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ANIMAL DRUG USER FEE ACT OF 2003

MAY 21, 2003.—Ordered to be printed

Mr. GREGG, from the Committee on Health, Education, Labor, and Pensions, submitted the following

R E P O R T

[To accompany S. 313]

The Committee on Health, Education, Labor, and Pensions, to which was referred the bill (S. 313) to amend the Federal Food, Drug, and Cosmetic Act to establish a program of fees relating to animal drugs, having considered the same, reports favorably thereon with amendments and recommends that the bill (as amended) do pass.

CONTENTS

I. PURPOSE AND SUMMARY OF LEGISLATION

The Animal Drug User Fee Act (ADUFA) of 2003 (S. 313) would authorize a program of fees by the Food and Drug Administration (FDA) relating to the review of new animal drugs. Under this proposal, the additional revenues generated from fees paid by the animal health industry would be dedicated for use in expediting the new animal drug review process, in accordance with performance goals that would be developed by FDA in consultation with the industry. This legislation will provide resources to improve the animal drug review process through the hiring of new personnel and purchase and maintenance of technological management and infor-

mation systems. The legislation will also increase the animal drug review program's performance capacity and efficiency, aligning it with the Government Performance and Results Act and the President's Management Agenda. The committee intends that the user fee levels reflected in this bill will be sufficient to meet the established performance goals that were negotiated by the industry and the FDA.

With the additional revenues, if appropriated by Congress, FDA should be able to: (1) eliminate existing backlogs of applications within 2 years; (2) over a 5-year period, move toward the goal of completing the review of 90 percent of new animal drug applications within 180 days; (3) resolve new and emerging scientific issues that affect the ability of FDA's Center for Veterinary Medicine (CVM) to make approval decisions; and (4) achieve an enhanced and predictable review performance.

S. 313 will extend the user fee approach to funding FDA animal medical product review activities. The legislation will directly benefit individual members of the regulated industries and speed access to new animal drugs for use by veterinarians and owners of agricultural stock and pets. The legislation also provides flexibility to FDA to adjust fees in appropriate circumstances.

The committee recognizes the value of implementing the full 5-year ADUFA program negotiated between the animal health industry and FDA through 2008. The committee also recognizes the value of the ADUFA being reauthorized at the same time as other FDA user fee programs are reauthorized. The committee anticipates that the animal health industry and FDA will initiate the ADUFA reauthorization process and discussions in 2007, to allow Congress to concurrently reauthorize all FDA user fee programs in 2007.

II. Committee Action

The S. 313, Animal Drug User Fee Act of 2003 was introduced on February 5, 2003 and subsequently marked up by the Committee on Health, Education, Labor, and Pensions executive session on February 12, 2003. At that time, Senator Gregg offered an amendment in the nature of a substitute that changed the initial authorization period for the user fee program from 4 to 5 years, and that made several technical changes to clarify the language of the bill. S. 313 was accepted by unanimous consent and reported favorably from the committee by voice vote.

III. Background and Need for Legislation

Congress, in enacting the Prescription Drug User Fee Act of 1992, Public Law 102–571 (PDUFA), for human pharmaceuticals, required FDA in section 108(a) to conduct a study to evaluate whether, and under what conditions, to impose user fees to supplement appropriated funds to improve the process of reviewing applications for new animal drugs under section 512 of the Federal Food, Drug, and Cosmetic (FD&C) Act.

FDA submitted a report to Congress in 1994. The report revealed several problems: inadequate review resources, a growing workload, and low quality applications submitted by industry. The combination of problems had slowed the approval process to an unac-

ceptable rate. The report noted that if Congress were to consider legislation authorizing the FDA to impose and collect user fees, approximately $11 million would need to be collected annually.

The problems identified in the report continue to persist. A prolonged decrease in resources in the 1990's resulted in a slower, less predictable animal drug review program. In recent years, while funding for CVM programs, in general, has increased significantly, most of these increases were earmarked for CVM activities other than its animal drug review process. Recent modest increases in drug review resources, combined with intense effort on the part of review personnel, have resulted in some improvement in review times. However, the level of effort needed to accomplish this improvement cannot be maintained over the long term without increased funds. The committee believes that a sustainable, predictable animal drug approval process can only be achieved with the additional funds provided by this legislation. Fees collected annually would increase from $5 million in the first year to $10 million in the third year and remain steady through the end of the 5-year period proposed in the legislation.

The veterinary pharmaceutical industry, represented by the Animal Health Institute (AHI), believes it is appropriate that the sponsors of applications, who would receive substantial and identifiable benefits from improved and predictable review performance, should share in financing the costs associated with these program enhancements. AHI and FDA strongly support an animal drug user fee program.

Most of the financial provisions of this act are patterned after those of PDUFA, as reauthorized in 2002, and are intended to work in a similar fashion. This includes provisions for annual revenue amounts, adjustments, and triggers. These provisions have been tested and modified over time and are known to provide an efficient and workable financial framework for a drug user fee program.

User fees collected under this program are to be considered an addition to, and not a replacement for, the annual appropriations amount designated for CVM through the annual appropriations process. This requirement is important for generic animal drug manufacturers, whose applications are reviewed by the same office at CVM that reviews new animal drug applications. Unlike the human generic drug industry, the animal generic drug industry is quite small, but it plays an important role in providing cost-effective animal health products. This legislation will not result in a decrease in resources available for generic animal drug review, and the committee expects that the pace of generic drug approvals will not be affected as a result of its enactment.

IV. COST ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, May 15, 2003.

Hon. JUDD GREGG,
Chairman, Committee on Health, Education, Labor, and Pensions, U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 313, the Animal Drug User Fee Act of 2003.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Thomas Bradley.

Sincerely,

BARRY B. ANDERSON
(For Douglas Holtz-Eakin, Director).

Enclosure.

S. 313—Animal Drug User Fee Act of 2003

Summary: S. 313 would amend the Federal Food, Drug, and Cosmetic Act to authorize the Food and Drug Administration (FDA) to collect fees to cover the cost of expediting the review of new and supplemental animal drug applications and investigational animal drug submissions. Such fees could be collected and made available for obligation only to the extent, and in the amount, provided in advance in appropriation acts.

S. 313 also would require that the Secretary of Health and Human Services submit annual performance and fiscal reports related to the animal drug user fee program to the Congressional committees of jurisdiction.

CBO estimates that implementing S. 313 would reduce net outlays by $1 million in 2004 and $4 million over the 2004–2008 period, assuming the necessary authorities are provided in appropriation acts.

S. 313 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would not affect the budgets of state, local, or tribal governments.

The bill would impose private-sector mandates as defined in UMRA on manufacturers of new animal drugs, by requiring them to pay fees to the Food and Drug Administration. CBO estimates that the direct cost of the mandates would not exceed the annual threshold specified in UMRA ($117 million in 2003, adjusted annually for inflation) in any of the first five years that the mandates would be effective.

Estimated cost to the Federal Government: The estimated budgetary impact of S. 313 is shown in the following table and assumes enactment of the bill by October 1, 2003. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—					
	2003	2004	2005	2006	2007	2008
CHANGES IN SPENDING SUBJECT TO APPROPRIATION: FOOD AND DRUG ADMINISTRATION						
Collection of User Fees:						
Estimated Authorization Level	0	−5	−8	−11	−11	−14
Estimated Outlays	0	−5	−8	−11	−11	−14

	By fiscal year, in millions of dollars—					
	2003	2004	2005	2006	2007	2008
Spending of User Fees:						
Estimated Authorization Level	0	5	8	11	11	11
Estimated Outlays	0	3	7	10	10	11
Administrative Expenses:						
Estimated Authorization Level	0	1	(1)	(1)	(1)	1
Estimated Outlays	0	1	(1)	(1)	(1)	1
Net Effect on Spending by the Food and Drug Administration:						
Estimated Authorization Level	0	1	(1)	(1)	(1)	−2
Estimated Outlays	0	−1	(1)	(1)	(1)	−2

[1] Note: = Less than $500,000.

Basis of estimate

Estimated authorizations

S. 313 would establish a new user fee program to help defray FDA's costs of expediting the review process for animal drugs. CBO estimates that implementing the bill would save $1 million in 2004 and $4 million over the 2004–2008 period.

User Fees. S. 313 would require FDA to assess and collect application and other user fees from manufacturers of drugs for animals to expedite the development of such drugs and the review of new and supplemental animal drug applications and investigational animal drug submissions. S. 313 would create four types of user fees: (1) animal drug application and supplement fees, (2) animal drug product fees, (3) animal drug establishment fees, and (4) animal drug sponsor fees. The fees could be refunded, waived, or reduced in certain situations. The aggregate amounts of such fees are specified for each fiscal year 2004 through 2008. Each year the amounts to be collected would be adjusted further for inflation, workload estimates, and other factors, when applicable. CBO assumes FDA would collect the amounts specified in the bill increased by the inflation index for wages and salaries for federal workers. In total, we estimate receipts from those fees would amount to $48 million over the 2004–2008 period. Such fees could be collected and made available for obligation only to the extent, and in the amount, provided in advance in appropriation acts.

Under the bill, those user fees could not be assessed in a given year unless appropriations for salaries and expenses of FDA (excluding the amount of user fees appropriated for such fiscal year) in that year satisfy a maintenance-of-effort requirement: the amount appropriated would have to exceed the amount appropriated for 2003 by the percentage increase since 2003 in the consumer price index for all urban consumers (CPI–U). In addition, fees could be collected and made available to defray increases in the cost of resources allocated to reviewing animal drug applications only to the extent that the percentage increase in those costs (excluding fees) exceeds the costs for fiscal year 2003 adjusted by CPI–U. (The bill defines special circumstances under which the Secretary would be considered to have met the maintenance-of-effort requirement.) This estimate assumes that these conditions would be met.

Before accounting for costs associated with additional administrative activities not covered by the user fees, CBO estimates that establishing the user fee program would reduce net outlays by $2

million in 2004 and $7 million over the 2004–2008 period, assuming appropriation of the necessary amounts. The estimated budget authority for collections and spending offset each other exactly from 2004 through 2007, while outlays would lag slightly, resulting in small savings each year. For fiscal year 2008, the bill would authorize the assessment and collection of up to three months of operating reserves for the review of animal drug applications for the first three months of fiscal year 2009. However, the user fee program is authorized only through fiscal year 2008. CBO assumes that the amounts available for obligation and spending in fiscal year 2008 would not include those special reserve funds collected in that year. The difference between the estimated collections and spending of the user fees in fiscal year 2008 would result in savings of $3 million for that year, CBO estimates.

Other Administrative Expenses. Based on the experience with similar activities of FDA, CBO assumes that funding for certain administrative activities associated with the new user fee program would not be fully covered by the new fees. The bill would require that FDA report annually to the Congress on its performance under the user fee program and on the fiscal status of the program. S. 313 also would require that FDA consult with the Congressional committees of jurisdiction and outside experts, including industry and consumer groups, and publish its recommendations concerning reauthorization of the user fee program. CBO estimates that the administrative activities associated with implementing the user fee program that are not covered by the user fees would cost about $2 million over the 2004–2008 period.

Estimated impact on State, local and tribal governments: S. 313 contains no intergovernmental mandates as defined in UMRA and would not affect the budgets of state, local, or tribal governments.

Estimated impact on the private sector: Subject to approval in an appropriation act, S. 313 would require manufacturers of new drugs for animals to pay application fees, product fees, establishment fees, and drug-sponsor fees to FDA. The application fees would apply to new or supplemental animal drug applications that are submitted after September 1, 2003. The product, establishment and drug sponsor fees would apply to manufacturers of new animal drug products that have an application pending with FDA after September 1, 2003. The duty to pay those fees would be a private-sector mandate under UMRA. CBO estimates that the fees collected over the 2004–2008 period would total $48 million. Those amounts would not exceed the annual threshold specified in UMRA ($117 million in 2003, adjusted annually for inflation) in any of the first five years that the mandates would be effective.

Estimate prepared by: Federal estimate: Julia Christensen; impact on State, local and tribal governments: Leo Lex; impact on the private sector: Anna Cook.

Estimate approved by: Robert A. Sunshine, Assistant Director for Budget Analysis.

V. Application of Law to the Legislative Branch

The Animal Drug User Fee Act of 2003 would amend the Federal FD&C Act by creating a program authorizing the collection of fees to expedite the new animal drug review process at CVM. As such, the legislation would not apply to the legislative branch.

VI. Regulatory Impact Statement

The regulatory impact of this legislation will be minimal because it authorizes the collection of fees to expedite and improve an existing animal drug review process at CVM. The legislation does not affect the substance of this process. This legislation requires the FDA to publish a notice of fees annually adjusted for workload and inflation as defined in the legislation, 60 days before the start of the fiscal year. Prior to consideration of reauthorization, the FDA is required to publish in the Federal Register a notice of recommendations for changes to the program, and a 30 day comment period is to be provided for written comments on the recommendations.

VII. Section-by-Section Analysis

Section 1. Short title

Section 1 designates the Short Title and Reference as the "Animal Drug User Fee Act of 2003," which amends the Federal FD&C Act.

Sec. 2. Findings

Section 2 declares the findings of Congress related to the authorization of animal drug user fees. In particular, the fees authorized will be dedicated toward expediting the animal drug development process as set forth in the goals in a letter from the Secretary to the authorizing committee chairmen.

Sec. 3. Fees relating to animal drugs

Section 4 adds to Chapter VII, Subchapter C of the Federal FD&C Act, a new Part 3, "Fees Relating to Animal Drugs."

New Section 739. Subsection (a) provides definitions for the following 11 terms, when used related to animal drug user fees: animal drug application, supplemental animal drug application, animal drug product, animal drug establishment, investigational animal drug submission, animal drug sponsor, final dosage form, process for the review of animal drug applications, costs of resources allocated for the process for the review of animal drug applications, adjustment factor, and affiliate. These definitions are necessary to give effect to the procedures instituted by the authorization of the ADUFA. The term "process for the review of animal drug applications," is a term of art that describes all of the functions related to the pre-market review of submissions and applications pertaining to animal drugs. The term is used throughout the document to provide simplicity and consistency in the language referring to the process funded by this legislation. "Affiliates" is also a term of art and is intended to include affiliates, partners and parent firms. An abbreviated new animal drug application—an application for approval of a generic animal drug—is not included in the term "animal drug application" and is not subject to the user fee program. A request to approve a change in a generic animal drug application after it has been approved is included in the term "supplemental animal drug application," and subject to the user fee program if the supplemental approval requires data to demonstrate safety or effectiveness. Changes that are subject to user fees under the program are limited to those that extend the generic animal

drug beyond the scope of its original approval, such as the addition of a new claim, the addition of a new species, a change in the treatment regimen, or a change in the drug's prescription or over-the-counter status. Changes to an approved generic animal drug that maintain the scope of its original approval, such as a change in the methods used in manufacturing, are not included in the term "supplemental animal drug application." The committee understands that CVM's policy allows for so-called "hybrids," where a generic animal drug applicant submits a request to copy the pioneer animal drug product and, at the same time, a request to make a change that differs from the pioneer animal drug product that requires data to demonstrate safety or effectiveness. In such circumstances, the committee intends that only the request for a change would be subject to the user fee program, and the request for a change would be construed to meet the definition of a "supplemental animal drug application."

Subsection (b) allows fees authorized under ADUFA to be assessed beginning on October 1, 2003. The fees authorized are animal drug application and supplement fees, animal drug product fees, animal drug establishment fees, and animal drug sponsor fees. Application fees, in general, are due upon submission of the application. Fees paid and not refunded for filed applications that were not approved or were withdrawn do not have to be paid a second time. If an application is refused for filing, the Secretary must refund 75 percent of the fee. If the application is withdrawn, the Secretary has sole discretion to refund the fee or any portion of the fee. Product, establishment, and sponsor fees are assessed in any fiscal year when certain specified criteria are met. Only one such fee per product, establishment, or sponsor must be paid each year. Transition rules for product, establishment, and sponsor fees related to products under review at the time of implementation of this law are specified.

Subsection (c) lists the total fee revenues for fiscal years 2004 through 2008 for application and supplement fees and for product, establishment, and sponsor fees.

Subsection (d) sets forth adjustments to take into account changes in workload and the cost of performing the work. The section provides for inflation, workload, final year and annual fee adjustments. The section also sets forth a limit on the total amount of fees charged for any year, not to exceed total costs for that fiscal year.

Subsection (e) sets the rules for the waiver or reduction of fees. The waivers and reductions are for those situations in which: (1) assessing the fees would be a barrier to innovation; (2) the fees exceed the anticipated costs; (3) the animal drug application or supplemental application is solely to provide for use of an approved Type A drug in a Type B medicated feed intended for use in the manufacture of Type C free-choice medicated feeds or a Type C free-choice medicated feed. (These are supplemental applications that occur usually after the Type A medicated article is approved. The Type A article can be used for a variety of feeding systems. However, when the Type A article is to be used in a "free-choice" feeding system, FDA requires the sponsor do a study to determine that the animals do not over eat or under eat the prerequisite amount of drug. They file this study as a supplemental new animal

drug application. If FDA did not waive the fee for this specific type of application, the sponsor will be charged twice for the same new animal drug product.); (4) the waiver or reduction is necessary to promote the availability of animal drugs for minor uses or minor species; or (5) the sponsor is a small business submitting its first animal drug application. Periodically, the Secretary shall publish a list of companies certifying they qualify for a small business waiver.

Subsection (f) states that, due to a failure to pay the required fees, the Secretary may consider an application or submission incomplete or discontinue review of an application or submission.

Subsection (g) states fees may not be assessed for any fiscal year after fiscal year 2003 unless appropriations are at least equal to the adjusted salaries and expenses for FDA for fiscal year 2003, excluding fees appropriated. If the trigger conditions for collecting fees are not met until later in a year, the full year's fees will still be required.

Subsection (h) authorizes appropriations (adjusted for workload and inflation) of $5 million, $8 million, $10 million, $10 million, $10 million for fiscal years 2004 through 2008, respectively, in amounts consistent with the total fee revenue amounts set forth in subsection (c). Such collected fees remain available until expended without fiscal year limitation.

Subsection (i) provides that fees overdue by 30 days shall be treated as a claim of the U.S. Government subject to subchapter II of Chapter 37 of 31 U.S.C.

Subsection (j) provides that written requests for waivers must be submitted within 180 days after the fee is due to qualify for consideration.

Subsection (k) states that the legislation may not be construed to require the number of full time equivalents in the Department of Health and Human Services to be reduced to offset full time equivalents under this user fee legislation.

Subsection (l) requires the FDA, to the extent practicable, to take appropriate action to segregate the review of generic animal drug applications, which are not under the user fee program, from the user fee funded program. It also requires the agency to adopt other administrative procedures to ensure that the review times for generic animal drugs do not increase from their current level due to activities under the user fee program.

Sec. 4. Accountability and reports

In developing recommendations to Congress for goals and plans for reauthorization of the legislation, the Secretary is required to consult with the authorizing committees, scientific and academic experts, veterinary professionals, consumer advocacy groups and the regulated industry in developing recommendations. The recommendations are to be published in the Federal Register, and a public meeting is to be held and a 30-day comment period is to be provided for written comments on the recommendations.

This section requires an annual Performance Report and an annual Financial Report to be submitted to the authorizing committees by the Secretary. The performance goals are set forth in a separate goals letter referenced in section 2 of the legislation.

Sec. 5. Sunset

Section 5 provides that the amendments made by section 3 (relating to definitions and to the authority to assess and use drug fees) cease to be effective on October 1, 2008. The section further provides that section 3, as it relates to annual reports, will cease to be effective 120 days after October 1, 2008. The additional 120 days will allow the animal drug user fee reports for fiscal year 2008 to be prepared and submitted.

VIII. CHANGES IN EXISTING LAW

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

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ANIMAL DRUG USER FEE ACT OF 2003

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CHAPTER VII—GENERAL AUTHORITY

Subchapter A—General Administrative Provisions

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Subchapter C—Fees

PART 1—FREEDOM OF INFORMATION FEES

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[PART 3—FEES RELATING TO ANIMAL DRUGS]

PART 4—FEES RELATING TO ANIMAL DRUGS

[SEC. 738. DEFINITIONS.]

[“For purposes of this subchapter:]

SEC. 739. AUTHORITY TO ASSESS AND USE ANIMAL DRUG FEES.

(a) DEFINITIONS.—For purposes of this subchapter:

(1) The term “animal drug application” means an application for approval of any new animal drug submitted under section 512(b)(1). Such term does not include either a new animal drug application submitted under section 512(b)(2) or a supplemental animal drug application.

(2) The term “supplemental animal drug application” means—

(A) a request to the Secretary to approve a change in an animal drug application which has been approved; or

(B) a request to the Secretary to approve a change to an application approved under section 512(c)(2) for which data with respect to safety or effectiveness are required.

(3) The term "animal drug product" means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an animal drug application or a supplemental animal drug application has been approved.

(4) The term "animal drug establishment" means a foreign or domestic place of business which is at one general physical location consisting of one or more buildings all of which are within 5 miles of each other, at which one or more animal drug products are manufactured in final dosage form.

(5) The term "investigational animal drug submission" means—

(A) the filing of a claim for an investigational exemption under section 512(j) for a new animal drug intended to be the subject of an animal drug application or a supplemental animal drug application, or

(B) the submission of information for the purpose of enabling the Secretary to evaluate the safety or effectiveness of an animal drug application or supplemental animal drug application in the event of their filing.

(6) The term "animal drug sponsor" means either an applicant named in an animal drug application, except for an approved application for which all subject products have been removed from listing under Section 510, or a person who has submitted an investigational animal drug submission that has not been terminated or otherwise rendered inactive by the Secretary.

(7) The term "final dosage form" means, with respect to an animal drug product, a finished dosage form which is approved for administration to an animal without substantial further manufacturing. Such term includes animal drug products intended for mixing in animal feeds.

(8) The term "process for the review of animal drug applications" means the following activities of the Secretary with respect to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions:

(A) The activities necessary for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(B) The issuance of action letters which approve animal drug applications or supplemental animal drug applications or which set forth in detail the specific deficiencies in animal drug applications, supplemental animal drug applications, or investigational animal drug submissions and, where appropriate, the actions necessary to place such applications, supplements or submissions in condition for approval.

(C) The inspection of animal drug establishments and other facilities undertaken as part of the Secretary's review of pending animal drug applications, supplemental animal

drug applications, and investigational animal drug submissions.

(D) Monitoring of research conducted in connection with the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(E) The development of regulations and policy related to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(F) Development of standards for products subject to review.

(G) Meetings between the agency and the animal drug sponsor.

(H) Review of advertising and labeling prior to approval of an animal drug application or supplemental animal drug application, but not such activities after an animal drug has been approved.

(9) The term "costs of resources allocated for the process for the review of animal drug applications" means the expenses incurred in connection with the process for the review of animal drug applications for—

(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees consulted with respect to the review of specific animal drug applications, supplemental animal drug applications, or investigational animal drug submissions, and costs related to such officers, employees, committees, and contractors, including costs for travel, education, and recruitment and other personnel activities,

(B) management of information, and the acquisition, maintenance, and repair of computer resources,

(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies, and

(D) collecting fees under section 739 and accounting for resources allocated for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(10) The term "adjustment factor" applicable to a fiscal year refers to the formula set forth in section 735(8) with the base or comparator year being 2003.

(11) The term "affiliate" refers to the definition set forth in section 735(9).

["SEC. 739. AUTHORITY TO ASSESS AND USE ANIMAL DRUG FEES.]

[(a)**]** *(b) TYPES OF FEES.—Beginning in fiscal year 2004, the Secretary shall assess and collect fees in accordance with this section as follows:*

(1) ANIMAL DRUG APPLICATION AND SUPPLEMENT FEE.—

(A) IN GENERAL.—Each person that submits, on or after September 1, 2003, an animal drug application or a supplemental animal drug application shall be subject to a fee as follows:

(i) A fee established in subsection [(b)] *(c) for an animal drug application; and*

(ii) A fee established in subsection [(b)] *(c) for a supplemental animal drug application for which safety or effectiveness data are required, in an amount that is equal to 50 percent of the amount of the fee under clause (i).*

(B) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the animal drug application or supplemental animal drug application.

(C) EXCEPTION FOR PREVIOUSLY FILED APPLICATION OR SUPPLEMENT.—If an animal drug application or a supplemental animal drug application was submitted by a person that paid the fee for such application or supplement, was accepted for filing, and was not approved or was withdrawn (without a waiver or refund), the submission of an animal drug application or a supplemental animal drug application for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

(D) REFUND OF FEE IF APPLICATION REFUSED FOR FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any animal drug application or supplemental animal drug application which is refused for filing.

(E) REFUND OF FEE IF APPLICATION WITHDRAWN.—If an animal drug application or a supplemental animal drug application is withdrawn after the application or supplement was filed, the Secretary may refund the fee or portion of the fee paid under subparagraph B if no substantial work was performed on the application or supplement after the application or supplement was filed. The Secretary shall have the sole discretion to refund the fee under this paragraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.

(2) ANIMAL DRUG PRODUCT FEE.—Each person—

(A) who is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product which has been submitted for listing under Section 510, and

(B) who, after September 1, 2003, had pending before the Secretary an animal drug application or supplemental animal drug application;

shall pay for each such animal drug product the annual fee established in subsection [(b)] *(c). Such fee shall be payable for the fiscal year in which the animal drug product is first submitted for listing under Section 510, or is submitted for relisting under section 510 if the animal drug product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be payable on or before January 31 of each year. Such fee shall be paid only once for each animal drug product for a fiscal year in which the fee is payable.*

(3) ANIMAL DRUG ESTABLISHMENT FEE.—Each person—

(A) who owns or operates, directly or through an affiliate, an animal drug establishment, and

(B) who is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product which has been submitted for listing under Section 510, and

(C) who, after September 1, 2003, had pending before the Secretary an animal drug application or supplemental animal drug application,

shall be assessed an annual fee established in subsection [(b)] *(c) for each animal drug establishment listed in its approved animal drug application as an establishment that manufactures the animal drug product named in the application. The annual establishment fee shall be assessed in each fiscal year in which the animal drug product named in the application is assessed a fee under paragraph (2) unless the animal drug establishment listed in the application does not engage in the manufacture of the animal drug product during the fiscal year. The fee shall be paid on or before January 31 of each year. The establishment shall be assessed only one fee per fiscal year under this section, provided, however, that where a single establishment manufactures both animal drug products and prescription drug products, as defined in section 735(3), such establishment shall be assessed both the animal drug establishment fee and the prescription drug establishment fee, as set forth in section 736(a)(2), within a single fiscal year.*

(4) ANIMAL DRUG SPONSOR FEE.—Each person—

(A) who meets the definition of an animal drug sponsor within a fiscal year; and

(B) who, after September 1, 2003, had pending before the Secretary an animal drug application, a supplemental animal drug application, or an investigational animal drug submission,

shall be assessed an annual fee established under subsection [(b)] *(c). The fee shall be paid on or before January 31 of each year. Each animal drug sponsor shall pay only one such fee each fiscal year.*

[(b)] *(c) FEE AMOUNTS.—Except as provided in subsection* [(a)(1)] *(b)(1) and subsections* [(c), (d), (f), and (g),] *(d), (e), (g), and (h), the fees required under subsection* [(a)] *(b) shall be established to generate fee revenue amounts as follows:*

(1) TOTAL FEE REVENUES FOR APPLICATION AND SUPPLEMENT FEES.—The total fee revenues to be collected in animal drug application fees under subsection [(a)(1)(A)(i)] *(b)(1)(A)(i) and supplemental animal drug application fees under subsection* [(a)(1)(A)(ii)] *(b)(1)(A)(ii) shall be $1,250,000 in fiscal year 2004, $2,000,000 in fiscal year 2005, and $2,500,000 in fiscal years 2006 and 2007.*

(2) TOTAL FEE REVENUES FOR PRODUCT FEES.—The total fee revenues to be collected in product fees under subsection [(a)(2)] *(b)(2) shall be $1,250,000 in fiscal year 2004, $2,000,000 in fiscal year 2005, and $2,500,000 in fiscal years 2006 and 2007.*

(3) TOTAL FEE REVENUES FOR ESTABLISHMENT FEES.—The total fee revenues to be collected in establishment fees under subsection [(a)(3)] *(b)(3) shall be $1,250,000 in fiscal year*

2004, $2,000,000 in fiscal year 2005, and $2,500,000 in fiscal years 2006 and 2007.

(4) TOTAL FEE REVENUES FOR SPONSOR FEES.—The total fee revenues to be collected in sponsor fees under subsection [(a)(4)] *(b)(4) shall be $1,250,000 in fiscal year 2004, $2,000,000 in fiscal year 2005, and $2,500,000 in fiscal years 2006 and 2007.*

[(c)] *(d) ADJUSTMENTS.—*

(1) INFLATION ADJUSTMENT.—The fees and total fee revenues established in subsection [(b)] *(c) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year according to the formula set forth in section 736(c)(1).*

(2) WORKLOAD ADJUSTMENT.—After the fee revenues are adjusted for inflation in accordance with subparagraph (1), the fee revenues shall be further adjusted each fiscal year after fiscal year 2004 to reflect changes in review workload. With respect to such adjustment:

(A) This adjustment shall be determined by the Secretary based on a weighted average of the change in the total number 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 submitted to the Secretary. The Secretary shall publish in the Federal Register the fees resulting from this adjustment and the supporting methodologies.

(B) Under no circumstances shall this workload adjustment result in fee revenues for a fiscal year that are less than the fee revenues for that fiscal year established in subsection [(b),] *(c), as adjusted for inflation under subparagraph* [(c)(1)] *(d)(1).*

(3) FINAL YEAR ADJUSTMENT.—For fiscal year 2007, the Secretary may further increase the fees to provide for up to 3 months of operating reserves of carryover user fees for the process for the review of animal drug applications for the first 3 months of fiscal year 2008. If the Food and Drug Administration has carryover balances for the process for the review of animal drug applications in excess of 3 months of such operating reserves, then this adjustment will not be made. If this adjustment is necessary, then the rationale for the amount of the increase shall be contained in the annual notice setting fees for fiscal year 2007.

(4) ANNUAL FEE SETTING.—The Secretary shall establish, 60 days before the start of each fiscal year that begins after September 30, 2003, for that fiscal year, animal drug application fees, supplemental animal drug application fees, animal drug sponsor fees, animal drug establishment fees, and animal drug product fees based on the revenue amounts established under subsection [(b)] *(c) and the adjustments provided under this subsection.*

(5) LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of animal drug applications.

[(d)] *(e) FEE WAIVER OR REDUCTION.—*

(1) IN GENERAL.—The Secretary shall grant a waiver from or a reduction of 1 or more fees assessed under subsection [(a)] *(b) where the Secretary finds that—*

(A) the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances,

(B) the fees to be paid by such person will exceed the anticipated present and future costs incurred by the Secretary in conducting the process for the review of animal drug applications for such person,

(C) the animal drug application or supplemental animal drug application is intended solely to provide for use of the animal drug in—

(i) a Type B medicated feed (as defined in section 558.3(b)(3) of title 21, Code of Federal Regulations (or any successor regulation)) intended for use in the manufacture of Type C free-choice medicated feeds, or

(ii) a Type C free-choice medicated feed (as defined in section 558.3(b)(4) of title 21, Code of Federal Regulations (or any successor regulation)),

(D) the animal drug application or supplemental animal drug application is intended solely to provide for a minor use or minor species indication, or

(E) the sponsor involved is a small business submitting its first animal drug application to the Secretary for review.

(2) USE OF STANDARD COSTS.—In making the finding in paragraph (1)(B), the Secretary may use standard costs.

(3) RULES FOR SMALL BUSINESSES.—

(A) DEFINITION.—In paragraph (1)(D), the term "small business" means an entity that has fewer than 500 employees, including employees of affiliates.

(B) WAIVER OF APPLICATION FEE.—The Secretary shall waive under paragraph (1)(D) the application fee for the first animal drug application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay application fees for all subsequent animal drug applications and supplemental animal drug applications for which safety or effectiveness data are required in the same manner as an entity that does not qualify as a small business.

(C) CERTIFICATION.—The Secretary shall require any person who applies for a waiver under paragraph (1)(D) to certify their qualification for the waiver. The Secretary shall periodically publish in the Federal Register a list of persons making such certifications.

[(e)] *(f) EFFECT OF FAILURE TO PAY FEES.—An animal drug application or supplemental animal drug application submitted by a person subject to fees under subsection* [(a)] *(b) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid. An investigational animal drug submission under section 738(5)(B) that is submitted by a person subject to fees under subsection* [(a)] *(b) shall be consid-*

ered incomplete and shall not be accepted for review by the Secretary until all fees owed by such person have been paid. The Secretary may discontinue review of any animal drug application, supplemental animal drug application or investigational animal drug submission from a person if such person has not submitted for payment all fees owed under this section by 30 days after the date upon which they are due.

[(f)**]** *(g) ASSESSMENT OF FEES.—*

(1) LIMITATION.—Fees may not be assessed under subsection (a) for a fiscal year beginning after fiscal year 2003 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 2003 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

(2) AUTHORITY.—If the Secretary does not assess fees under subsection **[**(a)**]** *(b) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for animal drug applications, supplemental animal drug applications, investigational animal drug submissions, sponsors, animal drug establishments and animal drug products at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.*

[(g)**]** *(h) CREDITING AND AVAILABILITY OF FEES.—*

(1) IN GENERAL.—Fees authorized under subsection **[**(a)**]** *(b) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to be appropriated to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salary and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of animal drug applications.*

(2) COLLECTIONS AND APPROPRIATION ACTS.—

(A) IN GENERAL.—The fees authorized by this section—

(i) shall be retained in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year, and

(ii) shall only be collected and available to defray increases in the costs of the resources allocated for the process for the review of animal drug applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 2003 multiplied by the adjustment factor.

(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of animal drug applications—

(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in subparagraph (A)(ii); and

(II) such costs are not more than 5 percent below the level specified in subparagraph (A)(ii).

(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for fees under this section—

(A) $5,000,000 for fiscal year 2004;

(B) $8,000,000 for fiscal year 2005;

(C) $10,000,000 for fiscal year 2006; and

(D) $10,000,000 for fiscal year 2007; as adjusted to reflect adjustments in the total fee revenues made under this section and changes in the total amounts collected by animal drug application fees, supplemental animal drug application fees, animal drug sponsor fees, animal drug establishment fees, and animal drug product fees.

(4) OFFSET.—Any amount of fees collected for a fiscal year under this section that exceeds the amount of fees specified in appropriations Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for a subsequent fiscal year.

[(h)**]** *(i) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection* **[**(a)**]** *(b) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.*

[(i)**]** *(j) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.—To qualify for consideration for a waiver or reduction under subsection* **[**(d),**]** *(e), or for a refund of any fee collected in accordance with subsection* **[**(a),**]** *(b), a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.*

[(j)**]** *(k) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in the process of the review of animal drug applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.*

[(k)**]** *(l) ADMINISTRATIVE PROCEDURE.—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.

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