FY 2019

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 or the Agency) Fiscal Year (FY) 2019 Animal Generic Drug User Fee Act (AGDUFA) performance report. This report marks the 11th year of AGDUFA and the 1st year of AGDUFA III (FY 2019 through FY 2023).

This report details FDA's preliminary performance for FY 2019 and finalizes performance results for FY 2018. It is my pleasure to report that FDA exceeded all performance goals for FY 2018. The Agency also met performance goals for all FY 2019 cohort submissions reviewed or due for review by September 30, 2019. With some reviews still pending, FDA has the potential to exceed all performance goals for FY 2019.

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.

Stephen M. Hahn
Commissioner of Food and Drugs

Acronyms

AGDUFA – Animal Generic Drug User Fee Act

ANADA – Abbreviated New Animal Drug Application

CFR – Code of Federal Regulations

CMC – Chemistry, Manufacturing, and Controls

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)

HHS – U.S. Department of Health and Human Services

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 AGDUFA, referred to as AGDUFA III, was signed into law, providing an additional 5 years (through FY 2023). The AGDUFA III program includes a comprehensive set of 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 (JINAD) submissions. The reauthorization also dramatically reduces review time goals across all submission types.

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

Information Included in this Report

This report summarizes FDA's performance in meeting AGDUFA goals and commitments for FY 2018 and FY 2019. Specifically, it updates and finalizes performance data initially reported in the FY 2018 AGDUFA Performance Report and presents preliminary data on FDA's progress in meeting FY 2019 review goals, implementation activities, and accomplishments.

Review Performance

FDA met or exceeded the expectations of the review performance goals in the first year of AGDUFA III and met or exceeded expectations of the review performance goals established under AGDUFA II for FY 2018. Key activities and accomplishments during FY 2019 included the following:

- FDA met review-time goals for almost all (337 of 339) FY 2018 submissions. FDA exceeded all (5 of 5) AGDUFA performance goals for the FY 2018 cohort.

- Preliminary performance results indicate that FDA met review-time goals for almost all (324 of 325) FY 2019 cohort submissions reviewed and acted on as of September 30, 2019. With 227 additional reviews pending that may yet be completed on time, FDA has the potential to exceed all five AGDUFA performance goals for the FY 2019 cohort.

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

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Table of Contents

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Introduction

The Animal Generic Drug User Fee Act (AGDUFA) requires the Secretary of the Department of Health and Human Services (HHS) to submit two annual reports to Congress: (1) a performance report and (2) a financial report. This report is the Food and Drug Administration's (FDA or Agency) first annual performance report to Congress under AGDUFA III. Under AGDUFA III, FDA agreed to meet review performance goals for certain submissions over 5 years (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 the FDA 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 2019 report.

Information Presented in This Report

In any given year, FDA 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 for the FY 2018 cohort and presents FDA's preliminary performance with respect to performance goals for the FY 2019 cohort submissions that were received early enough to be reviewed or due for review by September 30, 2019.

The following information refers to FDA performance 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 II and AGDUFA III performance goals.
- *Performance goal* refers to the percentage of total submissions, agreed to under AGDUFA II or AGDUFA III, where FDA is expected to meet the review-time goal for a given type of submission. The AGDUFA II and 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 approach is

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

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 2019 includes all submissions received in FY 2019. 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 2014 to FY 2019

In the table below, preliminary review workload numbers from FY 2019 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 performance. FDA received a large influx of JINAD Studies in FY 2018. Workload for all five application and submission types showed an increase in FY 2019 from the 5-year average. Please see Appendix A for more detail on the application and submission types included in the table below.

Review Workload for Applications and Submissions

Application/Submission Type	FY 14	FY 15	FY 16	FY 17	FY 18*	FY 19†	FY 14 to FY 18 5-Year Average	FY 19 Compared to 5-Year Average
Original ANADAs and Reactivations	27	22	16	17	19*	33	20	+65%
Administrative ANADAs	1	1	1	4	3	3	2	+50%
Manufacturing Supplemental ANADAs and Reactivations	151	152	156	173	180*	276	162	+70%
JINAD Studies	59	54	63	66	97*	157	68	+131%
JINAD Protocols	48	12	22	48	40	83	34	+144%

* Numbers were changed to reflect updates to data presented in the FY 2018 AGDUFA Performance Report.
† FY 2019 numbers are preliminary and will be updated in the FY 2020 AGDUFA Performance Report.

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FY 2018 and FY 2019 AGDUFA Performance

The tables that follow present FDA's review performance for the FY 2018 and FY 2019 AGDUFA cohort submissions.

Final FY 2018 Performance

FDA exceeded the 90 percent performance level for all five of the review performance goals for the FY 2018 cohort. Across all submission types, FDA met the review-time goal in 337 of 339 submissions. The entire FY 2018 cohort has closed; therefore, there are no pending submissions. Please see Appendix A for more detail on the submission types in the table below and the performance goals.

Submission Type	Filed	On Time	Overdue	Percent on Time
Original ANADAs and Reactivations	19*	19	0	100%
Administrative ANADAs	3	3	0	100%
Manufacturing Supplemental ANADAs and Reactivations	180*	178	2	99%
JINAD Studies	97*	97	0	100%
JINAD Protocols	40	40	0	100%

* Numbers were changed to reflect updates to data presented in the FY 2018 AGDUFA Performance Report

Preliminary FY 2019 Performance

As of September 30, 2019, preliminary performance data was available for 325 of 552 submissions filed in FY 2019. FDA is currently exceeding performance goals for all five submission types. Overall, FDA met review-time goals for 324 of 325 submissions acted on. With 227 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 detail on the submission types in the table below and the performance goals.

Submission Type	Filed	On Time	Overdue	Pending within Goal	Pending Overdue	Percent on Time
Original ANADAs and Reactivations	33	15	0	18	0	100%
Administrative ANADAs	3	2	0	1	0	100%
Manufacturing Supplemental ANADAs and Reactivations	276	140	1	135	0	99%
JINAD Studies	157	105	0	52	0	100%
JINAD Protocols	83	62	0	21	0	100%

FY 2019 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 the 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 that are specified in an ANADA, supplemental ANADA, or JINAD file and that may be subject to foreign PAIs. The table below shows the number of foreign PAIs conducted and the average time it took to complete a PAI during that fiscal year.

Fiscal Year	Number of Foreign PAIs Conducted	Average Time to Completion (in days)
2019	5	145
2020		
2021		
2022		
2023		

- **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.

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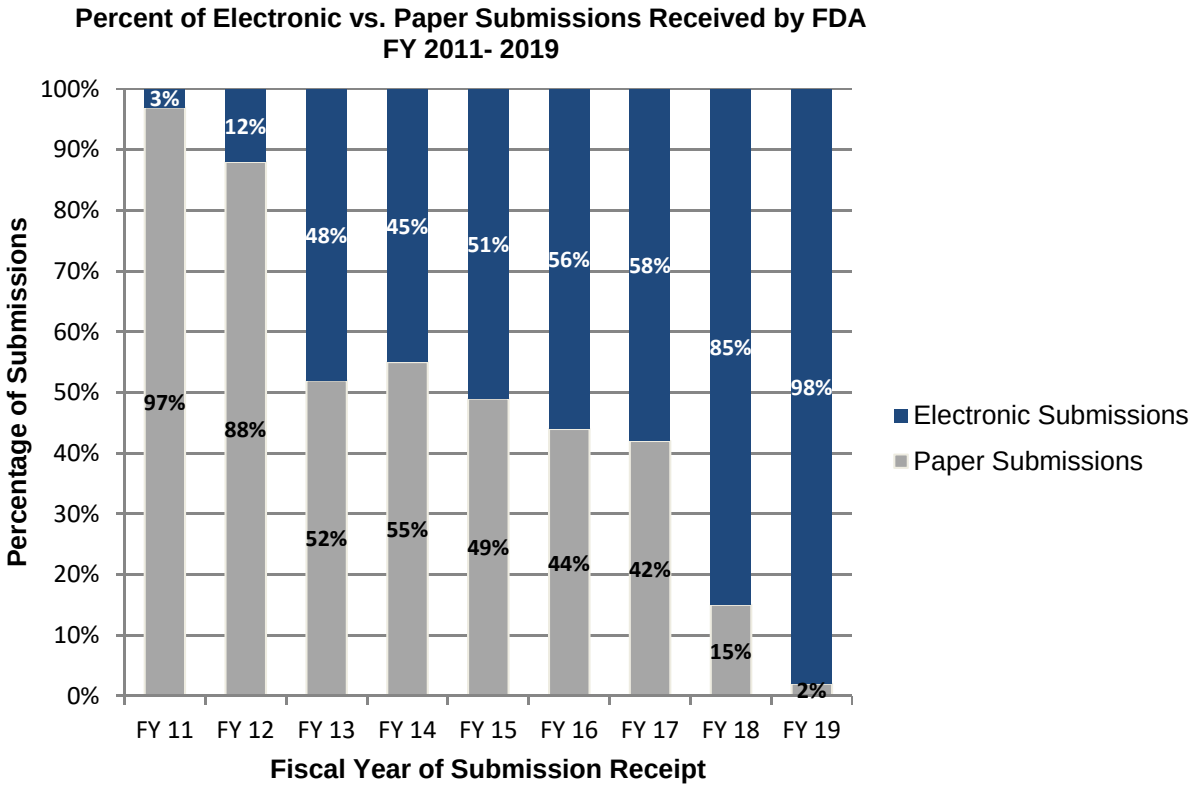
FY 2019 Additional Activities Toward Compliance with AGDUFA III

- **Sec. 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 the Federal Food, Drug, and Cosmetic Act (FD&C Act) section 512(b) and 571(a) must be created using the eSubmitter tool and submitted to the Agency through the Center for Veterinary Medicine's (CVM's) Electronic Submission System (ESS).

    - **Accomplishment:** CVM provided training and support documentation 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.



- **Sec. 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 the statement: "Approved by FDA under (A)NADA #" followed by their application number on their labeling by September 30, 2023, or else such drugs will be considered misbranded under section 502(w) of the FD&C Act.

    - **Accomplishment**: Worked toward the requirement of updating labeling across all ANADAs to carry the updated approval statement by September 30, 2023. Internally, CVM updated polices and documentation to prepare the review staff for reviewing supplemental labeling applications.

Externally, CVM delivered an eSubmitter broadcast to all (613) eSubmitter users on May 16, 2019, outlining the new labeling requirement. The broadcast is now posted on CVM's website.

Appendix

Appendix A: AGDUFA Performance Goals

The table below shows the Performance Goals for AGDUFA II (FY 2014-2018).

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

The table below shows the Performance Goals for AGDUFA III (FY 2019 – 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

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Department of Health and Human Services
Food and Drug Administration

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

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