

107TH CONGRESS
2D SESSION

S. 2665

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

JUNE 20, 2002

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

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 and

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

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

22 Subchapter C of chapter VII of the Federal Food,
23 Drug and Cosmetic Act (21 U.S.C. 379f et seq.) is amend-
24 ed 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”
5 means an application for approval of any new animal
6 drug submitted under section 512(b)(1). Such term
7 does not include either a new animal drug applica-
8 tion submitted under section 512(b)(2) or a supple-
9 mental animal drug application.

10 “(2) The term “supplemental animal drug ap-
11 plication” means—

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

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

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

1 a supplemental animal drug application has been ap-
2 proved.

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

9 “(5) The term “investigational animal drug
10 submission” means—

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

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

21 “(6) The term “animal drug sponsor” means
22 either an applicant named in an animal drug appli-
23 cation, except for an approved application for which
24 all subject products have been removed from listing
25 under Section 510, or a person who has submitted

1 an investigational animal drug submission that has
2 not been terminated or otherwise rendered inactive
3 by the Secretary.

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

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

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

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

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,

8 shall be assessed an annual fee established under
9 subsection (b). The fee shall be paid on or before
10 January 31 of each year. Each animal drug sponsor
11 shall pay only one 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) below,
14 the fees required under subsection (a) shall be determined
15 and 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 subparagraph (1), the fee revenues shall be fur-
6 ther adjusted each fiscal year after fiscal year 2003
7 to reflect changes in review workload. With respect
8 to such adjustment:

9 “(A) This 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 FY
4 2007, the Secretary may further increase the fees to
5 provide for up to 3 months of operating reserves of
6 carryover user fees for the process for the review of
7 animal drug applications for the first three months
8 of FY 2008. If the Food and Drug Administration
9 has carryover balances for the process for the review
10 of animal drug applications in excess of three
11 months of such operating reserves, then this adjust-
12 ment will not be made. If this adjustment is nec-
13 essary, then the rationale for the amount of the in-
14 crease shall be contained in the annual notice setting
15 fees for FY 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 of
2 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 fees assessed under subsection (a)
11 where the Secretary finds that—

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

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

21 “(C) the animal drug application is in-
22 tended solely to provide for a minor use or
23 minor species indication, 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 738(5)(B) that is sub-
14 mitted by a person subject to fees under subsection (a)
15 shall be considered incomplete and shall not be accepted
16 for review by the Secretary until all fees owed by such
17 person have been paid. The Secretary may discontinue re-
18 view of any animal drug application, supplemental animal
19 drug application or investigational animal drug submission
20 from a person if such person has not submitted for pay-
21 ment all fees owed under this section by 30 days after
22 the date 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 (A)(ii), 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 (A)(ii), 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, as
16 adjusted to reflect adjustments in the total fee
17 revenues made under this section and changes
18 in the total amounts collected by animal drug
19 application fees, supplemental animal drug ap-
20 plication fees, animal drug sponsor fees, animal
21 drug establishment fees, and animal drug prod-
22 uct fees.

23 “(4) OFFSET.—Any amount of fees collected
24 for a fiscal year under this section that exceeds the
25 amount of fees specified in appropriations Acts for

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

8 “(h) COLLECTION OF UNPAID FEES.—In any case
9 where the Secretary does not receive payment of a fee as-
10 sessed under subsection (a) within 30 days after it is due,
11 such fee shall be treated as a claim of the United States
12 Government subject to subchapter II of chapter 37 of title
13 31, United States Code.

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

21 “(j) CONSTRUCTION.—This section may not be con-
22 strued to require that the number of full-time equivalent
23 positions in the Department of Health and Human Serv-
24 ices, for officers, employees, and advisory committees not
25 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.

○