FY 2007

Food and Drug Administration
Department of Health and Human Services

PERFORMANCE REPORT TO CONGRESS

for the

Animal Drug User Fee Act

Center for Veterinary Medicine

Commissioner's Report

I am pleased to present the Food and Drug Administration's (FDA's) Fiscal Year (FY) 2007 Performance Report to Congress for the Animal Drug User Fee Act (ADUFA) of 2003. This report presents FDA's accomplishments for FY 2007, the fourth year operating under ADUFA, and also updates and finalizes the FY 2006 cohort data. It is my pleasure to report that FDA met or exceeded each performance goal for FY 2006 and is meeting or exceeding each performance goal targeted for FY 2007.

FDA's first 4 years under ADUFA have been highly productive and successful. Since FY 2004, FDA has met or exceeded all of the review performance goals established under ADUFA. This has been accomplished by such measures as hiring a substantial number of additional FDA staff; developing staff; and, developing and disseminating guidance, policy, and procedural documents. These actions are an integral part of FDA's commitment to improving the efficiency, quality, and predictability of the new animal drug review process. To meet the progressive and more demanding review time goals established under ADUFA in FY 2008, FDA plans to:

- Continue progress on management initiatives that include development of standard operating procedures for review processes, scientific policies for review staff, and implementation of a quality business system.

- Maintain staffing necessary to help FDA meet ADUFA review time goals.

- Develop and issue guidance to industry to explain current FDA thinking related to the new animal drug review process.

- Provide training and educational opportunities for FDA staff to enhance the knowledge base of the review organization.

FDA is committed to improving the efficiency, quality, and predictability of the new animal drug review process. We are dedicated to exploring new approaches and technologies that offer high quality and cost-effective improvements in FDA's review of new animal drug applications (NADA) and submissions. FDA looks forward to the continued success and significant improvements in the animal drug review process that ADUFA will help make achievable.

Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs

Executive Summary

On November 18, 2003, the President signed ADUFA into law. ADUFA amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) to authorize FDA to collect user fees from new animal drug sponsors. Under ADUFA, FDA agreed to pursue a comprehensive set of review performance goals to improve the timeliness and predictability of the review of NADAs and investigational new animal drug (INAD) submissions. This report updates and finalizes FY 2006 accomplishments, describes FDA's accomplishments toward meeting the FY 2007 performance goals, and outlines implementation plans for FY 2008 that will enable FDA to meet the progressive and more demanding review time goals set by ADUFA.

FDA continues to achieve expectations in implementing ADUFA. Among the key activities and accomplishments during FY 2007 were:

- **FDA exceeded all ADUFA performance goals for FY 2006 and is meeting or exceeding all for FY 2007.** All applications and submissions received in FY 2006 were reviewed and acted on, and FDA exceeded each of the FY 2006 ADUFA review time performance goals. FDA is meeting or exceeding all the ADUFA review time performance goals for FY 2007 applications and submissions that have been acted on as of September 30, 2007.

- **FDA published a draft guidance document for industry on target animal safety for veterinary pharmaceutical products.** In keeping with FDA's commitment to improve the efficiency and quality of the new animal drug review process, FDA published "Guidance #185: Draft Guidance for Industry on Target Animal Safety for Veterinary Pharmaceutical Products, VICH GL43." The draft guidance was developed for use by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) and as a harmonized standard to aid in development of mutually acceptable target animal safety studies for relevant governmental regulatory bodies. This guidance document and others are available on the Center for Veterinary Medicine (CVM) homepage on the FDA Web site at: http://www.fda.gov/cvm.

Table of Contents

Introduction

ADUFA was enacted on November 18, 2003, and authorized FDA to collect user fees to support the review of new animal drugs in four categories: applications, establishments, products, and sponsors. The Consolidated Appropriations Act of 2004, enacted on January 23, 2004, contained an appropriations provision enabling FDA's implementation of ADUFA. Under ADUFA, FDA agreed to meet specified performance goals for the review of certain submissions over 5 years. FDA agreed to review and act on submissions within shorter time periods for each new fiscal year. Information about ADUFA, including the text of the Department of Health and Human Services (HHS) Secretary's November 13, 2003, commitment letter to Congress, is located in Appendix A and can also be found at: http://www.fda.gov/oc/adufa.

ADUFA requires that the Secretary submit two annual reports to Congress for each fiscal year during which 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 and updates and finalizes FY 2006 cohort data. FDA's continuing progress in implementing ADUFA and in meeting quantifiable ADUFA review goals for FY 2007 is summarized in this report. This report also describes FDA's implementation plans for FY 2008.

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Overview of ADUFA

ADUFA was signed into law on November 18, 2003, amending the FD&C Act and providing FDA with important new responsibilities, resources, and challenges. The goal of ADUFA is to better serve animal health and public health by providing additional funds to augment FDA resources devoted to "the process for review of new animal drug applications."

Under ADUFA, FDA agreed to meet certain review performance goals. These goals strive to expedite the review of NADAs, supplemental NADAs, and INAD submissions.

This program is similar to the Prescription Drug User Fee Act (PDUFA) program for human drugs that has been in place for 15 years. The expectation is that ADUFA, like PDUFA, will continue to help FDA expedite and improve its review of applications for new animal drugs so that safe and effective new products will be available more quickly. The guidelines and definitions below apply to FDA's implementation of ADUFA. Further information can be found in Appendix A and can also be found at: http://www.fda.gov/oc/adufa.

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 which 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 and Refuse to Review Submissions. 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, sufficient to cause the quality of the entire submission to be questioned to the extent that FDA cannot reasonably review it. Within 60 days of submission, FDA will refuse to review an INAD 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 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.

Progressive Goal Setting Over 5 Years

ADUFA established review performance goals for FDA that are being phased in over a 5-year period. These performance goals run from FY 2004 through FY 2008 and are intended to achieve progressive, yearly improvements in the process for review of NADAs. FDA agreed to review and act on submissions within shorter periods of time each new year. With the fifth and final year of ADUFA ending on September 30, 2008, FDA has agreed to review and act on 90 percent of the following submission types within the specified times:

- NADAs and reactivations of such applications within 180 days after submission date.
- Non-manufacturing supplemental NADAs (that is, supplemental NADAs for which safety or effectiveness data are required) and reactivations of such supplemental applications within 180 days after submission date.
- Manufacturing supplemental NADAs and reactivations of such supplemental applications within 120 days after submission date.
- INAD study submissions within 180 days after submission date.
- INAD submissions consisting of protocols that FDA and the sponsor consider essential to making the decision to approve or disapprove an animal drug application or supplemental animal drug application, without substantial data, within 50 days after submission date.
- Administrative NADAs submitted after all scientific decisions have been made in the investigational animal drug process (that is, prior to submission of the NADA) within 60 days after submission date.

While the performance goal of reviewing 90 percent of submissions within specified times remains constant over the 5-year ADUFA period, the specified time frames incrementally decrease over this period for all submission types. The FY 2008 review time goals will be the most challenging and difficult for FDA to meet, as review time goals decrease to the shortest number of review days for this 5-year period. The 5-year progression of these goals is presented in Appendix B.

Fiscal Year Receipt Cohorts

All FDA 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 and more submissions in a receipt cohort. As more submissions are completed, the statistics for that year of receipt must be adjusted to reflect the new completions. Until all submissions in a cohort are completed, only a preliminary performance assessment can be provided for that cohort. In this report, FDA is providing final performance for FY 2006 and performance for FY 2007 as of September 30, 2007.

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ADUFA Implementation

As part of ADUFA implementation, FDA eliminated backlogs by hiring new employees, developing staff, issuing guidance to industry, and developing policy and procedure documents to improve the new animal drug review process. These actions were completed to position FDA to meet the progressively challenging performance goals of ADUFA.

FY 2007 Activities and Accomplishments

FDA continued to meet or exceed expectations in implementing ADUFA. Key activities and accomplishments during FY 2007 included:

- **FY 2006 ADUFA Cohort Performance**. All applications and submissions received in FY 2006 were reviewed and acted on, and FDA exceeded each of the FY 2006 ADUFA review time performance goals.

- **FY 2007 ADUFA Cohort Performance**. Preliminary performance results indicate FDA is meeting or exceeding each of the review time performance goals defined under ADUFA for applications and submissions that were acted on for the FY 2007 cohort. With additional FY 2007 submissions still pending action as of September 30, 2007, FDA will update FY 2007 performance in the FY 2008 report to reflect these pending actions.

- **Guidance Development**. During FY 2007, FDA published *Guidance #185: Draft Guidance for Industry on Target Animal Safety for Veterinary Pharmaceutical Products, VICH GL43.*

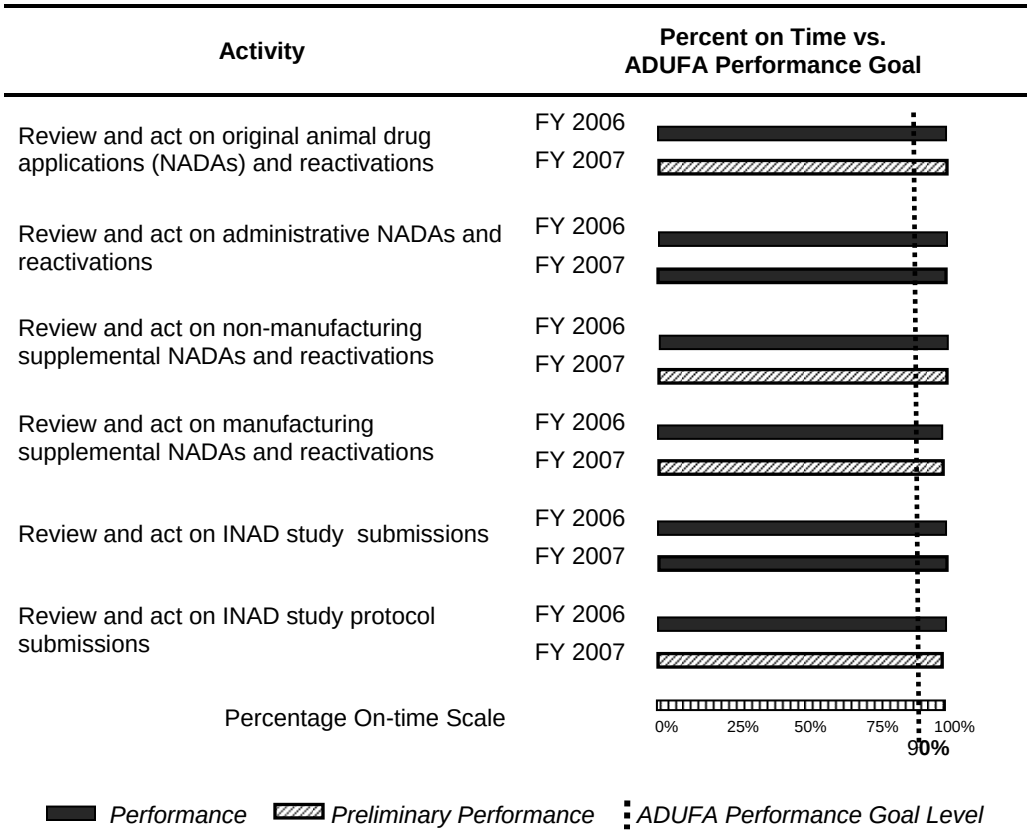
  This guidance document and others are available on the CVM homepage on FDA's Web site at: http://www.fda.gov/cvm/Guidance/published.htm.

Performance At-A-Glance for FY 2006 and FY 2007

FDA exceeded each of the ADUFA review performance goals (90 percent on time within the specified review times) for the FY 2006 cohort.

Preliminary performance results indicate FDA is meeting or exceeding each of the designated ADUFA review performance goals (90 percent on time within the specified review times) for the FY 2007 cohort acted on as of September 30, 2007. With submissions still pending action, it is too early to make a final performance determination for FY 2007.

The table below summarizes FDA's review performance on the FY 2006 and FY 2007 applications and submissions and the preliminary performance in reviewing FY 2007 applications and submissions.



Implementation Plans for FY 2008

During FY 2008, FDA will continue to expand its efforts to improve the timeliness and efficiency of animal drug review programs through employee hiring, training, and development of guidance. These efforts will enable FDA to meet the fifth and final year goals which are the most rigorous goals of ADUFA.

- **Employee Hiring.** FDA plans to maintain the staffing necessary to meet the ADUFA review time performance goals.

- **Management Initiatives.** FDA will continue to develop standard operating procedures for review processes, scientific policies for review staff, and procedures for expedient resolution of scientific issues. FDA will also continue the implementation of a quality business system, using an activity-based model to demonstrate better performance-to-budget efficiency.

- **Guidance Development.** FDA will continue to develop and issue guidance to the industry, clarifying current FDA thinking, as needed.

- **Staff Training.** FDA will continue to direct and target training and educational opportunities for staff and management to improve the knowledge base of the review organization, including core curricula for new reviewers, policy and procedure competency, and expansion of the scientific knowledge base. FDA will also offer training to review scientists to help them maintain and further develop their cutting edge knowledge base required in reviewing applications containing information on emerging technologies.

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Report on Final FY 2006 and Preliminary FY 2007 ADUFA Cohort Performance

This report updates and finalizes FY 2006 review performance and describes FDA's review performance in FY 2007 for all the ADUFA performance goals and commitments completed as of September 30, 2007. The following information refers to FDA performance presented in this report.

- FDA reviewed and acted on all applications and submissions received during FY 2006 and final performance with respect to achieving goals can now be reported.

- Only a preliminary performance assessment is possible on applications and submissions received and acted on during FY 2007. For submission categories with a longer review goal, for example, 200 days, early review performance data is limited. For those submissions with a review goal that is shorter, for example, 60 days, performance for submissions received early in the fiscal year may provide an early indicator of review performance.

- MUMS (Minor Use Minor Species) conditional approvals are not counted as NADA submissions and, 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 count for FY 2007 includes all submissions received in the last month of FY 2007 as filed. FDA makes a filing decision within 30 days of receiving an original application. FDA calculates ADUFA review times, however, from the original receipt of the filed application.

- Applications and submissions that FDA refused to file, applications that were withdrawn, and reviews that were stopped at the request of the sponsor (applies to INAD submissions only) are not included in the statistics used to measure performance. These applications and submissions are noted, however, in the relevant workload narratives for performance goals.

NADAs and Reactivations

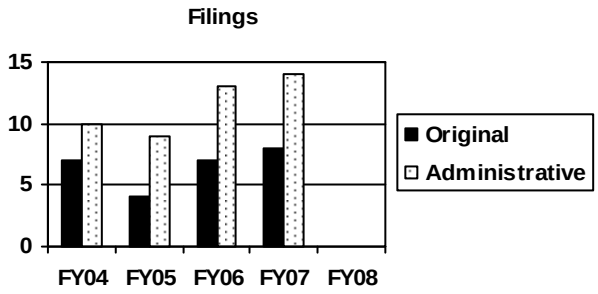
Goal: Review and act on original and administrative NADAs and reactivations

The table below summarizes the annual review time goals for original and administrative NADAs and reactivations. Over the 5-year period defined by ADUFA, 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 2004 – FY 2008 Submissions
	FY 04	FY 05	FY 06	FY 07	FY 08	
Original NADAs and Reactivations	295	270	230	200	180	90% on time
Administrative NADAs and Reactivations	90	85	80	70	60	90% on time

Workload

The total number of original and administrative NADAs and reactivations filed increased for the second straight year. Original and administrative NADAs and reactivations each increased by one from FY 2006 to FY 2007. In FY 2007, one original NADA received a "refuse to file" notification (see corresponding graph and table).



Filings					
Type	FY 04	FY 05	FY 06	FY 07	FY 08
Original NADAs and Reactivations	7	4	7*	8	--
Administrative NADAs and Reactivations	10	9	13	14	--
Total	17	13	20	22	

* FY 2006 numbers were updated to reflect corrections to the count of original NADAs and reactivations. Original NADAs and reactivations reflect removal of one MUMS conditional approval that should not have been counted as an original NADA and reactivation in the FY 2006 ADUFA Performance Report.

NADAs and Reactivations

Performance

FY 2006 Submissions

The 90 percent on-time ADUFA review performance goals were exceeded for all original and administrative NADAs and reactivations filed in FY 2006 (see table below). FDA reviewed and acted on all original NADAs and reactivations within 230 days, and all administrative NADAs and reactivations within 80 days.

Submission Type	Review Within	Reviewed and Acted On	Number On Time	Percent on Time	ADUFA Performance Goal
Original NADAs and Reactivations	230 days	7	7	**100%**	90%
Administrative NADAs and Reactivations	80 days	13	13	**100%**	90%

FY 2007 Submissions

The 90 percent on-time ADUFA review performance goal was exceeded for administrative NADAs and reactivations filed in FY 2007 (see table below). All of the administrative NADAs and reactivations filed in FY 2007 were reviewed and acted on, and all met the 70-day ADUFA review performance goal. One of eight original NADAs and reactivations filed in FY 2007 was reviewed and acted on and met the 200-day ADUFA review performance goal. With most submissions still pending action and not overdue, it is too early to make a final performance determination for FY 2007.

Submission Type	Review Within	Reviewed and Acted On	Number On Time	Percent on Time	ADUFA Performance Goal
Original NADAs and Reactivations	200 days	1	1	**100%**	90%
Administrative NADAs and Reactivations	70 days	14	14	**100%**	90%

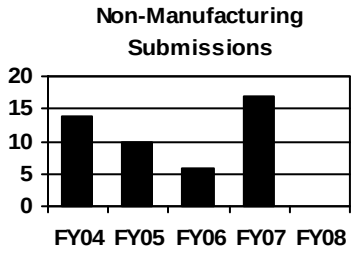
Supplemental NADAs and Reactivations

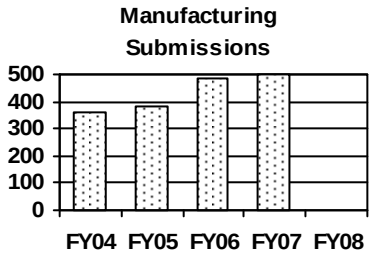
Goal: Review and act on non-manufacturing and manufacturing supplemental NADAs and reactivations

The table below summarizes the annual review time goals for non-manufacturing and manufacturing supplemental NADAs and reactivations. Over the 5-year period defined by ADUFA, 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 2004 – FY 2008 Submissions
	FY 04	FY 05	FY 06	FY 07	FY 08	
Non-manufacturing Supplemental NADAs and Reactivations	320	285	235	200	180	90% on time
Manufacturing Supplemental NADAs and Reactivations	225	190	140	120	120	90% on time

Workload





The total number of manufacturing supplemental NADAs and reactivations increased annually from FY 2004 to FY 2007, with the largest increase occurring from FY 2005 to FY 2006. The number of non-manufacturing supplements increased, reversing a 2-year decline. In FY 2007, three manufacturing supplements received "refuse to file" notifications, while seven were withdrawn by the sponsors (see corresponding graph and table).

Submissions					
Type	FY 04	FY 05	FY 06	FY 07	FY 08
Non-manufacturing Supplemental NADAs and Reactivations	14	10	6	17	--
Manufacturing Supplemental NADAs and Reactivations	363	385	486*	497	--
Total	377	395	492	514	

***** FY 2006 numbers were updated to reflect corrections to the count of manufacturing supplemental NADAs and reactivations. Two manufacturing supplements, originally reported in the FY 2006 ADUFA Performance Report, were withdrawn by the sponsor, while two were recoded and determined to be not applicable to ADUFA performance goals.

Supplemental NADAs and Reactivations

Performance

FY 2006 Submissions

The 90 percent on-time ADUFA review performance goals were exceeded for all non-manufacturing and manufacturing supplemental NADAs and reactivations in FY 2006 (see table below). FDA reviewed and acted on all of the non-manufacturing supplemental NADAs and reactivations within 235 days, and all but one (485 of 486) of the manufacturing supplemental NADAs and reactivations within 140 days.

Submission Type	Review Within	Reviewed and Acted On	Number On Time	Percent on Time	ADUFA Performance Goal
Non-manufacturing Supplemental NADAs and Reactivations	235 days	6	6	**100%**	90%
Manufacturing Supplemental NADAs and Reactivations	140 days	486	485	**99%**	90%

FY 2007 Submissions

Preliminary results indicate FDA is exceeding FY 2007 supplemental NADAs and reactivations review goals (see table below). Over one-third (6 of 17) non-manufacturing supplemental NADAs and reactivations submitted in FY 2007 were reviewed and acted on, and all met the 200-day ADUFA review performance goal. Over three-fourths (383 of 497) of the manufacturing supplemental NADAs and reactivations submitted in FY 2007 were reviewed and acted on, and all but one (382 of 383) met the 120-day ADUFA review performance goal (see table below). With submissions still pending action and not overdue, it is too early to make a final performance determination for FY 2007.

Submission Type	Review Within	Reviewed and Acted On	Number On Time	Percent on Time	ADUFA Performance Goal
Non-manufacturing Supplemental NADAs and Reactivations	200 days	6	6	**100%**	90%
Manufacturing Supplemental NADAs and Reactivations	120 days	383	382	**99%**	90%

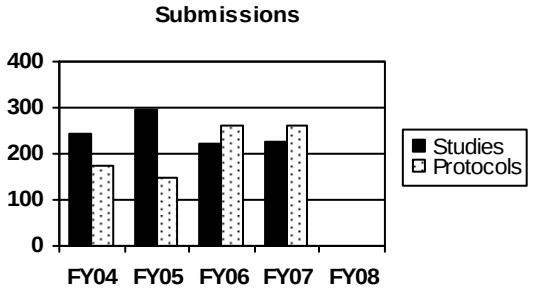
INAD Submissions

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

The table below summarizes the annual review time goals for INAD studies and study protocol submissions. Over the 5-year period defined by ADUFA, 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 2004 – FY 2008 Submissions
	FY 04	FY 05	FY 06	FY 07	FY 08	
INAD Studies	320	285	235	200	180	90% on time
INAD Study Protocols	125	100	80	60	50	90% on time

Workload



The total number of these INAD submissions increased annually from FY 2004 to FY 2007. More INAD studies were submitted than INAD study protocols in FY 2004 and FY 2005, with this pattern reversing in FY 2006 and FY 2007. In FY 2007, four INAD study submissions received "refuse to review" notifications, while three reviews were stopped at the request of the sponsor. In FY 2007, four investigational study protocols received "refuse to review" notifications, while two reviews were stopped at the request of the sponsor (see corresponding graph and table).

Submissions					
Type	FY 04	FY 05	FY 06	FY 07	FY 08
INAD Studies	243	295	222*	227	--
INAD Study Protocols	173	150	262	262	--
Total	416	445	484	489	

* FY 2006 numbers were updated to reflect corrections to the count of INAD studies. One INAD study was not reported in the FY 2006 ADUFA Performance Report as a received submission.

INAD Submissions

Performance

FY 2006 Submissions

The 90 percent on-time ADUFA review performance goals were exceeded for INAD studies and INAD study protocol submissions in FY 2006 (see table below). FDA reviewed and acted on all of the INAD studies within 235 days and all of the INAD study protocols within 80 days.

Submission Type	Review Within	Reviewed and Acted On	Number On Time	Percent on Time	ADUFA Performance Goal
INAD Studies	235 days	222	222	**100%**	90%
INAD Study Protocols	80 days	262	262	**100%**	90%

FY 2007 Submissions

The 90 percent on-time ADUFA review performance goal was exceeded for INAD studies and INAD study protocols in FY 2007 (see table below). Over half (123 of 227) of the INAD studies filed in FY 2007 were reviewed and acted on, and all met the 200-day ADUFA review performance goal. Almost all (246 of 262) of the INAD study protocols filed in FY 2007 were reviewed and acted on and 99 percent met the 60-day ADUFA review performance goal. With submissions still pending action and not overdue, it is too early to make a final performance determination for FY 2007.

Submission Type	Review Within	Reviewed and Acted On	Number On Time	Percent on Time	ADUFA Performance Goal
INAD Studies	200 days	123	123	**100%**	90%
INAD Study Protocols	60 days	246	243	**99%**	90%

Abbreviated New Animal Drug Applications

Section 740(k) Abbreviated New Animal Drug Applications of the FD&C Act provides:

The Secretary shall -

‘‘(1) to the extent practicable, segregate the review of abbreviated new animal drug applications from the process for the review of animal drug applications,” and

‘‘(2) adopt other administrative procedures to ensure that review times of abbreviated new animal drug applications do not increase from their current level, due to activities under the user fee program.’’

Performance

FDA’s CVM has established within its Office of New Animal Drug Evaluation (ONADE) a separate staff, the Generic Animal Drug Team, dedicated to the review of Abbreviated New Animal Drug Applications (ANADAs) and submissions. FDA also established a team within ONADE’s Division of Manufacturing Technologies to handle related ANADA chemistry reviews.

CVM maintains a separate review queue for ANADAs. It is important to emphasize that this queue is independent from the queue maintained for the process to review NADAs under ADUFA. This ensures that ANADAs are reviewed independently of applications under ADUFA by dedicated staff. Application management processes and adherence to them are being re-examined and continue to be worked on and improved within the Generic Animal Drug Team.

To ensure that review times for ANADAs and submissions do not increase due to activities under the user fee program, ONADE established a baseline of sentinel submission review times averaged over FY 2001 through FY 2003. FDA staff selected document and submission types for monitoring based on submission types that were analogous to the ADUFA sentinel submission types. FDA staff continually monitors current year completed review times for these submissions. The average review times increased slightly during FY 2007. This was due, in part, to the loss of a CVM manufacturing chemistry reviewer. This loss is in addition to the loss reported in the FY 2006 ADUFA Performance Report.

Appendix A: Department of Health and Human Services (HHS) Secretary's Commitment Letter to Congress

On November 13, 2003, HHS Secretary Tommy G. Thompson sent identical performance goal letters to the following four members of Congress:

The Honorable Judd Gregg
Chairman
Committee on Health, Education, Labor and Pensions
United States Senate

The Honorable Edward Kennedy
Ranking Minority Member
Committee on Health, Education, Labor and Pensions
United States Senate

The Honorable W. J. (Billy) Tauzin
Chairman
Committee on Energy and Commerce
U.S. House of Representatives

The Honorable John Dingell
Ranking Minority Member
Committee on Energy and Commerce
U.S. House of Representatives

This appendix provides one copy of the four identical letters and a summary of the goals and procedures of CVM as agreed to under the "Animal Drug User Fee Act of 2003."

THE SECRETARY OF HEALTH AND HUMAN SERVICES

Washington, DC, November 13, 2003

The Honorable Judd Gregg
Chairman
Committee on Health, Education, Labor and Pensions
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

As you are aware, the Food and Drug Administration has been working with representatives of the veterinary pharmaceutical industry and staff of your Committee to design a new animal drug "user fee" proposal. Under this proposal, the additional revenues generated from fees paid by this industry would be dedicated for use in expediting the process for the review of animal drug applications, in accordance with performance goals that have been developed by FDA in consultation with the industry. S.313, the "Animal Drug User Fee Act of 2003" reflects the fee mechanisms developed in these discussions. The performance goals are specific in the enclosure to this letter entitled, "Animal Drug User Fee Act Performance Goals and Procedures." I believe they represent a realistic projection of what FDA can accomplish with industry cooperation and the additional resources that would be provided by the bill and annual FDA appropriations that fully cover the costs of pay and inflation increases for the animal drug review process each year.

I appreciate the support of you and your staff, and the assistance of other Members of the Committee.

Sincerely,

TOMMY G. THOMPSON

Enclosure

Animal 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 Drug User Fee Act of 2003" are summarized as follows:

Five-Year Goals (to be implemented by September 30, 2008)

1. Review and act on 90 percent of complete animal drug applications (NADAs) and reactivations of such applications within 180 days after submission date.
2. 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.
3. Review and act on 90 percent of manufacturing supplemental animal drug applications and reactivations of such supplemental applications within 120 days after submissions date.
4. Review and act on 90 percent of investigational animal drug study submissions within 180 days after submission date.
5. 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.
6. 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.

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 drug submission which either (1) approves an animal drug application or supplemental application or notifies a sponsor that an investigational new 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 describe 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 animal drug applications, supplemental animal drug applications, and investigational animal drug submissions. 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, thereby effectively resetting the clock to the date FDA received the amendment. The Agency intends to establish the same policy for investigational animal drug 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 considered 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 an acknowledgment letter providing comments resulting from a complete review of the protocol. The acknowledgement 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 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 public or animal health concerns unrecognized at the time of protocol assessment under this process are evident.

Interim Backlog Goals

1. Review and act on pending animal drug applications, supplemental animal drug applications, and investigational animal drug submissions within 24 months of initiation of user fee payments.

Additional Interim Goals

1. Fifty percent of FDA incremental review staff recruited and on-board by first quarter of FY 2006. Total staff increment on-board by end of FY 2008.
2. FDA will review all submissions in accordance with procedures for working within a queue. An application/submission that is not reviewed within the applicable interim Application/Submission Goal time frame (noted below) will be reviewed with the highest possible priority among those pending.

Interim Application/Submission Goals

FY 04 Review and Act on 90 percent of:

- NADAs and reactivations of such applications received during FY 2004 are reviewed within 295 days.
- Non-manufacturing supplement animal drug application and reactivations of such supplemental Manufacturing supplemental animal drug applications and reactivations of such supplemental applications received during FY 2004 are reviewed within 320 days.
- Manufacturing supplemental animal drug applications and reactivations of such supplemental applications received applications received during FY 2004 are reviewed within 225 days.
- Investigational animal drug study submissions received during FY 2004 are reviewed within 320 days.

- 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 application, without substantial data received during FY 2004 are reviewed within 125 days.
- Administrative animal drug applications (administrative NADAs) received during FY 2004 are reviewed within 90 days.

FY 05 Review and Act on 90 percent of:

- NADAs and reactivations of NADAs received during FY 2005 are reviewed within 270 days.
- Non-manufacturing supplemental animal drug applications and reactivations of such supplemental applications received during FY 2005 are reviewed within 285 days.
- Manufacturing supplemental animal drug applications and reactivations of such supplemental applications received during FY 2005 are reviewed within 190 days.
- Investigational animal drug study submissions received during FY 2005 are reviewed within 285 days.
- Investigational animal 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 applications or supplemental animal drug application, without substantial data submissions received during FY 2005 are reviewed within 100 days.
- Administrative NADAs received during FY 2005 are reviewed within 85 days.

FY 06 Review and Act on 90 percent of:

- NADAs and reactivations of NADAs received during FY 2006 are reviewed within 230 days.
- Non-manufacturing supplemental animal drug applications and reactivations of such supplemental applications received during FY 2006 are reviewed within 235 days.
- Manufacturing supplemental animal drug applications and reactivations of such supplemental applications received during 2006 are reviewed within 140 days.
- Investigational animal drug study submissions received during FY 2006 are reviewed with in 235 days.
- 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 application, without substantial data submissions received during FY 2006 are reviewed within 80 days.
- Administrative NADAs received during FY 2006 are reviewed within 80 days.

FY 07 Review and Act on 90 percent of:

- NADAs and reactivations of NADAs received during FY 2007 are reviewed within 200 days.
- Non-manufacturing supplemental animal drug applications and reactivations of such supplemental applications received during FY 2007 are reviewed within 200 days.
- Manufacturing supplemental animal drug applications and reactivations of such supplemental applications received during FY 2007 are reviewed within 120 days.
- Investigational animal drug study submissions received during FY 2007 are reviewed within 200 days.
- 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 application, without substantial data submissions received during FY 2007 are reviewed within 60 days.
- Administrative NADAs received during FY 2007 are reviewed within 70 days.

FY 08 Review and Act on 90 percent of:

- NADAs and reactivations of NADAs received during FY 2008 are reviewed within 180 days.
- Non-manufacturing supplemental animal drug applications and reactivations of such supplemental applications received during FY 2008 are reviewed within 180 days.
- Manufacturing supplemental animal drug applications and reactivations of such supplemental applications received during FY 2008 are reviewed within 120 days.
- Investigational animal drug study submissions received during FY 2008 are reviewed within 180 days.
- 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 application, without substantial data submissions received during FY 2008 are reviewed within 50 days.
- Administrative NADAs received during FY 2008 are reviewed within 60 days.

Appendix B: Summary of the ADUFA Performance Goals

Activity	Performance Level	FDA Review Time (Days)				
		FY 04	FY 05	FY 06	FY 07	FY 08
Application/Submission Goals						
NADAs and reactivations of such applications	90%	295	270	230	200	180
Non-manufacturing supplemental NADAs and reactivations of such supplemental applications	90%	320	285	235	200	180
Manufacturing supplemental NADAs and reactivations of such supplemental applications	90%	225	190	140	120	120
INAD submissions	90%	320	285	235	200	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%	125	100	80	60	50
Administrative NADAs	90%	90	85	80	70	60
Interim Backlog Goals						
Review and act on pending animal drug applications, supplemental animal drug applications, and INAD submissions within 24 months of initiation of user fee payments.						
Additional Interim Goals						
Fifty percent of FDA incremental review staff recruited and on-board by first quarter of FY 2006. Total staff increment on-board by end of FY 2008.						
FDA will review all submissions in accordance with procedures for working within a queue. An application/submission that is not reviewed within the applicable Interim Application/Submission Goal timeframe will be reviewed with the highest possible priority among those pending.						

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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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