Food and Drug Administration
Department of Health and Human Services

FY 2004 PERFORMANCE REPORT TO THE 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 FY 2004 Performance Report to Congress for the Animal Drug User Fee Act (ADUFA) of 2003. The ADUFA was enacted on November 18, 2003, and authorized the Food and Drug Administration (FDA) to collect fees above base appropriations needed to build and modernize the animal drug review program. The Agency agreed, under this new Act, to meet a comprehensive set of performance goals established to show significant improvement in the timeliness and predictability of the new animal drug review process. The report that follows presents the Agency's accomplishments for FY 2004, the first year operating under ADUFA. It is my pleasure to report the FDA is meeting or exceeding each performance goal targeted for FY 2004.

As part of ADUFA implementation, the Agency has improved the new animal drug review process, hired additional FDA staff, and prepared guidance for the industry and staff. The Agency has also reached beyond the established ADUFA performance goals to work collaboratively with the industry to reduce the frequency of multiple review cycles in the new animal drug application process.

While FDA's first year under ADUFA was highly productive and successful, much work remains to complete the building process begun this year. In FY 2005, FDA plans to do the following:

- Continue hiring additional staff necessary to achieve the review capacity dictated by ADUFA.
- Continue work already begun on management initiatives (including quality business systems and new information technology systems and solutions).
- Develop improved standard operating procedures for review processes and develop scientific policies for review staff.
- Issue guidance to the industry to clarify current Agency thinking.
- Direct and target training and educational opportunities for staff and management to improve the knowledge base of the review organization.

The Agency 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, cost-effective improvements in FDA's review of new animal drug applications and submissions. Under the leadership of the President and in collaboration with the Congress and industry, the FDA looks forward to the continued success and significant improvements in the animal drug review process that ADUFA will make possible in the coming years.

Lester M. Crawford, D.V.M., Ph.D.
Acting Commissioner of Food and Drugs

Executive Summary

On November 18, 2003, the President signed the Animal Drug User Fee Act of 2003 (ADUFA) into law. ADUFA amends the Federal Food, Drug, and Cosmetic Act to authorize FDA to collect user fees from new animal drug sponsors. In exchange for this authority, ADUFA requires FDA to pursue a comprehensive set of review performance goals and commitments to improve the timeliness and predictability of the review of new animal drug applications (NADAs) and investigational new animal drug (INAD) submissions. This report describes FDA's accomplishments in FY 2004 toward meeting the performance goals prescribed under ADUFA.

FY 2004 Activities and Accomplishments

FY 2004 ADUFA Performance. FDA met or exceeded all the review time frames defined under ADUFA for FY 2004 for applications and submissions that have been acted on as of September 30, 2004. Additional applications and submissions received in FY 2004 are pending review and action, but are still within ADUFA time frames. FY 2004 performance will be updated in FY 2005 to reflect these pending actions.

FDA Backlog. The 833 submissions not associated with abbreviated new animal drug applications (ANADAs) that were pending before September 30, 2003, have been reviewed and acted upon**.** FDA was required to review and act on pending NADAs, supplemental NADAs, and INAD submissions within 24 months after user fee payments were initiated.

FDA Hiring. FDA has made substantial progress in recruiting for its review staff and will meet its goal of having 50 percent of additional FDA review staff recruited and on-board by the first quarter of FY 2006.

Guidance Development. On March 15, 2004, the Agency published *Guidance for Industry #170 Animal Drug User Fees and Fee Waivers and Reductions* to help industry understand the ADUFA fee structure and the options available to individuals who qualify for a fee waiver or reduction. On September 28, 2004, the Agency published *Guidance for Industry #173 Animal Drug Sponsor Fees under the Animal Drug User Fee Act (Draft Guidance).*

Implementation Plans for FY 2005

During FY 2005, FDA will expand its efforts, through employee hiring, training, and guidance development to improve the timeliness and efficiency of animal drug review programs and build FDA's capacity to meet the more challenging goals set for later years.

- **Employee Hiring.** FDA plans to hire the remaining review staff allocated to help meet the ADUFA performance goals by the end of the fiscal year and for project managers to guide the animal drug review process more efficiently. Higher levels of professional development will be offered to review scientists to maintain and further develop the cutting edge knowledge base they need to review emerging technologies in drug development.

- **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 continue to implement a quality business system using an activity-based model to demonstrate better performance-to-budget efficiency and to explore, and propose as needed, new IT systems and solutions for electronic receipt, review, and standardization of NADA submissions.

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

- **Staff Training.** FDA will direct and target training and educational opportunities for staff and management to improve the knowledge base of the review organization.

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Introduction

The Animal Drug User Fee Act of 2003 (ADUFA) was enacted on November 18, 2003. This statute authorized FDA to collect user fees for certain applications and supplements, establishments, products, and sponsors to support the review of new animal drugs. The Consolidated Appropriations Act of 2004, enacted on January 23, 2004, contained a required appropriations action enabling FDA's implementation of ADUFA. In return for stable appropriations and user fees, FDA must meet certain performance goals for the review of certain submissions over the next 5 years. Information about ADUFA, including the text of Secretary Thompson's November 13, 2003, letter to Congress are located in Appendix A and can also be found at http://www.fda.gov./oc/adufa.

This year's report summarizes FDA's progress in implementing ADUFA in FY 2004 and in meeting quantifiable ADUFA review goals for FY 2004. The report also describes FDA's implementation plans for FY 2005.

ADUFA requires the Secretary 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 document fulfills the first of these requirements for FY 2004.

Overview of ADUFA

The ADUFA was signed into law on November 18, 2003, amending the Federal Food, Drug, and Cosmetic Act to provide FDA 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 the FDA resources devoted to "the process for review of new animal drug applications."

ADUFA established review performance goals for the Agency. These goals aim 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 over 10 years and the recently enacted Medical Device User Fee and Modernization Act (MDUFMA). It is expected that ADUFA, like PDUFA and MDUFMA, will 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 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 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 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.

Progressive Goal Setting Over Five Years

The ADUFA performance goals are progressive over a 5-year period with each year requiring FDA to review and act in shorter periods of time. The fifth year of ADUFA will end on September 30, 2008. In that fifth year, FDA will be required to review and act on 90 percent of the following submissions within the following specified times:

- Complete NADAs and reactivations of such applications within 180 days after submission date.
- Non-manufacturing supplemental NADAs (i.e., 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 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 within 50 days after submission date.
- Administrative NADAs submitted after all scientific decisions have been made in the investigational animal drug process, (i.e., prior to submission of the NADA) within 60 days after submission date.

The five-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 consequence 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. With the exception of this report, where only information for the first reporting year (FY 2004) is available, FDA will report, in subsequent years on two performance years for ADUFA performance. Starting with the FY 2005 report, the status of the current year and an update on the previous year will be included.

ADUFA Implementation

FDA is taking action, as part of its ADUFA implementation, to address backlogs and hire new employees. These actions are intended to position FDA to meet the progressively challenging performance goals of ADUFA. Concurrently, FDA is also addressing more immediate needs.

FY 2004 Activities and Accomplishments

FDA has met or exceeded all of the interim goals for FY 2004.

- **Interim Backlog Goal.** On September 30, 2003, FDA had 833 pending submissions not associated with ANADAs. All submissions not associated with ANADAs that were pending before September 30, 2003, have been reviewed.

- **Employee Hiring**. FDA has made substantial progress in recruiting for its review staff and will meet its goal of having 50 percent of additional FDA review staff recruited and on-board by the first quarter of FY 2006.

- **Interim Application/Submission Review Goals.** FDA has met or exceeded all the interim review time frames for FY 2004.

- **Guidance Development.** On March 15, 2004, the Agency published a guidance document on animal drug user fees, fee waivers, and fee reductions (*Guidance for Industry #170 Animal Drug User Fees and Fee Waivers and Reductions*) to help industry understand the ADUFA fee structure and what options are available to those individuals who may quality for a fee waiver or reduction. On September 28, 2004, the Agency published a guidance document, *Guidance for Industry #173 Animal Drug Sponsor Fees under the Animal Drug User Fee Act (Draft Guidance)*, that discusses how the Agency intends to implement the animal drug sponsor fee provision of ADUFA.

Implementation Plans for FY 2005

During FY 2005, FDA will expand its efforts, through employee hiring, training, and guidance development, to improve the timeliness and efficiency of animal drug review programs and build FDA's capacity to meet the more challenging goals set for later years.

- **Employee Hiring.** FDA plans to hire the remaining review staff allocated to help meet the ADUFA performance goals by the end of the fiscal year. Project managers will be hired to guide the animal drug review process more efficiently.

Higher levels of professional development will be offered to review scientists to help them maintain and further develop the cutting edge knowledge base they need to review emerging technologies in drug development.

- **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 continue to implement a quality business system using an activity-based model to demonstrate better performance-to-budget efficiency and to explore, and propose as needed, new IT systems and solutions for electronic receipt, review, and standardization of NADA submissions.

- **Guidance Development.** FDA will continue to issue guidance to the industry clarifying current Agency thinking.

- **Staff Training.** FDA will 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.

Report on FY 2004 ADUFA Performance

This report presents the Agency's review performance as related to ADUFA performance goals and commitments in FY 2004. Only a preliminary performance assessment on applications submitted during FY 2004 is possible now. For submission categories with a longer review goal (e.g., 320 days), early review performance data is limited. For those submission categories with a review goal that is shorter (e.g., 90 days) performance on submissions received early in the fiscal year provides an early indicator of final review performance. Unless otherwise noted, all performance data in this section are as of September 30, 2004.

Original NADAs and Reactivations

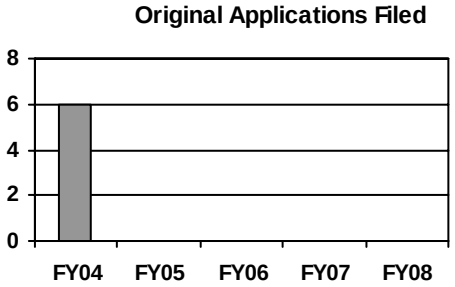
Goal - Review and act on original NADAs and reactivations

The ADUFA goal for applications received in FY 2004 requires FDA to review and act on 90 percent of complete NADAs and reactivations of such applications within 295 days after the submission date. Under ADUFA, FDA will gradually reduce the target review time from 295 days for submissions received in FY 2004 to 180 days for submissions received in FY 2008. The table below summarizes the review time goals for original NADAs and reactivations of such applications.

Original Application Type	Review Time Goal					Performance Goal FY 04 – FY 08 Submissions
	FY 04	FY 05	FY 06	FY 07	FY 08	
NADAs and Reactivations	295 days	270 days	230 days	200 days	180 days	90% on time

Workload

During FY 2004, seven original NADAs and reactivations were submitted to FDA and accepted for filing.[1] One original NADA received a "refuse to file" notification.



Original Applications Filed					
Filed	FY 04	FY 05	FY 06	FY 07	FY 08
NADAs and Reactivations	7	--	--	--	--

[1]The count of FY 2004 submissions assumes that all submissions received in the last month of FY 2004 are filed. When FDA files a submission, it is deemed "complete" by ADUFA definition. FDA makes a filing decision within 30 days of an original application's receipt. All calculations of ADUFA review times are made, however, from the original receipt date of the filed application.

Original NADAs and Reactivations

Performance

FY 2004 Submissions

As of September 30, 2004, approximately 71 percent (5 of 7) of the original NADAs and reactivations were reviewed and acted on within 295 days. With 2 submissions still pending and not overdue, it is too early to make a final performance determination for FY 2004. The table below reflects FDA's performance for these submissions that were reviewed and acted on in FY 2004.

FY 2004 Submissions					
Original Application Type	**Review Within**	**Reviewed and Acted On**	**Number On Time**	**ADUFA Performance Goal**	**Percent on Time**
NADAs and Reactivations	295 days	5	5	90%	100%

Non-Manufacturing Supplemental NADAs and Reactivations

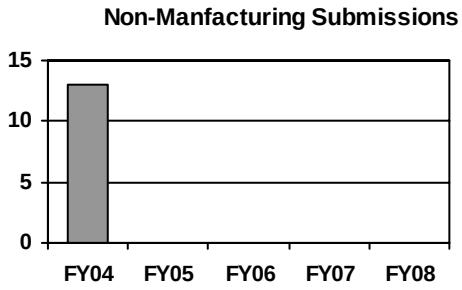
Goal - Review and act on non-manufacturing supplemental NADAs and reactivations

The ADUFA goal for applications received in FY 2004 requires FDA to review and act on 90 percent of the non-manufacturing supplemental NADAs (i.e., supplemental animal drug applications for which safety or effectiveness data are required) and reactivations of such supplemental applications within 320 days after the submission date. Under ADUFA, FDA will gradually reduce the target review time from 320 days for submissions received in FY 2004 to 180 days for submissions received in FY 2008. The table below summarizes the review time goals for non-manufacturing supplemental NADAs and reactivations of such supplemental NADAs.

Non-Manufacturing Submission Type	Review Time Goal					Performance Goal FY 04 – FY 08 Submissions
	FY 04	FY 05	FY 06	FY 07	FY 08	
Supplemental NADAs and Reactivations	320 days	285 days	235 days	200 days	180 days	90% on time

Workload

During FY 2004, 14 non-manufacturing supplemental NADAs and reactivations were submitted to FDA.



Non-Manufacturing Submissions					
Type	FY 04	FY 05	FY 06	FY 07	FY 08
Supplemental NADAs and Reactivations	14	--	--	--	--

Non-Manufacturing Supplemental NADAs and Reactivations

Performance

FY 2004 Submissions

As of September 30, 2004, approximately 57 percent (8 of 14) of the non-manufacturing supplemental NADAs and reactivations had been reviewed and acted on within the 320 days. With six submissions still pending and not overdue, it is too early to make a final performance determination for FY 2004. The table below reflects FDA's performance for these submissions that were reviewed and acted on in FY 2004. The FY 2005 ADUFA report will provide an update for FY 2004 submissions and report on FY 2005 submissions.

FY 2004 Submissions					
Non-Manufacturing Submission Type	**Review Within**	**Reviewed and Acted On**	**Number On Time**	**ADUFA Performance Goal**	**Percent on Time**
Supplemental NADAs and Reactivations	320 days	8	8	90%	100%

Manufacturing Supplemental NADAs and Reactivations

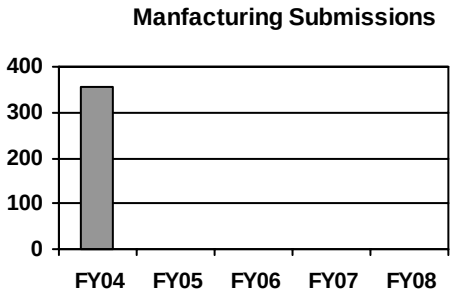
Goal - Review and act on manufacturing supplemental NADAs and reactivations

The ADUFA goal for applications received in FY 2004 requires FDA to review and act on 90 percent of the manufacturing supplemental NADAs (i.e., supplemental animal drug applications for which safety or effectiveness data are required) and reactivations of such supplemental applications within 225 days after submission date. Under ADUFA, FDA will gradually reduce the target review time from 225 days for submissions received in FY 2004 to 120 days for submissions received in FY 2007 and FY 2008. The table below summarizes the review time goals for manufacturing supplemental NADAs and reactivations of such supplemental NADAs.

Manufacturing Submission Type	Review Time Goal					Performance Goal FY 04 – FY 08 Submissions
	FY 04	FY 05	FY 06	FY 07	FY 08	
Supplemental NADAs and Reactivations	225 days	190 days	140 days	120 days	120 days	90% on time

Workload

During FY 2004, 357 manufacturing supplemental NADAs and reactivations were submitted to FDA and accepted for filing. Two manufacturing supplemental NADAs received a "refuse to file" notification.



Manufacturing Submissions					
Type	FY 04	FY 05	FY 06	FY 07	FY 08
Supplemental NADAs and Reactivations	357	--	--	--	--

Manufacturing Supplemental NADAs and Reactivations

Performance

FY 2004 Submissions

As of September 30, 2004, approximately 64 percent (230 of 357) of the manufacturing supplemental NADAs and reactivations were reviewed and acted on within the 225 days. With 127 submissions still pending and not overdue, it is too early to make a final performance determination for FY 2004. The table below reflects FDA's performance for these submissions that were reviewed and acted on in FY 2004. The FY 2005 ADUFA report will provide an update for FY 2004 submissions and report on FY 2005 submissions.

FY 2004 Submissions					
Manufacturing Submission Type	**Review Within**	**Reviewed and Acted On**	**Number On Time**	**ADUFA Performance Goal**	**Percent On Time**
Supplemental NADAs and Reactivations	225 days	230	230	90%	100%

INAD Study Submissions

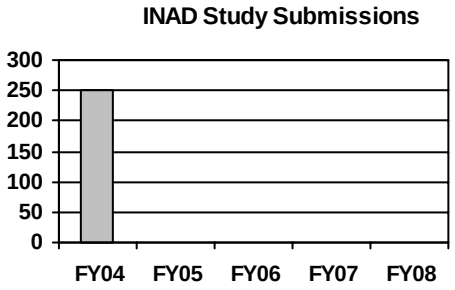
Goal - Review and act on INAD study submissions

The ADUFA goal for submissions received in FY 2004 requires FDA to review and act on 90 percent of the INAD study submissions within 320 days after the submission date. Under ADUFA, FDA will gradually reduce the target review time from 320 days for submissions received in FY 2004 to 180 days for submissions received in FY 2008. The table below summarizes the review time goals for INAD study submissions.

Submission Type	Review Time Goal					Performance Goal FY 04 – FY 08 Submissions
	FY 04	FY 05	FY 06	FY 07	FY 08	
INAD Studies	320 days	285 days	235 days	200 days	180 days	90% on time

Workload

During FY 2004, 251 INAD study submissions were submitted to FDA and accepted for filing. One INAD study submission received a "refuse to review" notification.



INAD Study Submissions					
Type	FY 04	FY 05	FY 06	FY 07	FY 08
INAD Studies	251	--	--	--	--

INAD Study Submissions

Performance

FY 2004 Submissions

As of September 30, 2004, approximately 43 percent (107 of 251) of the INAD study submissions had been reviewed and acted on within 320 days. With 144 submissions still pending and not overdue, it is too early to report final review performance determination for FY 2004. The table below reflects FDA's performance for these submissions that were reviewed and acted on in FY 2004. The FY 2005 ADUFA report will provide an update for FY 2004 submissions and report on FY 2005 submissions.

FY 2004 Submissions					
Submission Type	**Review Within**	**Reviewed and Acted On**	**Number On Time**	**ADUFA Performance Goal**	**Percent on Time**
INAD Studies	320 days	107	107	90%	100%

INAD Study Protocol Submissions

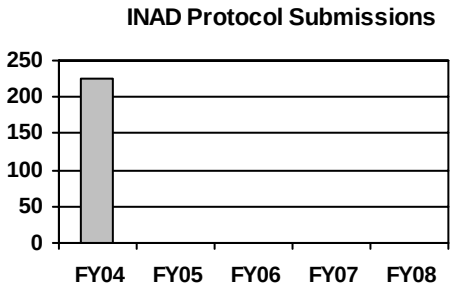
Goal - Review and act on INAD study protocol submissions

The ADUFA goal for submissions received in FY 2004 requires FDA to review and act on 90 percent of INAD study protocol submissions within 125 days after the submission date. Under ADUFA, FDA will gradually reduce the target review time from 125 days for submissions received in FY 2004 to 50 days for submissions received in FY 2008. The table below summarizes the review time goals for INAD study protocol submissions.

Submission Type	Review Time Goal					Performance Goal FY 04 – FY 08 Submissions
	FY 04	FY 05	FY 06	FY 07	FY 08	
INAD Protocols	125 days	100 days	80 days	60 days	50 days	90% on time

Workload

During FY 2004, 224 INAD protocols were submitted to FDA and accepted for filing. Four INAD protocols received a "refuse to review" notification.



INAD Protocol Submissions					
Type	FY 04	FY 05	FY 06	FY 07	FY 08
INAD Protocols	224	--	--	--	--

INAD Study Protocol Submissions

Performance

FY 2004 Submissions

As of September 30, 2004, approximately 66 percent (147 of 224) of the INAD study protocols had been reviewed and acted on within 125 days. With 77 submissions still pending and not overdue, it is too early to report final review performance determinations for FY 2004. The table below reflects FDA's performance for these submissions that were reviewed and acted on in FY 2004. The FY 2005 ADUFA report will provide an update for FY 2004 submissions and report on FY 2005 submissions.

FY 2004 Submissions					
Submission Type	**Review Within**	**Reviewed and Acted On**	**Number On Time**	**ADUFA Performance Goal**	**Percent on Time**
INAD Protocols	125 days	147	147	90%	100%

Administrative NADAs and Reactivations

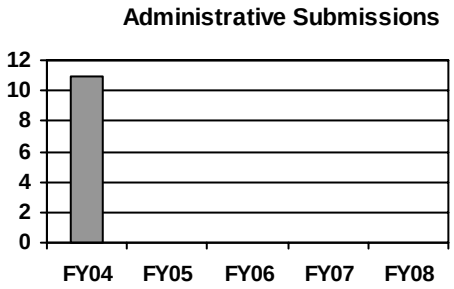
Goal - Review and act on administrative NADAs and reactivations

The ADUFA goal for applications received in FY 2004 requires FDA to review and act on 90 percent of administrative NADAs and reactivations of such applications within 90 days after the submission date. Under ADUFA, FDA will gradually reduce the target review time from 90 days for submissions received in FY 2004 to 60 days for submissions received in FY 2008. The table below summarizes the review time goals for administrative NADAs and reactivations of such applications.

Submission Type	Review Time Goal					Performance Goal FY 04 – FY 08 Submissions
	FY 04	FY 05	FY 06	FY 07	FY 08	
Administrative NADAs and Reactivations	90 days	85 days	80 days	70 days	60 days	90% on time

Workload

During FY 2004, 10 administrative NADAs and reactivations were submitted to FDA.



Administrative Submissions					
Type	FY 04	FY 05	FY 06	FY 07	FY 08
Administrative NADAs and Reactivations	10	--	--	--	--

Administrative NADAs and Reactivations

Performance

FY 2004 Submissions

As of September 30, 2004, 80 percent (8 of 10) of the administrative NADAs and reactivations had been reviewed and acted on within 90 days. With 2 applications pending and not overdue, it is too early to make a final performance determination for FY 2004. The table below reflects FDA's performance for these applications that were reviewed and acted on in FY 2004. The FY 2005 ADUFA report will provide an update for FY 2004 submissions and report on FY 2005 submissions.

FY 2004 Submissions					
Submission Type	**Review Within**	**Reviewed and Acted On**	**Number On Time**	**ADUFA Performance Goal**	**Percent on Time**
Administrative NADAs and Reactivations	90 days	8	8	90%	100%

Abbreviated New Animal Drug Applications

Section 740(k) Abbreviated New Animal Drug Applications of the ADUFA 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

CVM had already established within its Office of New Animal Drug Evaluation (ONADE) a separate staff, the Generic Animal Drug Team, dedicated specifically to the review of Abbreviated New Animal Drug Applications (ANADAs) and submissions. This staff was brought up to full pre-ADUFA capacity by filling existing vacancies during 2004. In addition, a specific team was established within ONADE’s Division of Manufacturing Technologies to handle related ANADA chemistry reviews.

CVM administers a totally 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 also ensures that ANADAs are reviewed independently of applications under ADUFA by dedicated staff. In addition, 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 has established a baseline of sentinel submission review times averaged over the previous 3 fiscal years (2001 – 2003). The document and submission types chosen for monitoring were those that represented analogous submission types to the ADUFA sentinel submission types. The office monitors on a continuous basis current year completed review times for these submissions. We are pleased to report that review times for completed sentinel submissions during FY 2004 did not increase, compared to the baseline.

Appendix A: DHHS Secretary Thompson's Commitment Letter to Congress

On November 13, 2003, the Department of Health and Human Services (DHHS) Secretary Thompson sent identical commitment 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 the FDA Center for Veterinary Medicine (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

The goals and procedures of the FDA Center for Veterinary Medicine (CVM) as agreed to under the "Animal Drug Fee Act 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 of 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 in condition for approval. Within 30 days of submission, FDA shall refuse to file and 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 animals 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 2004 -- *Review and Act on 90 percent of:*

- *Animal drug applications (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 225 days.*
- *Manufacturing supplemental animal drug applications and reactivations of such supplemental applications received applications received during FY 2004 are reviewed within 320 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 ADUFA's Performance Goals

Activity	Performance Level	FDA Review Time (in days)				
		FY 04	FY 05	FY 06	FY 07	FY 08
Application/Submission Goals						
Animal drug applications (NADAs) and reactivations of such applications	90%	295	270	230	200	180
Non-manufacturing supplemental animal drug applications and reactivations of such supplemental applications	90%	320	285	235	200	180
Manufacturing supplemental animal drug applications and reactivation of such supplemental applications	90%	225	190	140	120	120
Investigational animal drug study submissions	90%	320	285	235	200	180
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	90%	125	100	80	60	50
Administrative animal drug applications (administrative NADAs)	90%	90	85	80	70	60
Interim Backlog Goals						
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						
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.						

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

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