



FY 2017

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) 2017 Performance Report to Congress for the Animal Generic Drug User Fee Act (AGDUFA). On August 14, 2008, AGDUFA was signed into law. AGDUFA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by authorizing the first generic animal drug user fee program from FY 2009 through FY 2013. On June 13, 2013, AGDUFA was reauthorized for an additional 5 years (FY 2014 through FY 2018), referred to as AGDUFA II. This report marks the fourth year of AGDUFA II.

This report details FDA's preliminary performance for FY 2017, and finalizes performance results for FY 2016. It is my pleasure to report that FDA exceeded all performance goals for FY 2016. The Agency also met review-time goals for all FY 2016 cohort submissions reviewed or due for review by September 30, 2017. With some reviews still pending, FDA has the potential to exceed all performance goals for FY 2017.

The timely approval of generic animal drugs continues to be a critical component of animal health because it provides access to additional sources of more affordable 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. We look forward to continued success in the generic animal drug review program.

Scott Gottlieb, M.D.
Commissioner of Food and Drugs

Acronyms

AGDUFA – Animal Generic Drug User Fee Act
ANADA – Abbreviated New Animal Drug Application
CBE-30 – Changes Being Effected in 30 Days
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
PAI – Pre-Approval Inspection
QbR – Question-based Review

Executive Summary

On August 14, 2008, the Animal Generic Drug User Fee Act (AGDUFA) was signed into law. AGDUFA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by authorizing the first generic animal drug user fee program and providing the Food and Drug Administration (FDA or the Agency) with resources to enhance the performance of the generic new animal drug review process. In exchange for this authority, the Agency agreed to pursue a comprehensive set of review performance goals and commitments to improve the timeliness and predictability of generic new animal drug reviews. FDA initially agreed to meet increasingly challenging review performance goals for these submissions over a 5-year period (FY 2009 through FY 2013), known as AGDUFA I. AGDUFA II (FY 2014 through FY 2018) is a continuation of the successful implementation of AGDUFA I. The review performance goals help achieve greater predictability in FDA's review of abbreviated new animal drug applications (ANADAs) and reactivations, manufacturing supplemental ANADAs, and generic investigational new animal drug (JINAD) submissions.

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 2016 and FY 2017. Specifically, it updates and finalizes performance data initially reported in the FY 2016 AGDUFA Performance Report and presents preliminary data on FDA's progress in meeting FY 2017 review goals, implementation activities, and accomplishments.

Review Performance

For FY 2016, FDA exceeded expectations in the implementation and completion of all review performance goals established under AGDUFA II. Key activities and accomplishments during FY 2017 include the following:

- FDA has completed review on all 258 FY 2016 submissions. FDA exceeded all (five of five) AGDUFA performance goals for the FY 2016 cohort.
- Preliminary performance results indicate that FDA met review-time goals for almost all (114 of 115) FY 2017 cohort submissions reviewed and acted on as of September 30, 2017. FDA has the potential to exceed all five AGDUFA performance goals with 197 additional reviews pending for the FY 2017 cohort.

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

(This page left blank intentionally.)

Table of Contents

Introduction	1
Information Presented in This Report.....	1
AGDUFA Review Workload	3
FY 2016 and FY 2017 AGDUFA Performance.....	5
Final FY 2016 Performance	5
Preliminary FY 2017 Performance	6
FY 2017 Process Improvement	7
Major Accomplishments towards Process Improvements for FY 2017.....	9
Appendix.....	A-1
Appendix A: Definitions of Key Terms.....	A-1

(This page left blank intentionally.)

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 for each fiscal year fees are collected: (1) a performance report and (2) a financial report. This report is the Food and Drug Administration's (FDA or the Agency) fourth annual performance report to Congress under AGDUFA II. Under AGDUFA II, FDA agreed to meet review performance goals for certain submissions over 5 years (FY 2014 through FY 2018). Further details on FDA's commitments under AGDUFA II can be found in the AGDUFA II Performance Goals and Procedures document 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 will accelerate availability of safe and effective new generic animal drug products. The guidelines and definitions below and in Appendix A-1 apply to the information provided in the FY 2017 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 2016 cohort and FDA's preliminary performance with respect to performance goals for the FY 2017 cohort submissions that were received early enough to be reviewed, or due for review, by September 30, 2017.

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. AGDUFA review-time goals range from 100 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 performance 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 performance goals.
- *Performance goals* are the percent of total submissions for which FDA is expected to meet the review-time goal agreed to under AGDUFA II. There is a performance goal for each type of submission. For AGDUFA II, FDA agreed to meet the review-time goals 90 percent of the time for each 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 based on the fiscal year in which FDA received the submission, regardless of when FDA ultimately acted on the submission. A result of this approach is that the statistics shown for a particular year may change from one report to the next. As more submissions are completed, the statistics for the year of receipt are adjusted to reflect the new

²

www.fda.gov/downloads/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/UCM343235.pdf

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.

- Performance data are available on only some submissions received and acted on during FY 2017. 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 100 days, performance data for submissions received early in the fiscal year may provide an early indicator of review performance.
- Performance goal tables indicate the total number of submissions filed as well as the number of submissions reviewed on time, overdue, or still pending and not past its due date.
- The workload count presented in this report for FY 2017 includes all submissions received through the last month of FY 2017. For AGDUFA review times, FDA calculates from the original receipt of the application or submission.
- Submissions that FDA identified as withdrawn, and reviews that were designated as “stop review” (applies to JINAD submissions only), are not included in the statistics used to measure performance. These submissions are noted, however, in the relevant workload narratives and footnotes for performance goals.
- 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 amendments and supplements. This report presents original applications and reactivations, administrative applications, and supplements 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.

Sources:

ANADA - 21 CFR 514.3

www.ecfr.gov/cgi-bin/text-idx?SID=181eddb42cc61a7f590432800f56a462&node=se21.6.514_13&rgn=div8

JINAD file

www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/PoliciesProceduresManual/UCM204320.pdf

AGDUFA Review Workload

Review Workload: FY 2012 to FY 2017

In the table below, preliminary review workload numbers from FY 2017 are compared to the previous 5-year average 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 provide context for performance.

Review Workload for Applications and Submissions

Application/Submission Type	FY 12	FY 13	FY 14	FY 15	FY 16*	FY 17†	FY 12 to FY 16 5-Year Average	FY 17 Compared to 5-Year Average
Original ANADAs and Reactivations	34	36	27	22	16	17	27	- 37%
Administrative ANADAs	1	1	1	1	1	4	1	+ 300%
Manufacturing Supplemental ANADAs and Reactivations	116	132	151	152	156	175	141	+ 24%
JINAD Studies	34	25	59	54	63	67	47	+ 43%
JINAD Protocols	7	41	48	12	22	49	26	+ 88%

* FY 2016 numbers were changed to reflect updates to data presented in the FY 2016 AGDUFA Performance Report.

† FY 2017 numbers are preliminary and will be updated in the FY 2018 AGDUFA Performance Report.

(This page left blank intentionally.)

FY 2016 and FY 2017 AGDUFA Performance

The tables that follow present FDA's review performance for the FY 2016 and FY 2017 AGDUFA cohorts.

Final FY 2016 Performance

FDA exceeded the 90 percent performance level for all five of the review performance goals for the FY 2016 cohort. In total, FDA met or exceeded the performance goal for 253 of the 258 submissions.

Submission Type	Filed	Performance Goal: Act on 90 Percent within	On Time	Overdue	Percent on Time
Original ANADAs and Reactivations	16*	270 days	16	0	100%
Administrative ANADAs	1	100 days	1	0	100%
Manufacturing Supplemental ANADAs and Reactivations	156†	270 days	153	3	98%
JINAD Studies	63§	270 days	61	2	97%
JINAD Protocols	22^	100 days	22	0	100%

* A total of 21 submissions were received, but one was voided for administrative reasons and four were withdrawn at the request of the sponsor.

† A total of 161 submissions were received, but five were withdrawn at the request of the sponsor.

§ A total of 66 study submissions were received, but three received a refuse to review.

^ A total of 23 submissions were received, but one submission protocol received a stop review.

Preliminary FY 2017 Performance

As of September 30, 2017, performance data were available for 114 of 312 submissions filed in FY 2017. FDA is currently exceeding the review-time goal for all 5 performance goals. With 197 submissions pending within goal, FDA has the potential to exceed the 90 percent performance level for all 5 review performance goals.

Submission Type	Filed	Performance Goal: Act on 90 Percent within	On Time	Overdue	Percent on Time	Pending within Goal	Highest Possible Percent on Time
Original ANADAs and Reactivations	17	270 days	6	0	100%	11	100%
Administrative ANADAs	4	100 days	4	0	100%	0	100%
Manufacturing Supplemental ANADAs and Reactivations	175 [†]	270 days	50	0	100%	125	100%
JINAD Studies	67 [‡]	270 days	22	0	100%	45	100%
JINAD Protocols	49 [§]	100 days	32	1	97%	16	98%

[†] A total of 180 submissions were received, but five pending supplements were withdrawn at the request of the sponsor.

[‡] A total of 74 submissions were received, but one received a refuse to accept, four received refuse to review, and two received a stop review.

[§] A total of 54 submissions were received, but four received a refuse to review and one received a stop review.

FY 2017 Process Improvement

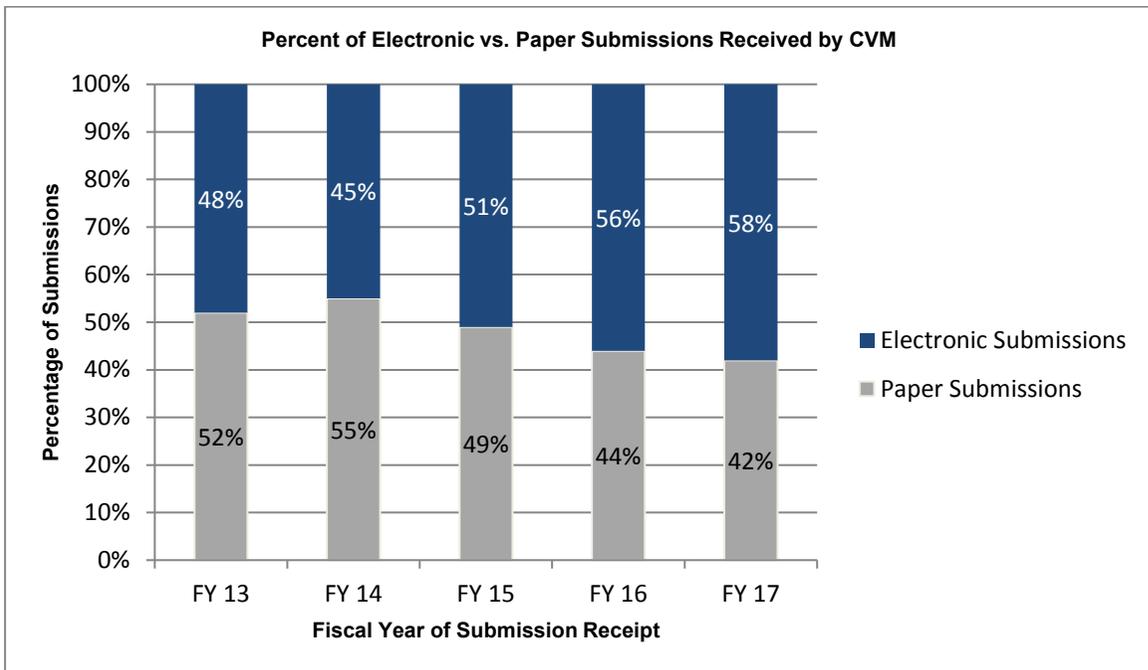
Under AGDUFA II, FDA committed to a variety of process improvements. FDA agreed to enhance and further improve the review process via the following changes:

- **Review Times.** The Agency agreed to develop a shortened review time process for certain ANADA and JINAD submissions.
- **Timely Foreign Pre-Approval Inspections (PAIs).** Under AGDUFA II, 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 that may be subject to foreign PAIs.
- **Multiple Data Submissions to the Chemistry, Manufacturing, and Controls (CMC) Technical Section.** The Agency agreed to develop guidance for a two-phased CMC Technical Section submission and review process under the JINAD file by the end of FY 2014.
- **Manufacturing Supplemental Animal Drug Applications.** The Agency agreed to permit prior approval manufacturing supplements to be resubmitted as “Supplement-Changes Being Effectuated in 30 Days” (CBE-30) (21 CFR 514.8(b)(3)).
- **CMC Comparability Protocols.** The Agency agreed to permit comparability protocols to be submitted as protocols without substantial data in a JINAD file.
- **A New Bioequivalence Submission Process.** Under AGDUFA II, by the end of FY 2016, the Agency was to develop and implement a new question-based review (QbR) process for bioequivalence submissions.

(This page left blank intentionally.)

Major Accomplishments towards Process Improvements for FY 2017

- **Foreign Pre-Approval Inspections.** In an effort to improve communications, timeliness, and predictability related to foreign pre-approval inspections, sponsors can voluntarily submit a list of foreign manufacturing facilities anticipated to be included in the sponsor's generic new animal drug applications for the following year. For FY 2017, one sponsor voluntarily submitted a list of foreign manufacturing facilities anticipated to be included in generic new animal drug applications. FDA completed seven foreign pre-approval inspection assignments in FY 2017, with an average time of 71 days to complete all aspects of the inspection (e.g., preparation, communication with the foreign jurisdiction, and actual time in the facility). In comparison, FDA completed two foreign pre-approval inspection assignments in FY 2016 with an average time of 136 days to complete all aspects of the inspection.
- **Electronic Submission and Review.** Since the release of CVM's eSubmitter tool in FY 2011, there has been an overall decline in paper submissions. CVM received approximately 58 percent of its regulatory submissions electronically in FY 2017 (compared to 3 percent in FY 2011, when electronic submission was implemented).



- **Enhancements to Chemistry, Manufacturing, and Controls (CMC)**
 - **Permit a two-phase data submissions process to the CMC Technical Section.** Submission of CMC information as a two-phased data submission is voluntary. This new submission process permits the submission and review of early completed CMC information that may increase the timely completion of the entire CMC Technical Section. In FY 2017, CVM received one first-phase submission under this process.
 - **Permit prior approval manufacturing supplements to be resubmitted as CBE-30.** In FY 2017, 8 incomplete prior-approval manufacturing supplements were permitted to be resubmitted as CBE-30. The total number of incomplete prior-approval manufacturing supplements was 16. This new process may allow for earlier distribution of animal drugs made with CMC changes.
 - **Permit comparability protocols to be submitted as protocols without substantial data in a JINAD file.** Submission of comparability protocols as protocols without substantial data in a JINAD file is voluntary. This new process can reduce the review time for most comparability protocols from 270 to 100 days. In FY 2017, CVM received two JINAD comparability protocols. In FY 2016, CVM received no JINAD comparability protocols.
 - **Develop a New Bioequivalence Submission Process.** In August 2017, FDA officially deployed the eSubmitter Blood Level Bioequivalence Study Protocol QbR Template. This template is designed to increase transparency and efficiency of the blood level bioequivalence study protocol review process as part of the generic animal drug approval process. The QbR for blood level bioequivalence data submissions is currently under development.

Appendix

Appendix A: Definitions of Key Terms

Application or Supplement Withdrawn. A sponsor can notify FDA that they no longer desire to seek approval of a submitted, but pending, ANADA application or supplement. This is distinct from the Stop Review final action because the decision is made after the ANADA or supplemental application for a product is received by FDA instead of during the JINAD period prior to approval. A sponsor may voluntarily request that FDA withdraw approval of an application if the sponsor represents that it is no longer marketing the product. FDA also may take action to compel withdrawal of an approved application based on safety, effectiveness, or certain other grounds after providing notice and an opportunity for hearing to the sponsor.

Refuse to Accept. As stated in section 741(e) of the FD&C Act, an ANADA or a JINAD submission for a generic new animal drug that is submitted by a person subject to fees cannot be accepted for review until all fees owed by such person have been paid.

Refuse to File Applications. Within 30 days of submission, FDA shall “refuse to file” an ANADA or supplemental ANADA (or a reactivation of them) that is determined to be inadequate or incomplete on its face or otherwise of unacceptable quality for review upon initial inspection, per Title 21 of the Code of Federal Regulations (CFR) section 514.110. FDA will refuse to file an application containing a large number or certain types of errors, or flaws in the development plan, that are sufficient to cause the quality of the entire submission to be questioned, such that FDA cannot reasonably review it.

Refuse to Review Submissions. Within 60 days of submission, FDA will refuse to review a JINAD submission that is determined to be insufficient on its face or otherwise of unacceptable quality upon initial inspection using criteria and procedures similar to those found in 21 CFR 514.110. A decision to refuse to review a submission, or to refuse to file an application as described above, will result in the application or submission being excluded from the review cohort for purposes of calculating FDA performance. FDA records the numbers and types of these exclusions and has included them in this annual performance report.

Review and Act on Applications and Submissions. The term “review and act on” means the issuance of a complete action letter after the complete review of an original ANADA, supplemental ANADA, or JINAD submission that either (1) approves an original or supplemental ANADA or notifies a sponsor that a JINAD submission is complete, or (2) sets forth in detail the specific deficiencies in such original or supplemental ANADA or JINAD submission and, where appropriate, the actions necessary to place such an original or supplemental ANADA or JINAD submission in condition for approval.

Stop Review. A sponsor may request that FDA stop the review of a particular JINAD submission while the submission is under review. Any resubmission of that information is treated as a new submission, independent of previous work or data.



**Department of Health and Human Services
Food and Drug Administration**

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

Office of Planning
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002
Phone: 301-796-4850

This report is available on the FDA Home Page at www.fda.gov.