

Calendar No. 104108TH CONGRESS
1ST SESSION**S. 313****[Report No. 108-51]**

To amend the Federal Food, Drug, and Cosmetic Act to establish a program of fees relating to animal drugs.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 5, 2003

Mr. ENSIGN (for himself, Mr. HARKIN, Mr. GREGG, Mr. KENNEDY, and Mr. LUGAR) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

MAY 21, 2003

Reported by Mr. GREGG, with amendments

[Omit the part struck through and insert the part printed in italics]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish a program of fees relating to animal drugs.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Animal Drug User Fee
5 Act of 2003”.

1 **SEC. 2. FINDINGS.**

2 Congress finds as follows:

3 (1) Prompt approval of safe and effective new
4 animal drugs is critical to the improvement of ani-
5 mal health and the public health.

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

11 (3) The fees authorized by this title will be
12 dedicated toward expediting the animal drug devel-
13 opment process and the review of new and supple-
14 mental animal drug applications and investigational
15 animal drug submissions as set forth in the goals
16 identified, for purposes of part 3 of subchapter C of
17 chapter VII of the Federal Food, Drug, and Cos-
18 metic Act, in the letters from the Secretary of
19 Health and Human Services to the Chairman of the
20 Committee on Energy and Commerce of the House
21 of Representatives and the Chairman of the Com-
22 mittee on Health, Education, Labor, and Pensions
23 of the Senate as set forth in the Congressional
24 Record.

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

2 Subchapter C of chapter VII of the Federal Food,
3 Drug and Cosmetic Act (21 U.S.C. 379f et seq.) is amend-
4 ed by adding at the end the following part:

5 **~~“PART 3—FEES RELATING TO ANIMAL DRUGS~~**

6 **~~“PART 4—FEES RELATING TO ANIMAL DRUGS~~**

7 **~~“SEC. 738. DEFINITIONS.~~**

8 ~~“For purposes of this subchapter:~~

9 **~~“SEC. 739. AUTHORITY TO ASSESS AND USE ANIMAL DRUG~~**

10 **~~FEES.~~**

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

12 “(1) The term ‘animal drug application’ means
13 an application for approval of any new animal drug
14 submitted under section 512(b)(1). Such term does
15 not include either a new animal drug application
16 submitted under section 512(b)(2) or a supplemental
17 animal drug application.

18 “(2) The term ‘supplemental animal drug appli-
19 cation’ means—

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

23 “(B) a request to the Secretary to approve
24 a change to an application approved under sec-
25 tion 512(c)(2) for which data with respect to
26 safety or effectiveness are required.

1 “(3) The term ‘animal drug product’ means
2 each specific strength or potency of a particular ac-
3 tive ingredient or ingredients in final dosage form
4 marketed by a particular manufacturer or dis-
5 tributor, which is uniquely identified by the labeler
6 code and product code portions of the national drug
7 code, and for which an animal drug application or
8 a supplemental animal drug application has been ap-
9 proved.

10 “(4) The term ‘animal drug establishment’
11 means a foreign or domestic place of business which
12 is at one general physical location consisting of one
13 or more buildings all of which are within 5 miles of
14 each other, at which one or more animal drug prod-
15 ucts are manufactured in final dosage form.

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

18 “(A) the filing of a claim for an investiga-
19 tional exemption under section 512(j) for a new
20 animal drug intended to be the subject of an
21 animal drug application or a supplemental ani-
22 mal drug application, or

23 “(B) the submission of information for the
24 purpose of enabling the Secretary to evaluate
25 the safety or effectiveness of an animal drug

1 application or supplemental animal drug appli-
2 cation in the event of their filing.

3 “(6) The term ‘animal drug sponsor’ means ei-
4 ther an applicant named in an animal drug applica-
5 tion, except for an approved application for which all
6 subject products have been removed from listing
7 under Section 510, or a person who has submitted
8 an investigational animal drug submission that has
9 not been terminated or otherwise rendered inactive
10 by the Secretary.

11 “(7) The term ‘final dosage form’ means, with
12 respect to an animal drug product, a finished dosage
13 form which is approved for administration to an ani-
14 mal without substantial further manufacturing. Such
15 term includes animal drug products intended for
16 mixing in animal feeds.

17 “(8) The term ‘process for the review of animal
18 drug applications’ means the following activities of
19 the Secretary with respect to the review of animal
20 drug applications, supplemental animal drug applica-
21 tions, and investigational animal drug submissions:

22 “(A) The activities necessary for the re-
23 view of animal drug applications, supplemental
24 animal drug applications, and investigational
25 animal drug submissions.

1 “(B) The issuance of action letters which
2 approve animal drug applications or supple-
3 mental animal drug applications or which set
4 forth in detail the specific deficiencies in animal
5 drug applications, supplemental animal drug
6 applications, or investigational animal drug sub-
7 missions and, where appropriate, the actions
8 necessary to place such applications, supple-
9 ments or submissions in condition for approval.

10 “(C) The inspection of animal drug estab-
11 lishments and other facilities undertaken as
12 part of the Secretary’s review of pending animal
13 drug applications, supplemental animal drug
14 applications, and investigational animal drug
15 submissions.

16 “(D) Monitoring of research conducted in
17 connection with the review of animal drug ap-
18 plications, supplemental animal drug applica-
19 tions, and investigational animal drug submis-
20 sions.

21 “(E) The development of regulations and
22 policy related to the review of animal drug ap-
23 plications, supplemental animal drug applica-
24 tions, and investigational animal drug submis-
25 sions.

1 “(F) Development of standards for prod-
2 ucts subject to review.

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

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

10 “(9) The term ‘costs of resources allocated for
11 the process for the review of animal drug applica-
12 tions’ means the expenses incurred in connection
13 with the process for the review of animal drug appli-
14 cations for—

15 “(A) officers and employees of the Food
16 and Drug Administration, contractors of the
17 Food and Drug Administration, advisory com-
18 mittees consulted with respect to the review of
19 specific animal drug applications, supplemental
20 animal drug applications, or investigational ani-
21 mal drug submissions, and costs related to such
22 officers, employees, committees, and contrac-
23 tors, including costs for travel, education, and
24 recruitment and other personnel activities,

1 “(B) management of information, and the
2 acquisition, maintenance, and repair of com-
3 puter resources,

4 “(C) leasing, maintenance, renovation, and
5 repair of facilities and acquisition, maintenance,
6 and repair of fixtures, furniture, scientific
7 equipment, and other necessary materials and
8 supplies, and

9 “(D) collecting fees under section 739 and
10 accounting for resources allocated for the re-
11 view of animal drug applications, supplemental
12 animal drug applications, and investigational
13 animal drug submissions.

14 “(10) The term ‘adjustment factor’ applicable
15 to a fiscal year refers to the formula set forth in sec-
16 tion 735(8) with the base or comparator year being
17 2003.

18 “(11) The term ‘affiliate’ refers to the defini-
19 tion set forth in section 735(9).

20 **“SEC. 739. AUTHORITY TO ASSESS AND USE ANIMAL DRUG**
21 **FEES.**

22 “(a) (b) TYPES OF FEES.—Beginning in fiscal year
23 2004, the Secretary shall assess and collect fees in accord-
24 ance with this section as follows:

1 “(1) ANIMAL DRUG APPLICATION AND SUPPLE-
2 MENT FEE.—

3 “(A) IN GENERAL.—Each person that sub-
4 mits, on or after September 1, 2003, an animal
5 drug application or a supplemental animal drug
6 application shall be subject to a fee as follows:

7 “(i) A fee established in subsection
8 ~~(b)~~ (c) for an animal drug application; and

9 “(ii) A fee established in subsection
10 ~~(b)~~ (c) for a supplemental animal drug ap-
11 plication for which safety or effectiveness
12 data are required, in an amount that is
13 equal to 50 percent of the amount of the
14 fee under clause (i).

15 “(B) PAYMENT.—The fee required by sub-
16 paragraph (A) shall be due upon submission of
17 the animal drug application or supplemental
18 animal drug application.

19 “(C) EXCEPTION FOR PREVIOUSLY FILED
20 APPLICATION OR SUPPLEMENT.—If an animal
21 drug application or a supplemental animal drug
22 application was submitted by a person that paid
23 the fee for such application or supplement, was
24 accepted for filing, and was not approved or
25 was withdrawn (without a waiver or refund),

1 the submission of an animal drug application or
2 a supplemental animal drug application for the
3 same product by the same person (or the per-
4 son's licensee, assignee, or successor) shall not
5 be subject to a fee under subparagraph (A).

6 “(D) REFUND OF FEE IF APPLICATION RE-
7 FUSED FOR FILING.—The Secretary shall re-
8 fund 75 percent of the fee paid under subpara-
9 graph (B) for any animal drug application or
10 supplemental animal drug application which is
11 refused for filing.

12 “(E) REFUND OF FEE IF APPLICATION
13 WITHDRAWN.—If an animal drug application or
14 a supplemental animal drug application is with-
15 drawn after the application or supplement was
16 filed, the Secretary may refund the fee or por-
17 tion of the fee paid under subparagraph B if no
18 substantial work was performed on the applica-
19 tion or supplement after the application or sup-
20 plement was filed. The Secretary shall have the
21 sole discretion to refund the fee under this
22 paragraph. A determination by the Secretary
23 concerning a refund under this paragraph shall
24 not be reviewable.

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

3 “(A) who is named as the applicant in an
4 animal drug application or supplemental animal
5 drug application for an animal drug product
6 which has been submitted for listing under Sec-
7 tion 510, and

8 “(B) who, after September 1, 2003, had
9 pending before the Secretary an animal drug
10 application or supplemental animal drug appli-
11 cation;

12 shall pay for each such animal drug product the an-
13 nual fee established in subsection ~~(b)~~ (c). Such fee
14 shall be payable for the fiscal year in which the ani-
15 mal drug product is first submitted for listing under
16 Section 510, or is submitted for relisting under sec-
17 tion 510 if the animal drug product has been with-
18 drawn from listing and relisted. After such fee is
19 paid for that fiscal year, such fee shall be payable
20 on or before January 31 of each year. Such fee shall
21 be paid only once for each animal drug product for
22 a fiscal year in which the fee is payable.

23 “(3) ANIMAL DRUG ESTABLISHMENT FEE.—
24 Each person—

1 “(A) who owns or operates, directly or
2 through an affiliate, an animal drug establish-
3 ment, and

4 “(B) who is named as the applicant in an
5 animal drug application or supplemental animal
6 drug application for an animal drug product
7 which has been submitted for listing under Sec-
8 tion 510, and

9 “(C) who, after September 1, 2003, had
10 pending before the Secretary an animal drug
11 application or supplemental animal drug appli-
12 cation,

13 shall be assessed an annual fee established in sub-
14 section ~~(b)~~ (c) for each animal drug establishment
15 listed in its approved animal drug application as an
16 establishment that manufactures the animal drug
17 product named in the application. The annual estab-
18 lishment fee shall be assessed in each fiscal year in
19 which the animal drug product named in the appli-
20 cation is assessed a fee under paragraph (2) unless
21 the animal drug establishment listed in the applica-
22 tion does not engage in the manufacture of the ani-
23 mal drug product during the fiscal year. The fee
24 shall be paid on or before January 31 of each year.
25 The establishment shall be assessed only one fee per

1 fiscal year under this section, provided, however,
 2 that where a single establishment manufactures both
 3 animal drug products and prescription drug prod-
 4 ucts, as defined in section 735(3), such establish-
 5 ment shall be assessed both the animal drug estab-
 6 lishment fee and the prescription drug establishment
 7 fee, as set forth in section 736(a)(2), within a single
 8 fiscal year.

9 “(4) ANIMAL DRUG SPONSOR FEE.—Each
 10 person—

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

13 “(B) who, after September 1, 2003, had
 14 pending before the Secretary an animal drug
 15 application, a supplemental animal drug appli-
 16 cation, or an investigational animal drug sub-
 17 mission,

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

22 “~~(b)~~ (c) FEE AMOUNTS.—Except as provided in sub-
 23 section ~~(a)(1)~~ (b)(1) and subsections ~~(e)~~, ~~(d)~~, ~~(f)~~, and ~~(g)~~,
 24 (d), (e), (g), and (h), the fees required under subsection

1 ~~(a)~~ (b) shall be established to generate fee revenue
2 amounts as follows:

3 “(1) TOTAL FEE REVENUES FOR APPLICATION
4 AND SUPPLEMENT FEES.—The total fee revenues to
5 be collected in animal drug application fees under
6 subsection ~~(a)(1)(A)(i)~~ (b)(1)(A)(i) and supplemental
7 animal drug application fees under subsection
8 ~~(a)(1)(A)(ii)~~ (b)(1)(A)(ii) shall be \$1,250,000 in fis-
9 cal year 2004, \$2,000,000 in fiscal year 2005, and
10 \$2,500,000 in fiscal years 2006 and 2007.

11 “(2) TOTAL FEE REVENUES FOR PRODUCT
12 FEES.—The total fee revenues to be collected in
13 product fees under subsection ~~(a)(2)~~ (b)(2) shall be
14 \$1,250,000 in fiscal year 2004, \$2,000,000 in fiscal
15 year 2005, and \$2,500,000 in fiscal years 2006 and
16 2007.

17 “(3) TOTAL FEE REVENUES FOR ESTABLISH-
18 MENT FEES.—The total fee revenues to be collected
19 in establishment fees under subsection ~~(a)(3)~~ (b)(3)
20 shall be \$1,250,000 in fiscal year 2004, \$2,000,000
21 in fiscal year 2005, and \$2,500,000 in fiscal years
22 2006 and 2007.

23 “(4) TOTAL FEE REVENUES FOR SPONSOR
24 FEES.—The total fee revenues to be collected in
25 sponsor fees under subsection ~~(a)(4)~~ (b)(4) shall be

1 \$1,250,000 in fiscal year 2004, \$2,000,000 in fiscal
2 year 2005, and \$2,500,000 in fiscal years 2006 and
3 2007.

4 “(e) (d) ADJUSTMENTS.—

5 “(1) INFLATION ADJUSTMENT.—The fees and
6 total fee revenues established in subsection ~~(b)~~ (c)
7 shall be adjusted by the Secretary by notice, pub-
8 lished in the Federal Register, for a fiscal year ac-
9 cording to the formula set forth in section 736(c)(1).

10 “(2) WORKLOAD ADJUSTMENT.—After the fee
11 revenues are adjusted for inflation in accordance
12 with subparagraph (1), the fee revenues shall be fur-
13 ther adjusted each fiscal year after fiscal year 2004
14 to reflect changes in review workload. With respect
15 to such adjustment:

16 “(A) This adjustment shall be determined
17 by the Secretary based on a weighted average
18 of the change in the total number of animal
19 drug applications, supplemental animal drug
20 applications for which data with respect to safe-
21 ty or effectiveness are required, manufacturing
22 supplemental animal drug applications, inves-
23 tigational animal drug study submissions, and
24 investigational animal drug protocol submis-
25 sions submitted to the Secretary. The Secretary

1 shall publish in the Federal Register the fees
2 resulting from this adjustment and the sup-
3 porting methodologies.

4 “(B) Under no circumstances shall this
5 workload adjustment result in fee revenues for
6 a fiscal year that are less than the fee revenues
7 for that fiscal year established in subsection
8 ~~(b)~~, *(c)*, as adjusted for inflation under subpara-
9 graph ~~(c)(1)~~ *(d)(1)*.

10 “(3) FINAL YEAR ADJUSTMENT.—For fiscal
11 year 2007, the Secretary may further increase the
12 fees to provide for up to 3 months of operating re-
13 serves of carryover user fees for the process for the
14 review of animal drug applications for the first 3
15 months of fiscal year 2008. If the Food and Drug
16 Administration has carryover balances for the pro-
17 cess for the review of animal drug applications in ex-
18 cess of 3 months of such operating reserves, then
19 this adjustment will not be made. If this adjustment
20 is necessary, then the rationale for the amount of
21 the increase shall be contained in the annual notice
22 setting fees for fiscal year 2007.

23 “(4) ANNUAL FEE SETTING.—The Secretary
24 shall establish, 60 days before the start of each fis-
25 cal year that begins after September 30, 2003, for

1 that fiscal year, animal drug application fees, sup-
2 plemental animal drug application fees, animal drug
3 sponsor fees, animal drug establishment fees, and
4 animal drug product fees based on the revenue
5 amounts established under subsection ~~(b)~~ (c) and the
6 adjustments provided under this subsection.

7 “(5) LIMIT.—The total amount of fees charged,
8 as adjusted under this subsection, for a fiscal year
9 may not exceed the total costs for such fiscal year
10 for the resources allocated for the process for the re-
11 view of animal drug applications.

12 “~~(d)~~ (e) FEE WAIVER OR REDUCTION.—

13 “(1) IN GENERAL.—The Secretary shall grant a
14 waiver from or a reduction of 1 or more fees as-
15 sessed under subsection ~~(a)~~ (b) where the Secretary
16 finds that—

17 “(A) the assessment of the fee would
18 present a significant barrier to innovation be-
19 cause of limited resources available to such per-
20 son or other circumstances,

21 “(B) the fees to be paid by such person
22 will exceed the anticipated present and future
23 costs incurred by the Secretary in conducting
24 the process for the review of animal drug appli-
25 cations for such person,

1 “(C) the animal drug application or sup-
2 plemental animal drug application is intended
3 solely to provide for use of the animal drug
4 in—

5 “(i) a Type B medicated feed (as de-
6 fined in section 558.3(b)(3) of title 21,
7 Code of Federal Regulations (or any suc-
8 cessor regulation)) intended for use in the
9 manufacture of Type C free-choice medi-
10 cated feeds, or

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

15 “(D) the animal drug application or sup-
16 plemental animal drug application is intended
17 solely to provide for a minor use or minor spe-
18 cies indication, or

19 “(E) the sponsor involved is a small busi-
20 ness submitting its first animal drug applica-
21 tion to the Secretary for review.

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

25 “(3) RULES FOR SMALL BUSINESSES.—

1 “(A) DEFINITION.—In paragraph (1)(D),
2 the term “small business” means an entity that
3 has fewer than 500 employees, including em-
4 ployees of affiliates.

5 “(B) WAIVER OF APPLICATION FEE.—The
6 Secretary shall waive under paragraph (1)(D)
7 the application fee for the first animal drug ap-
8 plication that a small business or its affiliate
9 submits to the Secretary for review. After a
10 small business or its affiliate is granted such a
11 waiver, the small business or its affiliate shall
12 pay application fees for all subsequent animal
13 drug applications and supplemental animal
14 drug applications for which safety or effective-
15 ness data are required in the same manner as
16 an entity that does not qualify as a small busi-
17 ness.

18 “(C) CERTIFICATION.—The Secretary shall
19 require any person who applies for a waiver
20 under paragraph (1)(D) to certify their quali-
21 fication for the waiver. The Secretary shall peri-
22 odically publish in the Federal Register a list of
23 persons making such certifications.

24 “(e) (f) EFFECT OF FAILURE TO PAY FEES.—An
25 animal drug application or supplemental animal drug ap-

1 plication submitted by a person subject to fees under sub-
2 section ~~(a)~~ (b) shall be considered incomplete and shall not
3 be accepted for filing by the Secretary until all fees owed
4 by such person have been paid. An investigational animal
5 drug submission under section 738(5)(B) that is sub-
6 mitted by a person subject to fees under subsection ~~(a)~~
7 (b) shall be considered incomplete and shall not be accept-
8 ed for review by the Secretary until all fees owed by such
9 person have been paid. The Secretary may discontinue re-
10 view of any animal drug application, supplemental animal
11 drug application or investigational animal drug submission
12 from a person if such person has not submitted for pay-
13 ment all fees owed under this section by 30 days after
14 the date upon which they are due.

15 “~~(f)~~ (g) ASSESSMENT OF FEES.—

16 “(1) LIMITATION.—Fees may not be assessed
17 under subsection (a) for a fiscal year beginning after
18 fiscal year 2003 unless appropriations for salaries
19 and expenses of the Food and Drug Administration
20 for such fiscal year (excluding the amount of fees
21 appropriated for such fiscal year) are equal to or
22 greater than the amount of appropriations for the
23 salaries and expenses of the Food and Drug Admin-
24 istration for the fiscal year 2003 (excluding the
25 amount of fees appropriated for such fiscal year)

1 multiplied by the adjustment factor applicable to the
2 fiscal year involved.

3 “(2) AUTHORITY.—If the Secretary does not
4 assess fees under subsection ~~(a)~~ (b) during any por-
5 tion of a fiscal year because of paragraph (1) and
6 if at a later date in such fiscal year the Secretary
7 may assess such fees, the Secretary may assess and
8 collect such fees, without any modification in the
9 rate, for animal drug applications, supplemental ani-
10 mal drug applications, investigational animal drug
11 submissions, sponsors, animal drug establishments
12 and animal drug products at any time in such fiscal
13 year notwithstanding the provisions of subsection (a)
14 relating to the date fees are to be paid.

15 “~~(g)~~ (h) CREDITING AND AVAILABILITY OF FEES.—

16 “(1) IN GENERAL.—Fees authorized under sub-
17 section ~~(a)~~ (b) shall be collected and available for ob-
18 ligation only to the extent and in the amount pro-
19 vided in advance in appropriations Acts. Such fees
20 are authorized to be appropriated to remain avail-
21 able until expended. Such sums as may be necessary
22 may be transferred from the Food and Drug Admin-
23 istration salaries and expenses appropriation account
24 without fiscal year limitation to such appropriation
25 account for salary and expenses with such fiscal year

1 limitation. The sums transferred shall be available
2 solely for the process for the review of animal drug
3 applications.

4 “(2) COLLECTIONS AND APPROPRIATION
5 ACTS.—

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

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

13 “(ii) shall only be collected and avail-
14 able to defray increases in the costs of the
15 resources allocated for the process for the
16 review of animal drug applications (includ-
17 ing increases in such costs for an addi-
18 tional number of full-time equivalent posi-
19 tions in the Department of Health and
20 Human Services to be engaged in such
21 process) over such costs, excluding costs
22 paid from fees collected under this section,
23 for fiscal year 2003 multiplied by the ad-
24 justment factor.

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

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

10 “(ii)(I) are more than 3 percent below
11 the level specified in subparagraph (A)(ii),
12 and fees assessed for the fiscal year fol-
13 lowing the subsequent fiscal year are de-
14 creased by the amount in excess of 3 per-
15 cent by which such costs fell below the
16 level specified in subparagraph (A)(ii); and

17 “(II) such costs are not more than 5
18 percent below the level specified in sub-
19 paragraph (A)(ii).

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

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

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

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

1 “(D) \$10,000,000 for fiscal year 2007;
2 as adjusted to reflect adjustments in the total fee
3 revenues made under this section and changes in the
4 total amounts collected by animal drug application
5 fees, supplemental animal drug application fees, ani-
6 mal drug sponsor fees, animal drug establishment
7 fees, and animal drug product fees.

8 “(4) OFFSET.—Any amount of fees collected
9 for a fiscal year under this section that exceeds the
10 amount of fees specified in appropriations Acts for
11 such fiscal year shall be credited to the appropria-
12 tion account of the Food and Drug Administration
13 as provided in paragraph (1), and shall be sub-
14 tracted from the amount of fees that would other-
15 wise be authorized to be collected under this section
16 pursuant to appropriation Acts for a subsequent fis-
17 cal year.

18 “~~(h)~~ (i) COLLECTION OF UNPAID FEES.—In any case
19 where the Secretary does not receive payment of a fee as-
20 sessed under subsection ~~(a)~~ (b) within 30 days after it is
21 due, such fee shall be treated as a claim of the United
22 States Government subject to subchapter II of chapter 37
23 of title 31, United States Code.

24 “~~(i)~~ (j) WRITTEN REQUESTS FOR WAIVERS, REDUC-
25 TIONS, AND REFUNDS.—To qualify for consideration for

1 a waiver or reduction under subsection ~~(d)~~, (e), or for a
 2 refund of any fee collected in accordance with subsection
 3 ~~(a)~~, (b), a person shall submit to the Secretary a written
 4 request for such waiver, reduction, or refund not later
 5 than 180 days after such fee is due.

6 “~~(j)~~ (k) CONSTRUCTION.—This section may not be
 7 construed to require that the number of full-time equiva-
 8 lent positions in the Department of Health and Human
 9 Services, for officers, employees, and advisory committees
 10 not engaged in the process of the review of animal drug
 11 applications, be reduced to offset the number of officers,
 12 employees, and advisory committees so engaged.

13 “~~(k)~~ (l) ADMINISTRATIVE PROCEDURE.—The Sec-
 14 retary shall—

15 “(1) to the extent practicable, segregate the re-
 16 view of abbreviated new animal drug applications
 17 from the process for the review of animal drug appli-
 18 cations, and

19 “(2) adopt other administrative procedures to
 20 ensure that review times of abbreviated new animal
 21 drug applications do not increase from their current
 22 level due to activities under the user fee program.”.

23 **SEC. 4. ACCOUNTABILITY AND REPORTS.**

24 (a) PUBLIC ACCOUNTABILITY.—

1 (1) CONSULTATION.—In developing rec-
2 ommendations to Congress for the goals and plans
3 for meeting the goals for the process for the review
4 of animal drug applications for the fiscal years after
5 fiscal year 2007, and for the reauthorization of sec-
6 tion 738 and 739 of the Federal Food, Drug, and
7 Cosmetic Act (as added by section 3), the Secretary
8 of Health and Human Services (referred to in this
9 section as the “Secretary”) shall consult with the
10 Committee on Energy and Commerce of the House
11 of Representatives, the Committee on Health, Edu-
12 cation, Labor, and Pensions of the Senate, appro-
13 priate scientific and academic experts, veterinary
14 professionals, representatives of consumer advocacy
15 groups, and the regulated industry.

16 (2) RECOMMENDATIONS.—The Secretary
17 shall—

18 (A) publish in the Federal Register rec-
19 ommendations under paragraph (1), after nego-
20 tiations with the regulated industry;

21 (B) present the recommendations to the
22 Committees referred to in that paragraph;

23 (C) hold a meeting at which the public
24 may comment on the recommendations; and

1 (D) provide for a period of 30 days for the
2 public to provide written comments on the rec-
3 ommendations.

4 (b) PERFORMANCE REPORTS.—Beginning with fiscal
5 year 2004, not later than 60 days after the end of each
6 fiscal year during which fees are collected under part 3
7 of subchapter C of chapter VII of the Federal Food, Drug,
8 and Cosmetic Act, the Secretary shall prepare and submit
9 to the Committee on Energy and Commerce of the House
10 of Representatives and the Committee on Health, Edu-
11 cation, Labor, and Pensions of the Senate a report con-
12 cerning the progress of the Food and Drug Administration
13 in achieving the goals identified in the letters described
14 in section 2(3) of this Act toward expediting the animal
15 drug development process and the review of the new and
16 supplemental animal drug applications and investigational
17 animal drug submissions during such fiscal year, the fu-
18 ture plans of the Food and Drug Administration for meet-
19 ing the goals, the review times for abbreviated new animal
20 drug applications, and the administrative procedures
21 adopted by the Food and Drug Administration to ensure
22 that review times for abbreviated new animal drug applica-
23 tions are not increased from their current level due to ac-
24 tivities under the user fee program.

1 (c) FISCAL REPORT.—Beginning with fiscal year
2 2004, not later than 120 days after the end of each fiscal
3 year during which fees are collected under the part de-
4 scribed in subsection (a), the Secretary shall prepare and
5 submit to the Committee on Energy and Commerce of the
6 House of Representatives and the Committee on Health,
7 Education, Labor, and Pensions of the Senate a report
8 on the implementation of the authority for such fees dur-
9 ing such fiscal year and the use, by the Food and Drug
10 Administration, of the fees collected during such fiscal
11 year for which the report is made.

12 **SEC. 5. SUNSET.**

13 The amendments made by section 3 shall not be in
14 effect after October 1, 2007 and section 4 shall not be
15 in effect after 120 days after such date.

Calendar No. 104

108TH CONGRESS
1ST SESSION

S. 313

[Report No. 108-51]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish a program of fees relating to animal drugs.

MAY 21, 2003

Reported with amendments