Performance Report to Congress

Animal Generic Drug User Fee Act

FY 2022

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 2021 and FY 2022. Specifically, it updates and finalizes performance data initially reported in the FY 2021 AGDUFA Performance Report and presents preliminary data on FDA's progress in meeting FY 2022 review goals, implementation activities, and accomplishments.

B. Review Performance

FDA met or exceeded the expectations of the review performance goals in the first 3 years of AGDUFA III and continued to meet or exceed the expectations of the review performance goals for FY 2022. Key activities and accomplishments during FY 2022 included the following:

- FDA met review-time goals for almost all (480 of 501) FY 2021 submissions. FDA exceeded all (5 of 5) AGDUFA performance goals for the FY 2021 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 (262 of 266) FY 2022 cohort submissions reviewed and acted on as of September 30, 2022. With 271 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 2022 cohort. Please see Appendix A for more details on the submission types and related performance goals.

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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

Introduction

The Animal Generic Drug User Fee Act (AGDUFA) requires the Secretary of Health and Human Services to submit two annual reports to the Committee on Health, Education, Labor, and Pensions of the Senate, and 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) fourth 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.

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 2021 cohort and presents FDA's preliminary performance results with respect to performance goals for the FY 2022 cohort submissions that were received early enough to be reviewed or due for review by September 30, 2022. The definitions below apply to the information provided in the FY 2022 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] www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm.

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 2022 includes all submissions received in FY 2022. 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 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

AGDUFA Review Workload

Review Workload: FY 2017 to FY 2022

In the table below, preliminary review workload numbers from FY 2022 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 three application and submission types showed an increase in FY 2022 from the 5-year average and two 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 17	FY 18	FY 19	FY 20	FY 21	FY 22*	FY 17 to FY 21 5-Year Average	FY 22 Compared to 5-Year Average
Original ANADAs and Reactivations	17	19	33	20	10	5	20	-75%
Administrative ANADAs	4	3	3	10	19	15	8	+88%
Manufacturing Supplemental ANADAs and Reactivations	173	180	185	139	204	306	176	+74%
JINAD Studies	66	97	153	149	216	166	136	+22%
JINAD Protocols	48	40	83	78	52	45	60	-25%

* FY 2022 numbers are preliminary and will be updated in the FY 2023 AGDUFA Performance Report.

FY 2021 and FY 2022 AGDUFA Performance Results

The tables that follow present FDA's review performance results for the FY 2021 and FY 2022 AGDUFA cohort submissions.

Final FY 2021 Performance Results

FDA exceeded the 90 percent performance level for all five of the review performance goals for the FY 2021 cohort. Across all submission types, FDA met the review-time goal in 480 of 501 submissions. The entire FY 2021 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	10	10	0	100%
Administrative ANADAs	19	19	0	100%
Manufacturing Supplemental ANADAs and Reactivations	204	196	8	96%
JINAD Studies	216	205	11	95%
JINAD Protocols	52	50	2	96%

Preliminary FY 2022 Performance Results

As of September 30, 2022, preliminary performance data was available for 266 of 537 submissions filed in FY 2022. 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 2022. Overall, FDA met review-time goals for 262 of 266 submissions acted on. With 271 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	5	3	0	2	0	100%
Administrative ANADAs	15	14	0	1	0	100%
Manufacturing Supplemental ANADAs and Reactivations	306	106	1	199	0	99%
JINAD Studies	166	103	3	60	0	97%
JINAD Protocols	45	36	0	9	0	100%

FY 2022 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. In 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. The table below shows the number of foreign PAIs conducted and the average time it took to complete a PAI during each FY.

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

- **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

[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.

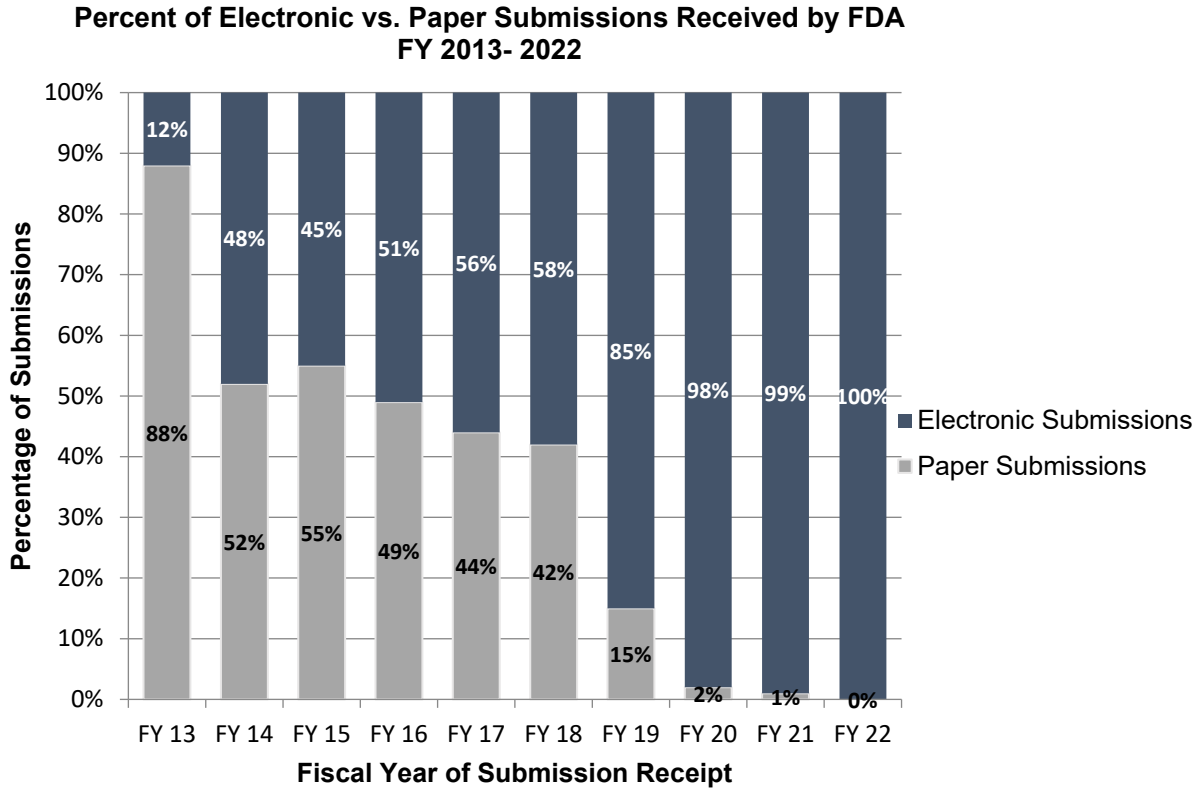
process for ANADA applications and data and protocol JINAD submissions (see Appendix A).

- **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.

FY 2022 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**: In July 2022, CVM emailed letters to the 17 largest sponsors of new animal drugs, that sponsor about 80-90 percent of currently approved new animal drugs, reminding them of the labeling requirement and encouraging the submission of revised labeling for marketed products by the end of 2022. In addition, CVM sent these sponsors a list of their approved new animal drugs, along with the marketing status and compliance status for the labeling statement for each product, per CVM records. This action spurred further submission, by these sponsors, of revised labeling, as well as improved accuracy of labeling databases for CVM and sponsors.

  CVM has also continued such outreach to smaller sponsors. By the end of FY 2022, the labeling of approximately 75 percent of approved and marketed products complied with the labeling requirement.

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:

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