

# FY 2012

## **PERFORMANCE REPORT TO CONGRESS**

*for the*

## ***Animal 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's) Fiscal Year (FY) 2012 Performance Report to Congress for the Animal Drug User Fee Act (ADUFA). On August 14, 2008, the reauthorization of ADUFA for an additional five years was signed into law. With this reauthorization, the first five-year period (FY 2004 through FY 2008) of ADUFA is now referred to as ADUFA I, and the additional five-year period (FY 2009 through FY 2013) is referred to as ADUFA II.

This report marks the ninth year of FDA performance review under ADUFA and finalizes performance results for FY 2011, the third year of ADUFA II. This report also presents FDA's accomplishments for FY 2012. It is my pleasure to report that FDA exceeded all performance goals for 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.

A key improvement under ADUFA II is the "end-review amendment" (ERA) process that allows FDA reviewers to work with the drug sponsor to amend certain pending submissions. The ERA process allows us to decrease the number of review cycles, ultimately leading to a shorter time to approval. Improved communication early in the process has the greatest potential to reduce review cycles. The greatest effect of this new tool under ADUFA II has been with submissions of investigational new animal drug (INAD) studies and study protocols.

FDA looks forward to the continued success and significant improvements in the animal drug review process made achievable by ADUFA.

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

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## ***Executive Summary***

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ADUFA was signed into law in 2003, amending the Federal Food, Drug, and Cosmetic Act (FD&C Act) and providing FDA with new responsibilities, resources, and challenges. On August 14, 2008, the reauthorization of ADUFA, extending and broadening the original agreement through FY 2013, was signed into law. The reauthorization is referred to as ADUFA II.

Under ADUFA I, defined as the original ADUFA legislation and goals agreement that covers the period from FY 2004 to FY 2008, FDA agreed to pursue a comprehensive set of review performance goals to improve the timeliness and predictability of the review of new animal drug applications (NADAs) and investigational new animal drug (INAD) submissions. With the reauthorization of ADUFA for an additional five years, FDA's plans under ADUFA II (FY 2009 to FY 2013) are to enhance and further improve the review process via the following changes:

- Incorporating an “end-review amendment” (ERA) process to amend pending submissions to achieve a complete review decision sooner and reduce the number of review cycles.
- Developing an electronic submission tool that allows industry to submit drug applications electronically.
- Participating with industry in public workshops on mutually agreed-upon topics.
- Improving communications by enhancing the timeliness and predictability of foreign pre-approval inspections.

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

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

- FDA completed reviews of 747 submissions related to ADUFA performance goals, including 249 that were pending from FY 2011 and 498 that were submitted in FY 2012.
- FDA met review-time goals for almost all (247 of 249) 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 ADUFA performance goals for the FY 2011 cohort.

- FDA met almost all (497 of 498) review-time goals for FY 2012 cohort submissions reviewed and acted on as of September 30, 2012. With 185 reviews pending within the goal deadlines, FDA has the potential to exceed all ADUFA performance goals for the FY 2012 cohort.
- During FY 2012, FDA received a total of 95 ERAs in response to requests issued in FY 2011 and FY 2012. Of these, 19 were for INAD studies (16 related to the FY 2011 cohort and three related to the FY 2012 cohort), and 76 were for INAD study protocols (25 related to the FY 2011 cohort and 51 related to the FY 2012 cohort). With INAD study and study protocol submissions pending within the goal deadlines, additional ERAs are possible for FY 2012 cohort submissions.

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## **Overview of ADUFA**

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ADUFA I was signed into law on November 18, 2003. This law amended the FD&C Act and provided FDA with new responsibilities, resources, and challenges. On August 14, 2008, the reauthorization of ADUFA, extending and broadening the original agreement through FY 2013, was signed into law. The goal of ADUFA is to better serve animal and public health by providing additional funds to augment FDA resources devoted to “the process for review of new animal drug applications.”

In order to support the review of new animal drugs, ADUFA I and ADUFA II authorize FDA to collect user fees in four categories: applications, establishments, products, and sponsors. Under both ADUFA I and II, FDA agreed to meet performance goals for certain submissions over five years. These performance goals strive to expedite the review of NADAs, supplemental NADAs, and INAD submissions. The guidelines and definitions below apply to FDA’s implementation of ADUFA II.

**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 animal drug application, supplemental animal drug application, or investigational animal drug submission that either (1) approves an animal drug application or supplemental application or notifies a sponsor that an INAD submission is complete, or (2) sets forth in detail the specific deficiencies in such animal drug application, supplemental animal drug application, or investigational animal drug submission and, where appropriate, the actions necessary to place such an application, supplemental application, or 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 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 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 an INAD 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.

**File No Reply with Memo.** When FDA determines that a submission is filed without a reply to the sponsor but documentation is needed, FDA includes a review document (for example, a memorandum) in the administrative file to summarize what was included in the submission.

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

**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 may also voluntarily request that FDA withdraw approval of an application for reasons other than safety or effectiveness. FDA may also compel withdrawal of an approved application on safety or effectiveness grounds.

ADUFA II 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 ninth annual performance report and finalizes FY 2011 cohort performance data. FDA's initial progress in meeting ADUFA performance goals for FY 2012 also is summarized in this report. Information about the reauthorization of ADUFA, including the text of the HHS Secretary's July 30, 2008, commitment letter to Congress, is located in Appendix A. The ADUFA II reauthorization performance goals and procedures are located at: [www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm044941.html](http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm044941.html).

## **ADUFA I: Progressive Goal Setting Over Five Years**

ADUFA I established review performance goals for FDA, phased in over a five-year period. These performance goals ran from FY 2004 through FY 2008 and were intended to achieve progressive, yearly improvements in the process for review of submissions.

While the performance goal of reviewing 90 percent of submissions within specified review time frames remained constant over the FY 2004 through FY 2008 ADUFA I

period, the specified review time frames incrementally decreased over this period for all submission types. As a result, the FY 2008 review-time goals were met under ADUFA I and were for the shortest number of review days. These goals also were the most challenging for FDA to meet. ADUFA I expired on September 30, 2008.

## **ADUFA II: Enhancing the Process**

ADUFA II goals are based on ADUFA I FY 2008 review time frames. Appendix B provides a summary of the ADUFA II performance goals. In addition to the goals FDA agreed to as part of ADUFA II, the following enhancements to the program to reduce review cycles and improve communications during reviews were provided:

- An ERA process that enables FDA reviewers to work with the drug sponsor to amend pending submissions to achieve a complete review decision sooner. The intent of the ERA process is to significantly reduce the number of submission review cycles. This ERA process is explained in greater detail in Appendix C.
- Development of an electronic submission tool within 24 months of appropriated ADUFA funds that will enable industry to submit applications and submissions electronically and provide reviewers with the ability to evaluate submissions online.
- Joint participation between FDA and regulated industry in 10 public workshops by the end of FY 2013 on mutually agreed-upon topics.
- Improved communications by enhancing the timeliness and predictability of foreign pre-approval inspections. Sponsors may voluntarily submit an annual facilities list and notification 30 days prior to submitting an NADA, a supplemental NADA, or an INAD submission that informs FDA that the application or submission includes a foreign manufacturing facility.

## **FY 2012 Activities and Accomplishments**

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

- **FY 2012 Review Activity.** FDA completed 747 ADUFA reviews in FY 2012. One-third (249 of 747) of the reviews completed were for submissions that had been pending within the goal deadlines at the start of FY 2012. FDA completed almost all reviews (744 of 747) on time.
- **FY 2011 ADUFA Cohort Performance.** In FY 2012, FDA reviewed and acted on all applications and submissions received in FY 2011 that were pending review within the goal deadlines at the start of FY 2012. FDA exceeded all FY 2011 ADUFA II performance goals.

- **FY 2012 ADUFA Cohort Performance.** Preliminary performance results indicate that FDA met almost all (497 of 498) review-time goals defined under ADUFA II for applications and submissions that were acted on for the FY 2012 cohort. With FY 2012 submissions still pending action as of September 30, 2012, FDA has the potential to exceed all FY 2012 performance goals. FDA will update FY 2012 performance results in the FY 2013 ADUFA Performance Report to reflect the outcome of these pending actions.
- **Applying the ERA Process.** FDA used the ERA process to request additional information on 186 submissions associated with the FY 2011 and FY 2012 cohort. All (186 of 186) of the requests were related to INAD submissions. In response, ERAs were submitted to 96 percent (178 of 186) of the requests, and 93 percent (165 of 178) of the submissions with ERAs had their reviews end with a favorable outcome in only one review cycle.
- **Public Workshops.** FDA conducted its eighth workshop titled: “Antiparasitic Drug Use and Resistance in Ruminants and Equines.” The main purpose of the meeting was to explore and discuss ways in which antiparasitic drugs can be used, alone or in combination to maximize antiparasitic drug efficacy and minimize development of parasitic resistance in ruminant and equine species. FDA secured industry agreement on the topics for the two remaining workshops to be held in FY 2013.
- **Foreign Pre-approval Inspections.** In an effort to improve communications and enhance the timeliness and predictability of foreign pre-approval inspections during FY 2012, 6 of 19 sponsors affiliated with foreign facilities submitted annual facilities lists. Of the six sponsors submitting annual facilities lists, one submitted a 30-day prior notification. FDA completed 19 foreign inspections in FY 2011, with an average time of 142 days to complete all aspects of an inspection (e.g., preparation, communication with the foreign jurisdiction, and actual time in the facility). FDA also completed 12 foreign inspections in FY 2012, with an average time of 110 days to complete all aspects of an inspection.
- **Electronic Submission and Review.** With the release of FDA’s eSubmitter tool in 2011, FDA now receives over 50 percent of its regulatory submissions using the eSubmitter tool. These electronic submissions are coming from over 70 percent of the animal drug sponsors. Along with the eSubmitter submissions, the remaining incoming paper submissions are scanned and made electronic. By doing this, it permits these submissions (along with the eSubmitter submissions) to be reviewed and closed out using FDA’s electronic review environment. Since the implementation of this electronic submission and review environment, FDA has significantly improved its review efficiency for new animal drugs.

## **Review Performance Presented in This Report**

In any given year, FDA performance includes reviews of submissions pending from previous fiscal years along with submissions received during the current fiscal year. This report presents FDA on-time review performance for actions completed in FY 2012 regardless of when they were submitted. This report also presents FDA performance with respect to performance goals for the FY 2011 cohort (final) and the FY 2012 cohort (preliminary) that were received early enough to be reviewed or due for review.

**On-Time Review of ADUFA 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 the previous fiscal year along with submissions that are due and completed within the current fiscal year. This report provides a snapshot of on-time review performance for reviews completed or due for completion during FY 2012, regardless of the year of submission. Included are 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 during FY 2012.

**ADUFA Performance Goals.** ADUFA II review-time goals range from 60 days to 345 days. To meet ADUFA II performance goals, FDA must meet review-time goals at least 90 percent of the time for a defined group of applications and submissions. FDA annually reports on these performance goal results for each fiscal year cohort (as defined from October 1 to September 30 of the following year). Applications and submissions received too late to be reviewed by the end of a fiscal year will be reported on after FDA takes an 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.

Final performance goal results presented in this report are for FY 2011 cohort submissions and based on reviews in FY 2011 and FY 2012. Preliminary performance goal results presented in this report are for FY 2012 cohort submissions that had reviews completed or pending overdue in FY 2012. Final performance goal results for FY 2012 cohort submissions will be presented in the FY 2013 ADUFA Performance Report and will include reviews due to be completed in FY 2013.

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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 FDA's performance with respect to meeting or exceeding ADUFA performance goals. ADUFA 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 (744 of 747) reviews completed (or due for completion) during FY 2012 on time. One-third (249 of 747) of these reviews were for submissions received in FY 2011.
- Reviews of manufacturing supplemental NADAs and reactivations accounted for over two-fifths (335 of 747) of reviews completed in FY 2012.
- Reviews of INAD studies and ERAs to INAD studies made up just under one-third (239 of 747) of reviews completed in FY 2012.
- Reviews of INAD study protocols and ERAs to INAD study protocols accounted for just under one-fifth (147 of 747) of reviews completed in FY 2012.
- Reviews of original and administrative NADAs and reactivations accounted for less than three percent (20 of 747) of reviews completed in FY 2012.
- Reviews of non-manufacturing supplemental NADAs and reactivations made up less than one percent (6 of 747) of reviews completed in FY 2012.

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

<b>Application/Submission Type</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 NADAs and Reactivations	0 / 0	1 / 1	1 / 1	<b>100%</b>
ERAs for Original NADAs and Reactivations <sup>†</sup>	0 / 0	0 / 0	0 / 0	--
Administrative NADAs and Reactivations	0 / 1	17 / 18	17 / 19	<b>89%</b>
Non-manufacturing Supplemental NADAs and Reactivations	4 / 4	2 / 2	6 / 6	<b>100%</b>
ERAs for Non-manufacturing Supplemental NADAs and Reactivations <sup>†</sup>	0 / 0	0 / 0	0 / 0	--
Manufacturing Supplemental NADAs and Reactivations	110 / 110	225 / 225	335 / 335	<b>100%</b>
INAD Studies	81 / 81	139 / 139	220 / 220	<b>100%</b>
ERAs for INAD Studies	16 / 16	3 / 3	19 / 19	<b>100%</b>
INAD Study Protocols	8 / 9	56 / 56	64 / 65	<b>98%</b>
ERAs for INAD Study Protocols	28 / 28 <sup>‡</sup>	54 / 54 <sup>§</sup>	82 / 82	<b>100%</b>
<b>Totals</b>	<b>247 / 249</b>	<b>497 / 498</b>	<b>744 / 747</b>	<b>99%</b>

\* Includes reviews that were completed (on time or past the goal) and submissions still 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 ADUFA performance goals.

<sup>‡</sup> Includes three ERAs requested but not submitted and 25 ERAs requested and submitted.

<sup>§</sup> Includes three ERAs requested but not submitted and 51 ERAs requested and submitted.

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## ***Report on Final FY 2011 and Preliminary FY 2012 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 2011 review performance and describes FDA's review performance in FY 2012 for all ADUFA 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 NADAs and reactivations, supplemental NADAs and reactivations, and INAD submissions 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 ADUFA performance goal.
- Performance goals are the percent of total submissions, agreed to under ADUFA, where FDA is expected to meet the review-time goal for a given type of submission. ADUFA 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 FDA completes work on a greater percentage of a receipt cohort over time. 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.
- All applications and submissions received during FY 2011 were reviewed and acted on, or were past the goal date, as of September 30, 2012.

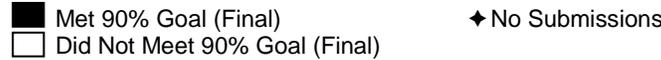
- Performance data are available on only some applications and submissions received and acted on during FY 2012. For submission types with a longer review-time goal, for example, 345 days, early review performance data are usually limited. For those submissions with a shorter review-time goal, for example, 60 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 within the goal deadline. The total number of review submissions when summed together equals the total number filed. For example, with respect to the FY 2012 INAD studies (for which performance is summarized in the table on page 19), FDA filed a total of 239 studies distributed across the three submission types: 1) no ERAs requested included 139 review actions completed on time, and 97 pending within the goal deadline for a total of 236; 2) ERAs requested but not submitted (none); and 3) ERAs requested and submitted included three on time, none overdue, and none pending within the goal deadline. The totals from these three submission types are summed together (236 plus 0 plus 3) to equal the total number of submissions filed (239).
- Minor Use or Minor Species (MUMS) conditional approvals are not counted as NADAs. Therefore, review performance on them is not presented in this report. The goal of MUMS is to encourage development of products for treatment of minor species or for treatment of animal diseases and conditions of major species that occur infrequently or in limited geographic areas.
- The workload count for FY 2012 includes all NADAs and INAD submissions received in the last month of FY 2012 as filed or submitted, respectively. FDA makes a filing decision within 30 days of receiving an NADA, or a proceed-to-review decision within 60 days of receiving an INAD submission, but calculates ADUFA review times from the original receipt of the application or submission.
- Applications and submissions that FDA identified as refused to file and reviews that were stopped at the request of the sponsor are not included in the statistics used to measure performance. However, these applications and submissions are noted in the relevant workload narratives and footnotes for performance goals.

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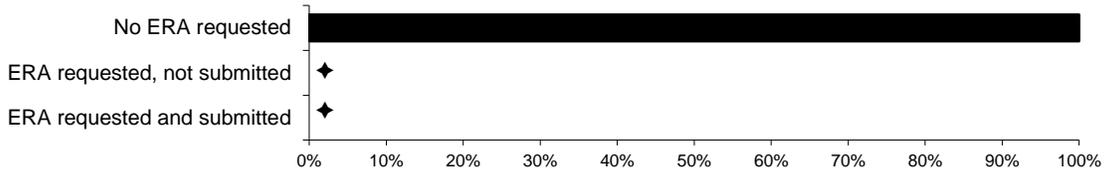
## Review Performance Goals At-A-Glance for FY 2011 and FY 2012

The graphs below summarize FDA's review performance for FY 2011 and FY 2012 cohort submissions.

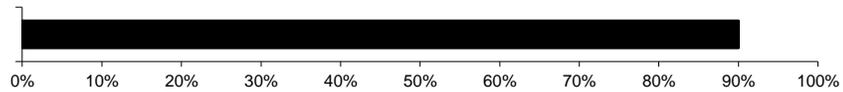
**FY 2011 Final Performance.** Final review performance is now available to report for the FY 2011 cohort. FDA exceeded performance for all FY 2011 ADUFA review performance goals.



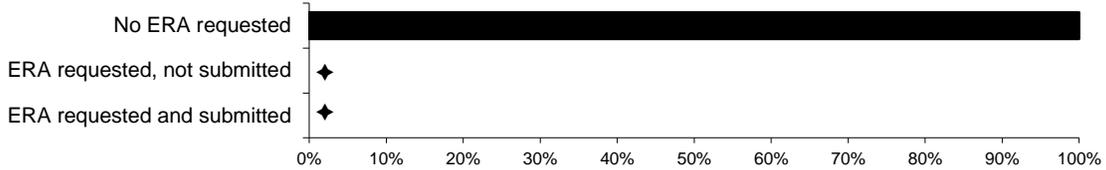
### Original NADAs and Reactivations



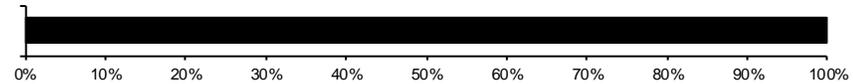
### Administrative NADAs and Reactivations



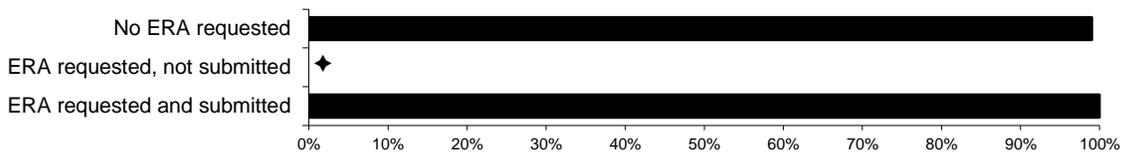
### Non-Manufacturing Supplemental NADAs and Reactivations



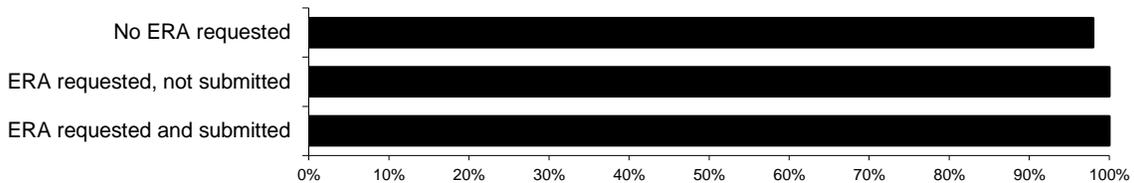
### Manufacturing Supplemental NADAs and Reactivations



### INAD Studies



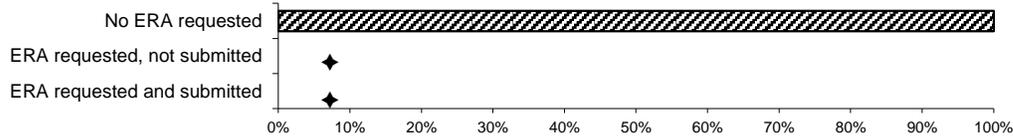
### INAD Study Protocols



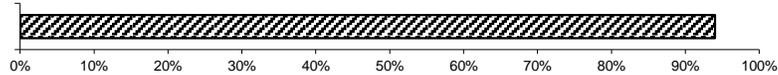
**FY 2012 Preliminary Performance.** Preliminary on-time performance results indicate FDA is exceeding the performance levels for all FY 2012 performance goals. With reviews pending within the goal deadlines as of September 30, 2012, FDA will update performance for each goal area in the FY 2013 ADUFA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

- ▨ Met 90% Goal (Preliminary)
- ◆ No Submissions
- Did Not Meet 90% Goal (Preliminary)

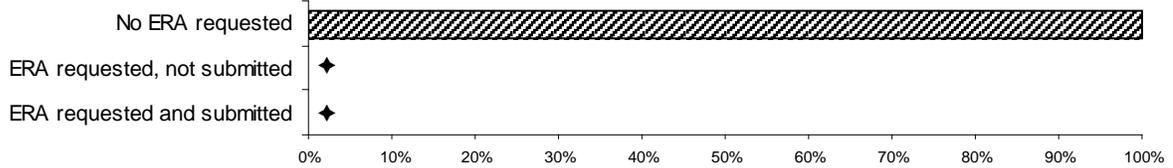
**Original NADAs and Reactivations**



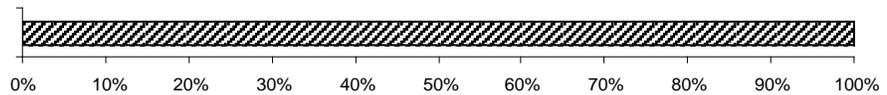
**Administrative NADAs and Reactivations**



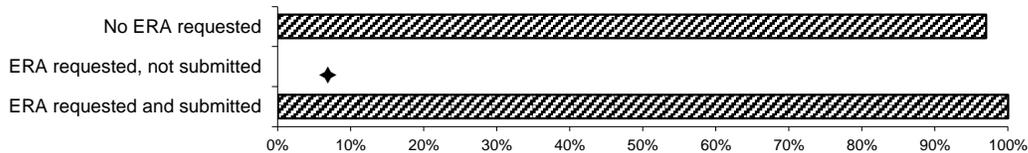
**Non-Manufacturing Supplemental NADAs and Reactivations**



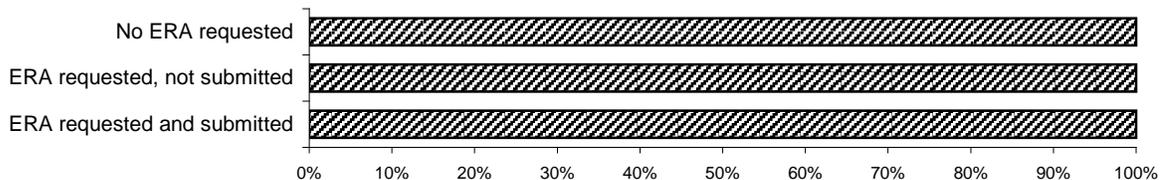
**Manufacturing Supplemental NADAs and Reactivations**



**INAD Studies**



**INAD Study Protocols**



Additional information in detail on individual goals follows.

## NADAs and Reactivations

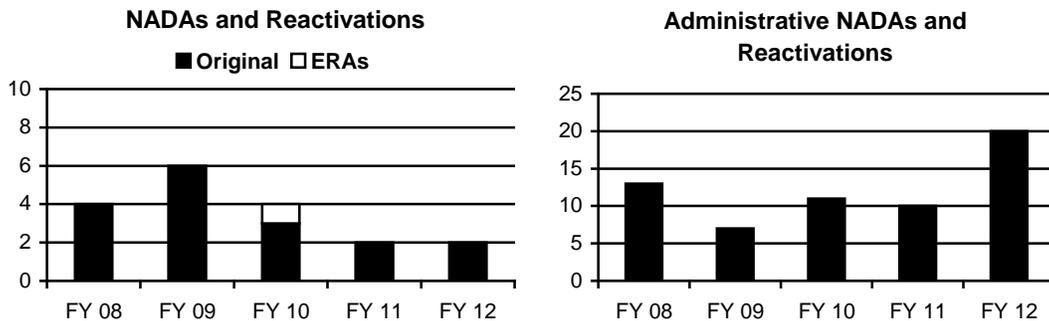
### Goal: Review and act on original and administrative NADAs and reactivations

The table below summarizes the review-time and performance goals for original and administrative NADAs and reactivations for ADUFA II and includes ERA review-time goals for original NADAs and reactivations. Performance goals are set at 90 percent of reviews on time.

Application Type	Review-Time Goal (Days) FY 2009 – FY 2013		Performance Goal
	No ERA Requested	ERA Requested	
Original NADAs and Reactivations	No ERA Requested	180	90% on time
	ERA Requested Not Submitted	220	
	ERA Requested And Submitted	345	
Administrative NADAs and Reactivations	60		

### Workload

The number of original NADAs filed in FY 2012 remained the same for the second consecutive year, staying at the lowest level in five years. The number of administrative NADAs filed increased in FY 2012 and reached a five-year high (see corresponding graphs and table below).



### NADAs and Reactivations Filed

Type	FY 08	FY 09	FY 10	FY 11	FY 12
Original NADAs and Reactivations	4	6	3	2	2
ERAs for Original NADAs and Reactivations	--*	0	1	0	0
Administrative NADAs and Reactivations	13	7	11	10	20

\* ERAs were not an option under ADUFA I.

## NADAs and Reactivations

### Performance

#### FY 2011 Submissions

FDA reviewed on time all (2 of 2) original NADAs and reactivations, and (9 of 10) administrative NADAs and reactivations submitted in FY 2011 (see table below). FDA exceeded the performance goals for original NADAs and reactivations and met the performance goal for administrative NADAs and reactivations.

NADA and Reactivation Type	Filed	Performance Goal		Performance as of September 30, 2011				Final Performance		
		ERA Status	Act on 90 Percent Within	On Time	Overdue	Percent On Time	Pending within Goal	On Time	Overdue	Percent On Time
Original	2	None Requested	180 days	2	0	100%	0	2	0	100%
		Requested Not Submitted	220 days	0	0	--	0	0	0	--
		Requested And Submitted	345 days	0	0	--	0	0	0	--
Administrative	10	--	60 days	9	0	90%	1	9	1	90%

#### FY 2012 Submissions

As of September 30, 2012, performance data was available for 1 of 2 original NADAs and reactivations filed in FY 2012, and FDA met the review-time goal for this submission (see table below). With one original NADA and reactivation submission pending action within the goal deadline, FDA has the potential to exceed the performance goals, including ERA goals should any ERAs be requested. Performance data were available for 18 of 20 administrative NADAs and reactivations filed in FY 2012, and FDA met the review-time goal for almost all (17 of 18) submissions. With two administrative NADA and reactivation submissions pending action within the goal deadline, FDA has the potential to exceed the performance goal.

NADA and Reactivation Type	Filed	Performance Goal		Performance as of September 30, 2012			
		ERA Status	Act on 90 Percent Within	On Time	Overdue	Percent On Time	Pending Within Goal
Original	2	None Requested	180 days	1	0	100%	1
		Requested Not Submitted	220 days	0	0	--	0
		Requested And Submitted	345 days	0	0	--	0
Administrative	20	--	60 days	17	1	94%	2

## Supplemental NADAs and Reactivations

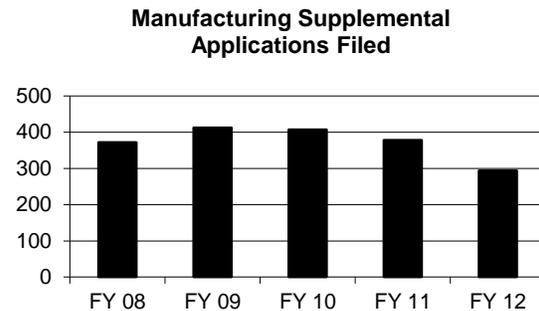
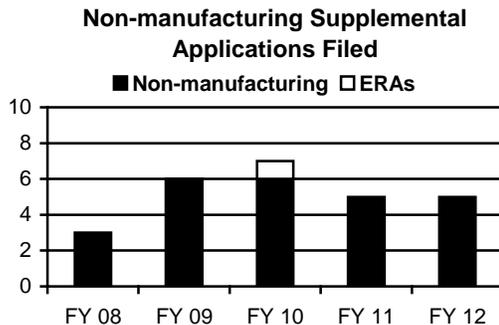
### Goal: Review and act on non-manufacturing and manufacturing supplemental NADAs and reactivations

The table below summarizes the review-time and performance goals for non-manufacturing and manufacturing supplemental NADAs and reactivations for ADUFA II and includes ERA review-time goals for non-manufacturing supplemental NADAs and reactivations. Performance goals are set at 90 percent of reviews on time.

Application Type	Review-Time Goal (Days) FY 2009 – FY 2013		Performance Goal
	No ERA Requested	ERA Requested	
Non-manufacturing Supplemental NADAs and Reactivations	No ERA Requested	180	90% on time
	ERA Requested Not Submitted	220	
	ERA Requested And Submitted	345	
Manufacturing Supplemental NADAs and Reactivations	120		

### Workload

The total number of non-manufacturing supplemental NADAs filed in FY 2012 remained the same for the second consecutive year while the total number of manufacturing supplemental NADAs decreased in FY 2012 to the lowest level in five years (see corresponding graphs and table below).



### Non-manufacturing and Manufacturing Supplemental Applications Filed

Type	FY 08	FY 09	FY 10	FY 11	FY 12
Non-manufacturing Supplemental NADAs and Reactivations	3	6	6	5	5 <sup>†</sup>
ERAs for Non-manufacturing Supplemental NADAs and Reactivations	--*	0	1	0	0
Manufacturing Supplemental NADAs and Reactivations	372	412	407	378	294 <sup>‡</sup>

\* ERAs were not an option for FY 2008 under ADUFA I.

<sup>†</sup> A total of six submissions were received, but 1 submission was withdrawn.

<sup>‡</sup> A total of 302 submissions were received, but eight submissions were withdrawn.

## Supplemental NADAs and Reactivations

### Performance

#### FY 2011 Submissions

FDA reviewed on time all (5 of 5) non-manufacturing submissions and all (378 of 378) manufacturing submissions filed in FY 2011 (see table below). FDA exceeded the performance goals for both non-manufacturing and manufacturing submissions.

Supplemental NADA and Reactivation Type	Filed	Performance Goal		Performance as of September 30, 2011				Final Performance		
		ERA Status	Act on 90 Percent Within	On Time	Overdue	Percent On Time	Pending within Goal	On Time	Overdue	Percent On Time
Non-manufacturing	5	None Requested	180 days	1	0	100%	4	5	0	100%
		Requested Not Submitted	220 days	0	0	--	0	0	0	--
		Requested And Submitted	345 days	0	0	--	0	0	0	--
Manufacturing	378	--	120 days	268	0	100%	110	378	0	100%

#### FY 2012 Submissions

As of September 30, 2012, performance data was available for 2 of 5 non-manufacturing submissions filed in FY 2012, and FDA met the review-time goal for both submissions (see table below). With three non-manufacturing submissions pending action within the goal deadline, FDA has the potential to exceed the performance goals, including ERA goals should any ERAs be requested. Performance data were available for over three-fourths (225 of 294) of manufacturing submissions filed in FY 2012, and FDA met the review-time goal for all submissions. With 69 manufacturing submissions pending action within the goal deadline, FDA has the potential to exceed the performance goal.

Supplemental NADA and Reactivation Type	Filed	Performance Goal		Performance as of September 30, 2012			
		ERA Status	Act on 90 Percent Within	On Time	Overdue	Percent On Time	Pending Within Goal
Non-manufacturing	5*	None Requested	180 days	2	0	100%	3
		Requested Not Submitted	220 days	0	0	--	0
		Requested And Submitted	345 days	0	0	--	0
Manufacturing	294 <sup>†</sup>	--	120 days	225	0	100%	69

\* A total of six submissions were received, but one submission was withdrawn.

<sup>†</sup> A total of 302 submissions were received, but eight submissions were withdrawn.

## INAD Submissions

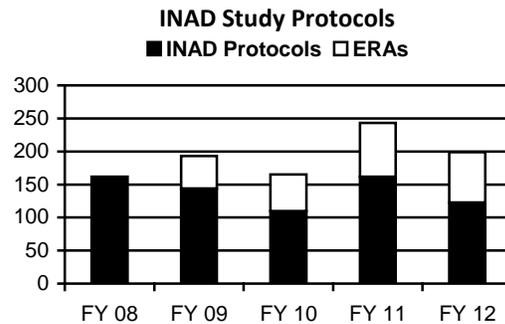
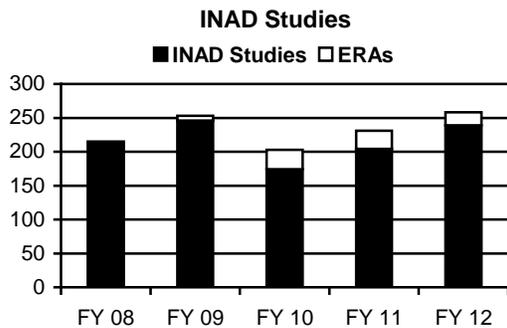
### Goal: Review and act on INAD studies and study protocol submissions

The table below summarizes the review-time and performance goals for INAD studies and study protocol submissions for ADUFA II and includes ERA review-time goals for INAD studies and INAD study protocols. Performance goals are set at 90 percent of reviews on time.

Submission Type	Review-Time Goal (Days) FY 2009 – FY 2013		Performance Goal
INAD Studies	No ERA Requested	180	90% on time
	ERA Requested Not Submitted	220	
	ERA Requested And Submitted	270	
INAD Study Protocols	No ERA Requested	60	
	ERA Requested Not Submitted	75	
	ERA Requested And Submitted	$60 \leq X \leq 80$	

### Workload

INAD studies submitted in FY 2012 increased for the second consecutive year, reaching the second highest level in five years. The number of INAD study protocols decreased in FY 2012 from the five-year high in FY 2011. FDA received 19 ERAs for INAD studies in FY 2012 (16 for FY 2011 cohort and three for the FY 2012 cohort). FDA received 76 ERAs for INAD study protocols in FY 2012 (25 for the FY 2011 cohort, and 51 for the FY 2012 cohort) (see corresponding graphs below and table on next page).



## INAD Submissions

### Workload

#### INAD Submissions

Type	FY 08	FY 09	FY 10	FY 11	FY 12
INAD Studies	215	247	174	204 <sup>†</sup>	239 <sup>†</sup>
ERAs for INAD Studies	--*	7	29	27	19
INAD Study Protocols	162	144	110	162	123 <sup>§</sup>
ERAs for INAD Study Protocols	--*	49	55	81	76

\* ERAs were not an option for FY 2008 under ADUFA I.

<sup>†</sup> FY 2011 number was changed to reflect updates to data presented in the FY 2011 ADUFA Performance Report. A total of 208 submissions were received, but two received a refuse to review and two received a stop review.

<sup>‡</sup> A total of 240 submissions were received, but one received a refuse to review.

<sup>§</sup> A total of 124 submissions were received, but one received a file no reply with memo.

### Performance

#### FY 2011 Submissions

FDA reviewed on time 203 of 204 INAD studies and 161 of 162 study protocols submitted in FY 2011 (see table below). FDA exceeded all performance goals for INAD studies and study protocols.

INAD Submission Type	Filed	Performance Goal		Performance as of September 30, 2011				Final Performance		
		ERA Status	Act on 90 Percent Within	On Time	Overdue	Percent On Time	Pending within Goal	On Time	Overdue	Percent On Time
Studies	204*	None Requested	180 days	97	1	99%	98	178	1	99%
		Requested Not Submitted	220 days	0	0	--	0	0	0	--
		Requested And Submitted	270 days	9	0	100%	0	25	0	100%
Study Protocols	162	None Requested	60 days	49	0	100%	37	57	1	98%
		Requested Not Submitted	75 days	2	0	100%	0	5	0	100%
		Requested And Submitted	60 to 80 days	74	0	100%	0	99	0	100%

\* FY 2011 number was changed to reflect updates to data presented in the FY 2011 ADUFA Performance Report. A total of 208 submissions were received, but two received a refuse to review and two received a stop review.

## ***INAD Submissions***

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### **FY 2012 Submissions**

As of September 30, 2012, performance data was available for over half (142 of 239) of INAD studies filed in FY 2012 (see table below). FDA met the review-time goals for all (142 of 142) INAD studies, including 139 submissions where no ERAs were requested and three submissions with ERAs requested and submitted. With 97 INAD studies pending action within the goal deadline, FDA has the potential to exceed the performance goals.

Performance data was available for most (110 of 123) of INAD study protocols filed in FY 2012. FDA met the review-time goals for all (110 of 110) INAD study protocols, including 56 submissions where no ERA was requested, three submissions where ERAs were requested but not submitted, and 51 submissions where ERAs were requested and submitted. With 13 INAD study protocols pending action within the goal deadline, FDA has the potential to exceed the performance goals.

INAD Submission Type	Submitted	Performance Goal		Performance as of September 30, 2012			
		ERA Status	Act On 90 Percent Within	On Time	Overdue	Percent On Time	Pending Within Goal
Studies	239*	None Requested	180 days	139	0	100%	97
		Requested Not Submitted	220 days	0	0	--	0
		Requested And Submitted	270 days	3	0	100%	0
Study Protocols	123†	None Requested	60 days	56	0	100%	13
		Requested Not Submitted	75 days	3	0	100%	0
		Requested And Submitted	60 to 80 days	51	0	100%	0

\* A total of 240 submissions were received, but one received a refuse to review.

† A total of 124 submissions were received, but one received a file no reply with memo.

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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, D. C. 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 Drug User Fee Act Performance Goals and Procedures**

### **ADUFA I: Five-Year Goals (to be implemented by September 30, 2008)**

1. Review and act on 90 percent of complete NADAs and reactivations of such applications within 180 days after submission date.
2. Review and act on 90 percent of administrative NADAs ( submitted after all scientific decisions have been made in the investigational animal drug process, i.e., prior to the submission of the NADAs) within 60 days after the submission date.
3. Review and act on 90 percent of non-manufacturing supplemental animal drug applications (i.e., supplemental animal drug applications for which safety or effectiveness data are required) and reactivations of such supplemental applications within 180 days after submission date.
4. Review and act on 90 percent of manufacturing supplemental animal drug applications and reactivations of such supplemental applications within 120 days after submissions date.
5. Review and act on 90 percent of investigational animal drug study submissions within 180 days after submission date.
6. Review and act on 90 percent of investigational animal drug 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 applications, without substantial data within 50 days after submission date.

### **ADUFA II: Reauthorization Performance Goals (FY 2009 - FY 2013)**

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

#### **1. Application/Submission Goals**

- a. For the application/submission goals below, the term "review and act on" is understood to mean the issuance of a complete action letter after the complete review of an animal drug application, supplemental animal drug application, or investigational animal drug submission which either (1) approves an animal drug application or supplemental application or notifies a sponsor that an investigational animal drug submission is complete or (2) sets forth in detail the specific deficiencies in such animal drug application, supplemental animal drug application, or investigational animal drug submission and, where appropriate, the actions necessary to place such an application, supplemental application, or submission in condition for approval. 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 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 an investigational animal drug 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.
- b. FDA may request minor amendments to animal drug applications, supplemental animal drug applications, and investigational animal drug 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 investigational animal drug submissions.
  - c. The term “end-review amendment” is understood to mean an amendment to an animal drug application, supplemental animal drug application, or investigational animal drug submission that is requested by the Agency after it has completed its review of the submitted information and determines that the submission of additional non-substantial data or information would likely complete the application or submission. This term does not include minor amendments requested by the Agency during review of applications or submissions that do not impact upon the user fee goals, as described in paragraph 1.b.
  - d. The term “submission date” is understood to mean the date CVM’s Document Control Unit receives an application or submission.

## **2. Non-administrative Animal Drug Applications**

- a. The Agency will review and act on 90 percent of non-administrative animal drug applications and reactivations of such applications within
  - i. 180 days after the submission date (Day 180) if the Agency determines that the application is complete or incomplete. An application is incomplete if it would require substantial data or information to enable the Agency to complete a comprehensive review of the application and reach a decision on the approvability of the application; or
  - ii. 220 days after the submission date if the Agency determines that the submission of additional non-substantial data or information would likely complete the application and electronically requests an end-review amendment to the application on or before Day 180, but the sponsor fails to file such amendment on or before Day 210. If a sponsor files an amendment after Day 210, then the amendment is ineligible for consideration as an end-review amendment, the extended performance goal (345 days) will not apply, and a complete action letter will be issued by Day 220 for the original application; or
  - iii. 345 days after the submission date if the Agency electronically requests an end-review amendment to the application on or before Day 180 and the sponsor files an end-review amendment on or before Day 210.

- b. The end-review amendment procedure is not intended to prevent the use of minor amendments during agency review of an animal drug application as described in paragraph 1.b. above.

### **3. Administrative Animal Drug Applications**

- a. Review and act on 90 percent of administrative animal drug applications NADAs (submitted after all scientific decisions have been made in the investigational animal drug process, i.e., prior to the submission of the NADA) within 60 days after the submission date.

### **4. Non-manufacturing Supplemental Animal Drug Applications**

- a. The agency will review and act on 90 percent of non-manufacturing supplemental animal drug applications (i.e. supplemental animal drug applications for which safety or effectiveness data are required) and reactivations of such supplemental applications within
  - i. 180 days after the submission date (Day 180) if the agency determines that the application is complete or incomplete. An application is incomplete if it would require substantial data or information to enable the agency to complete a comprehensive review of the application and reach a decision on the approvability of the application; or
  - ii. 220 days after the submission date if the agency determines that the submission of additional non-substantial data or information would likely complete the application and electronically requests an end-review amendment to the application on or before Day 180, but the sponsor fails to file such amendment on or before Day 210. If a sponsor files an amendment after Day 210, then the amendment is ineligible for consideration as an end-review amendment, the extended performance goal (345 days) will not apply, and a complete action letter will be issued by Day 220 for the original application; or
  - iii. 345 days after the submission date if the agency electronically requests an end-review amendment to the application on or before Day 180 and the sponsor files an end-review amendment on or before Day 210.
- b. The end-review amendment procedure is not intended to prevent the use of minor amendments during agency review of a supplemental new animal drug application as described in paragraph 1.b. above.

### **5. Manufacturing Supplemental Animal Drug Applications**

- a. Review and act on 90 percent of manufacturing supplemental animal drug applications and reactivations of such supplemental applications within 120 days after the submission date.

### **6. Investigational Animal Drug Study Submissions**

- a. The agency will review and act on 90 percent of investigational animal drug study submissions within
  - i. 180 days after the submission date (Day 180) if the agency determines that the submission is complete or incomplete. A submission is incomplete if it would

require substantial data or information to enable the agency to complete a comprehensive review of the study submission and reach a decision on the issue(s) presented in the submission; or

- ii. 220 days after the submission date if the agency determines that the submission of additional non-substantial data or information would likely complete the submission and electronically requests an end-review amendment to the submission on or before Day 180, but the sponsor fails to submit such amendment on or before Day 210. If a sponsor submits an amendment after Day 210, then the amendment is ineligible for consideration as an end-review amendment, the extended performance goal (270 days) will not apply, and a complete action letter will be issued by Day 220 for the original submission; or
  - iii. 270 days after the submission date if the agency electronically requests an end-review amendment to the submission on or before Day 180 and the sponsor submits an end-review amendment on or before Day 210.
- b. The end-review amendment procedure is not intended to prevent the use of minor amendments during agency review of a study submission as described in paragraph 1.b. above.

## **7. Investigational Animal Drug Protocol without Data Submissions**

- a. Review and act on 90 percent of investigational animal drug 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 animal drug application or supplemental animal drug application, within
  - i. 60 days after the submission date (Day 60) if the agency does not request an end-review amendment to the protocol.
    - (1) If the agency determines that the protocol is acceptable, the agency will notify the sponsor of this decision electronically on or before Day 50, followed by a complete action letter; or
    - (2) If the agency determines that a protocol is not acceptable, the agency will notify the sponsor of this decision electronically, providing preliminary broad areas of protocol deficiency, on or before Day 50, with the subsequently issued complete action letter providing the detailed protocol assessment. The sponsor may contact the agency for a brief clarification of these areas of deficiency prior to the issuance of the complete action letter; or
  - ii. 75 days after the submission date if the agency electronically requests an end-review amendment to the protocol on or before Day 50, but the sponsor fails to submit such amendment within 10 days of the amendment request date. If a sponsor files an amendment more than 10 days after the amendment request date, then the amendment is ineligible for consideration as an end-review amendment, the extended performance goal (refer to 7.a.iii below) will not apply, and a complete action letter will be issued by Day 75 for the original submission; or
  - iii. The greater of 60 days after the original protocol is received by the agency or 20 days after the amended protocol is received by the agency if the agency electronically requests an end-review amendment on or before Day 50 and the sponsor submits such amendment within 10 days of the date the amendment is requested.

- b. 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 animal drug application or supplemental animal drug application, 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.
- c. 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 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 by written order determines 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.
- d. The end-review amendment procedure is not intended to prevent the use of minor amendments during agency review of a protocol without data submission as described in paragraph 1.b. above.

## **8. Electronic Review of Applications/Submissions**

- a. The agency will develop an electronic submission tool for industry submissions and online review capability within 24 months of appropriated ADUFA funds for FY 2009. The agency will consult with the sponsors in the development of this tool.

## **9. Pre-Approval Foreign Inspections**

- a. The agency and regulated industry are committed to improving the review and business processes that will facilitate the timely scheduling and conducting of pre-approval inspections (PAIs). To improve the timeliness and predictability of foreign PAIs, sponsors may voluntarily submit one) at the beginning of the calendar year, a list of foreign manufacturing facilities that are subjects of animal drug applications, supplemental animal drug applications, or investigational animal drug submissions and may be subject to foreign PAIs for the following fiscal year; and two) a notification 30 days prior to submitting an animal drug application, a supplemental animal drug application, or investigational animal drug submission that informs the agency that the application includes a foreign manufacturing facility. Should any changes to the annual list occur after its submission to the agency, the sponsor may provide the updated information to the agency.
- b. The agency will keep a record of the number of foreign PAIs conducted for new animal drug applications, along with the average time for completing the PAIs, and include this information in its annual performance report. The time for completing the PAI is understood to mean the time from the inspection scheduling request through notification to the Center of inspectional findings.

## **10. Public Workshops**

- a. The agency and regulated industry agree to participate in 10 public workshops by the end of FY 2013 on mutually agreed-upon topics.

## **11. Additional Efforts Related to Performance Goals**

- a. 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 above) will be reviewed with the highest possible priority among those pending.
- b. The agency and the regulated industry agree that the use of both formal meetings (e.g., presubmission conferences, workshops, etc.) and informal communication by both parties is critical to ensure high submission quality such that the above performance goals can be achieved.
- c. The agency and the regulated industry agree to explore and discuss the applicable use of pharmacokinetic/pharmacodynamic data in the development and evaluation of new animal drugs submitted for approval.
- d. The agency and the regulated industry agree to explore opportunities for exchange of information regarding the characteristics of a new animal drug, and to identify safety and effectiveness issues as early as possible in the drug development process.
- e. The agency and regulated industry commit to work together to explore shorter timeframes commensurate with the magnitude of the submitted data/information referenced under 11.c and 11.d.

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## Appendix B: Summary of ADUFA II Performance Goals

### Performance Goals

Submission Types	Performance Level	FDA Review Time (Days)				
		FY 09	FY 10	FY 11	FY 12	FY 13
Original NADAs and reactivations	90%	180	180	180	180	180
Administrative NADAs and reactivations	90%	60	60	60	60	60
Non-manufacturing supplemental NADAs and reactivations	90%	180	180	180	180	180
Manufacturing supplemental NADAs and reactivations	90%	120	120	120	120	120
INAD study submissions	90%	180	180	180	180	180
INAD 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%	60	60	60	60	60

### End Review Amendments – Interim Time Frames and Performance Goals\*

Submission Types	Complete/ Incomplete Performance Goal (90th percentile)	ERA Request Date	ERA Submission Time Frame	ERA Not Submitted <sup>†</sup> Performance Goal (90th percentile)	ERA Submitted Performance Goal (90th percentile)
Original NADAs and reactivations	180	180	210	220	345
Administrative NADAs and reactivations	60	N/A	N/A	N/A	N/A
Non-manufacturing supplemental NADAs and reactivations	180	180	210	220	345
Manufacturing supplemental NADAs and reactivations of such supplemental applications	120	N/A	N/A	N/A	N/A
INAD study submissions	180	180	210	220	270
INAD 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	60 <sup>‡</sup>	50	+10 <sup>◇</sup>	75	60 ≤ X ≤ 80

\* Expressed as number of days from date of receipt of original application or submission unless otherwise noted.

<sup>†</sup> ERA either not submitted or submitted after specified time frame.

<sup>‡</sup> CVM will notify sponsor by day 50 with protocol status. If sponsor does not concur with need for ERA, then FDA will provide broad areas of deficiencies.

<sup>◇</sup> Days from date of CVM request for ERA.

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## **Appendix C: End-Review Amendment (ERA) Process**

The ERA process enables FDA reviewers to work with the drug sponsor to amend pending submissions to achieve a complete review decision sooner. The intent of the ERA process is to reduce the number of submission review cycles. FDA will request an amendment for applications or submissions when it is determined that the additional non-substantial data or information will likely complete the application or submission. Because the request for an amendment interrupts the review cycle, extended ERA on-time review goals were included in ADUFA II. ERAs apply to original NADAs and reactivations, non-manufacturing supplemental NADAs and reactivations, INAD studies, and INAD study protocols. As agreed to in the ADUFA II goals letter (see Appendix A), under the ERA process, three conditions can apply, each with a different on-time review goal.

- 1) **No ERA Requested.** If no ERA was requested by FDA, the same 180-day review-time goal applies under ADUFA II that was developed under ADUFA I with the exception of INAD protocols (see table below).
- 2) **ERA Requested but Not Submitted Within Time Frame.** If an ERA was requested by FDA, and the sponsor failed to submit the ERA within the specified time frame, then a 220-day review-time goal for FDA to act applies for the original application.
- 3) **ERA Requested and Submitted Within Time Frame.** If an ERA was requested by FDA, and the sponsor submitted the ERA within the specified time frame, extended on-time review goals are applied to the application or submission to allow for FDA to review the new material.

**Effect of ERA Process on FY 2008 ADUFA I Goals**

Application/Submission Type	ADUFA I FY 2008 Review- Time Goal Days	ADUFA II FY 2009 Review-Time Goal Days		
		(1) No ERA Requested	(2) ERA Requested but Not Submitted	(3) ERA Requested and Submitted Within Time Frame
Original NADAs and Reactivations	180	180	220	345
Non-manufacturing Supplemental NADAs and Reactivations	180	180	220	345
INAD Studies	180	180	220	270
INAD Study Protocols	50	60*	75	$60 \leq X \leq 80$

\* CVM will notify sponsor (via email) by day 50 with protocol status. If sponsor does not concur with need for ERA, then FDA will provide broad areas of deficiencies.

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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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