

# FY 2012

## 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 the Food and Drug Administration's (FDA) fiscal year (FY) 2012 Performance Report to Congress for the Animal Generic Drug User Fee Act (AGDUFA). On August 14, 2008, AGDUFA was signed into law. AGDUFA amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) by authorizing the first generic animal drug user fee program for FY 2009 through FY 2013. AGDUFA follows the Animal Drug User Fee Act (ADUFA) model and also is similar to the Prescription Drug User Fee Act (PDUFA) program.

This report marks the fourth year of FDA performance review under AGDUFA and finalizes performance results for FY 2010 and FY 2011, the second and third years of AGDUFA. This report also presents FDA's preliminary accomplishments for FY 2012. It is my pleasure to report that FDA exceeded all performance goals for FY 2010 and FY 2011. FDA also met review-time goals for all FY 2012 cohort submissions reviewed or due for review by September 30, 2012. With reviews pending within the goal deadlines, FDA is on track to exceed all performance goals for FY 2012.

Each year under AGDUFA, the number of days to meet the review-time goals is decreased while the overall performance goal level of 90 percent of reviews is maintained. FDA agreed to these increasingly challenging goals as part of our commitment to improve the efficiency, quality, and predictability of the generic new animal drug review process. We look forward to the improvements in the generic new animal drug review process that AGDUFA will make possible in the coming years.

The report that follows presents FDA's accomplishments for FY 2012, the fourth year operating under AGDUFA.

Margaret A. Hamburg, M.D.  
Commissioner of Food and Drugs

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## ***Executive Summary***

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On August 14, 2008, AGDUFA was signed into law. AGDUFA amends the FD&C Act by authorizing the first generic animal drug user fee program and provides FDA with resources to enhance the performance of the generic new animal drug review process. In exchange for this authority, under AGDUFA, FDA agreed to pursue a comprehensive set of review performance goals and commitments to improve the timeliness and predictability of generic new animal drug reviews. These review performance goals help to expedite the review of abbreviated new animal drug applications (ANADAs) and reactivations, manufacturing supplemental ANADAs, and generic investigational new animal drug (JINAD) submissions. Additionally, FDA agreed to meet increasingly challenging review performance goals for these submissions over five years (FY 2009 through FY 2013). This report presents FDA's implementation activities and accomplishments in FY 2012, the fourth year of AGDUFA.

### **FY 2012 Activities and Accomplishments**

FDA exceeded expectations in the implementation and completion of goals under AGDUFA in FY 2012. Key activities and accomplishments during FY 2012 included:

- FDA completed 227 reviews in FY 2012 related to AGDUFA performance goals, including 8 that were pending from FY 2010, 144 that were pending from FY 2011, and 75 that were submitted in FY 2012.
- FDA met review-time goals for all (8 of 8) FY 2010 submissions that were pending review within the goal deadlines at the start of FY 2012 that were acted on in FY 2012. FDA exceeded all AGDUFA performance goals for the FY 2010 cohort.
- FDA met review-time goals for almost all (143 of 144) FY 2011 submissions that were pending review within the goal deadlines at the start of FY 2012 that were acted on in FY 2012. FDA exceeded all AGDUFA performance goals for the FY 2011 cohort.
- FDA met review-time goals for all (75 of 75) FY 2012 cohort submissions reviewed and acted on as of September 30, 2012. FDA exceeded the FY 2012 performance goal for JINAD protocols. With submissions pending within the goal deadlines, FDA has the potential to exceed all other AGDUFA performance goals for the FY 2012 cohort.

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## **Overview of AGDUFA**

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On August 14, 2008, AGDUFA was signed into law. AGDUFA amends the FD&C Act by authorizing the first generic animal drug user fee program. AGDUFA provides FDA with additional funds to help enhance the performance of the generic new animal drug review process. The authorization of AGDUFA also helps to enable FDA's continued assurance that generic new animal drug products are safe and effective and consumers are provided a lower cost alternative to pioneer drugs.

In order to support the review of generic new animal drugs, AGDUFA authorizes FDA to collect user fees in three categories: applications, products, and sponsors. Under AGDUFA, FDA agreed to meet review performance goals for certain submissions over five years (FY 2009 through FY 2013). These review performance goals strive to expedite the review of ANADAs and reactivations, supplemental ANADAs, and JINAD submissions. AGDUFA follows the model used for ADUFA I and also is similar to the PDUFA program. 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, with the result that safe and effective new products will be more readily available. The guidelines and definitions below apply to FDA's implementation of AGDUFA.

**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.

**Refuse to File Applications.** Within 30 days of submission, FDA shall "refuse to file" an animal drug application, supplemental animal drug application, or their reactivation, which is determined to be insufficient on its face or otherwise 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 numbers or 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.

**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 this decision is made at the supplement/application level instead of the submission level. A sponsor also may voluntarily request that FDA withdraw approval of an application for reasons other than safety or effectiveness. FDA also may compel withdrawal of an approved application on safety or effectiveness grounds.

**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.

**Refuse to Accept.** As stated in Section 741(e) of the FD&C Act, an abbreviated application or an investigational submission for a generic new animal drug that is submitted by a person subject to fees is considered to be incomplete and can not be accepted for review until all fees owed by such person have been paid.

AGDUFA requires the Secretary for 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 due within 60 days of the end of the fiscal year and 2) a financial report within 120 days of the end of the fiscal year. This report is FDA's fourth annual performance report to Congress under AGDUFA. Information about AGDUFA, including the text of the HHS Secretary's July 30, 2008, commitment letter to Congress, is located in Appendix A. Additional information about AGDUFA is located at: [www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm](http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm).

## **AGDUFA: Progressively Expediting and Improving Review**

AGDUFA established increasingly challenging review performance goals for FDA that are phased in over a five-year period from FY 2009 through FY 2013. The AGDUFA performance goals lead to progressive, yearly performance improvements, with the on-time goal for review and action on submissions getting shorter each fiscal year. By the

final year of AGDUFA, FDA agrees to review and act on 90 percent of the following submission types within the specified times (number of days):

- Original ANADAs and reactivations within 270 days after the submission date.
- Administrative ANADAs (ANADAs submitted after all scientific decisions have been made during the JINAD process, i.e., prior to the submission of the original ANADAs) within 100 days after the submission date.
- Manufacturing supplemental ANADAs and reactivations within 270 days after the submission date.
- JINAD study submissions within 270 days after the submission date.
- JINAD protocol submissions (protocols without substantial data that FDA and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an ANADA or supplemental ANADA) within 100 days after the submission date.

The five-year progression of these goals is summarized in Appendix B.

## **FY 2012 Activities and Accomplishments**

FDA exceeded expectations in the implementation and completion of goals under AGDUFA in FY 2012. Key activities and accomplishments during FY 2012 included:

- **FY 2012 Review Activity.** FDA completed 227 reviews in FY 2012 related to AGDUFA performance goals. Over two-thirds (152 of 227) of the reviews completed were for submissions received in FY 2010 (8) and FY 2011 (144) and pending within the goal deadlines at the start of FY 2012. FDA completed almost all (226 of 227) reviews on time.
- **FY 2010 AGDUFA Cohort Performance.** In FY 2012, FDA reviewed and acted on all submissions received in FY 2010 that were pending review within the goal deadlines at the start of FY 2012. FDA exceeded the performance level for all (4 of 4) FY 2010 performance goals.
- **FY 2011 AGDUFA Cohort Performance.** In FY 2012, FDA reviewed and acted on all submissions received in FY 2011 that were pending review within the goal deadlines at the start of FY 2012. FDA exceeded the performance level for all (4 of 4) FY 2011 performance goals.
- **FY 2012 AGDUFA Cohort Performance.** Preliminary performance results indicate that FDA met all (75 of 75) review-time goals for submissions that were acted on for the FY 2012 cohort. FDA exceeded the FY 2012 performance goal for JINAD protocols. With FY 2012 submissions still pending action as of September 30, 2012, FDA has the potential to exceed all other FY 2012 performance goals. FDA will update FY 2012 performance results in the

FY 2013 AGDUFA Performance Report to reflect the outcome of these pending actions.

## **Review Performance 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 on-time review performance for actions completed or due for completion in FY 2012, regardless of when they were submitted. This report also updates FDA's final performance for the FY 2010 and FY 2011 cohorts and presents FDA's preliminary performance with respect to performance goals for the FY 2012 cohort that were received early enough to be reviewed or due for review.

**On-Time Review of AGDUFA Applications.** FDA on-time review performance is presented for each application or submission type to provide an indication of how FDA is performing within a given fiscal year. On-time review performance in a given fiscal year affects multiple years of performance goals because in any given fiscal year, reviews are due and completed for submissions pending from previous fiscal years along with submissions that are due and completed within the current fiscal year. This report provides a snapshot of on-time review performance for AGDUFA reviews completed or due for completion during FY 2012, regardless of the year of submission. Included are FY 2010 and FY 2011 submissions that were pending within the goal deadlines at the beginning of FY 2012, and FY 2012 submissions that were received early enough to be reviewed or due for review.

**AGDUFA Performance Goals.** AGDUFA review-time goals for FY 2010 through FY 2012 range from 105 days to 680 days. To meet AGDUFA performance goals, FDA must meet review-time goals at least 90 percent of the time for a defined group of applications and submissions. FDA reports on the performance goal results for each fiscal year cohort (as defined from October 1 and continuing to September 30 of the following year). For applications and submissions received too late to be reviewed by the end of the fiscal year, these applications and submissions will be reported on after FDA takes action, or the goal review-time period expires (pending overdue), whichever comes first. When determining FDA performance, 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.

Performance goal results presented in this report are for FY 2010, FY 2011, and FY 2012 cohort submissions that were acted on or pending overdue as of September 30, 2012. Final FY 2010 and FY 2011 performance results are presented in this report based on reviews in FY 2010, FY 2011, and FY 2012. FDA will report on FY 2012 cohort submissions that are acted on or overdue as of September 30, 2013, in the FY 2013 AGDUFA Performance Report with final FY 2012 performance goal results reported in the FY 2014 AGDUFA Performance Report.

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## ***On-Time Review Performance for FY 2012***

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This section summarizes FDA's on-time review performance for actions completed or due for completion in FY 2012, regardless of the year of submission. On-time review performance provides a snapshot of FDA's overall on-time review performance for the given fiscal year. On-time review performance is based on how well FDA met review-time goals during the fiscal year and provides an indication of how well FDA is performing during that fiscal year. However, it does not provide performance with respect to meeting or exceeding AGDUFA performance goals. AGDUFA performance goals are based on the fiscal year cohort of submission and combine on-time review performance with FDA commitments to meet specified performance goal levels. These goals are presented in the next section.

FDA can now report:

- FDA reviewed almost all (226 of 227) reviews completed (or due for completion) during FY 2012 on time. Over three-fifths (144 of 227) of reviews completed were for submissions received in FY 2011 and pending within the goal deadlines at the start of FY 2012.
- Original ANADAs and reactivations accounted for over one-tenth (25 of 227) of reviews completed in FY 2012.
- No administrative ANADAs were filed in FY 2009, FY 2010, FY 2011, and FY 2012.
- Manufacturing supplemental ANADAs and reactivations accounted for two-thirds (150 of 227) of reviews completed in FY 2012.
- JINAD studies (37) and JINAD protocols (15) accounted for over one-fifth (52 of 227) of reviews completed in FY 2012.

**Reviews Completed or Due for Completion During FY 2012\***

<b>Application/Submission Type</b>	<b>FY 2010 Cohort On Time / Reviewed</b>	<b>FY 2011 Cohort On Time / Reviewed</b>	<b>FY 2012 Cohort On Time / Reviewed</b>	<b>Total On Time / Reviewed</b>	<b>Total Percent On Time<sup>†</sup></b>
Original ANADAs and Reactivations	2 / 2	16 / 16	7 / 7	25 / 25	<b>100%</b>
Administrative ANADAs	0 / 0	0 / 0	0 / 0	0 / 0	--
Manufacturing Supplemental ANADAs and Reactivations	4 / 4	100 / 100	46 / 46	150 / 150	<b>100%</b>
JINAD Studies	2 / 2	20 / 20	15 / 15	37 / 37	<b>100%</b>
JINAD Protocols	0 / 0	7 / 8	7 / 7	14 / 15	<b>93%</b>
<b>Total</b>	<b>8 / 8</b>	<b>143 / 144</b>	<b>75 / 75</b>	<b>226 / 227</b>	<b>99%</b>

\* Includes reviews that were completed (on time or past the goal) and submissions pending action but overdue.

<sup>†</sup> Percentages reflect FDA's overall on-time review performance during FY 2012 and do not provide performance with respect to meeting or exceeding AGDUFA performance goals.

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## **Report on FY 2010 through FY 2012 AGDUFA Performance Goal Cohorts**

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This section summarizes performance reported by the year submissions were filed, unlike the previous section that summarized performance for actions completed or due for completion in FY 2012, regardless of the year when submissions were filed. This report finalizes FY 2010 and FY 2011 review performance and describes FDA's review performance in FY 2012 for all AGDUFA performance goals and commitments completed as of September 30, 2012. 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 goals are the targeted time period identified in number of days for when individual submissions are to be acted on. An on-time review indicates that FDA completed action within the number of days specified by the review-time goal.
- Percent on time refers to the percent 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 FDA's performance, and whether FDA met or exceeded the AGDUFA performance goal.
- 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.
- Review performance statistics are based on a fiscal year 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. This is because, as time passes, FDA completes work on more submissions in a receipt cohort. 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 cohort.

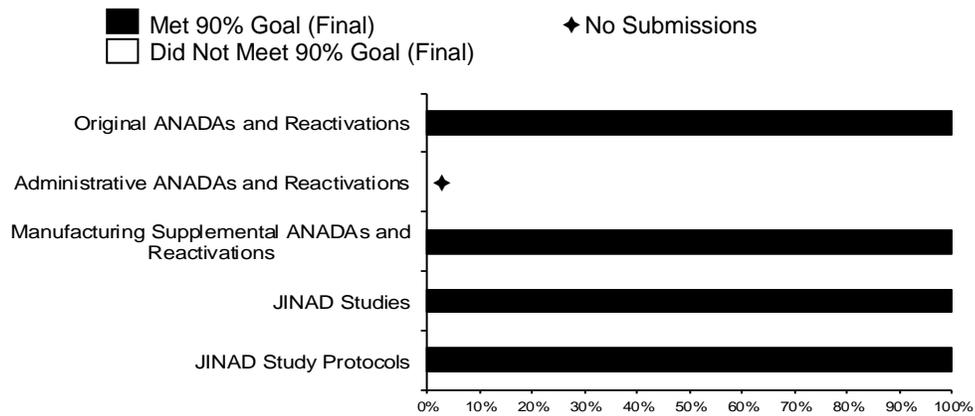
- Performance data are available on only some applications and submissions received and acted on during FY 2012. For submissions with a review-time goal that is shorter, for example, a 105-day review-time goal, individual review performance data may be available for the majority of the cohort. When this happens, final performance may be available or preliminary review performance data may be a valid indicator of overall goal performance. However, for submission categories with a longer review-time goal, for example, a review-time goal of 500 days, early review performance data are usually limited.
- The workload count for FY 2012 includes all applications and submissions received in the last month of FY 2012 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.
- Applications and submissions that FDA identified as withdrawn, and reviews that were stop review (applies to JINAD submissions only), are not included in the statistics used to measure performance. These applications and submissions are noted, however, in the relevant workload narratives and footnotes for performance goals.

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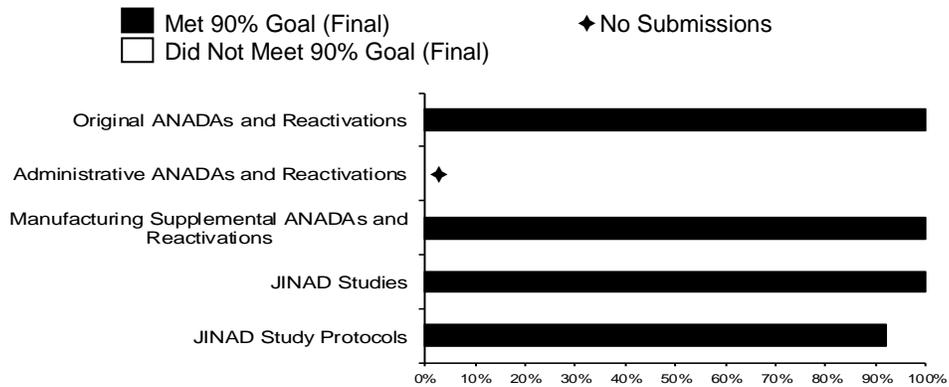
## Review Performance Goals At-A-Glance: FY 2010 through FY 2012

The tables below summarize FDA’s review performance for FY 2010, FY 2011, and FY 2012 AGDUFA applications and submissions.

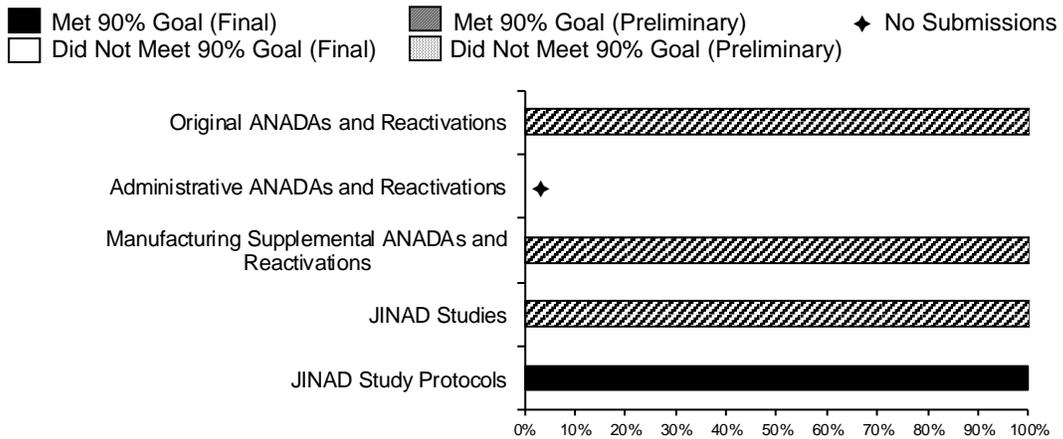
**FY 2010 Performance.** Final review performance is now available to report for the FY 2010 cohort. FDA exceeded performance for all FY 2010 AGDUFA review performance goals.



**FY 2011 Performance.** Final review performance is now available to report for the FY 2011 cohort. FDA exceeded performance for all FY 2011 AGDUFA review performance goals.



**FY 2012 Performance.** Preliminary on-time performance results indicate FDA exceeded the FY 2012 performance goal for JINAD protocols and is exceeding the performance level for all other FY 2012 performance goals. With reviews pending within the goal deadlines as of September 30, 2012, FDA will update FY 2012 performance for each goal area in the FY 2013 AGDUFA Performance Report.



## ***ANADAs and Reactivations***

### **Goal: Review and act on original ANADAs and reactivations and administrative ANADAs**

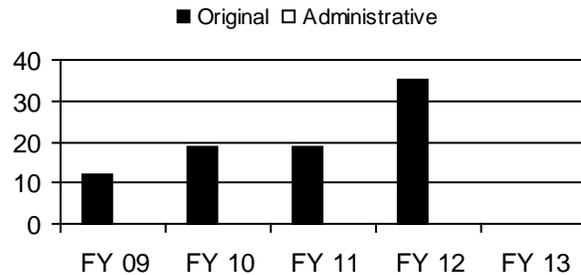
The table below summarizes the review-time and performance goals for original ANADAs and reactivations and administrative ANADAs. Over the five-year period defined by AGDUFA, the number of review days is incrementally reduced for each type of submission while the goal of reviewing 90 percent of submissions remains constant.

Application Type	Review-Time Goal (Days)					Performance Goal
	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	
Original ANADAs and Reactivations	700	680	500	380	270	90% on time
Administrative ANADAs	120	115	110	105	100	

### ***Workload***

The number of original ANADAs and reactivations filed in FY 2012 increased and reached a 4-year high. No administrative ANADAs were filed in FY 2009, FY 2010, FY 2011, and FY 2012 (see corresponding graph and table).

**Original ANADAs and Reactivations and Administrative ANADAs Filed**



**Original ANADAs and Reactivations and Administrative ANADAs Filed**

Type	FY 09	FY 10	FY 11	FY 12	FY 13
Original ANADAs and Reactivations	12	19	19	35*	--
Administrative ANADAs	0	0	0	0	--

\* A total of 36 submissions were received, but one received a refuse to accept.

## ***ANADAs and Reactivations***

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### ***Performance***

#### **FY 2010 Submissions**

FDA reviewed on time all (19 of 19) original ANADAs and reactivations submitted in FY 2010 (see table below). FDA exceeded the performance goal for original ANADAs and reactivations. FDA had no administrative ANADAs and reactivations submitted in FY 2010 and, therefore, no measurable performance activity for this goal.

ANADA and Reactivation Type	Filed	Performance Goal: Act on 90 Percent Within	Performance as of September 30, 2011				Final Performance		
			On Time	Overdue	Percent On Time	Pending Within Goal	On Time	Overdue	Percent On Time
Original	19	680 days	17	0	100%	2	19	0	100%
Administrative	0	115 days	0	0	--	0	0	0	--

#### **FY 2011 Submissions**

FDA reviewed on time all (19 of 19) original ANADAs and reactivations submitted in FY 2011 (see table below). FDA exceeded the performance goal for original ANADAs and reactivations. FDA had no administrative ANADAs and reactivations submitted in FY 2011 and, therefore, no measurable performance activity for this goal.

ANADA and Reactivation Type	Filed	Performance Goal: Act on 90 Percent Within	Performance as of September 30, 2011				Final Performance		
			On Time	Overdue	Percent On Time	Pending Within Goal	On Time	Overdue	Percent On Time
Original	19	500 days	3	0	100%	16	19	0	100%
Administrative	0	110 days	0	0	--	0	0	0	--

## ***ANADAs and Reactivations***

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### **FY 2012 Submissions**

As of September 30, 2012, performance data were available for 7 of 35 original ANADAs and reactivations, and FDA met the review-time goal for all submissions (see table below). With 28 submissions pending action within the goal deadline, FDA has the potential to exceed the performance goal. FDA had no administrative ANADAs and reactivations submitted in FY 2012 and, therefore, no measurable performance activity for this goal.

<b>ANADA and Reactivation Type</b>	<b>Filed</b>	<b>Performance Goal: Act on 90 Percent Within</b>	<b>Performance as of September 30, 2012</b>			
			<b>On Time</b>	<b>Overdue</b>	<b>Percent On Time</b>	<b>Pending Within Goal</b>
Original	35*	380 days	7	0	100%	28
Administrative	0	105 days	0	0	--	0

\* A total of 36 submissions were received, but one received a refuse to accept.

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## ***Manufacturing Supplemental ANADAs and Reactivations***

### **Goal: Review and act on manufacturing supplemental ANADAs and reactivations**

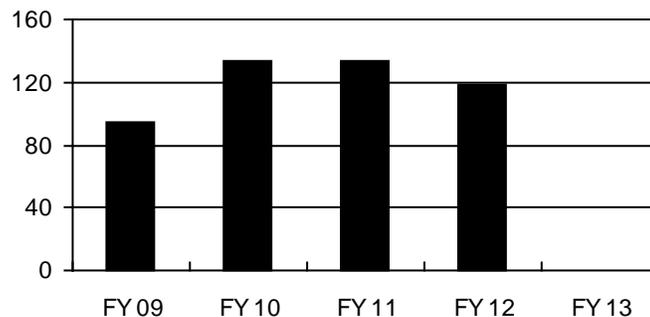
The table below summarizes the review-time and performance goals for manufacturing supplemental ANADAs and reactivations. Over the five-year period defined by AGDUFA, the number of review days is incrementally reduced for each type of submission while the goal of reviewing 90 percent of submissions remains constant.

Application Type	Review-Time Goal (Days)					Performance Goal
	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	
Manufacturing Supplemental ANADAs and Reactivations	600	570	420	340	270	90% on time

### ***Workload***

The number of manufacturing supplemental ANADAs and reactivations filed in FY 2012 decreased from the highest levels reached in FY 2010 and FY 2011 (see corresponding graph and table).

**Manufacturing Supplemental ANADAs and Reactivations Filed**



**Manufacturing Supplemental ANADAs and Reactivations Filed**

Type	FY 09	FY 10	FY 11	FY 12	FY 13
Manufacturing Supplemental ANADAs and Reactivations	94	134	134*	118†	--

\* The FY 2011 number was changed to reflect updates to data presented in the FY 2011 AGDUFA Performance Report. A total of 142 submissions were received, but eight were supplement withdrawn.

† A total of 127 submissions were received, but two were application withdrawn and seven were supplement withdrawn.

## ***Manufacturing Supplemental ANADAs and Reactivations***

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### ***Performance***

#### **FY 2010 Submissions**

FDA reviewed on time all (134 of 134) manufacturing supplemental ANADAs and reactivations submitted in FY 2010 (see table below). FDA exceeded the performance goal for manufacturing submissions.

Supplemental ANADA and Reactivation Type	Filed	Performance Goal: Act on 90 Percent Within	Performance as of September 30, 2011				Final Performance		
			On Time	Overdue	Percent On Time	Pending Within Goal	On Time	Overdue	Percent On Time
Manufacturing	134	570 days	130	0	100%	4	134	0	100%

#### **FY 2011 Submissions**

FDA reviewed on time all (134 of 134) manufacturing supplemental ANADAs and reactivations submitted in FY 2011 (see table below). FDA exceeded the performance goal for manufacturing submissions.

Supplemental ANADA and Reactivation Type	Filed	Performance Goal: Act on 90 Percent Within	Performance as of September 30, 2011				Final Performance		
			On Time	Overdue	Percent On Time	Pending Within Goal	On Time	Overdue	Percent On Time
Manufacturing	134*	420 days	34	0	100%	100 <sup>†</sup>	134	0	100%

\* The FY 2011 number was changed to reflect updates to data presented in the FY 2011 AGDUFA Performance Report. A total of 142 submissions were received, but eight were supplement withdrawn.

<sup>†</sup> The FY 2011 number was changed to reflect updates to data presented in the FY 2011 AGDUFA Performance Report.

## ***Manufacturing Supplemental ANADAs and Reactivations***

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### **FY 2012 Submissions**

As of September 30, 2012, performance data were available for 46 of 118 manufacturing supplemental ANADAs and reactivations, and FDA met the review-time goal for all submissions (see table below). With 72 submissions pending action within the goal deadline, FDA has the potential to exceed the performance goal.

<b>Supplemental ANADA and Reactivation Type</b>	<b>Filed</b>	<b>Performance Goal: Act on 90 Percent Within</b>	<b>Performance as of September 30, 2012</b>			
			<b>On Time</b>	<b>Overdue</b>	<b>Percent On Time</b>	<b>Pending Within Goal</b>
Manufacturing	118*	340 days	46	0	100%	72

\* A total of 127 submissions were received, but two were application withdrawn and seven were supplement withdrawn.

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## JINAD Submissions

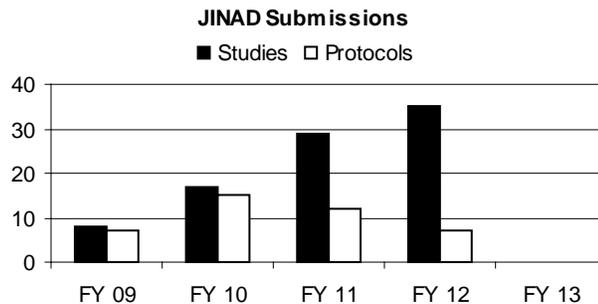
### Goal: Review and act on JINAD studies and protocol submissions

The table below summarizes the review-time and performance goals for JINAD studies and JINAD protocols. Over the five-year period defined by AGDUFA, the number of review days is incrementally reduced for each type of submission while the goal of reviewing 90 percent of submissions remains constant.

Submission Type	Review-Time Goal (Days)					Performance Goal
	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	
JINAD Studies	700	680	500	380	270	90% on time
JINAD Protocols	400	390	290	190	100	

### Workload

JINAD studies submitted in FY 2012 increased and reached a four-year high. JINAD protocols submitted in FY 2012 decreased to the same level as FY 2009 (see corresponding graph and table).



**JINAD Submissions**

Type	FY 09	FY 10	FY 11	FY 12	FY 13
JINAD Studies	8	17	29*	35‡	--
JINAD Protocols	7	15	12†	7§	--

\* The FY 2011 number was changed to reflect updates to data presented in the FY 2011 AGDUFA Performance Report. A total of 31 submissions were received, but one was stop review and one was refuse to review.

† The FY 2011 number was changed to reflect updates to data presented in the FY 2011 AGDUFA Performance Report. A total of 11 submissions were reported, with one submission added that was previously not reported due to an administrative error.

‡ A total of 37 submissions were received, but one was refuse to accept and one was file no reply.

§ A total of nine submissions were received, but two were stop review.

## JINAD Submissions

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### Performance

#### FY 2010 Submissions

FDA reviewed on time all (17 of 17) JINAD studies and all (15 of 15) JINAD protocols submitted in FY 2010 (see table below). FDA exceeded the performance goal for JINAD studies and JINAD protocols.

JINAD Submission Type	Filed	Performance Goal: Act on 90 Percent Within	Performance as of September 30, 2011				Final Performance		
			On Time	Overdue	Percent On Time	Pending Within Goal	On Time	Overdue	Percent On Time
Studies	17	680 days	15	0	100%	2	17	0	100%
Protocols	15	390 days	15	0	100%	0	15	0	100%

#### FY 2011 Submissions

FDA reviewed on time all (29 of 29) JINAD studies and almost all (11 of 12) JINAD protocols submitted in FY 2011 (see table below). FDA exceeded the performance goal for JINAD studies and JINAD protocols.

JINAD Submission Type	Filed	Performance Goal: Act on 90 Percent Within	Performance as of September 30, 2011				Final Performance		
			On Time	Overdue	Percent On Time	Pending Within Goal	On Time	Overdue	Percent On Time
Studies	29*	500 days	9	0	100%	20 <sup>†</sup>	29	0	100%
Protocols	12 <sup>‡</sup>	290 days	4	0	100%	8 <sup>§</sup>	11	1	92%

\* The FY 2011 number was changed to reflect updates to data presented in the FY 2011 AGDUFA Performance Report. A total of 31 submissions were received, but one was stop review and one was refuse to review.

<sup>†</sup> The FY 2011 number was changed to reflect updates to data presented in the FY 2011 AGDUFA Performance Report.

<sup>‡</sup> The FY 2011 number was changed to reflect updates to data presented in the FY 2011 AGDUFA Performance Report. A total of 11 submissions were reported with one submission added that was previously not reported due to an administrative error.

<sup>§</sup> The FY 2011 number was changed to reflect updates to data presented in the FY 2011 AGDUFA Performance Report.

## **JINAD Submissions**

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### **FY 2012 Submissions**

As of September 30, 2012, performance data were available for 15 of 35 JINAD studies, and FDA met the review-time goal for all submissions (see table below). Performance data were available for 7 of 7 JINAD protocols, and FDA met the review-time goal for all submissions. With 20 JINAD studies pending action within the goal deadline, FDA has the potential to exceed the performance goal. FDA exceeded the performance goal for JINAD protocols.

JINAD Submission Type	Filed	Performance Goal: Act on 90 Percent Within	Performance as of September 30, 2012			
			On Time	Overdue	Percent On Time	Pending Within Goal
Studies	35*	380 days	15	0	100%	20
Protocols	7†	190 days	7	0	100%	0

\* A total of 37 submissions were received, but one was refuse to accept and one was file no reply.

† A total of nine submissions were received, but two were stop review.

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## **APPENDICES**

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### **Appendix A: Commitment Letter from HHS Secretary to Congress**

#### **THE SECRETARY OF HEALTH AND HUMAN SERVICES**

WASHINGTON, DC, July 30, 2008

The Honorable Edward M. Kennedy  
Chairman  
Committee on Health, Education, Labor and Pensions  
United States Senate  
Washington, DC 20510

Dear Mr. Chairman:

I am writing to formally transmit the agreements on the goals and procedures for the reauthorization of the Animal Drug User Fee Act and new authorization for Animal Generic Drug User Fees. These documents incorporate the agreement made between the animal drug industry and FDA and contain the goals for the review of animal drug applications over the FY 2009 through FY 2013 period. These goals and procedures are a companion to the authorizing legislation reauthorizing the animal drug user fees and enacting new animal generic drug fees and they represent the commitment of the administration to apply the user fees authorized by Congress towards the outlined goals and procedures. We appreciate your leadership and considerable efforts of your committee to make it possible to reauthorize the important animal drug user fee program and enact a corresponding user fee program for generic animal drugs.

Sincerely,

MICHAEL O. LEAVITT

Attachments

## **Animal Generic Drug User Fee Act Performance Goals and Procedures**

The goals and procedures of the FDA Center for Veterinary Medicine (CVM) as agreed to under the "Animal Generic Drug User Fee Act of 2008" are summarized as follows:

### **Five-Year Goals (to be implemented by September 30, 2013)**

1. Review and act on 90 percent of non-administrative original abbreviated new animal drug applications (ANADAs) and reactivations of such applications within 270 days after the submission date.
2. Review and act on 90 percent of administrative ANADAs (ANADAs submitted after all scientific decisions have been made in the JINAD process, i.e., prior to the submission of the ANADA) within 100 days after the submission date.
3. Review and act on 90 percent of manufacturing supplemental ANADAs and reactivations of such supplemental applications within 270 days after the submission date.
4. Review and act on 90 percent of generic investigational new animal drug (JINAD) study submissions within 270 days after the submission date.
5. Review and act on 90 percent of JINAD submissions consisting of protocols without substantial data, that the agency and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an ANADA or supplemental ANADA, within 100 days after the submission date.

For the application/submission goals above, 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 which 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 ("incomplete letter"). Within 30 days of submission, FDA shall refuse to file an original or supplemental ANADA, or their reactivation, which is determined to be insufficient on its face or otherwise of unacceptable quality for review upon initial inspection as per 21 CFR 514.110. Thus, the agency will refuse to file an application containing numbers or types of errors, or flaws in the development plan, sufficient to cause the quality of the entire submission to be questioned to the extent that it cannot reasonably be reviewed. Within 60 days of submission, FDA will refuse to review a JINAD submission which 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 file an application or to refuse to review a submission as described above will result in the application or submission not being entered into the cohort upon which the relevant user fee goal is based. The agency will keep a record of the numbers and types of such refusals and include them in its annual performance report.

FDA may request minor amendments to original or supplemental ANADAs and JINAD submissions during its review of the application or submission. At its discretion, the agency may extend an internal due date (but not a user fee goal) to allow for the complete review of an application or submission for which a minor amendment is requested. If a pending application is amended with significant changes, the amended application may be considered resubmitted, and thereby effectively resetting the clock to the date FDA received the amendment. The same policy applies for JINAD submissions.

Sponsors are not required to submit study protocols for review. However, for each voluntarily submitted protocol for a study that the agency and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an original or supplemental ANADA, the agency will issue a complete action letter providing comments resulting from a complete review of the protocol. The complete action letter will be as detailed as possible considering the quality and level of detail of the protocol submission; will include a succinct assessment of the protocol; and will state whether the agency agrees, disagrees, or lacks sufficient information to reach a decision that the protocol design, execution plans, and data analyses are adequate to achieve the objectives of the study. If the agency determines that a protocol is acceptable, this represents an agreement that the data generated by the protocol can be used to support a safety or effectiveness decision regarding the subject new animal drug. The fundamental agreement is that having agreed to the design, execution, or analyses proposed in protocols reviewed under this process, the agency will not later alter its perspectives on the issues of design, execution, or analyses unless the agency issues a written order that a substantiated scientific requirement essential to the assessment of the study appeared after the agency's protocol assessment, or public or animal health concerns unrecognized at the time of protocol assessment under this process are evident.

The agency and the regulated industry agree that the use of both formal meetings (e.g., presubmission conferences) and informal communication by both parties is critical to ensure high submission quality such that performance goals can be achieved.

The term "submission date" is understood to mean the date the FDA Center for Veterinary Medicine (CVM) Document Control Unit (DCU) receives an application or submission. DCU date stamps an application or submission on the day of receipt.

### **Work Queue Review Procedures**

The agency will review all submissions in accordance with procedures for working within a queue. An application/submission that is not reviewed within the applicable Application/Submission Goal time frame (noted below) will be reviewed with the highest possible priority among those pending.

## **Interim Application/Submission Goals for Each Fiscal Year Under AGDUFA**

**FY 2009** - FDA agreed to review and act on 90 percent of:

- Original (non-administrative) ANADAs and reactivations of ANADAs within 700 days of the submission date.
- Administrative ANADAs (ANADAs submitted after all scientific decisions have been made in the JINAD process, i.e., prior to the submission of the ANADA) within 120 days after the submission date.
- Manufacturing supplemental ANADAs and reactivations of supplemental ANADAs within 600 days after the submission date.
- Generic investigational new animal drug (JINAD) study submissions within 700 days after the submission date.
- JINAD submissions consisting of protocols without substantial data that FDA and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an ANADA or supplemental ANADA within 400 days after the submission date.

**FY 2010** - FDA agreed to review and act on 90 percent of:

- Original (non-administrative) ANADAs and reactivations of ANADAs within 680 days of the submission date.
- Administrative ANADAs (ANADAs submitted after all scientific decisions have been made in the JINAD process, i.e., prior to the submission of the ANADA) within 115 days after the submission date.
- Manufacturing supplemental ANADAs and reactivations of supplemental ANADAs within 570 days after the submission date.
- Generic investigational new animal drug (JINAD) study submissions within 680 days after the submission date.
- JINAD submissions consisting of protocols without substantial data that FDA and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an ANADA or supplemental ANADA within 390 days after the submission date.

**FY 2011**- FDA agreed to review and act on 90 percent of:

- Original (non-administrative) ANADAs and reactivations of ANADAs within 500 days of the submission date.
- Administrative ANADAs (ANADAs submitted after all scientific decisions have been made in the JINAD process, i.e., prior to the submission of the ANADA) within 110 days after the submission date.
- Manufacturing supplemental ANADAs and reactivations of supplemental ANADAs within 420 days after the submission date.
- Generic investigational new animal drug (JINAD) study submissions within 500 days after the submission date.
- JINAD submissions consisting of protocols without substantial data that FDA and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an ANADA or supplemental ANADA within 290 days after the submission date.

**FY 2012** - FDA agreed to review and act on 90 percent of:

- Original (non-administrative) ANADAs and reactivations of ANADAs within 380 days of the submission date.
- Administrative ANADAs (ANADAs submitted after all scientific decisions have been made in the JINAD process, i.e., prior to the submission of the ANADA) within 105 days after the submission date.
- Manufacturing supplemental ANADAs and reactivations of supplemental ANADAs within 340 days after the submission date.
- Generic investigational new animal drug (JINAD) study submissions within 380 days after the submission date.
- JINAD submissions consisting of protocols without substantial data that FDA and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an ANADA or supplemental ANADA within 190 days after the submission date.

**FY 2013** - FDA agreed to review and act on 90 percent of:

- Original (non-administrative) ANADAs and reactivations of ANADAs within 270 days of the submission date.
- Administrative ANADAs (ANADAs submitted after all scientific decisions have been made in the JINAD process, i.e., prior to the submission of the ANADA) within 100 days after the submission date.
- Manufacturing supplemental ANADAs and reactivations of supplemental ANADAs within 270 days after the submission date.
- Generic investigational new animal drug (JINAD) study submissions within 270 days after the submission date.
- JINAD submissions consisting of protocols without substantial data that FDA and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an ANADA or supplemental ANADA within 100 days after the submission date.

### **Amending Similar Applications and Submissions**

The agency and regulated industry agree that applications and submissions to the agency will be complete and of sufficient quality to allow the agency's complete and timely review. The agency will refuse to file poor quality and incomplete applications and submissions rather than allowing them to serve as "placeholders" in the review queue that are subsequently amended to add the missing or inadequate portions.

The agency recognizes that there are circumstances in which a controlled amendment process can make the review of similar, pending submissions more efficient, without compromising the sponsor's responsibility for high quality submissions. Thus, starting no later than FY 2012, if the agency requests an amendment to a non-administrative original ANADA, manufacturing supplemental ANADA, JINAD study submission, or a JINAD protocol submission (a "CVM initiated amendment"), or issues an incomplete letter for such an application or submission, a sponsor may request to amend other, similar applications or submissions it has pending with the agency ("sponsor-initiated amendment(s)") in accordance with the following criteria:

1. The amended information for these similar applications or submissions must be the same as in the CVM-requested amendment or incomplete letter; and
2. The amended information must not significantly change the pending application or submission; and
3. The amended information for these similar applications or submissions must be submitted no later than:
  - a. 120 days after the submission date for a pending non-administrative original ANADA, manufacturing supplemental ANADA, or JINAD study submission; or
  - b. 50 days after the submission date for a pending JINAD protocol submission

If the agency determines that the above criteria have been met, it will not change the user fee goal for a pending application or submission that has been amended by a sponsor-initiated amendment. If the above criteria have not been met, the agency may consider the application or submission resubmitted on the date of the sponsor-initiated amendment, thereby resetting the clock to the date FDA received the amendment.

## **Appendix B: Summary of AGDUFA Performance Goals**

The table below summarizes the AGDUFA performance goals for FY 2009 through FY 2013.

Activity	Performance Level	FDA Review Time (Days)				
		FY 09	FY 10	FY 11	FY 12	FY 13
Original ANADAs and reactivations of such applications	90%	700	680	500	380	270
Administrative ANADAs and reactivations	90%	120	115	110	105	100
Manufacturing supplemental ANADAs and reactivations of such supplemental applications	90%	600	570	420	340	270
JINAD study submissions	90%	700	680	500	380	270
JINAD submissions consisting of protocols, that the agency and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an animal drug application or supplemental animal drug application, without substantial data	90%	400	390	290	190	100

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



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

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