

# FY 2015

## *PERFORMANCE REPORT TO CONGRESS*

*for the*

## *Animal Generic Drug User Fee Act*



**Center for Veterinary Medicine**



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



## ***Commissioner's Report***

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I am pleased to present to the President and Congress the Food and Drug Administration's (FDA or the Agency) Fiscal Year (FY) 2015 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 second year of AGDUFA II.

This report details FDA's preliminary performance for FY 2015 and finalizes performance results for FY 2014. It is my pleasure to report that FDA exceeded all performance goals for FY 2014. The Agency also met review-time goals for all FY 2015 cohort submissions reviewed or due for review by September 30, 2015. FDA is on track to exceed all performance goals for FY 2015.

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 animal drugs at a lower cost for ranchers, farmers, and pet owners. Since AGDUFA was enacted, FDA has been able to dramatically reduce average review times from 700 days to 270 days. We look forward to the continued success in the generic new 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 Effectuated 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

**STARS** – Submission Tracking and Reporting System

## ***Executive Summary***

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On August 14, 2008, AGDUFA was signed into law. AGDUFA amended the FD&C Act by authorizing the first generic animal drug user fee program and providing FDA 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.<sup>1</sup>

### **Information Included in This Report**

This report summarizes FDA's performance in meeting AGDUFA goals and commitments for FY 2014 and FY 2015. Specifically, it updates and finalizes performance data initially reported in the FY 2014 AGDUFA Performance Report and presents preliminary data on FDA's progress in meeting FY 2015 review goals, implementation activities, and accomplishments.

### **Review Performance**

FDA exceeded expectations in the implementation and completion of all goals under AGDUFA in FY 2015. Key activities and accomplishments during FY 2015 included the following:

- FDA completed all 253 reviews related to AGDUFA performance goals in FY 2014 on time, including 155 submissions pending from FY 2014 and 98 submissions submitted in FY 2015 and due by September 30, 2015.
- FDA also exceeded all AGDUFA performance goals for reviews initiated during FY 2014.
- With submissions pending that may be completed on time, FDA has the potential to achieve 100 percent performance on all AGDUFA performance goals for the FY 2015 cohort.

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<sup>1</sup> [www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm](http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm)

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## **Introduction**

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For each fiscal year fees are collected, 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 second 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.<sup>2</sup> The expectation is that AGDUFA will bring predictability in review times for the animal drug industry and provide FDA with resources to improve its review of applications for generic new animal drugs, the result being that safe and effective new products will be more readily available. The guidelines and definitions below apply to the information provided in the FY 2015 report.

**Application or Supplement Withdrawn.** A sponsor can notify FDA that they no longer desire to seek approval of a submitted, but pending, 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.

**B1 Generics.** The term "B1 generic" as used in this report means a generic new animal drug product whose ANADA is the subject of an approved supplemental animal drug application (as defined in section 739(2)(B) of the FD&C Act) for which safety or effectiveness data was required. These products are referred to as "B1 generics" because the supplemental animal drug application is submitted under section 512(b)(1) of the FD&C Act (the provision under which applications for pioneer new animal drugs are generally submitted) and approved under section 512(c)(1) of the FD&C Act.

**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.

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<sup>2</sup> [www.fda.gov/downloads/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/UCM343235.pdf](http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/UCM343235.pdf)

**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.

#### **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 (JINAD) 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](http://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](http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/PoliciesProceduresManual/UCM204320.pdf)

## 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 2014 cohort and presents FDA's preliminary performance with respect to performance goals for the FY 2015 cohort that were received early enough to be reviewed or due for review by September 30, 2015.

The following information refers to FDA performance presented in this report:

- The term *submission* is used to refer to ANADAs and reactivations, supplemental ANADAs and reactivations, 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 past the due date, whichever comes first, only a preliminary performance assessment is provided for that fiscal year cohort.
- For submissions with a review-time goal that is shorter (e.g., a 100-day review-time goal), individual review performance data may be available for the majority of the cohort. For submission categories with a longer review-time goal (e.g., a review-time goal of 270 days), early review performance data are usually limited.
- The workload count for FY 2015 includes all submissions received in the last month of FY 2015 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. FDA calculates AGDUFA review times, however, 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.

## ***AGDUFA Workload FY 2010 to FY 2015***

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In the table below, preliminary review workload numbers from FY 2015 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 variations in workload over time can provide context for performance. Certain submission types (e.g., JINAD protocols) have reduced workloads, while others (e.g., JINAD studies) had increased workloads.

**AGDUFA Workload FY 2010 to FY 2015**

<b>Submission Type</b>	<b>FY 10</b>	<b>FY 11</b>	<b>FY 12</b>	<b>FY 13</b>	<b>FY 14*</b>	<b>FY 15†</b>	<b>FY 10 to FY 14 5 Year Average</b>	<b>FY 15 Compared to 5 Year Average</b>
Original ANADAs and Reactivations	19	19	34	36	27	23	27	- 17%
Administrative ANADAs	0	0	1	1	1	1	1	0%
Manufacturing Supplemental ANADAs and Reactivations	134	134	116	132	151	156	133	+ 17%
JINAD Studies	17	29	34	25	59	56	33	+ 70%
JINAD Protocols	15	12	7	41	48	12	25	-108%

\* FY 2014 numbers were changed to reflect updates to data presented in the FY 2014 AGDUFA Performance Report.

† FY 2015 numbers are preliminary. Submissions with reviews completed on or after October 1, 2015, will be updated in the FY 2016 AGDUFA Performance Report.

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## ***FY 2014 and FY 2015 AGDUFA Performance***

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The tables below present FDA’s review performance for the FY 2014 and FY 2015 AGDUFA cohort submissions.

### **Final FY 2014 Performance**

FDA exceeded all five performance goals for FY 2014 cohort submissions. All performance goals were met, with 100 percent of submissions reviewed on time.

<b>Submission Type</b>	<b>Filed</b>	<b>Performance Goal: Act on 90 Percent within</b>	<b>On Time</b>	<b>Overdue</b>	<b>Percent on Time</b>
Original ANADAs and Reactivations	27*	270 days	27	0	100%
Administrative ANADAs	1	100 days	1	0	100%
Manufacturing Supplemental ANADAs and Reactivations	151†	270 days	151	0	100%
JINAD Studies	59§	270 days	59	0	100%
JINAD Protocols	48	100 days	48	0	100%

\* A total of 29 submissions were received, but 2 of the original ANADAs were withdrawn at the request of the sponsor.

† In the FY 2014 report, FDA reported 157 Manufacturing Supplemental ANADAs and Reactivations filed. Of these submissions, 2 will be reported under ADUFA performance because they were B1 generics. Another 2 submissions had a significant amendment to them that warranted the review clock starting over. In the case of these 2 submissions, the resetting of the clock moved them from the FY 2014 cohort to the FY 2015 cohort. Of the remaining 153 submissions, 2 were withdrawn at the request of the sponsor.

§ A total of 61 submissions were received, but 1 one received a “refuse to accept” and 1 received a “stop review.”

## Preliminary FY 2015 Performance

As of September 30, 2015, FDA is currently exceeding all five performance goals for the FY 2015 cohort with 100 percent of submissions reviewed on time. With submissions pending within goal, FDA has the potential to exceed all five performance goals for FY 2015 and achieve 100 percent performance for all 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	23*	270 days	12	0	100%	11	100%
Administrative ANADAs	1	100 days	1	0	100%	0	100%
Manufacturing Supplemental ANADAs and Reactivations	156 <sup>†</sup>	270 days	53	0	100%	103	100%
JINAD Studies	56 <sup>‡</sup>	270 days	22	0	100%	34	100%
JINAD Protocols	12	100 days	10	0	100%	2	100%

\* A total of 24 submissions were received, but 1 pending application was withdrawn at the request of the sponsor.

<sup>†</sup> A total of 161 submissions were received, but 5 pending supplements were withdrawn at the request of the sponsor.

<sup>‡</sup> A total of 57 submissions were received, but 1 received a "refuse to review."



## ***FY 2015 Process Improvement Performance***

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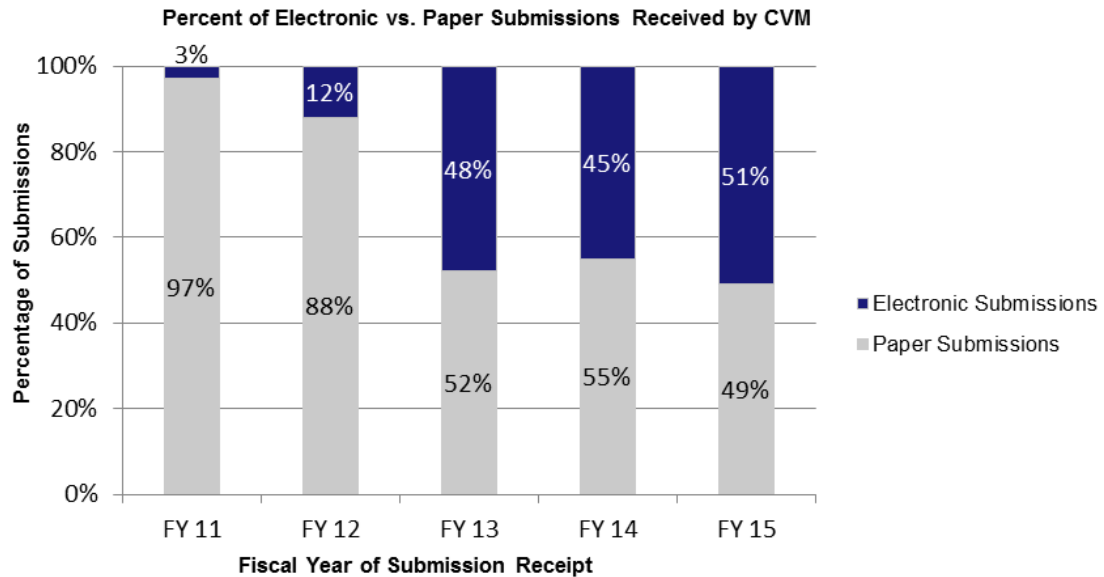
Under AGDUFA II, FDA committed to a variety of process improvements. FDA agreed to enhance and further improve the review process via the following changes:

- **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)(i)).
- **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.

Major accomplishments during FY 2015 include:

- **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 2015, three sponsors voluntarily submitted lists of foreign manufacturing facilities anticipated to be included in generic new animal drug applications. 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 (e.g., preparation, communication with the foreign jurisdiction, and actual time in the facility). In comparison, FDA completed 14 foreign pre-approval inspection assignments in FY 2014 with an average time of 157 days to complete all aspects of an inspection.

- **Electronic Submission and Review.** Since the release of the Center for Veterinary Medicine’s (CVM) eSubmitter tool in FY 2011, CVM now receives approximately 51 percent of its regulatory submissions electronically (compared to 3 percent in FY 2011).



- **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 2015, 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 2015, 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 2015, six incomplete prior-approval manufacturing supplements were permitted to be resubmitted as CBE-30. The total number of incomplete prior-approval manufacturing supplements was 13. This new process may allow for earlier distribution of animal drugs made with CMC changes.
- **Develop a New Bioequivalence Submission Process.** Progress is being made on the QbR for blood-level bioequivalence submissions and will be available in the CVM’s

eSubmitter tool when completed. The QbR for blood level bioequivalence data submissions is still in development.



**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

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