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.

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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.

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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.

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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.