IMPLEMENTING THE ANIMAL DRUG USER FEE ACT OF 2003 (ADUFA)

I. PURPOSE

The purposes of this document are to:

- Define sentinel submissions and the criteria that they must meet in order to be considered in the user fee-related metric calculations, and
- Explain how ADUFA applies to the review of generic applications and submissions.

II. BACKGROUND

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, the Department of Health and Human Services (Department) (on behalf of CVM) agreed to meet certain performance goals for the review of certain submissions over the next five years. These performance goals are contained in the Goals Letter.

III. DEFINITIONS

A. Goals Letter

The "Goals Letter," dated November 13, 2003, contains the performance goals that the Department (on behalf of CVM) has agreed to meet with the increased funding provided by ADUFA. The letter was signed by the Secretary of the Department of Health and Human Services, Tommy Thompson, and addressed to the Chairman and Ranking Member of the U.S. Senate Committee on Health, Education, Labor and Pensions, and the Chairman and Ranking Member of the U.S. House of Representatives Committee on Energy and Commerce (Appendix 1).

B. Sentinel submission

"Sentinel" submissions are selected types of submissions that CVM will use as indicators of overall performance in reviewing all submissions in a timely manner. CVM will compare the time CVM spends reviewing these sentinel submissions against timeframes for these submissions that are established in the Goals Letter. The six classes of sentinel submissions identified in the Goals Letter are:

- Original approvals and reactivations,
- Non-manufacturing supplemental approvals and reactivations,
- Manufacturing supplemental approvals and reactivations,
- Investigational animal drug study submissions,
- Investigational animal drug protocol submissions, and
- Administrative new animal drug applications (NADAs).

C. Sentinel submission cohort

Sentinel submission cohorts are the subsets of sentinel submissions that CVM will use to calculate whether CVM has met the performance goals established in the Goals Letter.

D. Cohort year

A cohort year runs concurrently with the government's fiscal year, October 1st of one year through September 30th of the next year. Cohort Year 2004 (CoY-04) is October 1, 2003 through September 30, 2004.

E. Determining the cohort year for a submission

Generally, a submission is included in the cohort year in which it is received. This determination may be modified when, for example, the sponsor has failed to make timely user fee payments (see section V.A) or has amended the submission.[1]

IV. SENTINEL SUBMISSION COHORT REVIEW TIMES

The following table presents the target review times that the Department (on behalf of CVM) agreed to meet in the Goals Letter. CVM has agreed to complete 90% of the reviews for each type of submission within the target review times.

Target Review Times (Days) to be Met for 90% of Each of the Sentinel Submissions Cohorts During the Five Years of User Fees					
	CoY-04	CoY-05	CoY-06	CoY-07	CoY-08
Original approval and reactivations	295	270	230	200	180
Non-manufacturing supplemental approval and reactivations	320	285	235	200	180
Manufacturing supplemental approvals and reactivations	225	190	140	120	120
Phased data submissions	320	285	235	200	180
Review of protocols without data	125	100	80	60	50
Administrative NADAs	90	85	80	70	60

V. GENERIC APPLICATIONS AND SUBMISSIONS

ADUFA prohibits the collection or use of user fee funds to review most submissions relating to abbreviated new animal drug applications (ANADAs) or investigational new animal drug files used to support ANADAs (JINADs), but ADUFA requires CVM

[1] See P&P 1243.3024, Amending STARS Submissions, will describe ONADE's procedures for amending submissions. Until this document is available, talk to your team leader or division director for instruction.

to ensure that review times for these generic submissions do not increase due to ADUFA-related activities.

CVM may collect and use user fee funds to review supplements to approved ANADAs submitted under section 512(b)(1) of the act [(b)(1) supplements]. Because these submissions require, or relate to, the review of safety or effectiveness information (other than that required to demonstrate bioequivalence), they will be reviewed in the target animal divisions, rather than by the Generic Drugs Team, under new INADs and NADAs. Submissions that relate to these (b)(1) supplements could include both sentinel submissions (e.g., protocol reviews, phased data reviews, and supplements and reactivations) and non-sentinel (e.g., meeting requests and drug shipment notices) submissions. The STARS coding of final actions for these (b)(1) submissions to NADAs and INADs will also follow the guidance presented below.

Submissions under section 512(b)(2) of the act that supplement ANADAs will continue to be reviewed by the Generic Drugs Team and will not be subject to user fees. Manufacturing supplements to ANADAs will continue to be reviewed by a dedicated generic review staff in CVM's Division of Manufacturing Technologies.

VI. REASONS TO NOT REVIEW A SUBMISSION

A. Refuse to accept for filing

CVM will not accept submissions from a sponsor subject to ADUFA fees when CVM's ADUFA Team has determined that the sponsor is not current on fee payments. In these cases, the ADUFA Team will either final out the submission (STARS action code 063; Refuse to accept submission for filing; acct in arrears; letter sent) or forward the submissions to the review staff only after the fee payments are current. The receipt date of these submissions marks both the cohort year determination and the beginning of CVM's review clock for them.[2] A submission's receipt date is either the date that the submission was physically received (and date-stamped) by the Document Control Unit (DCU) or, in those instances where sponsors subject to ADUFA user fees are not current in their payment and the submission has not been closed out with a final action code of 063 (Refuse to accept submission for filing; acct in arrears; letter sent), the receipt

[2] The cohort year a submission is assigned may change if the submission is amended.

date becomes the date on which CVM is notified that the sponsor is current on all ADUFA user fees.[3]

B. Refuse to file applications

The regulations, 21 CFR 514.110, and the Goals Letter specify that CVM has 30 days to determine if an application will be filed. CVM will refuse to file any application that CVM determines to be incomplete on its face or otherwise of unacceptable quality for review as per §514.110.

C. Refuse to review submissions

As stated in the Goals Letter, CVM has 60 days to determine if we will refuse to review an individual submission to an INAD because it is of unacceptable quality on its face or is otherwise unacceptable for review.[4]

VII. SENTINEL SUBMISSION COHORT GROUPS

A. Original NADA Applications and Reactivations

1. STARS Codes:

   NADA As and Es (and associated amendments, Ms and Ts, respectively)

2. The only permissible STARS coding for final actions of completed submissions are:

   a. Document withdrawn by request of sponsor; letter sent (021),

   b. Incomplete application; letter sent (024),

   c. Incomplete application; account in arrears; letter sent (026),

   d. Original application approved date of letter; letter sent (056),

   e. Refuse to file application; letter sent (060),

[3] The ADUFA Team enters the date of payment as the receipt date. The stamp date will continue to show the date CVM physically received the submission.

[4] See Guidance for Industry: How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug (#119).

f. Refuse to accept submission for filing; account in arrears; letter sent (063),

g. Review suspended by fraud policy; letter sent (090),

h. Quality control closeout; action taken; submission lost (665), and

i. Mark submission as void to preserve submission number (666).

3. Considerations for inclusion in the cohort:

a. To be in the cohort, the submission must have one of the following final action codes:

i. Incomplete application; letter sent (024),

ii. Incomplete application; account in arrears; letter sent (026), or

iii. Original application approved date of letter; letter sent (056).

b. Submissions enter the cohort on their receipt date.

c. If CVM "refuses to file" (RTF) the original application (STARS final action code 060), subsequent submissions attempting to re-file the original application will be assigned the "A" submission type code and numbered consecutively for each attempt.

B. Non-Manufacturing Supplemental Approvals and Reactivations

1. STARS Codes:

NADA Cs and Rs (and associated amendments, Ss and Us, respectively)

2. The only permissible STARS coding for final actions of completed submissions are:

a. Document withdrawn by agency; letter sent (020),

b. Document withdrawn by request of sponsor; letter sent (021),

c. Supplement withdrawn by request of sponsor; letter sent (022),

d. Incomplete application; letter sent (024),

e. Incomplete application; account in arrears; letter sent (026),

f. Minor supplement approved date of letter; letter sent (050),

g. Significant supplement approved date of letter; letter sent (051),

h. Refuse to file application; letter sent (060),

i. Refuse to accept submission for filing; account in arrears; letter sent (063),

j. Review suspended by fraud policy; letter sent (090),

k. Quality control closeout; action taken; submission lost (665), and

l. Mark submission as void to preserve submission number (666).

3. Considerations for inclusion in the cohort:

a. To be in the cohort, the submission must have one of the following final action codes:

i. Incomplete application; letter sent (024),

ii. Incomplete application; account in arrears; letter sent (026),

iii. Minor supplement approved date of letter; letter sent (050), or

iv. Significant supplement approved date of letter; letter sent (051).

b. Submissions enter the cohort on their receipt date.

c. If CVM refuses to file (STARS final action code 060) the supplemental application, subsequent submissions attempting to re-file the supplemental application will be assigned the "C" submission type code and numbered consecutively for each attempt.

C. Manufacturing Supplemental Approvals and Reactivations

1. STARS Codes:

   NADA Cs and Rs (and associated amendments, Ss and Us, respectively)

2. The only permissible STARS coding for final actions of completed submissions are:

   a. Document withdrawn by agency; letter sent (020),

   b. Document withdrawn by request of sponsor; letter sent (021),

   c. Supplement withdrawn by request of sponsor; letter sent (022),

   d. Incomplete application; letter sent (024),

   e. Incomplete application; account in arrears; letter sent (026),

   f. Minor supplement approved date of letter; letter sent (050),

   g. Significant supplement approved date of letter; letter sent (051),

   h. Refuse to file application; letter sent (060),

   i. Refuse to accept submission for filing; account in arrears; letter sent (063),

   j. Review suspended by fraud policy; letter sent (090),

   k. Quality control closeout; action taken; submission lost (665), and

   l. Mark submission as void to preserve submission number (666).

3. Considerations for inclusion in the cohort:

   a. To be in the cohort, the submission must have one of the following final action codes:

      i. Incomplete application; letter sent (024),

      ii. Incomplete application; account in arrears; letter sent (026),

iii. Minor supplement approved date of letter; letter sent (050), or

iv. Significant supplement approved date of letter; letter sent (051).

b. Submissions enter the cohort on their receipt date.

c. If CVM refuses to file (STARS final action code 060) the supplemental application, subsequent submissions attempting to re-file the supplemental application will be assigned the "C" submission type code and numbered consecutively for each attempt.

D. Investigational New Animal Drug Study Submissions

1. STARS Codes:

   INAD Ps (and associated amendments, Ts)

2. The only permissible STARS coding for final actions of completed submissions are:

   a. Submission filed with review documentation; no letter sent (009),

   b. Refuse to accept submission for filing; account in arrears; letter sent (063),

   c. Submission unacceptable for review; letter sent (065),

   d. Submission review terminated at sponsor request; letter sent (066),

   e. Review suspended by fraud policy; letter sent (090),

   f. Technical section incomplete; submitted information not acceptable; letter sent (201),

   g. Technical section complete; letter sent (202),

   h. Technical section incomplete; submitted information acceptable; letter sent (203),

   i. Quality control closeout; action taken; submission lost (665), and

j. Mark submission as void to preserve submission number (666).

3. Considerations for inclusion in the cohort:

a. To be in the cohort, the submission must have one of the following final action codes:

i. Technical section incomplete; submitted information not acceptable; letter sent (201),

ii. Technical section complete; letter sent (202), or

iii. Technical section incomplete; submitted information acceptable; letter sent (203).

b. Submissions enter the cohort on their receipt date.

c. A "P" submission must provide, in whole or in part, information supporting a Technical Section. Any submissions formerly coded as an "H" ("Study Data") will now be coded as a "P" submission.

E. Investigational New Animal Drug Protocol Reviews

1. STARS Codes – INAD Es (and associated amendments, Ts, in certain documents)

2. The only permissible STARS coding for final actions of completed submissions are:

a. Submission filed with review documentation; no letter sent (009),

b. Protocol acceptable as submitted; letter sent (045),

c. Protocol not acceptable as submitted; letter sent (046),

d. Refuse to accept submission for filing; account in arrears; letter sent (063),

e. Submission unacceptable for review; letter sent (065),

f. Submission review terminated at sponsor request; letter sent (066),

g. Review suspended by fraud policy; letter sent (090),

h. Quality control closeout; action taken; submission lost (665), and

i. Mark submission as void to preserve submission number (666).

3. Considerations for inclusion in the cohort:

a. To be in the cohort, the submission must have one of the following final action codes:

i. Protocol acceptable as submitted; letter sent (045), or

ii. Protocol not acceptable as submitted; letter sent (046).

b. Submissions enter the cohort on their receipt date.

c. Only one protocol (site-specific or general, and pivotal or non-pivotal) is permitted per submission. If more than one protocol is submitted under a single cover letter, the protocols will be "unbundled," assigned separate submission numbers, and treated as multiple submissions.

F. Administrative NADAs

1. STARS Codes – NADA As, Es, Cs, and Rs (Administrative NADA status flagged by action code in STARS)

2. The only permissible STARS coding for final actions of completed submissions are:

a. Document withdrawn by agency; letter sent (020),

b. Document withdrawn by request of sponsor; letter sent (021),

c. Supplement withdrawn by request of sponsor; letter sent (022),

d. Incomplete application; letter sent (024),

e. Incomplete application; acct in arrears; letter sent (026),

f. Minor supplement approved date of letter; letter sent (050),

g. Significant supplement approved date of letter; letter sent (051),

h. Original application approved date of letter; letter sent (056),

i. Refuse to file application; letter sent (060),

j. Refuse to accept submission for filing; acct in arrears; letter sent (063),

k. Review suspended by fraud policy; letter sent (090),

l. Quality control closeout; action taken; submission lost (665), and

m. Mark submission as void to preserve submission number (666).

3. Considerations for inclusion in the cohort:

a. To be in the cohort, the submission must have one of the following final action codes:

i. Incomplete application; letter sent (024),

ii. Incomplete application; account in arrears; letter sent (026),

iii. Minor supplement approved date of letter; letter sent (050),

iv. Significant supplement approved date of letter; letter sent (051), or

v. Original application approved date of letter; letter sent (056).

b. Submissions enter the cohort on their receipt date.

c. Submissions must have technical section complete letters for all applicable technical sections. The inclusion of any additional data or information defines this as a non-administrative NADA.

d. Any amendment (CVM- or sponsor-initiated), other than a minor one, to a pending submission of this type redefines this application as a non-administrative NADA.

VIII. REFERENCES

Code of Federal Regulations

21 CFR 10, Administrative practices and procedures

21 CFR 514.11, Confidentiality of data and information in a new animal drug application file

21 CFR 514.110, Reasons for refusing to file applications

CVM Program Policy and Procedures Manual

1243.3024, Amending STARS Submissions

CVM Guidance for Industry

How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug (#119)

APPENDIX 1: THE GOALS LETTER

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

NOV 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 Under 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 staffs, and the assistance of other Members of the Committee.

Sincerely,

Tommy G. Thompson

Enclosure

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

NOV 13 2003

The Honorable Edward Kennedy
Ranking Member
Committee on Health, Education, Labor
and Pensions
United States Senate
Washington, DC 20510

Dear Senator Kennedy:

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 Under 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 staffs, and the assistance of other Members of the Committee.

Sincerely,

Tommy G. Thompson

Enclosure

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

The Honorable W. J. (Billy) Tauzin
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

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 Under 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 staffs, and the assistance of other Members of the Committee.

Sincerely,

Tommy G. Thompson

Enclosure

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

NOV 13

The Honorable John Dingell
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Dingell:

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 Under 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 staffs, 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 submission 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 application, 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 submission of the NADA) within 60 days after 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 animal drug submission which either (1) approves an animal drug application or supplemental animal drug 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 described above will result in the application or submission not being entered into the cohort upon which the relevant user fee goal is based. The Agency will keep a record of the numbers and types of such refusals and include them in its annual performance report.

FDA may request minor amendments to 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 consider to be an essential part of the basis for making the decision to approve or not approve an animal drug application or supplemental animal drug application, the Agency will issue an acknowledgment letter providing comments resulting from a complete review of the protocol. The acknowledgment 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 90 percent of:

Animal drug applications (NADAs) and reactivations of such applications received during FY 2003 are reviewed within 295 days.

Non-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 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 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 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 2005 are reviewed within 100 days.

Administrative NADAs received during FY 2005 are reviewed within 85 days.

FY 06 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 FY 2006 are reviewed within 140 days.

Investigational animal drug study submissions received during FY 2006 are reviewed within 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 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 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.

Workload Adjustment

The Animal Drug User Fee Act of 2003, requires FDA to annually adjust fee revenues after FY 2004 to reflect changes in review workload utilizing a weighted average of animal drug applications, supplemental animal drug applications for which data with respect to safety or effectiveness are required, manufacturing supplemental animal drug applications, investigational animal drug study submissions, and investigational animal drug protocol submissions. The Agency currently intends to utilize the method detailed below to calculate the workload adjustment, and the percent increase in fees will be the amount of the sum of the output from the workload adjuster that is greater than one (1.0). However, the weighting of the specific factors may change in light of discussions with the animal drug industry and the results of ongoing activity based costing analyses within the Center for Veterinary Medicine.

The term "workload adjuster" applicable to a fiscal year consists of the sum of the following 5 components:

(A) The percent of change in the total number of original and reactivated animal drug applications submitted (comparing the three-year average number of such submissions for fiscal year 2001 – 2003 to the three-year average for the most recent three year period ending June 30 before the start of the fiscal year) times 3 percent.

(B) The percent of change in the total number of original and reactivated supplemental animal drug applications for which data with respect to safety or effectiveness are required (comparing the three-year average number of such submissions for fiscal year 2001 – 2003 to the three- year average for the most recent three year period ending June 30 before the start of the fiscal year) times 12 percent.

(C) The percent of change in the total number of original and reactivated manufacturing supplemental animal drug applications (comparing the three-year average number of such submissions for fiscal year 2001 – 2003 to the three-year average for the most recent three year period ending June 30 before the start of the fiscal year) times 25 percent.

(D) The percent of change in the total number of investigational animal drug study submissions (comparing the three-year average number of such submissions for fiscal year 2001 – 2003 to the three-year average for the most recent three year period ending June 30 before the start of the fiscal year) times 46 percent.

(E) The percent of change in the total number of reviewed investigational animal drug protocol submissions (comparing the three-year average number of such submissions for fiscal year 2001 – 2003 to the three-year average for the most recent three year period ending June 30 before the start of the fiscal year) times 14 percent.