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108TH CONGRESS  
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# H. R. 1260

[Report No. 108-287]

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

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 13, 2003

Mr. UPTON (for himself, Ms. DEGETTE, Mr. GREENWOOD, Mr. TOWNS, Mr. BILIRAKIS, and Mr. JOHN) introduced the following bill; which was referred to the Committee on Energy and Commerce

SEPTEMBER 30, 2003

Additional sponsors: Mr. OTTER, Mr. PICKERING, Mr. WHITFIELD, Mr. GILCHREST, Mr. BOSWELL, Mr. ROGERS of Michigan, Mr. PUTNAM, Mr. DEAL of Georgia, Mr. SOUDER, Mr. TERRY, Mr. BOUCHER, Mr. MORAN of Kansas, Mr. THORNBERRY, Mr. CHOCOLA, and Mr. GOODLATTE

SEPTEMBER 30, 2003

Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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## 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,*

1 **SECTION 1. SHORT TITLE.**

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

4 **SEC. 2. FINDINGS.**

5 Congress finds as follows:

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

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

14 (3) The fees authorized by this title will be  
15 dedicated toward expediting the animal drug devel-  
16 opment process and the review of new and supple-  
17 mental animal drug applications and investigational  
18 animal drug submissions as set forth in the goals  
19 identified, for purposes of part 4 of subchapter C of  
20 chapter VII of the Federal Food, Drug, and Cos-  
21 metic Act, in the letters from the Secretary of  
22 Health and Human Services to the Chairman of the  
23 Committee on Energy and Commerce of the House  
24 of Representatives and the Chairman of the Com-  
25 mittee on Health, Education, Labor, and Pensions

1 of the Senate as set forth in the Congressional  
2 Record.

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

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

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

8 **“SEC. 739. DEFINITIONS.**

9 “For purposes of this subchapter:

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

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

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

21 “(B) a request to the Secretary to approve  
22 a change to an application approved under sec-  
23 tion 512(c)(2) for which data with respect to  
24 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 740 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. 740. AUTHORITY TO ASSESS AND USE ANIMAL DRUG**  
21                               **FEES.**

22          “(a) 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) for an animal drug application; and

9                   “(ii) A fee established in subsection  
10                  (b) for a supplemental animal drug appli-  
11                  cation 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 per-  
2       son—

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). Such fee shall  
14      be payable for the fiscal year in which the animal  
15      drug product is first submitted for listing under sec-  
16      tion 510, or is submitted for relisting under section  
17      510 if the animal drug product has been withdrawn  
18      from listing and relisted. After such fee is paid for  
19      that fiscal year, such fee shall be payable on or be-  
20      fore January 31 of each year. Such fee shall be paid  
21      only once for each animal drug product for a fiscal  
22      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) for each animal drug establishment listed  
15          in its approved animal drug application as an estab-  
16          lishment that manufactures the animal drug product  
17          named in the application. The annual establishment  
18          fee shall be assessed in each fiscal year in which the  
19          animal drug product named in the application is as-  
20          sessed a fee under paragraph (2) unless the animal  
21          drug establishment listed in the application does not  
22          engage in the manufacture of the animal drug prod-  
23          uct during the fiscal year. The fee shall be paid on  
24          or before January 31 of each year. The establish-  
25          ment shall be assessed only one fee per fiscal year

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

8 “(4) ANIMAL DRUG SPONSOR FEE.—Each per-  
9 son—

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

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

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

21 “(b) FEE AMOUNTS.—Except as provided in sub-  
22 section (a)(1) and subsections (c), (d), (f), and (g), the  
23 fees required under subsection (a) shall be established to  
24 generate fee revenue amounts as follows:

1           “(1) TOTAL FEE REVENUES FOR APPLICATION  
2           AND SUPPLEMENT FEES.—The total fee revenues to  
3           be collected in animal drug application fees under  
4           subsection (a)(1)(A)(i) and supplemental animal  
5           drug application fees under subsection (a)(1)(A)(ii)  
6           shall be \$1,250,000 in fiscal year 2004, \$2,000,000  
7           in fiscal year 2005, and \$2,500,000 in fiscal years  
8           2006, 2007, and 2008.

9           “(2) TOTAL FEE REVENUES FOR PRODUCT  
10          FEES.—The total fee revenues to be collected in  
11          product fees under subsection (a)(2) shall be  
12          \$1,250,000 in fiscal year 2004, \$2,000,000 in fiscal  
13          year 2005, and \$2,500,000 in fiscal years 2006,  
14          2007, and 2008.

15          “(3) TOTAL FEE REVENUES FOR ESTABLISH-  
16          MENT FEES.—The total fee revenues to be collected  
17          in establishment fees under subsection (a)(3) shall  
18          be \$1,250,000 in fiscal year 2004, \$2,000,000 in fis-  
19          cal year 2005, and \$2,500,000 in fiscal years 2006,  
20          2007, and 2008.

21          “(4) TOTAL FEE REVENUES FOR SPONSOR  
22          FEES.—The total fee revenues to be collected in  
23          sponsor fees under subsection (a)(4) shall be  
24          \$1,250,000 in fiscal year 2004, \$2,000,000 in fiscal

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

3 “(c) ADJUSTMENTS.—

4 “(1) INFLATION ADJUSTMENT.—The revenues  
5 established in subsection (b) shall be adjusted by the  
6 Secretary by notice, published in the Federal Reg-  
7 ister, for a fiscal year to reflect the greater of—

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

14 “(B) the total percentage change for the  
15 previous fiscal year in basic pay under the Gen-  
16 eral Schedule in accordance with section 5332  
17 of title 5, United States Code, as adjusted by  
18 any locality-based comparability payment pur-  
19 suant to section 5304 of such title for Federal  
20 employees stationed in the District of Columbia.

21 The adjustment made each fiscal year by this sub-  
22 section will be added on a compounded basis to the  
23 sum of all adjustments made each fiscal year after  
24 fiscal year 2004 under this subsection.

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

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

20           “(B) Under no circumstances shall this  
21 workload adjustment result in fee revenues for  
22 a fiscal year that are less than the fee revenues  
23 for that fiscal year established in subsection  
24 (b), as adjusted for inflation under subpara-  
25 graph (c)(1).

1           “(3) FINAL YEAR ADJUSTMENT.—For fiscal  
2           year 2008, the Secretary may further increase the  
3           fees to provide for up to 3 months of operating re-  
4           serves of carryover user fees for the process for the  
5           review of animal drug applications for the first 3  
6           months of fiscal year 2009. If the Food and Drug  
7           Administration has carryover balances for the proc-  
8           ess for the review of animal drug applications in ex-  
9           cess of 3 months of such operating reserves, then  
10          this adjustment will not be made. If this adjustment  
11          is necessary, then the rationale for the amount of  
12          the increase shall be contained in the annual notice  
13          setting fees for fiscal year 2008.

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

23          “(5) LIMIT.—The total amount of fees charged,  
24          as adjusted under this subsection, for a fiscal year  
25          may not exceed the total costs for such fiscal year

1 for the resources allocated for the process for the re-  
2 view of animal drug applications.

3 “(d) FEE WAIVER OR REDUCTION.—

4 “(1) IN GENERAL.—The Secretary shall grant a  
5 waiver from or a reduction of 1 or more fees as-  
6 sessed under subsection (a) where the Secretary  
7 finds that—

8 “(A) the assessment of the fee would  
9 present a significant barrier to innovation be-  
10 cause of limited resources available to such per-  
11 son or other circumstances,

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

17 “(C) the animal drug application or sup-  
18 plemental animal drug application is intended  
19 solely to provide for use of the animal drug  
20 in—

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

1 manufacture of Type C free-choice medi-  
2 cated feeds, or

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

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

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

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

17 “(3) RULES FOR SMALL BUSINESSES.—

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

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

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

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

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

1 person have been paid. The Secretary may discontinue re-  
2 view of any animal drug application, supplemental animal  
3 drug application or investigational animal drug submission  
4 from a person if such person has not submitted for pay-  
5 ment all fees owed under this section by 30 days after  
6 the date upon which they are due.

7 “(f) ASSESSMENT OF FEES.—

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

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

1 animal drug applications, supplemental animal drug  
2 applications, investigational animal drug submis-  
3 sions, sponsors, animal drug establishments and ani-  
4 mal drug products at any time in such fiscal year  
5 notwithstanding the provisions of subsection (a) re-  
6 lating to the date fees are to be paid.

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

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

21 “(2) COLLECTIONS AND APPROPRIATION  
22 ACTS.—

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

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

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

18          “(B) COMPLIANCE.—The Secretary shall  
19          be considered to have met the requirements of  
20          subparagraph (A)(ii) in any fiscal year if the  
21          costs funded by appropriations and allocated for  
22          the process for the review of animal drug appli-  
23          cations—

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

4           “(ii)(I) are more than 3 percent below  
5 the level specified in subparagraph (A)(ii),  
6 and fees assessed for the fiscal year fol-  
7 lowing the subsequent fiscal year are de-  
8 creased by the amount in excess of 3 per-  
9 cent by which such costs fell below the  
10 level specified in subparagraph (A)(ii); and

11           “(II) such costs are not more than 5  
12 percent below the level specified in sub-  
13 paragraph (A)(ii).

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

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

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

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

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

21           and

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

23           as adjusted to reflect adjustments in the total fee  
24 revenues made under this section and changes in the  
25 total amounts collected by animal drug application

1 fees, supplemental animal drug application fees, ani-  
2 mal drug sponsor fees, animal drug establishment  
3 fees, and animal drug product fees.

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

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

20 “(i) WRITTEN REQUESTS FOR WAIVERS, REDUC-  
21 TIONS, AND REFUNDS.—To qualify for consideration for  
22 a waiver or reduction under subsection (d), or for a refund  
23 of any fee collected in accordance with subsection (a), a  
24 person shall submit to the Secretary a written request for

1 such waiver, reduction, or refund not later than 180 days  
2 after such fee is due.

3 “(j) CONSTRUCTION.—This section may not be con-  
4 strued to require that the number of full-time equivalent  
5 positions in the Department of Health and Human Serv-  
6 ices, for officers, employees, and advisory committees not  
7 engaged in the process of the review of animal drug appli-  
8 cations, be reduced to offset the number of officers, em-  
9 ployees, and advisory committees so engaged.

10 “(k) ABBREVIATED NEW ANIMAL DRUG APPLICA-  
11 TIONS.—The Secretary shall—

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

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

20 **SEC. 4. ACCOUNTABILITY AND REPORTS.**

21 (a) PUBLIC ACCOUNTABILITY.—

22 (1) CONSULTATION.—In developing rec-  
23 ommendations to Congress for the goals and plans  
24 for meeting the goals for the process for the review  
25 of animal drug applications for the fiscal years after

1 fiscal year 2008, and for the reauthorization of sec-  
2 tions 739 and 740 of the Federal Food, Drug, and  
3 Cosmetic Act (as added by section 3), the Secretary  
4 of Health and Human Services (referred to in this  
5 section as the “Secretary”) shall consult with the  
6 Committee on Energy and Commerce of the House  
7 of Representatives, the Committee on Health, Edu-  
8 cation, Labor, and Pensions of the Senate, appro-  
9 priate scientific and academic experts, veterinary  
10 professionals, representatives of consumer advocacy  
11 groups, and the regulated industry.

12 (2) RECOMMENDATIONS.—The Secretary  
13 shall—

14 (A) publish in the Federal Register rec-  
15 ommendations under paragraph (1), after nego-  
16 tiations with the regulated industry;

17 (B) present the recommendations to the  
18 Committees referred to in that paragraph;

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

21 (D) provide for a period of 30 days for the  
22 public to provide written comments on the rec-  
23 ommendations.

24 (b) PERFORMANCE REPORTS.—Beginning with fiscal  
25 year 2004, not later than 60 days after the end of each

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

20 (c) FISCAL REPORT.—Beginning with fiscal year  
21 2004, not later than 120 days after the end of each fiscal  
22 year during which fees are collected under the part de-  
23 scribed in subsection (a), the Secretary shall prepare and  
24 submit to the Committee on Energy and Commerce of the  
25 House of Representatives and the Committee on Health,

1 Education, Labor, and Pensions of the Senate a report  
2 on the implementation of the authority for such fees dur-  
3 ing such fiscal year and the use, by the Food and Drug  
4 Administration, of the fees collected during such fiscal  
5 year for which the report is made.

6 **SEC. 5. SUNSET.**

7       The amendments made by section 3 shall not be in  
8 effect after October 1, 2008, and section 4 shall not be  
9 in effect after 120 days after such date.

**Union Calendar No. 167**

108TH CONGRESS  
1ST SESSION

**H. R. 1260**

**[Report No. 108-287]**

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**A BILL**

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

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SEPTEMBER 30, 2003

Committed to the Committee of the Whole House on the State of the Union and ordered to be printed