

107TH CONGRESS  
2D SESSION

# H. R. 4955

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

---

## IN THE HOUSE OF REPRESENTATIVES

JUNE 18, 2002

Mr. GANSKE (for himself, Mr. NORWOOD, Mr. WHITFIELD, Mr. PICKERING, and Mr. BILIRAKIS) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

## 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 2002”.

6       **SEC. 2. FINDINGS.**

7       The Congress finds as follows:

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

1           (2) Animal health and the public health will be  
2 served by making additional funds available for the  
3 purpose of augmenting the resources of the Food  
4 and Drug Administration that are devoted to the  
5 process for review of new animal drug applications.

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

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

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

1 **“PART 3—FEES RELATING TO ANIMAL DRUGS**

2 **“SEC. 738. DEFINITIONS.**

3 “For purposes of this subchapter:

4 “(1) The term ‘animal drug application’ means  
5 an application for approval of any new animal drug  
6 submitted under section 512(b)(1). Such term does  
7 not include a supplemental animal drug application.

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

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

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

17 “(3) The term ‘animal drug product’ means  
18 each specific strength or potency of a particular ac-  
19 tive ingredient or ingredients in final dosage form  
20 marketed by a particular manufacturer or dis-  
21 tributor, which is uniquely identified by the labeler  
22 code and product code portions of the national drug  
23 code, and for which an animal drug application or  
24 a supplemental animal drug application has been ap-  
25 proved.

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

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

9                   “(A) the filing of a claim for an investiga-  
10 tional exemption under section 512(j) for a new  
11 animal drug intended to be the subject of an  
12 animal drug application or a supplemental ani-  
13 mal drug application; or

14                   “(B) the submission of information for the  
15 purpose of enabling the Secretary to evaluate  
16 the safety or effectiveness of an animal drug  
17 application or supplemental animal drug appli-  
18 cation in the event of their filing.

19           “(6) The term ‘animal drug sponsor’ means ei-  
20 ther an applicant named in an animal drug applica-  
21 tion, except for an approved application for which all  
22 subject products have been removed from listing  
23 under section 510, or a person who has submitted  
24 an investigational animal drug submission that has

1 not been terminated or otherwise rendered inactive  
2 by the Secretary.

3 “(7) The term ‘final dosage form’ means, with  
4 respect to an animal drug product, a finished dosage  
5 form which is approved for administration to an ani-  
6 mal without substantial further manufacturing. Such  
7 term includes animal drug products intended for  
8 mixing in animal feeds.

9 “(8) The term ‘process for the review of animal  
10 drug applications’ means the following activities of  
11 the Secretary with respect to the review of animal  
12 drug applications, supplemental animal drug applica-  
13 tions, and investigational animal drug submissions:

14 “(A) The activities necessary for the re-  
15 view of animal drug applications, supplemental  
16 animal drug applications, and investigational  
17 animal drug submissions.

18 “(B) The issuance of action letters which  
19 approve animal drug applications or supple-  
20 mental animal drug applications or which set  
21 forth in detail the specific deficiencies in animal  
22 drug applications, supplemental animal drug  
23 applications, and investigational animal drug  
24 submissions and, where appropriate, the actions

1 necessary to place such applications, supple-  
2 ments or submissions in condition for approval.

3 “(C) The inspection of animal drug estab-  
4 lishments and other facilities undertaken as  
5 part of the Secretary’s review of pending animal  
6 drug applications, supplemental animal drug  
7 applications, and investigational animal drug  
8 submissions.

9 “(D) Monitoring of research conducted in  
10 connection with the review of animal drug ap-  
11 plications, supplemental animal drug applica-  
12 tions, and investigational animal drug submis-  
13 sions.

14 “(E) The development of regulations and  
15 policy related to the review of animal drug ap-  
16 plications, supplemental animal drug applica-  
17 tions, and investigational animal drug submis-  
18 sions.

19 “(F) Development of standards for prod-  
20 ucts subject to review.

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

23 “(H) Review of advertising and labeling  
24 prior to approval of an animal drug application  
25 or supplemental animal drug application, but

1 not such activities after an animal drug has  
2 been approved.

3 “(9) The term ‘costs of resources allocated for  
4 the process for the review of animal drug applica-  
5 tions’ means the expenses incurred in connection  
6 with the process for the review of animal drug appli-  
7 cations for—

8 “(A) officers and employees of the Food  
9 and Drug Administration, contractors of the  
10 Food and Drug Administration, advisory com-  
11 mittees consulted with respect to the review of  
12 specific animal drug applications, supplemental  
13 animal drug applications, or investigational ani-  
14 mal drug submissions, and costs related to such  
15 officers, employees, committees, and contrac-  
16 tors, including costs for travel, education, and  
17 recruitment and other personnel activities;

18 “(B) management of information, and the  
19 acquisition, maintenance, and repair of com-  
20 puter resources;

21 “(C) leasing, maintenance, renovation, and  
22 repair of facilities and acquisition, maintenance,  
23 and repair of fixtures, furniture, scientific  
24 equipment, and other necessary materials and  
25 supplies; and

1           “(D) collecting fees under section 739 and  
2           accounting for resources allocated for the re-  
3           view of animal drug applications, supplemental  
4           animal drug applications, and investigational  
5           animal drug submissions.

6           “(10) The term ‘adjustment factor’ applicable  
7           to a fiscal year refers to the formula set forth in sec-  
8           tion 735(8) with the base or comparator year being  
9           2002.

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

12   **“SEC. 739. AUTHORITY TO ASSESS AND USE ANIMAL DRUG**  
13           **FEES.**

14           “(a) TYPES OF FEES.—Beginning in fiscal year  
15   2003, the Secretary shall assess and collect fees in accord-  
16   ance with this section as follows:

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

19           “(A) IN GENERAL.—Each person that sub-  
20           mits, on or after September 1, 2002, an animal  
21           drug application or a supplemental animal drug  
22           application shall be subject to a fee as follows:

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

1                   “(ii) A fee established in subsection  
2                   (b) for a supplemental animal drug appli-  
3                   cation for which safety or effectiveness  
4                   data are required.

5                   “(B) PAYMENT.—The fee required by sub-  
6                   paragraph (A) shall be due upon submission of  
7                   the animal drug application or supplemental  
8                   animal drug application.

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

21                  “(D) REFUND OF FEE IF APPLICATION RE-  
22                  FUSED FOR FILING.—The Secretary shall re-  
23                  fund 75 percent of the fee paid under subpara-  
24                  graph (B) for any animal drug application or

1 supplemental animal drug application which is  
2 refused for filing.

3 “(E) REFUND OF FEE IF APPLICATION  
4 WITHDRAWN.—If an animal drug application or  
5 a supplemental animal drug application is with-  
6 drawn after the application or supplement was  
7 filed, the Secretary may refund the fee or por-  
8 tion of the fee paid under subparagraph B if no  
9 substantial work was performed on the applica-  
10 tion or supplement after the application or sup-  
11 plement was filed. The Secretary shall have the  
12 sole discretion to refund the fee under this  
13 paragraph. A determination by the Secretary  
14 concerning a refund under this paragraph shall  
15 not be reviewable.

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

18 “(A) who is named as the applicant in an  
19 animal drug application or supplemental animal  
20 drug application for an animal drug product  
21 which has been submitted for listing under sec-  
22 tion 510; and

23 “(B) who, after September 1, 2002, had  
24 pending before the Secretary an animal drug

1 application or supplemental animal drug appli-  
2 cation;  
3 shall pay for each such animal drug product the an-  
4 nual fee established in subsection (b). Such fee shall  
5 be payable for the fiscal year in which the animal  
6 drug product is first submitted for listing under Sec-  
7 tion 510, or is submitted for relisting under section  
8 510 if the animal drug product has been withdrawn  
9 from listing and relisted. After such fee is paid for  
10 that fiscal year, such fee shall be payable on or be-  
11 fore January 31 of each year. Such fee shall be paid  
12 only once for each animal drug product for a fiscal  
13 year in which the fee is payable.

14 “(3) ANIMAL DRUG ESTABLISHMENT FEE.—

15 Each person—

16 “(A) who owns or operates, directly or  
17 through an affiliate, an animal drug establish-  
18 ment;

19 “(B) who is named as the applicant in an  
20 animal drug application or supplemental animal  
21 drug application for an animal drug product  
22 which has been submitted for listing under Sec-  
23 tion 510; and

24 “(C) who, after September 1, 2002, had  
25 pending before the Secretary an animal drug

1 application or supplemental animal drug appli-  
2 cation;  
3 shall be assessed an annual fee established in sub-  
4 section (b) for each animal drug establishment listed  
5 in its approved animal drug application as an estab-  
6 lishment that manufactures the animal drug product  
7 named in the application. The annual establishment  
8 fee shall be assessed in each fiscal year in which the  
9 animal drug product named in the application is as-  
10 sessed a fee under paragraph (2) unless the animal  
11 drug establishment listed in the application does not  
12 engage in the manufacture of the animal drug prod-  
13 uct during the fiscal year. The fee shall be paid on  
14 or before January 31 of each year. The establish-  
15 ment shall be assessed only one fee per fiscal year  
16 under this section, provided, however, that where a  
17 single establishment manufactures both animal drug  
18 products and prescription drug products, as defined  
19 in section 735(3), such establishment shall be as-  
20 sessed both the animal drug establishment fee and  
21 the prescription drug establishment fee, as set forth  
22 in section 736(a)(2), within a single fiscal year.

23 “(4) ANIMAL DRUG SPONSOR FEE.—Each  
24 person—

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

3           “(B) who, after September 1, 2002, had  
4 pending before the Secretary an animal drug  
5 application, a supplemental animal drug appli-  
6 cation, or an investigational animal drug sub-  
7 mission, shall be assessed an annual fee estab-  
8 lished under subsection (b). The fee shall be  
9 paid on or before January 31 of each year.  
10 Each animal drug sponsor shall pay only one  
11 such fee each fiscal year.

12       “(b) FEE AMOUNTS.—Except as provided in sub-  
13 section (a)(1) and subsections (c), (d), (f), and (g), the  
14 fees required under subsection (a) shall be determined and  
15 assessed as follows:

16       “(1) APPLICATION AND SUPPLEMENT FEES.—

17           “(A) The animal drug application fee  
18 under subsection (a)(1)(A)(i) shall be \$35,750  
19 in fiscal year 2003, \$57,150 in fiscal year  
20 2004, and \$71,500 in fiscal years 2005, 2006,  
21 and 2007.

22           “(B) The supplemental animal drug appli-  
23 cation fee under subsection (a)(1)(A)(ii) shall  
24 be \$17,850 in fiscal year 2003, \$28,575 in fis-

1 cal year 2004, and \$35,700 in fiscal years  
2 2005, 2006, and 2007.

3 “(2) TOTAL FEE REVENUES FOR PRODUCT  
4 FEES.—The total fee revenues to be collected in  
5 product fees under subsection (a)(2) shall be  
6 \$1,250,000 in fiscal year 2003, \$2,000,000 in fiscal  
7 year 2004, and \$2,500,000 in fiscal years 2005,  
8 2006, and 2007.

9 “(3) TOTAL FEE REVENUES FOR ESTABLISH-  
10 MENT FEES.—The total fee revenues to be collected  
11 in establishment fees under subsection (a)(3) shall  
12 be \$1,250,000 in fiscal year 2003, \$2,000,000 in fis-  
13 cal year 2004, and \$2,500,000 in fiscal years 2005,  
14 2006, and 2007.

15 “(4) TOTAL FEE REVENUES FOR SPONSOR  
16 FEES.—The total fee revenues to be collected in  
17 sponsor fees under subsection (a)(4) shall be  
18 \$1,250,000 in fiscal year 2003, \$2,000,000 in fiscal  
19 year 2004, and \$2,500,000 in fiscal years 2005,  
20 2006, and 2007.

21 “(c) ADJUSTMENTS.—

22 “(1) INFLATION ADJUSTMENT.—The fees and  
23 total fee revenues established in subsection (b) shall  
24 be adjusted by the Secretary by notice, published in

1 the Federal Register, for a fiscal year according to  
2 the formula set forth in section 736(c)(1).

3 “(2) WORKLOAD ADJUSTMENT.—After the fee  
4 revenues are adjusted for inflation in accordance  
5 with paragraph (1), the fee revenues shall be further  
6 adjusted each fiscal year after fiscal year 2003 to re-  
7 flect changes in review workload. With respect to  
8 such adjustment:

9 “(A) The adjustment shall be determined  
10 by the Secretary based on a weighted average  
11 of the change in the total number of animal  
12 drug applications, supplemental animal drug  
13 applications for which data with respect to safe-  
14 ty or effectiveness are required, manufacturing  
15 supplemental animal drug applications, inves-  
16 tigational animal drug study submissions, and  
17 investigational animal drug protocol submis-  
18 sions submitted to the Secretary. The Secretary  
19 shall publish in the Federal Register the fees  
20 resulting from this adjustment and the sup-  
21 porting methodologies.

22 “(B) Under no circumstances shall this  
23 workload adjustment result in fee revenues for  
24 a fiscal year that are less than the fee revenues  
25 for that fiscal year established in subsection

1 (b), as adjusted for inflation under subpara-  
2 graph (c)(1).

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

16 “(4) ANNUAL FEE ADJUSTMENT.—Subject to  
17 the amount appropriated for a fiscal year under sub-  
18 section (g), the Secretary shall, within 60 days after  
19 the end of each fiscal year beginning after Sep-  
20 tember 30, 2002, adjust the fees established by the  
21 schedule in subsection (b) for the fiscal year in  
22 which the adjustment occurs so that the revenues  
23 collected from each of the categories of fees de-  
24 scribed in paragraphs (1), (2), (3), and (4) of sub-

1 section (b) shall be set to be equal to 25 percent  
2 of the total fees appropriated under subsection (g).

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

8 “(d) FEE WAIVER OR REDUCTION.—

9 “(1) IN GENERAL.—The Secretary shall grant a  
10 waiver from or a reduction of one or more fees as-  
11 sessed under subsection (a) where the Secretary  
12 finds that—

13 “(A) the assessment of the fee would  
14 present a significant barrier to innovation be-  
15 cause of limited resources available to such per-  
16 son or other circumstances;

17 “(B) the fees to be paid by such person  
18 will exceed the anticipated present and future  
19 costs incurred by the Secretary in conducting  
20 the process for the review of animal drug appli-  
21 cations for such person;

22 “(C) such waiver or reduction is necessary  
23 to promote the availability of animal drug prod-  
24 ucts for minor uses or for use in minor species;  
25 or

1           “(D) the sponsor involved is a small busi-  
2           ness submitting its first animal drug applica-  
3           tion to the Secretary for review.

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

7           “(3) RULES FOR SMALL BUSINESSES.—

8           “(A) DEFINITION.—In paragraph (1)(D),  
9           the term ‘small business’ means an entity that  
10          has fewer than 500 employees, including em-  
11          ployees of affiliates.

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

1           “(C) CERTIFICATION.—The Secretary shall  
2           require any person who applies for a waiver  
3           under paragraph (1)(D) to certify their quali-  
4           fication for the waiver. The Secretary shall peri-  
5           odically publish in the Federal Register a list of  
6           persons making such certifications.

7           “(e) EFFECT OF FAILURE TO PAY FEES.—An ani-  
8           mal drug application or supplemental animal drug applica-  
9           tion submitted by a person subject to fees under sub-  
10          section (a) shall be considered incomplete and shall not  
11          be accepted for filing by the Secretary until all fees owed  
12          by such person have been paid. An investigational animal  
13          drug submission under section (5)(B) that is submitted  
14          by a person subject to fees under subsection (a) shall be  
15          considered incomplete and shall not be accepted for review  
16          by the Secretary until all fees owed by such person have  
17          been paid. The Secretary may discontinue review of any  
18          animal drug application, supplemental animal drug appli-  
19          cation or investigational animal drug submission from a  
20          person if such person has not submitted for payment all  
21          fees owed under this section by 30 days after the date  
22          upon which they are due.

23          “(f) ASSESSMENT OF FEES.—

24                  “(1) LIMITATION.—Fees may not be assessed  
25          under subsection (a) for a fiscal year beginning after

1 fiscal year 2002 unless appropriations for salaries  
2 and expenses of the Food and Drug Administration  
3 for such fiscal year (excluding the amount of fees  
4 appropriated for such fiscal year) are equal to or  
5 greater than the amount of appropriations for the  
6 salaries and expenses of the Food and Drug Admin-  
7 istration for the fiscal year 2002 (excluding the  
8 amount of fees appropriated for such fiscal year)  
9 multiplied by the adjustment factor applicable to the  
10 fiscal year involved.

11 “(2) AUTHORITY.—If the Secretary does not  
12 assess fees under subsection (a) during any portion  
13 of a fiscal year because of paragraph (1) and if at  
14 a later date in such fiscal year the Secretary may as-  
15 sess such fees, the Secretary may assess and collect  
16 such fees, without any modification in the rate, for  
17 animal drug applications, supplemental animal drug  
18 applications, investigational animal drug submis-  
19 sions, sponsors, animal drug establishments and ani-  
20 mal drug products at any time in such fiscal year  
21 notwithstanding the provisions of subsection (a) re-  
22 lating to the date fees are to be paid.

23 “(g) CREDITING AND AVAILABILITY OF FEES.—

24 “(1) IN GENERAL.—Fees authorized under sub-  
25 section (a) shall be collected and available for obliga-

1       tion only to the extent and in the amount provided  
2       in advance in appropriations Acts. Such fees are au-  
3       thorized to be appropriated to remain available until  
4       expended. Such sums as may be necessary may be  
5       transferred from the Food and Drug Administration  
6       salaries and expenses appropriation account without  
7       fiscal year limitation to such appropriation account  
8       for salary and expenses with such fiscal year limita-  
9       tion. The sums transferred shall be available solely  
10      for the process for the review of animal drug appli-  
11      cations.

12           “(2)   COLLECTIONS    AND    APPROPRIATION  
13      ACTS.—

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

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

21           “(ii) shall only be collected and avail-  
22           able to defray increases in the costs of the  
23           resources allocated for the process for the  
24           review of animal drug applications (includ-  
25           ing increases in such costs for an addi-

1 tional number of full-time equivalent posi-  
2 tions in the Department of Health and  
3 Human Services to be engaged in such  
4 process) over such costs, excluding costs  
5 paid from fees collected under this section,  
6 for fiscal year 2002 multiplied by the ad-  
7 justment factor.

8 “(B) COMPLIANCE WITH REQUIREMENT.—

9 The Food and Drug Administration will be con-  
10 sidered to have met the requirements of sub-  
11 paragraph (A)(ii) in any fiscal year if—

12 “(i) the costs funded by appropria-  
13 tions and allocated for the process for the  
14 review of animal drug applications are not  
15 more than 3 percent below the level speci-  
16 fied in (B)(i); or

17 “(ii) the costs funded by appropria-  
18 tions and allocated for the process for the  
19 review of animal drug applications are  
20 more than 3 percent below the level speci-  
21 fied in (B)(i), and fees assessed for a sub-  
22 sequent fiscal year are decreased by the  
23 amount in excess of 3 percent by which the  
24 costs funded by appropriations and allo-  
25 cated for the process for the review of ani-

1           mal drug applications fell below the level  
2           specified in (B)(i), provided that the costs  
3           funded by appropriations and allocated for  
4           the process for the review of animal drug  
5           applications are not more than 5 percent  
6           below the level specified in (B)(i).

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

10                   “(A) \$5,000,000 for fiscal year 2003;

11                   “(B) \$8,000,000 for fiscal year 2004;

12                   “(C) \$10,000,000 for fiscal year 2005;

13                   “(D) \$10,000,000 for fiscal year 2006;

14                   and

15                   “(E) \$10,000,000 for fiscal year 2007;

16           as adjusted to reflect adjustments in the total fee  
17           revenues made under this section and changes in the  
18           total amounts collected by animal drug application  
19           fees, supplemental animal drug application fees, ani-  
20           mal drug sponsor fees, animal drug establishment  
21           fees, and animal drug product fees.

22           “(4) OFFSET.—Any amount of fees collected  
23           for a fiscal year under this section that exceeds the  
24           amount of fees specified in appropriations Acts for  
25           such fiscal year shall be credited to the appropria-

1       tion account of the Food and Drug Administration  
2       as provided in paragraph (1), and shall be sub-  
3       tracted from the amount of fees that would other-  
4       wise be authorized to be collected under this section  
5       pursuant to appropriation Acts for a subsequent fis-  
6       cal year.

7       “(h) COLLECTION OF UNPAID FEES.—In any case  
8       where the Secretary does not receive payment of a fee as-  
9       sessed under subsection (a) within 30 days after it is due,  
10      such fee shall be treated as a claim of the United States  
11      Government subject to subchapter II of chapter 37 of title  
12      31, United States Code.

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

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

1 cations, be reduced to offset the number of officers, em-  
2 ployees, and advisory committees so engaged.”.

3 **SEC. 4. ANNUAL REPORTS.**

4 (a) **PERFORMANCE REPORT.**—Beginning with fiscal  
5 year 2003, not later than 60 days after the end of each  
6 fiscal year during which fees are collected under part 2  
7 of subchapter C of chapter VII of the Federal Food, Drug,  
8 and Cosmetic Act, the Secretary of Health and Human  
9 Services shall prepare and submit to the Committee on  
10 Energy and Commerce of the House of Representatives  
11 and the Committee on Health, Education, Labor, and  
12 Pensions of the Senate a report concerning the progress  
13 of the Food and Drug Administration in achieving the  
14 goals identified in the letters described in section 2(3) of  
15 this Act toward expediting the animal drug development  
16 process and the review of the new and supplemental ani-  
17 mal drug applications and investigational animal drug  
18 submissions during such fiscal year and the future plans  
19 of the Food and Drug Administration for meeting the  
20 goals.

21 (b) **FISCAL REPORT.**—Beginning with fiscal year  
22 2003, not later than 120 days after the end of each fiscal  
23 year during which fees are collected under the part de-  
24 scribed in subsection (a), the Secretary of Health and  
25 Human Services shall prepare and submit to the Com-

1 mittee on Energy and Commerce of the House of Rep-  
2 resentatives and the Committee on Health, Education,  
3 Labor, and Pensions of the Senate a report on the imple-  
4 mentation of the authority for such fees during such fiscal  
5 year and the use, by the Food and Drug Administration,  
6 of the fees collected during such fiscal year for which the  
7 report is made.

8 **SEC. 5. SUNSET.**

9       The amendments made by section 3 shall not be in  
10 effect after October 1, 2007, and section 4 shall not be  
11 in effect after 120 days after such date.

○