FY 2016

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) 2016 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 third year of AGDUFA II.

This report details FDA's preliminary performance for FY 2016, and finalizes performance results for FY 2015. It is my pleasure to report that FDA exceeded all performance goals for FY 2015. The Agency also met review-time goals for all FY 2015 cohort submissions reviewed or due for review by September 30, 2016. FDA is on track to exceed all performance goals for FY 2016.

The timely approval of generic animal drugs continues to be a critical component of animal health because it provides quicker access to additional sources of more affordable animal drugs for ranchers, farmers, and pet owners. Since AGDUFA was enacted, FDA has been able to dramatically reduce average review times from 700 days to less than 270 days. We look forward to the continued success in the generic animal drug review process that the AGDUFA program will make possible in the coming years.

Robert M. Califf, 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 2015 and FY 2016. Specifically, it updates and finalizes performance data initially reported in the FY 2015 AGDUFA Performance Report and presents preliminary data on FDA's progress in meeting FY 2016 review goals, implementation activities, and accomplishments.

Review Performance

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

- FDA completed 141 of 143 submissions that were pending from FY 2015. FDA exceeded all (5 of 5) AGDUFA performance goals for the FY 2015 cohort.

- Preliminary performance results indicate that FDA met review-time goals for all (98 of 98) FY 2016 cohort submissions reviewed and acted on as of September 30, 2016. With 164 additional reviews pending that may yet be completed on time, FDA has the potential to exceed all five AGDUFA performance goals for the FY 2016 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 FDA's third 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] The expectation is that AGDUFA will bring predictability in review times for the generic animal drug industry and provide FDA with resources to improve its review of applications for generic new animal drugs, with the result that safe and effective new products will be more readily available. The guidelines and definitions below and in Appendix A apply to the information provided in the FY 2016 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 updates FDA's final performance for the FY 2015 cohort and presents FDA's preliminary performance with respect to performance goals for the FY 2016 cohort submissions that were received early enough to be reviewed or due for review by September 30, 2016.

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 performance goals.
- *Performance goals* are the percent of total submissions, agreed to under AGDUFA, where FDA is expected to meet the review-time goal for a given type of submission. AGDUFA performance goals are established 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 for the fiscal year FDA received them, regardless of when FDA ultimately acted on or approved the submissions. 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 that year of receipt are adjusted to reflect the new completions. Therefore, until all submissions in a cohort are acted on or have

[2] www.fda.gov/downloads/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/UCM343235.pdf

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 2016. For submission types with a longer review-time goal, for example, 270 days, review performance data are usually limited at the time this report is prepared. For those submissions with a shorter review-time goal, for example 100 days, performance 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 whether the submission was reviewed on time, was overdue, or is still pending and not past its due date. The number of review submissions when summed together equals the total number filed.
- The workload count presented in this report for FY 2016 includes all submissions received in the last month of FY 2016 as filed (e.g., ANADA) or submitted (e.g., JINAD). FDA makes a filing decision within 30 days of receiving an original application, or a proceed-to-review decision within 60 days of receiving a submission. 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 the original application, amendments, and supplements 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.

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 2011 to FY 2016

In the table below, preliminary review workload numbers from FY 2016 are compared to the previous 5-year averages for all AGDUFA application and submission types filed. There are no performance goals associated with workload, but the variations in workload over time can provide context for performance.

Review Workload for Applications and Submissions

Application/Submission Type	FY 11	FY 12	FY 13	FY 14	FY 15*	FY 16†	FY 11 to FY 15 5-Year Average	FY 16 Compared to 5-Year Average
Original ANADAs and Reactivations	19	34	36	27	22	17	28	- 39%
Administrative ANADAs	0	1	1	1	1	1	1	0%
Manufacturing Supplemental ANADAs and Reactivations	134	116	132	151	152	160	137	+ 17%
JINAD Studies	29	34	25	59	54	62	40	+ 55%
JINAD Protocols	12	7	41	48	12	22	24	-8%

* FY 2015 numbers were changed to reflect updates to data presented in the FY 2015 AGDUFA Performance Report.
† FY 2016 numbers are preliminary and will be updated in the FY 2017 AGDUFA Performance Report.

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FY 2015 and FY 2016 AGDUFA Performance

The tables that follow present FDA's review performance for the FY 2015 and FY 2016 AGDUFA cohort submissions.

Final FY 2015 Performance

FDA exceeded the 90 percent performance level for all (5 of 5) of the review performance goals for submission types where submissions were received in FY 2015. Across all submission types, FDA met the performance goal in 239 of 241 submissions.

Submission Type	Filed	Performance Goal: Act on 90 Percent within	On Time	Overdue	Percent on Time
Original ANADAs and Reactivations	22*	270 days	22	0	100%
Administrative ANADAs	1†	100 days	1	0	100%
Manufacturing Supplemental ANADAs and Reactivations	152‡	270 days	151	1	99%
JINAD Studies	54§	270 days	53	1	98%
JINAD Protocols	12	100 days	12	0	100%

* A total of 23 submissions were received, but one of the original ANADAs was withdrawn at the request of the sponsor.
† A total of two submissions were received, but one was withdrawn at the request of the sponsor.
‡ A total of 161 submissions were received, but nine were withdrawn at the request of the sponsor.
§ A total of 56 submissions were received, but one received a refuse to review and one received a stop review.

Preliminary FY 2016 Performance

As of September 30, 2016, performance data were available for 98 of 262 submissions filed in FY 2016. FDA is currently exceeding the review-time goal for all 5 performance goals. With 164 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	8	0	100%	9	100%
Administrative ANADAs	1	100 days	1	0	100%	0	100%
Manufacturing Supplemental ANADAs and Reactivations	160†	270 days	49	0	100%	111	100%
JINAD Studies	62‡	270 days	23	0	100%	39	100%
JINAD Protocols	22§	100 days	17	0	100%	5	100%

* A total of 21 submissions were received, but three applications were withdrawn at the request of the sponsor and one application received an administrative void.
† A total of 162 submissions were received, but two pending supplements were withdrawn at the request of the sponsor.
‡ A total of 65 submissions were received, but three received a "refuse to review."
§ A total of 23 submissions were received, but one received a stop review.

FY 2016 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.

- **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 Effected 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.

- **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.

- **A New Bioequivalence Submission Process.** Under AGDUFA II, by the end of FY 2016, the Agency will develop and implement a new question-based review (QbR) process for bioequivalence submissions.

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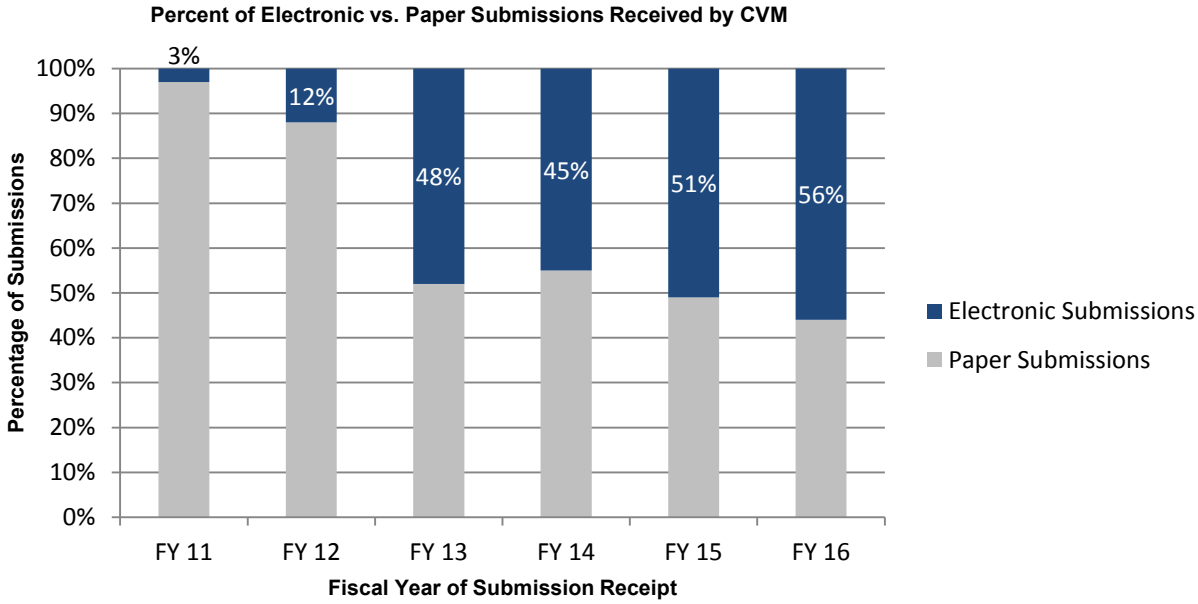
Major Accomplishments during FY 2016

- **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 2016, two sponsors voluntarily submitted lists of foreign manufacturing facilities anticipated to be included in generic new animal drug applications. FDA completed two foreign pre-approval inspection assignments in FY 2016, with an average time of 136 days to complete all aspects of an inspection (e.g., preparation, communication with the foreign jurisdiction, and actual time in the facility). In comparison, FDA completed 18 foreign pre-approval inspection assignments in FY 2015 with an average time of 115 days to complete all aspects of an inspection.

- **Electronic Submission and Review.** CVM received approximately 56 percent of its regulatory submissions electronically in FY 2016 (compared to 3 percent in FY 2011 when the eSubmitter tool was released).



- **Enhancements to 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. In FY 2016, CVM received three first-phase submissions according to the two-phased data submission process. 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.

  - **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. In FY 2016, CVM received no JINAD comparability protocols. This new process can reduce the review time for most comparability protocols from 270 to 100 days.

- **Permit prior approval manufacturing supplements to be resubmitted as CBE-30.** In FY 2016, three incomplete prior-approval manufacturing supplements were permitted to be resubmitted as CBE-30. The total number of incomplete prior-approval manufacturing supplements was eight. This new process may allow for earlier distribution of animal drugs made with CMC changes.

- **Develop a New Bioequivalence Submission Process.** The QbR for blood level bioequivalence protocol submissions has been developed and moved into the testing phase. The QbR for blood level bioequivalence data submissions is still in 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. Thus, 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 to the extent 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 cohort upon which the relevant user fee goal is based. 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" is understood to mean 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:

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