 19	FY 20	FY 21	FY 22	FY 23*	FY 18 to FY 22 5-Year Average	FY 23 Compared to 5-Year Average
Original ANADAs and Reactivations	19	33	20	10	5	1	17	-94%
Administrative ANADAs	3	3	10	19	15	23	10	130%
Manufacturing Supplemental ANADAs and Reactivations	180	185	139	204	303	292	202	45%
JINAD Studies	97	153	149	216	164	169	156	8%
JINAD Protocols	40	83	78	52	45	31	58	-48%

* The FY 2023 numbers are preliminary and will be updated in the FY 2024 AGDUFA Performance Report.

III. FY 2022 and FY 2023 AGDUFA Performance Results

The tables that follow present FDA's review performance results for the FY 2022 and FY 2023 AGDUFA cohort submissions.

A. Final FY 2022 Performance Results

FDA exceeded the 90 percent performance level for all five of the review performance goals for the FY 2022 cohort. Across all submission types, FDA met the review-time goal in 522 of 532 submissions. The entire FY 2022 cohort has closed; therefore, there are no pending submissions. Please see Appendix A for more details on the submission types in the table below and the performance goals.

Application/Submission Type	Filed	On Time	Overdue	Percent on Time
Original ANADAs and Reactivations	5	5	0	100%
Administrative ANADAs	15	15	0	100%
Manufacturing Supplemental ANADAs and Reactivations	*303	298	5	98%
JINAD Studies	*164	159	5	97%
JINAD Protocols	45	45	0	100%

* The numbers were changed to reflect updates to the data presented in the FY 2022 ADUFA Performance Report

B. Preliminary FY 2023 Performance Results

As of September 30, 2023, preliminary performance data was available for 243 of 516 submissions filed in FY 2023. FDA will meet one performance goal and is currently exceeding performance goals for the other four submission types that have at least one submission acted on in FY 2023. Overall, FDA met review-time goals for 239 of 243 submissions acted on. With 273 submissions pending within goal, FDA has the potential to meet or exceed the 90 percent performance goal for all five submission types. Please see Appendix A for more details on the submission types in the table below and the performance goals.

Application/ Submission Type	Filed	On Time	Overdue	Pending Within Goal	Pending Overdue	Percent on Time
Original ANADAs and Reactivations	1	1	0	0	0	100%
Administrative ANADAs	23	22	0	1	0	100%
Manufacturing Supplemental ANADAs and Reactivations	292	99	1	192	0	99%
JINAD Studies	169	97	3	69	0	98%
JINAD Protocols	31	20	0	11	0	100%

IV. FY 2023 Process Improvements and Major Accomplishments

Under AGDUFA III, 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 III, 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:** During the COVID-19 pandemic, remote regulatory assessments[3] were used, when appropriate, to support risk-based PAI decisions[4] when travel restrictions limited foreign travel. FY 2022 FDA initially resumed prioritized foreign travel and later resumed routine foreign travel as travel restrictions eased. The average time to complete a PAI increased in FY 2022 because FDA resumed inspections that had been pending due to prior COVID-19 public health emergency travel restrictions. In FY 2023, the average time to complete a PAI improved as foreign inspection travel was mostly normalized; however, this average time still reflects some delays that were attributed to the inspections initiated during the pandemic. The table below shows the number of foreign PAIs conducted and the average time it took to complete a PAI during each FY.

[3] https://www.fda.gov/media/160173/download.

[4] See FDA's Resiliency Roadmap for FDA Inspectional Oversight report (November 2021) at https://www.fda.gov/media/154293/download.

Fiscal Year	Number of Foreign PAIs Conducted	Average Time to Completion (in Days)
2019	5	145
2020	1	135
2021	0	N/A
2022	5	555
2023	6	145

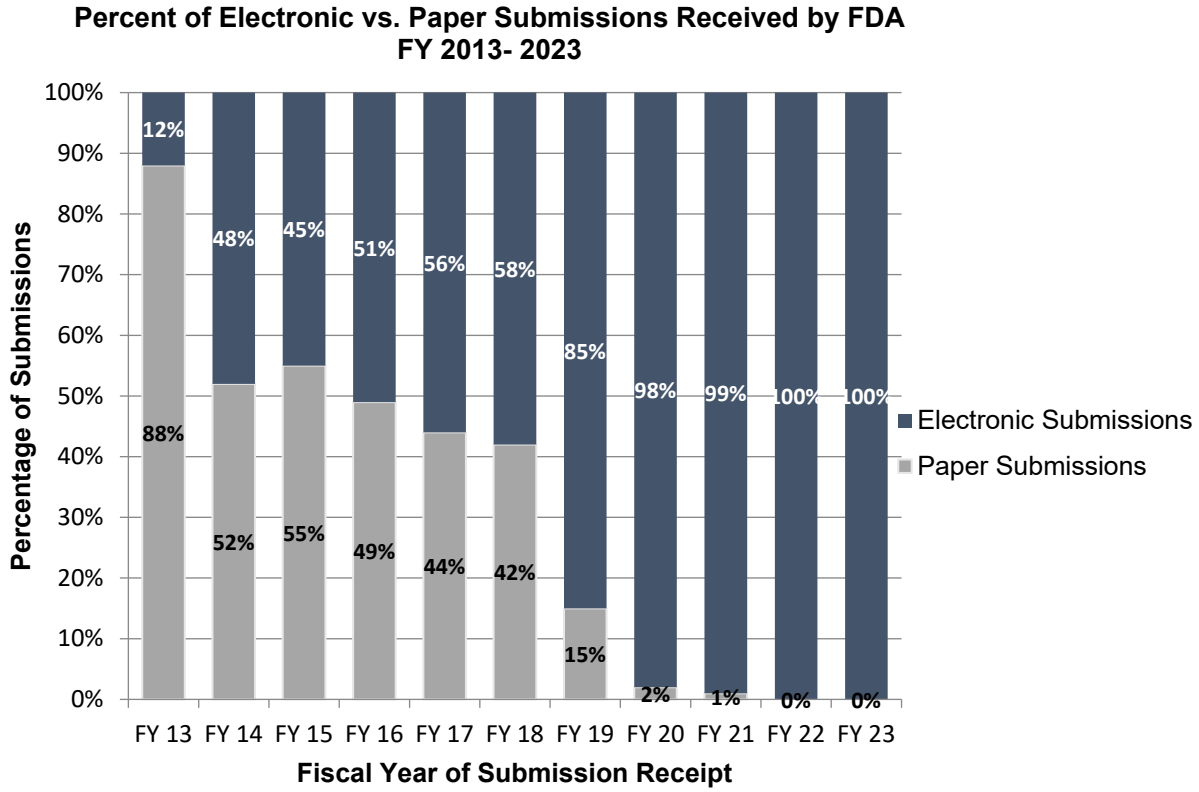
- **Review Times.** The Agency reduced review times for all sentinel submission types by up to 33 percent and reduced the review time for JINAD data submissions by 60 days. The Agency continued using the shortened review time process for ANADA applications and data and protocol JINAD submissions (see Appendix A).

- **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.

V. FY 2023 Additional Activities Toward Compliance with AGDUFA III

The following sections are found in Title III of the Animal Drug and Animal Generic Drug User Fee Amendments of 2018, the legislation reauthorizing the AGDUFA program from FY 2019 through FY 2023 (AGDUFA III).

- **Section 301 of the Animal Drug and Animal Generic Drug User Fee Amendments of 2018. Electronic submissions.** Beginning October 1, 2018, all applications and submissions under sections 512(b) and 571(a) of the Federal Food, Drug, and Cosmetic (FD&C) Act must be created using the eSubmitter tool and submitted to the Agency through the Center for Veterinary Medicine's (CVM's) Electronic Submission System.
    - **Accomplishment**: CVM provided support to industry users to facilitate their transition to using eSubmitter for all submissions to CVM. No applications or submissions were submitted in paper.



- **Section 303. Misbranded drugs and devices.** This section of the reauthorization legislation mandates that, with limited exceptions, pioneer and

generic new animal drugs approved under section 512 of the FD&C Act must include a specific statement (i.e., “Approved by FDA under (A)NADA #”), followed by the application number on the sponsor’s labeling, by September 30, 2023, or else such drugs will be considered misbranded under section 502(w) of the FD&C Act.

- **Accomplishment**: By the end of FY 2023, 665 of the 668 (99.5%) actively marketed and approved (A)NADAs were fully compliant with the ADUFA IV/AGDUFA III requirement and now carry the “approved by” statement to clearly identify new animal drug products approved by FDA/CVM, distinguishing them from the products on the market that are unapproved.

Appendix A: AGDUFA Performance Goals

The tables in this appendix show how the AGDUFA performance goals have progressed from FY 2014 (AGDUFA II) to the current AGDUFA III goals.

AGDUFA III

Submission Type	Performance Goal: Act on 90 Percent Within
Original ANADAs and Reactivations	
Original ANADAs	240 days
Original ANADAs Reactivations	240 days
Shortened Review Original ANADAs Reactivations	120 days
Administrative ANADAs	60 days
Manufacturing Supplemental ANADAs and Reactivations	
Manufacturing Supplements and Reactivations (Prior Approval)	180 days
Manufacturing Supplements and Reactivations (Changes Being Effected)	270 days
JINAD Study Submissions	
JINAD Data Submissions	180 days
JINAD Data Resubmissions	180 days
Shortened Review JINAD Data submissions	60 days
JINAD Protocol Submissions	75 days

AGDUFA II

Submission Type	Performance Goal: Act on 90 Percent Within
Original ANADAs and Reactivations	
Original ANADAs	270 days
Original ANADAs Reactivations	270 days
Shortened Review Original ANADA Reactivations	190 days
Administrative ANADAs	100 days
Manufacturing Supplemental ANADAs and Reactivations	
Manufacturing Supplements and Reactivations (Prior Approval)	270 days
Manufacturing Supplements and Reactivations (Changes Being Effected)	270 days
JINAD Study Submissions	
JINAD Data Submissions	270 days
JINAD Data Resubmissions	270 days
Shortened Review JINAD Data Resubmissions	90 days
JINAD Protocol Submissions	100 days

This report was prepared by FDA's Office of Planning, Evaluation, and Risk Management. For information on obtaining additional copies, please contact:

Office of Planning, Evaluation, and Risk Management
Office of the Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002
Phone: 301-796-4850
E-mail: OPERM_ADMIN_Team@fda.hhs.gov

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