

108TH CONGRESS
1ST SESSION

S. 313

AMENDMENT

In the House of Representatives, U. S.,

November 4, 2003.

Resolved, That the bill from the Senate (S. 313) entitled “An Act to amend the Federal Food, Drug, and Cosmetic Act to establish a program of fees relating to animal drugs”, do pass with the following

AMENDMENT:

Strike out all after the enacting clause and insert:

1 ***SECTION 1. SHORT TITLE.***

2 *This Act may be cited as the “Animal Drug User Fee*
3 *Act of 2003”.*

4 ***SEC. 2. FINDINGS.***

5 *Congress finds as follows:*

6 *(1) Prompt approval of safe and effective new*
7 *animal drugs is critical to the improvement of ani-*
8 *mal health and the public health.*

9 *(2) Animal health and the public health will be*
10 *served by making additional funds available for the*
11 *purpose of augmenting the resources of the Food and*
12 *Drug Administration that are devoted to the process*
13 *for review of new animal drug applications.*

1 (3) *The fees authorized by this Act will be dedi-*
 2 *cated toward expediting the animal drug development*
 3 *process and the review of new and supplemental ani-*
 4 *mal drug applications and investigational animal*
 5 *drug submissions as set forth in the goals identified,*
 6 *for purposes of part 4 of subchapter C of chapter VII*
 7 *of the Federal Food, Drug, and Cosmetic Act, in the*
 8 *letters from the Secretary of Health and Human*
 9 *Services to the Chairman of the Committee on Energy*
 10 *and Commerce of the House of Representatives and*
 11 *the Chairman of the Committee on Health, Edu-*
 12 *cation, Labor, and Pensions of the Senate as set forth*
 13 *in the Congressional Record.*

14 **SEC. 3. FEES RELATING TO ANIMAL DRUGS.**

15 *Subchapter C of chapter VII of the Federal Food,*
 16 *Drug, and Cosmetic Act (21 U.S.C. 379f et seq.) is amended*
 17 *by adding at the end the following part:*

18 **“PART 4—FEES RELATING TO ANIMAL DRUGS**

19 **“SEC. 739. DEFINITIONS.**

20 *“For purposes of this subchapter:*

21 *“(1) The term ‘animal drug application’ means*
 22 *an application for approval of any new animal drug*
 23 *submitted under section 512(b)(1). Such term does not*
 24 *include either a new animal drug application sub-*

1 *mitted under section 512(b)(2) or a supplemental ani-*
2 *mal drug application.*

3 *“(2) The term ‘supplemental animal drug appli-*
4 *cation’ means—*

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

8 *“(B) a request to the Secretary to approve*
9 *a change to an application approved under sec-*
10 *tion 512(c)(2) for which data with respect to*
11 *safety or effectiveness are required.*

12 *“(3) The term ‘animal drug product’ means each*
13 *specific strength or potency of a particular active in-*
14 *gredient or ingredients in final dosage form marketed*
15 *by a particular manufacturer or distributor, which is*
16 *uniquely identified by the labeler code and product*
17 *code portions of the national drug code, and for which*
18 *an animal drug application or a supplemental ani-*
19 *mal drug application has been approved.*

20 *“(4) The term ‘animal drug establishment’*
21 *means a foreign or domestic place of business which*
22 *is at one general physical location consisting of one*
23 *or more buildings all of which are within 5 miles of*
24 *each other, at which one or more animal drug prod-*
25 *ucts are manufactured in final dosage form.*

1 “(5) The term ‘investigational animal drug sub-
2 mission’ means—

3 “(A) the filing of a claim for an investiga-
4 tional exemption under section 512(j) for a new
5 animal drug intended to be the subject of an ani-
6 mal drug application or a supplemental animal
7 drug application, or

8 “(B) the submission of information for the
9 purpose of enabling the Secretary to evaluate the
10 safety or effectiveness of an animal drug applica-
11 tion or supplemental animal drug application in
12 the event of their filing.

13 “(6) The term ‘animal drug sponsor’ means ei-
14 ther an applicant named in an animal drug applica-
15 tion, except for an approved application for which all
16 subject products have been removed from listing under
17 section 510, or a person who has submitted an inves-
18 tigational animal drug submission that has not been
19 terminated or otherwise rendered inactive by the Sec-
20 retary.

21 “(7) The term ‘final dosage form’ means, with
22 respect to an animal drug product, a finished dosage
23 form which is approved for administration to an ani-
24 mal without substantial further manufacturing. Such

1 *term includes animal drug products intended for mix-*
2 *ing in animal feeds.*

3 “(8) *The term ‘process for the review of animal*
4 *drug applications’ means the following activities of*
5 *the Secretary with respect to the review of animal*
6 *drug applications, supplemental animal drug appli-*
7 *cations, and investigational animal drug submissions:*

8 “(A) *The activities necessary for the review*
9 *of animal drug applications, supplemental ani-*
10 *mal drug applications, and investigational ani-*
11 *mal drug submissions.*

12 “(B) *The issuance of action letters which*
13 *approve animal drug applications or supple-*
14 *mental animal drug applications or which set*
15 *forth in detail the specific deficiencies in animal*
16 *drug applications, supplemental animal drug*
17 *applications, or investigational animal drug*
18 *submissions and, where appropriate, the actions*
19 *necessary to place such applications, supple-*
20 *ments or submissions in condition for approval.*

21 “(C) *The inspection of animal drug estab-*
22 *lishments and other facilities undertaken as part*
23 *of the Secretary’s review of pending animal drug*
24 *applications, supplemental animal drug applica-*

1 *tions, and investigational animal drug submis-*
2 *sions.*

3 *“(D) Monitoring of research conducted in*
4 *connection with the review of animal drug appli-*
5 *cations, supplemental animal drug applications,*
6 *and investigational animal drug submissions.*

7 *“(E) The development of regulations and*
8 *policy related to the review of animal drug ap-*
9 *plications, supplemental animal drug applica-*
10 *tions, and investigational animal drug submis-*
11 *sions.*

12 *“(F) Development of standards for products*
13 *subject to review.*

14 *“(G) Meetings between the agency and the*
15 *animal drug sponsor.*

16 *“(H) Review of advertising and labeling*
17 *prior to approval of an animal drug application*
18 *or supplemental animal drug application, but*
19 *not such activities after an animal drug has been*
20 *approved.*

21 *“(9) The term ‘costs of resources allocated for the*
22 *process for the review of animal drug applications’*
23 *means the expenses incurred in connection with the*
24 *process for the review of animal drug applications*
25 *for—*

1 “(A) officers and employees of the Food and
2 Drug Administration, contractors of the Food
3 and Drug Administration, advisory committees
4 consulted with respect to the review of specific
5 animal drug applications, supplemental animal
6 drug applications, or investigational animal
7 drug submissions, and costs related to such offi-
8 cers, employees, committees, and contractors, in-
9 cluding costs for travel, education, and recruit-
10 ment and other personnel activities,

11 “(B) management of information, and the
12 acquisition, maintenance, and repair of com-
13 puter resources,

14 “(C) leasing, maintenance, renovation, and
15 repair of facilities and acquisition, maintenance,
16 and repair of fixtures, furniture, scientific equip-
17 ment, and other necessary materials and sup-
18 plies, and

19 “(D) collecting fees under section 740 and
20 accounting for resources allocated for the review
21 of animal drug applications, supplemental ani-
22 mal drug applications, and investigational ani-
23 mal drug submissions.

1 “(10) The term ‘adjustment factor’ applicable to
2 a fiscal year refers to the formula set forth in section
3 735(8) with the base or comparator year being 2003.

4 “(11) The term ‘affiliate’ refers to the definition
5 set forth in section 735(9).

6 **“SEC. 740. AUTHORITY TO ASSESS AND USE ANIMAL DRUG**
7 **FEES.**

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

11 “(1) *ANIMAL DRUG APPLICATION AND SUPPLE-*
12 *MENT FEE.*—

13 “(A) *IN GENERAL.*—Each person that sub-
14 mits, on or after September 1, 2003, an animal
15 drug application or a supplemental animal drug
16 application shall be subject to a fee as follows:

17 “(i) A fee established in subsection (b)
18 for an animal drug application; and

19 “(ii) A fee established in subsection (b)
20 for a supplemental animal drug application
21 for which safety or effectiveness data are re-
22 quired, in an amount that is equal to 50
23 percent of the amount of the fee under
24 clause (i).

1 “(B) *PAYMENT.*—*The fee required by sub-*
 2 *paragraph (A) shall be due upon submission of*
 3 *the animal drug application or supplemental*
 4 *animal drug application.*

5 “(C) *EXCEPTION FOR PREVIOUSLY FILED*
 6 *APPLICATION OR SUPPLEMENT.*—*If an animal*
 7 *drug application or a supplemental animal drug*
 8 *application was submitted by a person that paid*
 9 *the fee for such application or supplement, was*
 10 *accepted for filing, and was not approved or was*
 11 *withdrawn (without a waiver or refund), the*
 12 *submission of an animal drug application or a*
 13 *supplemental animal drug application for the*
 14 *same product by the same person (or the person’s*
 15 *licensee, assignee, or successor) shall not be sub-*
 16 *ject to a fee under subparagraph (A).*

17 “(D) *REFUND OF FEE IF APPLICATION RE-*
 18 *FUSED FOR FILING.*—*The Secretary shall refund*
 19 *75 percent of the fee paid under subparagraph*
 20 *(B) for any animal drug application or supple-*
 21 *mental animal drug application which is refused*
 22 *for filing.*

23 “(E) *REFUND OF FEE IF APPLICATION*
 24 *WITHDRAWN.*—*If an animal drug application or*
 25 *a supplemental animal drug application is with-*

1 *drawn after the application or supplement was*
 2 *filed, the Secretary may refund the fee or portion*
 3 *of the fee paid under subparagraph (B) if no*
 4 *substantial work was performed on the applica-*
 5 *tion or supplement after the application or sup-*
 6 *plement was filed. The Secretary shall have the*
 7 *sole discretion to refund the fee under this para-*
 8 *graph. A determination by the Secretary con-*
 9 *cerning a refund under this paragraph shall not*
 10 *be reviewable.*

11 “(2) *ANIMAL DRUG PRODUCT FEE.*—*Each*
 12 *person—*

13 “(A) *who is named as the applicant in an*
 14 *animal drug application or supplemental ani-*
 15 *mal drug application for an animal drug prod-*
 16 *uct which has been submitted for listing under*
 17 *section 510, and*

18 “(B) *who, after September 1, 2003, had*
 19 *pending before the Secretary an animal drug ap-*
 20 *plication or supplemental animal drug applica-*
 21 *tion;*

22 *shall pay for each such animal drug product the an-*
 23 *nuual fee established in subsection (b). Such fee shall*
 24 *be payable for the fiscal year in which the animal*
 25 *drug product is first submitted for listing under sec-*

tion 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) for each animal drug establishment listed in its approved animal drug application as an establishment that manufactures the animal drug product

1 *named in the application. The annual establishment*
 2 *fee shall be assessed in each fiscal year in which the*
 3 *animal drug product named in the application is as-*
 4 *essed a fee under paragraph (2) unless the animal*
 5 *drug establishment listed in the application does not*
 6 *engage in the manufacture of the animal drug prod-*
 7 *uct during the fiscal year. The fee shall be paid on*
 8 *or before January 31 of each year. The establishment*
 9 *shall be assessed only one fee per fiscal year under*
 10 *this section, provided, however, that where a single es-*
 11 *tablishment manufactures both animal drug products*
 12 *and prescription drug products, as defined in section*
 13 *735(3), such establishment shall be assessed both the*
 14 *animal drug establishment fee and the prescription*
 15 *drug establishment fee, as set forth in section*
 16 *736(a)(2), within a single fiscal year.*

17 “(4) *ANIMAL DRUG SPONSOR FEE.—Each*
 18 *person—*

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

21 “(B) *who, after September 1, 2003, had*
 22 *pending before the Secretary an animal drug ap-*
 23 *plication, a supplemental animal drug applica-*
 24 *tion, or an investigational animal drug submis-*
 25 *sion,*

1 *shall be assessed an annual fee established under sub-*
 2 *section (b). The fee shall be paid on or before January*
 3 *31 of each year. Each animal drug sponsor shall pay*
 4 *only one such fee each fiscal year.*

5 *“(b) FEE AMOUNTS.—Except as provided in sub-*
 6 *section (a)(1) and subsections (c), (d), (f), and (g), the fees*
 7 *required under subsection (a) shall be established to gen-*
 8 *erate fee revenue amounts as follows:*

9 *“(1) TOTAL FEE REVENUES FOR APPLICATION*
 10 *AND SUPPLEMENT FEES.—The total fee revenues to be*
 11 *collected in animal drug application fees under sub-*
 12 *section (a)(1)(A)(i) and supplemental animal drug*
 13 *application fees under subsection (a)(1)(A)(ii) shall*
 14 *be \$1,250,000 in fiscal year 2004, \$2,000,000 in fiscal*
 15 *year 2005, and \$2,500,000 in fiscal years 2006, 2007,*
 16 *and 2008.*

17 *“(2) TOTAL FEE REVENUES FOR PRODUCT*
 18 *FEES.—The total fee revenues to be collected in prod-*
 19 *uct fees under subsection (a)(2) shall be \$1,250,000 in*
 20 *fiscal year 2004, \$2,000,000 in fiscal year 2005, and*
 21 *\$2,500,000 in fiscal years 2006, 2007, and 2008.*

22 *“(3) TOTAL FEE REVENUES FOR ESTABLISH-*
 23 *MENT FEES.—The total fee revenues to be collected in*
 24 *establishment fees under subsection (a)(3) shall be*
 25 *\$1,250,000 in fiscal year 2004, \$2,000,000 in fiscal*

1 *year 2005, and \$2,500,000 in fiscal years 2006, 2007,*
 2 *and 2008.*

3 “(4) *TOTAL FEE REVENUES FOR SPONSOR*
 4 *FEES.—The total fee revenues to be collected in spon-*
 5 *sor fees under subsection (a)(4) shall be \$1,250,000 in*
 6 *fiscal year 2004, \$2,000,000 in fiscal year 2005, and*
 7 *\$2,500,000 in fiscal years 2006, 2007, and 2008.*

8 “(c) *ADJUSTMENTS.—*

9 “(1) *INFLATION ADJUSTMENT.—The revenues es-*
 10 *tablished in subsection (b) shall be adjusted by the*
 11 *Secretary by notice, published in the Federal Register,*
 12 *for a fiscal year to reflect the greater of—*

13 “(A) *the total percentage change that oc-*
 14 *curred in the Consumer Price Index for all*
 15 *urban consumers (all items; United States city*
 16 *average) for the 12-month period ending June 30*
 17 *preceding the fiscal year for which fees are being*
 18 *established; or*

19 “(B) *the total percentage change for the pre-*
 20 *vious fiscal year in basic pay under the General*
 21 *Schedule in accordance with section 5332 of title*
 22 *5, United States Code, as adjusted by any local-*
 23 *ity-based comparability payment pursuant to*
 24 *section 5304 of such title for Federal employees*
 25 *stationed in the District of Columbia.*

1 *The adjustment made each fiscal year by this sub-*
2 *section will be added on a compounded basis to the*
3 *sum of all adjustments made each fiscal year after fis-*
4 *cal year 2004 under this subsection.*

5 “(2) *WORKLOAD ADJUSTMENT.*—*After the fee*
6 *revenues are adjusted for inflation in accordance with*
7 *paragraph (1), the fee revenues shall be further ad-*
8 *justed each fiscal year after fiscal year 2004 to reflect*
9 *changes in review workload. With respect to such ad-*
10 *justment:*

11 “(A) *This adjustment shall be determined*
12 *by the Secretary based on a weighted average of*
13 *the change in the total number of animal drug*
14 *applications, supplemental animal drug applica-*
15 *tions for which data with respect to safety or ef-*
16 *fectiveness are required, manufacturing supple-*
17 *mental animal drug applications, investiga-*
18 *tional animal drug study submissions, and in-*
19 *vestigational animal drug protocol submissions*
20 *submitted to the Secretary. The Secretary shall*
21 *publish in the Federal Register the fees resulting*
22 *from this adjustment and the supporting meth-*
23 *odologies.*

24 “(B) *Under no circumstances shall this*
25 *workload adjustment result in fee revenues for a*

1 *fiscal year that are less than the fee revenues for*
2 *that fiscal year established in subsection (b), as*
3 *adjusted for inflation under paragraph (1).*

4 “(3) *FINAL YEAR ADJUSTMENT.*—*For fiscal year*
5 *2008, the Secretary may further increase the fees to*
6 *provide for up to 3 months of operating reserves of*
7 *carryover user fees for the process for the review of*
8 *animal drug applications for the first 3 months of fis-*
9 *cal year 2009. If the Food and Drug Administration*
10 *has carryover balances for the process for the review*
11 *of animal drug applications in excess of 3 months of*
12 *such operating reserves, then this adjustment will not*
13 *be made. If this adjustment is necessary, then the ra-*
14 *tionale for the amount of the increase shall be con-*
15 *tained in the annual notice setting fees for fiscal year*
16 *2008.*

17 “(4) *ANNUAL FEE SETTING.*—*The Secretary shall*
18 *establish, 60 days before the start of each fiscal year*
19 *beginning after September 30, 2003, for that fiscal*
20 *year, animal drug application fees, supplemental ani-*
21 *mal drug application fees, animal drug sponsor fees,*
22 *animal drug establishment fees, and animal drug*
23 *product fees based on the revenue amounts established*
24 *under subsection (b) and the adjustments provided*
25 *under this subsection.*

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

6 “(d) *FEE WAIVER OR REDUCTION.*—

7 “(1) *IN GENERAL.*—*The Secretary shall grant a*
 8 *waiver from or a reduction of 1 or more fees assessed*
 9 *under subsection (a) where the Secretary finds that—*

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

14 “(B) *the fees to be paid by such person will*
 15 *exceed the anticipated present and future costs*
 16 *incurred by the Secretary in conducting the*
 17 *process for the review of animal drug applica-*
 18 *tions for such person,*

19 “(C) *the animal drug application or supple-*
 20 *mental animal drug application is intended sole-*
 21 *ly to provide for use of the animal drug in—*

22 “(i) *a Type B medicated feed (as de-*
 23 *defined in section 558.3(b)(3) of title 21, Code*
 24 *of Federal Regulations (or any successor*
 25 *regulation)) intended for use in the manu-*

1 *facture of Type C free-choice medicated*
 2 *feeds, or*

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

7 “(D) *the animal drug application or sup-*
 8 *plemental animal drug application is intended*
 9 *solely to provide for a minor use or minor spe-*
 10 *cies indication, or*

11 “(E) *the sponsor involved is a small busi-*
 12 *ness submitting its first animal drug application*
 13 *to the Secretary for review.*

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

17 “(3) *RULES FOR SMALL BUSINESSES.—*

18 “(A) *DEFINITION.—In paragraph (1)(E),*
 19 *the term ‘small business’ means an entity that*
 20 *has fewer than 500 employees, including employ-*
 21 *ees of affiliates.*

22 “(B) *WAIVER OF APPLICATION FEE.—The*
 23 *Secretary shall waive under paragraph (1)(E)*
 24 *the application fee for the first animal drug ap-*
 25 *plication that a small business or its affiliate*

1 *submits to the Secretary for review. After a small*
2 *business or its affiliate is granted such a waiver,*
3 *the small business or its affiliate shall pay ap-*
4 *plication fees for all subsequent animal drug ap-*
5 *plications and supplemental animal drug appli-*
6 *cations for which safety or effectiveness data are*
7 *required in the same manner as an entity that*
8 *does not qualify as a small business.*

9 *“(C) CERTIFICATION.—The Secretary shall*
10 *require any person who applies for a waiver*
11 *under paragraph (1)(E) to certify their quali-*
12 *fication for the waiver. The Secretary shall peri-*
13 *odically publish in the Federal Register a list of*
14 *persons making such certifications.*

15 *“(e) EFFECT OF FAILURE TO PAY FEES.—An animal*
16 *drug application or supplemental animal drug application*
17 *submitted by a person subject to fees under subsection (a)*
18 *shall be considered incomplete and shall not be accepted for*
19 *filing by the Secretary until all fees owed by such person*
20 *have been paid. An investigational animal drug submission*
21 *under section 739(5)(B) that is submitted by a person sub-*
22 *ject to fees under subsection (a) shall be considered incom-*
23 *plete and shall not be accepted for review by the Secretary*
24 *until all fees owed by such person have been paid. The Sec-*
25 *retary may discontinue review of any animal drug applica-*

1 *tion, supplemental animal drug application or investiga-*
 2 *tional animal drug submission from a person if such person*
 3 *has not submitted for payment all fees owed under this sec-*
 4 *tion by 30 days after the date upon which they are due.*

5 “(f) *ASSESSMENT OF FEES.*—

6 “(1) *LIMITATION.*—*Fees may not be assessed*
 7 *under subsection (a) for a fiscal year beginning after*
 8 *fiscal year 2003 unless appropriations for salaries*
 9 *and expenses of the Food and Drug Administration*
 10 *for such fiscal year (excluding the amount of fees ap-*
 11 *propriated for such fiscal year) are equal to or greater*
 12 *than the amount of appropriations for the salaries*
 13 *and expenses of the Food and Drug Administration*
 14 *for the fiscal year 2003 (excluding the amount of fees*
 15 *appropriated for such fiscal year) multiplied by the*
 16 *adjustment factor applicable to the fiscal year in-*
 17 *volved.*

18 “(2) *AUTHORITY.*—*If the Secretary does not as-*
 19 *sess fees under subsection (a) during any portion of*
 20 *a fiscal year because of paragraph (1) and if at a*
 21 *later date in such fiscal year the Secretary may assess*
 22 *such fees, the Secretary may assess and collect such*
 23 *fees, without any modification in the rate, for animal*
 24 *drug applications, supplemental animal drug appli-*
 25 *cations, investigational animal drug submissions,*

1 *animal drug sponsors, animal drug establishments*
 2 *and animal drug products at any time in such fiscal*
 3 *year notwithstanding the provisions of subsection (a)*
 4 *relating to the date fees are to be paid.*

5 “(g) *CREDITING AND AVAILABILITY OF FEES.*—

6 “(1) *IN GENERAL.*—*Fees authorized under sub-*
 7 *section (a) shall be collected and available for obliga-*
 8 *tion only to the extent and in the amount provided*
 9 *in advance in appropriations Acts. Such fees are au-*
 10 *thorized to be appropriated to remain available until*
 11 *expended. Such sums as may be necessary may be*
 12 *transferred from the Food and Drug Administration*
 13 *salaries and expenses appropriation account without*
 14 *fiscal year limitation to such appropriation account*
 15 *for salary and expenses with such fiscal year limita-*
 16 *tion. The sums transferred shall be available solely for*
 17 *the process for the review of animal drug applica-*
 18 *tions.*

19 “(2) *COLLECTIONS AND APPROPRIATION ACTS.*—

20 “(A) *IN GENERAL.*—*The fees authorized by*
 21 *this section—*

22 “(i) *shall be retained in each fiscal*
 23 *year in an amount not to exceed the*
 24 *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 fol-

lowing 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;

“(D) \$10,000,000 for fiscal year 2007; and

“(E) \$10,000,000 for fiscal year 2008;

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*

1 *account of the Food and Drug Administration as pro-*
 2 *vided in paragraph (1), and shall be subtracted from*
 3 *the amount of fees that would otherwise be authorized*
 4 *to be collected under this section pursuant to appro-*
 5 *propriation Acts for a subsequent fiscal year.*

6 “(h) *COLLECTION OF UNPAID FEES.—In any case*
 7 *where the Secretary does not receive payment of a fee as-*
 8 *sessed under subsection (a) within 30 days after it is due,*
 9 *such fee shall be treated as a claim of the United States*
 10 *Government subject to subchapter II of chapter 37 of title*
 11 *31, United States Code.*

12 “(i) *WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS,*
 13 *AND REFUNDS.—To qualify for consideration for a waiver*
 14 *or reduction under subsection (d), or for a refund of any*
 15 *fee collected in accordance with subsection (a), a person*
 16 *shall submit to the Secretary a written request for such*
 17 *waiver, reduction, or refund not later than 180 days after*
 18 *such fee is due.*

19 “(j) *CONSTRUCTION.—This section may not be con-*
 20 *strued to require that the number of full-time equivalent*
 21 *positions in the Department of Health and Human Serv-*
 22 *ices, for officers, employees, and advisory committees not*
 23 *engaged in the process of the review of animal drug applica-*
 24 *tions, be reduced to offset the number of officers, employees,*
 25 *and advisory committees so engaged.*

1 “(k) *ABBREVIATED NEW ANIMAL DRUG APPLICA-*
 2 *TIONS.—The Secretary shall—*

3 “(1) *to the extent practicable, segregate the re-*
 4 *view of abbreviated new animal drug applications*
 5 *from the process for the review of animal drug appli-*
 6 *cations, and*

7 “(2) *adopt other administrative procedures to*
 8 *ensure that review times of abbreviated new animal*
 9 *drug applications do not increase from their current*
 10 *level due to activities under the user fee program.”.*

11 **SEC. 4. ACCOUNTABILITY AND REPORTS.**

12 (a) *PUBLIC ACCOUNTABILITY.—*

13 (1) *CONSULTATION.—In developing recommenda-*
 14 *tions to Congress for the goals and plans for meeting*
 15 *the goals for the process for the review of animal drug*
 16 *applications for the fiscal years after fiscal year 2008,*
 17 *and for the reauthorization of sections 739 and 740*
 18 *of the Federal Food, Drug, and Cosmetic Act (as*
 19 *added by section 3), the Secretary of Health and*
 20 *Human Services (referred to in this section as the*
 21 *“Secretary”)* shall consult with the Committee on En-
 22 *ergy and Commerce of the House of Representatives,*
 23 *the Committee on Health, Education, Labor, and*
 24 *Pensions of the Senate, appropriate scientific and*
 25 *academic experts, veterinary professionals, representa-*

1 *tives of consumer advocacy groups, and the regulated*
 2 *industry.*

3 (2) *RECOMMENDATIONS.—The Secretary shall—*

4 (A) *publish in the Federal Register rec-*
 5 *ommendations under paragraph (1), after nego-*
 6 *tiations with the regulated industry;*

7 (B) *present the recommendations to the*
 8 *Committees referred to in that paragraph;*

9 (C) *hold a meeting at which the public may*
 10 *comment on the recommendations; and*

11 (D) *provide for a period of 30 days for the*
 12 *public to provide written comments on the rec-*
 13 *ommendations.*

14 (b) *PERFORMANCE REPORTS.—Beginning with fiscal*
 15 *year 2004, not later than 60 days after the end of each fiscal*
 16 *year during which fees are collected under part 4 of sub-*
 17 *chapter C of chapter VII of the Federal Food, Drug, and*
 18 *Cosmetic Act, the Secretary shall prepare and submit to the*
 19 *Committee on Energy and Commerce of the House of Rep-*
 20 *resentatives and the Committee on Health, Education,*
 21 *Labor, and Pensions of the Senate a report concerning the*
 22 *progress of the Food and Drug Administration in achieving*
 23 *the goals identified in the letters described in section 2(3)*
 24 *of this Act toward expediting the animal drug development*
 25 *process and the review of the new and supplemental animal*

1 *drug applications and investigational animal drug submis-*
2 *sions during such fiscal year, the future plans of the Food*
3 *and Drug Administration for meeting the goals, the review*
4 *times for abbreviated new animal drug applications, and*
5 *the administrative procedures adopted by the Food and*
6 *Drug Administration to ensure that review times for abbre-*
7 *viated new animal drug applications are not increased*
8 *from their current level due to activities under the user fee*
9 *program.*

10 (c) *FISCAL REPORT.*—*Beginning with fiscal year*
11 *2004, not later than 120 days after the end of each fiscal*
12 *year during which fees are collected under the part de-*
13 *scribed in subsection (b), the Secretary shall prepare and*
14 *submit to the Committee on Energy and Commerce of the*
15 *House of Representatives and the Committee on Health,*
16 *Education, Labor, and Pensions of the Senate a report on*
17 *the implementation of the authority for such fees during*
18 *such fiscal year and the use, by the Food and Drug Admin-*
19 *istration, of the fees collected during such fiscal year for*
20 *which the report is made.*

1 **SEC. 5. SUNSET.**

2 *The amendments made by section 3 shall not be in ef-*
3 *fect after October 1, 2008, and section 4 shall not be in*
4 *effect after 120 days after such date.*

Attest:

Clerk.