FY 2021

PERFORMANCE REPORT TO CONGRESS

for the

Animal Generic Drug User Fee Act

Commissioner's Report

I am pleased to present to Congress the Food and Drug Administration's (FDA's or the Agency's) fiscal year (FY) 2021 Animal Generic Drug User Fee Act (AGDUFA) performance report. FY 2021 marks the 13th year of AGDUFA, and this report covers the third year of the second reauthorization of AGDUFA, referred to as AGDUFA III (which authorized animal generic drug user fees from FY 2019 through FY 2023).

This report details FDA's preliminary performance for FY 2021 and finalizes FDA's performance results for FY 2020. It is my pleasure to report that FDA exceeded all performance goals for FY 2020. In addition, the Agency met the performance goals for all FY 2021 cohort submissions reviewed or due for review by September 30, 2021. With some reviews still pending, FDA has the potential to exceed all performance goals for FY 2021.

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FDA is committed to improving the efficiency, quality, and predictability of the generic new animal drug review process. The timely approval of generic animal drugs continues to be a critical component of animal health because it provides access to additional sources of animal drugs for ranchers, farmers, and pet owners. Since AGDUFA was enacted, FDA has dramatically reduced average review times from 700 days to less than 270 days. Under the leadership of the President, and in collaboration with Congress and industry, FDA looks forward to continued success in the generic new animal drug review program.

Janet Woodcock, M.D.
Acting Commissioner of Food and Drugs

Acronyms

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

ONADE – Office of New Animal Drug Evaluation

PAI – Pre-Approval Inspection

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]

Information Included in this Report

This report summarizes FDA's performance results in meeting AGDUFA goals and commitments for FY 2020 and FY 2021. Specifically, it updates and finalizes performance data initially reported in the FY 2020 AGDUFA Performance Report and presents preliminary data on FDA's progress in meeting FY 2021 review goals, implementation activities, and accomplishments.

Review Performance

FDA met or exceeded the expectations of the review performance goals in the first 2 years of AGDUFA III and continued to meet or exceed the expectations of the review performance goals for FY 2021. Key activities and accomplishments during FY 2021 included the following:

- FDA met review-time goals for almost all (379 of 396) FY 2020 submissions. FDA exceeded all (5 of 5) AGDUFA performance goals for the FY 2020 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 (226 of 235) FY 2021 cohort submissions reviewed and acted on as of September 30, 2021. With 266 additional reviews pending that may yet be completed on time, FDA has the potential to exceed all five AGDUFA performance goals for the FY 2021 cohort. Please see Appendix A for more details on the submission types and related performance goals.

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

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Introduction

The Animal Generic Drug User Fee Act (AGDUFA) requires the Secretary of Health and Human Services to submit two annual reports to Congress: (1) a performance report and (2) a financial report. The fiscal year (FY) 2021 report is the Food and Drug Administration's (FDA's or the Agency's) third 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 (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. The guidelines and definitions below apply to the information provided in the FY 2021 report.

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 2020 cohort and presents FDA's preliminary performance results with respect to performance goals for the FY 2021 cohort submissions that were received early enough to be reviewed or due for review by September 30, 2021.

The following information refers to FDA's performance results presented in this 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 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.

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

- 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 2021 includes all submissions received in FY 2021. 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 including 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 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 2016 to FY 2021

In the table below, preliminary review workload numbers from FY 2021 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 can also be 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 2021 from the 5-year average, one application and submission type decreased, and another application and submission type decreased insignificantly. 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 16	FY 17	FY 18	FY 19	FY 20	FY 21†	FY 16 to FY 20 5-Year Average	FY 21 Compared to 5-Year Average
Original ANADAs and Reactivations	16	17	19	33	20*	10	21	-52%
Administrative ANADAs	1	4	3	3	10	19	4	+375%
Manufacturing Supplemental ANADAs and Reactivations	156	173	180	185‡	139**	204	167	+22%
JINAD Studies	63	66	97	153	149*	216	106	+104%
JINAD Protocols	22	48	40	83	78	52	54	-4%

* Number was changed to reflect updates to the data presented in the FY 2020 AGDUFA Performance Report.
† FY 2021 numbers are preliminary and will be updated in the FY 2022 AGDUFA Performance Report.
‡ Number was changed to reflect a correction to the calculations of the data presented in the FY 2019 and FY 2020 AGDUFA Performance Reports. This correction has no impact on the conclusions that performance goals were met in FY 2019 and FY 2020 or on the calculation of fees in FY 2019 or FY 2020.
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FY 2020 and FY 2021 AGDUFA Performance Results

The tables that follow present FDA's review performance results for the FY 2020 and FY 2021 AGDUFA cohort submissions.

Final FY 2020 Performance Results

FDA exceeded the 90 percent performance level for all five of the review performance goals for the FY 2020 cohort. Across all submission types, FDA met the review-time goal in 379 of 396 submissions. The entire FY 2020 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	20*	20	0	100%
Administrative ANADAs	10	10	0	100%
Manufacturing Supplemental ANADAs and Reactivations	139†	133†	6	96%
JINAD Studies	149*	141	8	95%
JINAD Protocols	78	75	3	96%

* Number was changed to reflect updates to the data presented in the FY 2020 AGDUFA Performance Report.
† Number was changed to reflect a correction to the calculations of the data presented in the FY 2020 AGDUFA Performance Report. This correction has no impact on the conclusion that performance goals were met in FY 2020 or on the calculation of fees in FY 2020.

Preliminary FY 2021 Performance Results

As of September 30, 2021, preliminary performance data was available for 235 of 501 submissions filed in FY 2021. FDA exceeded performance goals for all five submission types. Overall, FDA met review-time goals for 226 of 235 submissions acted on. With 266 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	10	4	0	6	0	100%
Administrative ANADAs	19	12	0	7	0	100%
Manufacturing Supplemental ANADAs and Reactivations	204	37	3	164	0	93%
JINAD Studies	216	131	4	81	0	97%
JINAD Protocols	52	42	2	8	0	96%

FY 2021 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, at the beginning of the calendar year, a list of foreign manufacturing facilities (1) that are specified in an ANADA, supplemental ANADA, or JINAD file and (2) that may be subject to foreign PAIs.

    - **Accomplishment:** Due to staff travel restrictions implemented by FDA in response to the COVID-19 pandemic, no foreign inspections were completed in FY 2021; however, alternatives to in-person inspections, including records requests under section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), were used where possible to inform approval decisions on applications and manufacturing supplements.[3] The table below shows the number of foreign PAIs conducted and the average time it took to complete a PAI during each fiscal year.

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

- **Review Times.** The Agency agreed to develop a shortened review-time process for certain ANADA and 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.

[3] See FDA's Resiliency Roadmap for FDA Inspectional Oversight report (May 2021) at www.fda.gov/media/148197/download.

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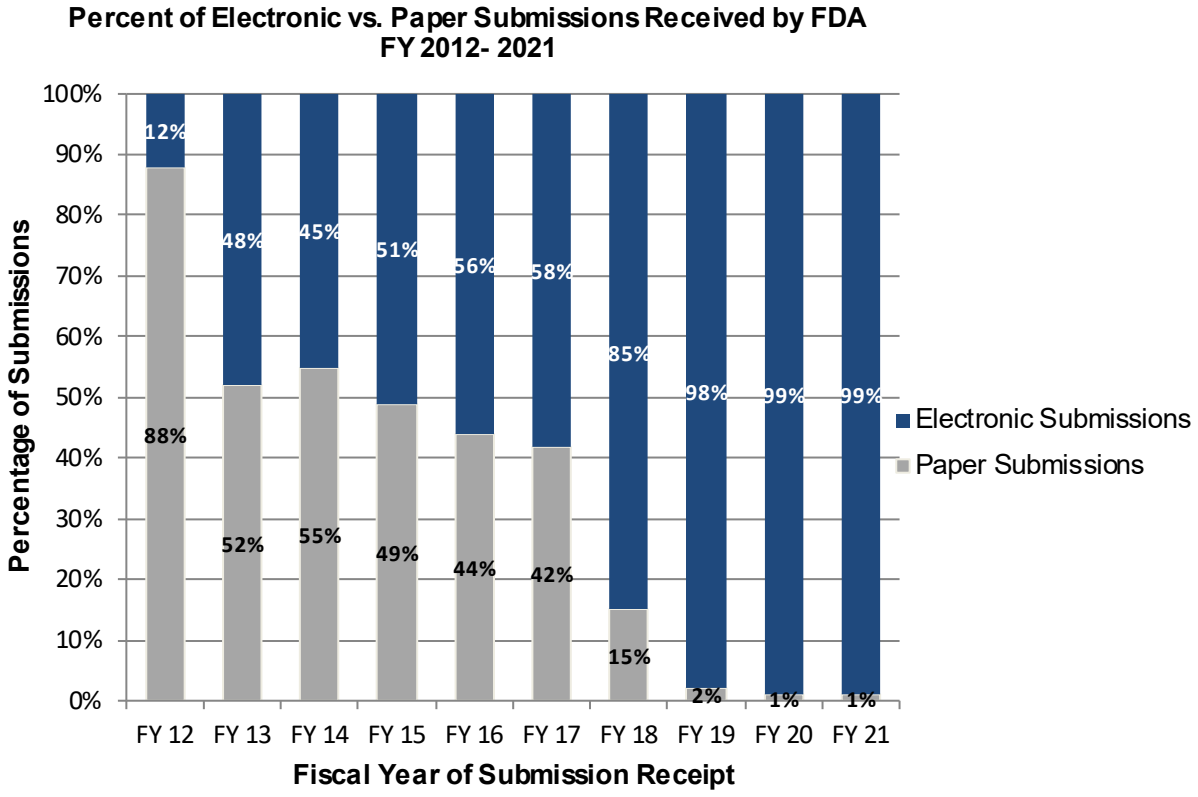
FY 2021 Additional Activities Toward Compliance with AGDUFA III

- **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 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. A small percentage of applications and 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**: CVM issued an electronic message to all animal drug sponsors on September 2, 2021, reminding them of the upcoming labeling requirement deadline and encouraging the submission of supplements to ANADAs to update

labeling by the end of 2022. In addition, the message was posted on CVM's website.[4] CVM continued to remind and encourage sponsors of approved pioneer and generic new animal drugs to update their products' labeling with the new statement. CVM also conducted outreach to smaller sponsors. By the end of FY 2021, the labeling of approximately one-half of the approved and marketed products was in compliance with the labeling requirement.

[4] https://www.fda.gov/animal-veterinary/resources-you/approved-fda-labeling-statement-approved-new-animal-drugs.

Appendix

Appendix A: AGDUFA Performance Goals

The table below shows the performance goals for AGDUFA III (FY 2019 to FY 2023).

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

The table below shows the performance goals for AGDUFA II (FY 2014 to FY 2018).

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

U.S. Department of Health and Human Services
U.S. Food and Drug Administration

This report was prepared by FDA's Office of Planning in collaboration with the Center for Veterinary Medicine. For information on obtaining additional copies, contact:

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