

## Calendar No. 31

113TH CONGRESS  
1ST SESSION**S. 622**

To amend the Federal Food, Drug, and Cosmetic Act to reauthorize user fee programs relating to new animal drugs and generic new animal drugs.

---

IN THE SENATE OF THE UNITED STATES

MARCH 20, 2013

Mr. HARKIN, from the Committee on Health, Education, Labor, and Pensions, reported the following original bill; which was read twice and placed on the calendar

---

**A BILL**

To amend the Federal Food, Drug, and Cosmetic Act to reauthorize user fee programs relating to new animal drugs and generic new 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 and Ani-  
5       mal Generic Drug User Fee Reauthorization Act of  
6       2013”.

1 **SEC. 2. TABLE OF CONTENTS; REFERENCES IN ACT.**

2 (a) TABLE OF CONTENTS.—The table of contents of  
3 this Act is as follows:

Sec. 1. Short title.

Sec. 2. Table of contents; references in Act.

**TITLE I—FEES RELATING TO ANIMAL DRUGS**

Sec. 101. Short title; finding.

Sec. 102. Definitions.

Sec. 103. Authority to assess and use animal drug fees.

Sec. 104. Reauthorization; reporting requirements.

Sec. 105. Savings clause.

Sec. 106. Effective date.

Sec. 107. Sunset dates.

**TITLE II—FEES RELATING TO GENERIC ANIMAL DRUGS**

Sec. 201. Short title; finding.

Sec. 202. Authority to assess and use generic new animal drug fees.

Sec. 203. Reauthorization; reporting requirements.

Sec. 204. Savings clause.

Sec. 205. Effective date.

Sec. 206. Sunset dates.

4 (b) REFERENCES IN ACT.—Except as otherwise spec-  
5 ified, amendments made by this Act to a section or other  
6 provision of law are amendments to such section or other  
7 provision of the Federal Food, Drug, and Cosmetic Act  
8 (21 U.S.C. 301 et seq.).

9 **TITLE I—FEES RELATING TO**  
10 **ANIMAL DRUGS**

11 **SEC. 101. SHORT TITLE; FINDING.**

12 (a) SHORT TITLE.—This title may be cited as the  
13 “Animal Drug User Fee Amendments of 2013”.

14 (b) FINDING.—Congress finds that the fees author-  
15 ized by the amendments made in this title will be dedi-  
16 cated toward expediting the animal drug development

1 process and the review of new and supplemental animal  
2 drug applications and investigational animal drug submis-  
3 sions as set forth in the goals identified, for purposes of  
4 part 4 of subchapter C of chapter VII of the Federal Food,  
5 Drug, and Cosmetic Act, in the letters from the Secretary  
6 of Health and Human Services to the Chairman of the  
7 Committee on Energy and Commerce of the House of  
8 Representatives and the Chairman of the Committee on  
9 Health, Education, Labor, and Pensions of the Senate as  
10 set forth in the Congressional Record.

11 **SEC. 102. DEFINITIONS.**

12 Section 739 of the Federal Food, Drug, and Cosmetic  
13 Act (21 U.S.C. 379j–11) is amended to read as follows:

14 **“SEC. 739. DEFINITIONS.**

15 “For purposes of this part:

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

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

1           “(A) a request to the Secretary to approve  
2           a change in an animal drug application which  
3           has been approved; or

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

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

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

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

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

6           “(B) the submission of information for the  
7           purpose of enabling the Secretary to evaluate  
8           the safety or effectiveness of an animal drug  
9           application or supplemental animal drug appli-  
10          cation in the event of their filing.

11          “(6) The term ‘animal drug sponsor’ means ei-  
12          ther an applicant named in an animal drug applica-  
13          tion that has not been withdrawn by the applicant  
14          and for which approval has not been withdrawn by  
15          the Secretary , or a person who has submitted an in-  
16          vestigational animal drug submission that has not  
17          been terminated or otherwise rendered inactive by  
18          the Secretary.

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

1           “(8) The term ‘process for the review of animal  
2           drug applications’ means the following activities of  
3           the Secretary with respect to the review of animal  
4           drug applications, supplemental animal drug applica-  
5           tions, and investigational animal drug submissions:

6                   “(A) The activities necessary for the re-  
7                   view of animal drug applications, supplemental  
8                   animal drug applications, and investigational  
9                   animal drug submissions.

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

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

1           “(D) Monitoring of research conducted in  
2           connection with the review of animal drug ap-  
3           plications, supplemental animal drug applica-  
4           tions, and investigational animal drug submis-  
5           sions.

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

11          “(F) Development of standards for prod-  
12          ucts subject to review.

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

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

19          “(9) The term ‘costs of resources allocated for  
20          the process for the review of animal drug applica-  
21          tions’ means the expenses in connection with the  
22          process for the review of animal drug applications  
23          for—

24                 “(A) officers and employees of the Food  
25                 and Drug Administration, contractors of the

1 Food and Drug Administration, advisory com-  
2 mittees consulted with respect to the review of  
3 specific animal drug applications, supplemental  
4 animal drug applications, or investigational ani-  
5 mal drug submissions, and costs related to such  
6 officers, employees, committees, and contrac-  
7 tors, including costs for travel, education, and  
8 recruitment and other personnel activities;

9 “(B) management of information and the  
10 acquisition, maintenance, and repair of com-  
11 puter resources;

12 “(C) leasing, maintenance, renovation, and  
13 repair of facilities and acquisition, maintenance,  
14 and repair of fixtures, furniture, scientific  
15 equipment, and other necessary materials and  
16 supplies; and

17 “(D) collecting fees under section 740 and  
18 accounting for resources allocated for the re-  
19 view of animal drug applications, supplemental  
20 animal drug applications, and investigational  
21 animal drug submissions.

22 “(10) The term ‘adjustment factor’ applicable  
23 to a fiscal year refers to the formula set forth in sec-  
24 tion 735(8) with the base or comparator month  
25 being October 2002.



1           “(11) The term ‘person’ includes an affiliate  
2           thereof.

3           “(12) The term ‘affiliate’ refers to the defini-  
4           tion set forth in section 735(11).”.

5   **SEC. 103. AUTHORITY TO ASSESS AND USE ANIMAL DRUG**  
6           **FEES.**

7           Section 740 of the Federal Food, Drug, and Cosmetic  
8   Act (21 U.S.C. 379j–12) is amended to read as follows:

9   **“SEC. 740. AUTHORITY TO ASSESS AND USE ANIMAL DRUG**  
10           **FEES.**

11           “(a) TYPES OF FEES.—Beginning in fiscal year  
12   2004, the Secretary shall assess and collect fees in accord-  
13   ance with this section as follows:

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

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

20           “(i) A fee established in subsection (c)  
21           for an animal drug application, except an  
22           animal drug application subject to the cri-  
23           teria set forth in section 512(d)(4).

24           “(ii) A fee established in subsection  
25           (c), in an amount that is equal to 50 per-

1 cent of the amount of the fee under clause  
2 (i), for—

3 “(I) a supplemental animal drug  
4 application for which safety or effec-  
5 tiveness data are required; and

6 “(II) an animal drug application  
7 subject to the criteria set forth in sec-  
8 tion 512(d)(4).

9 “(B) PAYMENT.—The fee required by sub-  
10 paragraph (A) shall be due upon submission of  
11 the animal drug application or supplemental  
12 animal drug application.

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

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

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

20          “(2) ANIMAL DRUG PRODUCT FEE.—

21               “(A) IN GENERAL.—Each person—

22                   “(i) who is named as the applicant in  
23                   an animal drug application or supple-  
24                   mental animal drug application for an ani-

1 mal drug product which has been sub-  
2 mitted for listing under section 510; and

3 “(ii) who, after September 1, 2003,  
4 had pending before the Secretary an ani-  
5 mal drug application or supplemental ani-  
6 mal drug application,

7 shall pay for each such animal drug product the  
8 annual fee established in subsection (c).

9 “(B) PAYMENT; FEE DUE DATE.—Such fee  
10 shall be payable for the fiscal year in which the  
11 animal drug product is first submitted for list-  
12 ing under section 510, or is submitted for re-  
13 listing under section 510 if the animal drug  
14 product has been withdrawn from listing and  
15 relisted. After such fee is paid for that fiscal  
16 year, such fee shall be due each subsequent fis-  
17 cal year that the product remains listed, upon  
18 the later of—

19 “(i) the first business day after the  
20 date of enactment of an appropriations Act  
21 providing for the collection and obligation  
22 of fees for such fiscal year under this sec-  
23 tion; or

24 “(ii) January 31 of each year.

1           “(C) LIMITATION.—Such fee shall be paid  
2 only once for each animal drug product for a  
3 fiscal year in which the fee is payable.

4           “(3) ANIMAL DRUG ESTABLISHMENT FEE.—

5           “(A) IN GENERAL.—Each person—

6                   “(i) who owns or operates, directly or  
7 through an affiliate, an animal drug estab-  
8 lishment;

9                   “(ii) who is named as the applicant in  
10 an animal drug application or supple-  
11 mental animal drug application for an ani-  
12 mal drug product which has been sub-  
13 mitted for listing under section 510; and

14                   “(iii) who, after September 1, 2003,  
15 had pending before the Secretary an ani-  
16 mal drug application or supplemental ani-  
17 mal drug application,

18 shall be assessed an annual establishment fee as  
19 established in subsection (c) for each animal  
20 drug establishment listed in its approved animal  
21 drug application as an establishment that man-  
22 ufactures the animal drug product named in the  
23 application.

24           “(B) PAYMENT; FEE DUE DATE.—The an-  
25 nual establishment fee shall be assessed in each

1       fiscal year in which the animal drug product  
2       named in the application is assessed a fee under  
3       paragraph (2) unless the animal drug establish-  
4       ment listed in the application does not engage  
5       in the manufacture of the animal drug product  
6       during the fiscal year. The fee under this para-  
7       graph for a fiscal year shall be due upon the  
8       later of—

9               “(i) the first business day after the  
10              date of enactment of an appropriations Act  
11              providing for the collection and obligation  
12              of fees for such fiscal year under this sec-  
13              tion; or

14             “(ii) January 31 of each year.

15             “(C) LIMITATION.—

16             “(i) IN GENERAL.—An establishment  
17             shall be assessed only one fee per fiscal  
18             year under this section, subject to clause  
19             (ii).

20             “(ii) CERTAIN MANUFACTURERS.—If  
21             a single establishment manufactures both  
22             animal drug products and prescription  
23             drug products, as defined in section  
24             735(3), such establishment shall be as-  
25             sessed both the animal drug establishment

1 fee and the prescription drug establish-  
2 ment fee, as set forth in section 736(a)(2),  
3 within a single fiscal year.

4 “(4) ANIMAL DRUG SPONSOR FEE.—

5 “(A) IN GENERAL.—Each person—

6 “(i) who meets the definition of an  
7 animal drug sponsor within a fiscal year;  
8 and

9 “(ii) who, after September 1, 2003,  
10 had pending before the Secretary an ani-  
11 mal drug application, a supplemental ani-  
12 mal drug application, or an investigational  
13 animal drug submission,

14 shall be assessed an annual sponsor fee as es-  
15 tablished under subsection (c).

16 “(B) PAYMENT; FEE DUE DATE.—The fee  
17 under this paragraph for a fiscal year shall be  
18 due upon the later of—

19 “(i) the first business day after the  
20 date of enactment of an appropriations Act  
21 providing for the collection and obligation  
22 of fees for such fiscal year under this sec-  
23 tion; or

24 “(ii) January 31 of each year.

1           “(C) LIMITATION.—Each animal drug  
2           sponsor shall pay only one such fee each fiscal  
3           year.

4           “(b) FEE REVENUE AMOUNTS.—

5           “(1) IN GENERAL.—Subject to subsections (c),  
6           (d), (f), and (g)—

7           “(A) for fiscal year 2014, the fees required  
8           under subsection (a) shall be established to gen-  
9           erate a total revenue amount of \$23,600,000;  
10          and

11          “(B) for each of fiscal years 2015 through  
12          2018, the fees required under subsection (a)  
13          shall be established to generate a total revenue  
14          amount of \$21,600,000.

15          “(2) TYPES OF FEES.—Of the total revenue  
16          amount determined for a fiscal year under para-  
17          graph (1)—

18          “(A) 20 percent shall be derived from fees  
19          under subsection (a)(1) (relating to animal  
20          drug applications and supplements);

21          “(B) 27 percent shall be derived from fees  
22          under subsection (a)(2) (relating to animal  
23          drug products);



1           “(C) 26 percent shall be derived from fees  
2           under subsection (a)(3) (relating to animal  
3           drug establishments); and

4           “(D) 27 percent shall be derived from fees  
5           under subsection (a)(4) (relating to animal  
6           drug sponsors).

7           “(c) ANNUAL FEE SETTING; ADJUSTMENTS.—

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

17          “(2) INFLATION ADJUSTMENT.—For fiscal year  
18          2015 and subsequent fiscal years, the revenue  
19          amounts established in subsection (b) shall be ad-  
20          justed by the Secretary by notice, published in the  
21          Federal Register, for a fiscal year, by an amount  
22          equal to the sum of—

23                  “(A) one;

24                  “(B) the average annual percent change in  
25          the cost, per full-time equivalent position of the

1 Food and Drug Administration, of all personnel  
2 compensation and benefits paid with respect to  
3 such positions for the first 3 of the preceding  
4 4 fiscal years for which data are available, mul-  
5 tiplied by the average proportion of personnel  
6 compensation and benefits costs to total Food  
7 and Drug Administration costs for the first 3  
8 years of the preceding 4 fiscal years for which  
9 data are available; and

10 “(C) the average annual percent change  
11 that occurred in the Consumer Price Index for  
12 urban consumers (Washington-Baltimore, DC-  
13 MD-VA-WV; not seasonally adjusted; all items  
14 less food and energy; annual index) for the first  
15 3 years of the preceding 4 years for which data  
16 are available multiplied by the average propor-  
17 tion of all costs other than personnel compensa-  
18 tion and benefits costs to total Food and Drug  
19 Administration costs for the first 3 years of the  
20 preceding 4 fiscal years for which data are  
21 available.

22 The adjustment made each fiscal year under this  
23 paragraph shall be added on a compounded basis to  
24 the sum of all adjustments made each fiscal year  
25 after fiscal year 2014 under this paragraph.

1           “(3) WORKLOAD ADJUSTMENT.—For fiscal  
2           year 2015 and subsequent fiscal years, after the rev-  
3           enue amounts established in subsection (b) are ad-  
4           justed for inflation in accordance with paragraph  
5           (2), the revenue amounts shall be further adjusted  
6           for such fiscal year to reflect changes in the work-  
7           load of the Secretary for the process for the review  
8           of animal drug applications. With respect to such  
9           adjustment—

10               “(A) such adjustment shall be determined  
11               by the Secretary based on a weighted average  
12               of the change in the total number of animal  
13               drug applications, supplemental animal drug  
14               applications for which data with respect to safe-  
15               ty or effectiveness are required, manufacturing  
16               supplemental animal drug applications, inves-  
17               tigational animal drug study submissions, and  
18               investigational animal drug protocol submis-  
19               sions submitted to the Secretary;

20               “(B) the Secretary shall publish in the  
21               Federal Register the fees resulting from such  
22               adjustment and the supporting methodologies;  
23               and

24               “(C) under no circumstances shall such ad-  
25               justment result in fee revenues for a fiscal year

1           that are less than the fee revenues for that fis-  
2           cal year established in subsection (b), as ad-  
3           justed for inflation under paragraph (2).

4           “(4) FINAL YEAR ADJUSTMENT.—For fiscal  
5           year 2018, the Secretary may, in addition to other  
6           adjustments under this subsection, further increase  
7           the fees under this section, if such an adjustment is  
8           necessary, to provide for up to 3 months of oper-  
9           ating reserves of carryover user fees for the process  
10          for the review of animal drug applications for the  
11          first 3 months of fiscal year 2019. If the Food and  
12          Drug Administration has carryover balances for the  
13          process for the review of animal drug applications in  
14          excess of 3 months of such operating reserves, then  
15          this adjustment will not be made. If this adjustment  
16          is necessary, then the rationale for the amount of  
17          the increase shall be contained in the annual notice  
18          setting fees for fiscal year 2018.

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

24          “(d) FEE WAIVER OR REDUCTION.—

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

5                   “(A) the assessment of the fee would  
6                   present a significant barrier to innovation be-  
7                   cause of limited resources available to such per-  
8                   son or other circumstances;

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

14                  “(C) the animal drug application or sup-  
15                  plemental animal drug application is intended  
16                  solely to provide for use of the animal drug  
17                  in—

18                           “(i) a Type B medicated feed (as de-  
19                           fined in section 558.3(b)(3) of title 21,  
20                           Code of Federal Regulations (or any suc-  
21                           cessor regulation)) intended for use in the  
22                           manufacture of Type C free-choice medi-  
23                           cated feeds; or

24                           “(ii) a Type C free-choice medicated  
25                           feed (as defined in section 558.3(b)(4) of

1 title 21, Code of Federal Regulations (or  
2 any successor regulation));

3 “(D) the animal drug application or sup-  
4 plemental animal drug application is intended  
5 solely to provide for a minor use or minor spe-  
6 cies indication; or

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

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

13 “(3) RULES FOR SMALL BUSINESSES.—

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

18 “(B) WAIVER OF APPLICATION FEE.—The  
19 Secretary shall waive under paragraph (1)(E)  
20 the application fee for the first animal drug ap-  
21 plication that a small business or its affiliate  
22 submits to the Secretary for review. After a  
23 small business or its affiliate is granted such a  
24 waiver, the small business or its affiliate shall  
25 pay application fees for all subsequent animal

1 drug applications and supplemental animal  
2 drug applications for which safety or effective-  
3 ness data are required in the same manner as  
4 an entity that does not qualify as a small busi-  
5 ness.

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

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

1 ment all fees owed under this section by 30 days after  
2 the date upon which they are due.

3 “(f) ASSESSMENT OF FEES.—

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

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



1       fiscal year notwithstanding the provisions of sub-  
2       section (a) relating to the date fees are to be paid.

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

4               “(1) IN GENERAL.—Subject to paragraph  
5       (2)(C), fees authorized under subsection (a) shall be  
6       collected and available for obligation only to the ex-  
7       tent and in the amount provided in advance in ap-  
8       propriations Acts. Such fees are authorized to be ap-  
9       propriated to remain available until expended. Such  
10      sums as may be necessary may be transferred from  
11      the Food and Drug Administration salaries and ex-  
12      penses appropriation account without fiscal year lim-  
13      itation to such appropriation account for salary and  
14      expenses with such fiscal year limitation. The sums  
15      transferred shall be available solely for the process  
16      for the review of animal drug applications.

17              “(2) COLLECTIONS AND APPROPRIATION  
18      ACTS.—

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

21                      “(i) subject to subparagraph (C), shall  
22                      be collected and available in each fiscal  
23                      year in an amount not to exceed the  
24                      amount specified in appropriation Acts, or

1 otherwise made available for obligation for  
2 such fiscal year, and

3 “(ii) shall be available to defray in-  
4 creases in the costs of the resources allo-  
5 cated for the process for the review of ani-  
6 mal drug applications (including increases  
7 in such costs for an additional number of  
8 full-time equivalent positions in the De-  
9 partment of Health and Human Services  
10 to be engaged in such process) over such  
11 costs, excluding costs paid from fees col-  
12 lected under this section, for fiscal year  
13 2003 multiplied by the adjustment factor.

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

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

23 “(ii)(I) are more than 3 percent below  
24 the level specified in subparagraph (A)(ii),  
25 and fees assessed for the fiscal year fol-

lowing the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in subparagraph (A)(ii); and

“(II) such costs are not more than 5 percent below the level specified in subparagraph (A)(ii).

“(C) PROVISION FOR EARLY PAYMENTS.—

Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

“(3) AUTHORIZATION OF APPROPRIATIONS.—

For each of the fiscal years 2014 through 2018, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted or otherwise affected under subsection (c) and paragraph (4).

“(4) OFFSET OF OVERCOLLECTIONS; RECOVERY OF COLLECTION SHORTFALLS.—

“(A) OFFSET OF OVERCOLLECTIONS.—If the sum of the cumulative amount of fees collected under this section for fiscal years 2014

1 through 2016 and the amount of fees estimated  
2 to be collected under this section for fiscal year  
3 2017 (including any increased fee collections at-  
4 tributable to subparagraph (B)), exceeds the  
5 cumulative amount appropriated pursuant to  
6 paragraph (3) for the fiscal years 2014 through  
7 2017, the excess amount shall be credited to  
8 the appropriation account of the Food and  
9 Drug Administration as provided in paragraph  
10 (1), and shall be subtracted from the amount of  
11 fees that would otherwise be authorized to be  
12 collected under this section pursuant to appro-  
13 priation Acts for fiscal year 2018.

14 “(B) RECOVERY OF COLLECTION SHORT-  
15 FALLS.—

16 “(i) FISCAL YEAR 2016.—For fiscal  
17 year 2016, the amount of fees otherwise  
18 authorized to be collected under this sec-  
19 tion shall be increased by the amount, if  
20 any, by which the amount collected under  
21 this section and appropriated for fiscal  
22 year 2014 falls below the amount of fees  
23 authorized for fiscal year 2014 under para-  
24 graph (3).

1           “(ii) FISCAL YEAR 2017.—For fiscal  
2           year 2017, the amount of fees otherwise  
3           authorized to be collected under this sec-  
4           tion shall be increased by the amount, if  
5           any, by which the amount collected under  
6           this section and appropriated for fiscal  
7           year 2015 falls below the amount of fees  
8           authorized for fiscal year 2015 under para-  
9           graph (3).

10           “(iii) FISCAL YEAR 2018.—For fiscal  
11           year 2018, the amount of fees otherwise  
12           authorized to be collected under this sec-  
13           tion (including any reduction in the au-  
14           thorized amount under subparagraph (A)),  
15           shall be increased by the cumulative  
16           amount, if any, by which the amount col-  
17           lected under this section and appropriated  
18           for fiscal years 2016 and 2017 (including  
19           estimated collections for fiscal year 2017)  
20           falls below the cumulative amount of fees  
21           authorized under paragraph (3) for fiscal  
22           years 2016 and 2017.

23           “(h) COLLECTION OF UNPAID FEES.—In any case  
24           where the Secretary does not receive payment of a fee as-  
25           sessed under subsection (a) within 30 days after it is due,

1 such fee shall be treated as a claim of the United States  
2 Government subject to subchapter II of chapter 37 of title  
3 31, United States Code.

4 “(i) WRITTEN REQUESTS FOR WAIVERS, REDUC-  
5 TIONS, AND REFUNDS.—To qualify for consideration for  
6 a waiver or reduction under subsection (d), or for a refund  
7 of any fee collected in accordance with subsection (a), a  
8 person shall submit to the Secretary a written request for  
9 such waiver, reduction, or refund not later than 180 days  
10 after such fee is due.

11 “(j) CONSTRUCTION.—This section may not be con-  
12 strued to require that the number of full-time equivalent  
13 positions in the Department of Health and Human Serv-  
14 ices, for officers, employees, and advisory committees not  
15 engaged in the process of the review of animal drug appli-  
16 cations, be reduced to offset the number of officers, em-  
17 ployees, and advisory committees so engaged.

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

20 “(1) to the extent practicable, segregate the re-  
21 view of abbreviated new animal drug applications  
22 from the process for the review of animal drug appli-  
23 cations; and

24 “(2) adopt other administrative procedures to  
25 ensure that review times of abbreviated new animal

1 drug applications do not increase from their current  
2 level due to activities under the user fee program.”.

3 **SEC. 104. REAUTHORIZATION; REPORTING REQUIREMENTS.**

4 Section 740A of the Federal Food, Drug, and Cos-  
5 metic Act (21 U.S.C. 379j–13) is amended to read as fol-  
6 lows:

7 **“SEC. 740A. REAUTHORIZATION; REPORTING REQUIRE-**  
8 **MENTS.**

9 “(a) PERFORMANCE REPORT.—Beginning with fiscal  
10 year 2014, not later than 120 days after the end of each  
11 fiscal year during which fees are collected under this part,  
12 the Secretary shall prepare and submit to the Committee  
13 on Health, Education, Labor, and Pensions of the Senate  
14 and the Committee on Energy and Commerce of the  
15 House of Representatives a report concerning the progress  
16 of the Food and Drug Administration in achieving the  
17 goals identified in the letters described in section 101(b)  
18 of the Animal Drug User Fee Amendments of 2013 to-  
19 ward expediting the animal drug development process and  
20 the review of the new and supplemental animal drug appli-  
21 cations and investigational animal drug submissions dur-  
22 ing such fiscal year, the future plans of the Food and  
23 Drug Administration for meeting the goals, the review  
24 times for abbreviated new animal drug applications, and  
25 the administrative procedures adopted by the Food and

1 Drug Administration to ensure that review times for ab-  
2 breviated new animal drug applications are not increased  
3 from their current level due to activities under the user  
4 fee program.

5 “(b) FISCAL REPORT.—Beginning with fiscal year  
6 2014, not later than 120 days after the end of each fiscal  
7 year during which fees are collected under this part, the  
8 Secretary shall prepare and submit to the Committee on  
9 Health, Education, Labor, and Pensions of the Senate and  
10 the Committee on Energy and Commerce of the House  
11 of Representatives a report on the implementation of the  
12 authority for such fees during such fiscal year and the  
13 use, by the Food and Drug Administration, of the fees  
14 collected during such fiscal year for which the report is  
15 made.

16 “(c) PUBLIC AVAILABILITY.—The Secretary shall  
17 make the reports required under subsections (a) and (b)  
18 available to the public on the Internet Web site of the  
19 Food and Drug Administration.

20 “(d) REAUTHORIZATION.—

21 “(1) CONSULTATION.—In developing rec-  
22 ommendations to present to the Congress with re-  
23 spect to the goals, and plans for meeting the goals,  
24 for the process for the review of animal drug appli-  
25 cations for the first 5 fiscal years after fiscal year



1       2018, and for the reauthorization of this part for  
2       such fiscal years, the Secretary shall consult with—

3               “(A) the Committee on Health, Education,  
4       Labor, and Pensions of the Senate;

5               “(B) the Committee on Energy and Com-  
6       merce of the House of Representatives;

7               “(C) scientific and academic experts;

8               “(D) veterinary professionals;

9               “(E) representatives of patient and con-  
10      sumer advocacy groups; and

11              “(F) the regulated industry.

12              “(2) PRIOR PUBLIC INPUT.—Prior to beginning  
13      negotiations with the regulated industry on the reau-  
14      thorization of this part, the Secretary shall—

15              “(A) publish a notice in the Federal Reg-  
16      ister requesting public input on the reauthoriza-  
17      tion;

18              “(B) hold a public meeting at which the  
19      public may present its views on the reauthoriza-  
20      tion, including specific suggestions for changes  
21      to the goals referred to in subsection (a);

22              “(C) provide a period of 30 days after the  
23      public meeting to obtain written comments from  
24      the public suggesting changes to this part; and

1           “(D) publish the comments on the Food  
2           and Drug Administration’s Internet Web site.

3           “(3) PERIODIC CONSULTATION.—Not less fre-  
4           quently than once every 4 months during negotia-  
5           tions with the regulated industry, the Secretary shall  
6           hold discussions with representatives of veterinary,  
7           patient, and consumer advocacy groups to continue  
8           discussions of their views on the reauthorization and  
9           their suggestions for changes to this part as ex-  
10          pressed under paragraph (2).

11          “(4) PUBLIC REVIEW OF RECOMMENDA-  
12          TIONS.—After negotiations with the regulated indus-  
13          try, the Secretary shall—

14               “(A) present the recommendations devel-  
15               oped under paragraph (1) to the Congressional  
16               committees specified in such paragraph;

17               “(B) publish such recommendations in the  
18               Federal Register;

19               “(C) provide for a period of 30 days for  
20               the public to provide written comments on such  
21               recommendations;

22               “(D) hold a meeting at which the public  
23               may present its views on such recommenda-  
24               tions; and

1           “(E) after consideration of such public  
2 views and comments, revise such recommenda-  
3 tions as necessary.

4           “(5) TRANSMITTAL OF RECOMMENDATIONS.—  
5 Not later than January 15, 2018, the Secretary  
6 shall transmit to Congress the revised recommenda-  
7 tions under paragraph (4) a summary of the views  
8 and comments received under such paragraph, and  
9 any changes made to the recommendations in re-  
10 sponse to such views and comments.

11           “(6) MINUTES OF NEGOTIATION MEETINGS.—

12           “(A) PUBLIC AVAILABILITY.—Before pre-  
13 senting the recommendations developed under  
14 paragraphs (1) through (5) to Congress, the  
15 Secretary shall make publicly available, on the  
16 Internet Web site of the Food and Drug Ad-  
17 ministration, minutes of all negotiation meet-  
18 ings conducted under this subsection between  
19 the Food and Drug Administration and the reg-  
20 ulated industry.

21           “(B) CONTENT.—The minutes described  
22 under subparagraph (A) shall summarize any  
23 substantive proposal made by any party to the  
24 negotiations as well as significant controversies

1           or differences of opinion during the negotiations  
2           and their resolution.”.

3 **SEC. 105. SAVINGS CLAUSE.**

4           Notwithstanding the amendments made by this title,  
5 part 4 of subchapter C of chapter VII of the Federal Food,  
6 Drug, and Cosmetic Act (21 U.S.C. 379j–11 et seq.), as  
7 in effect on the day before the date of the enactment of  
8 this title, shall continue to be in effect with respect to ani-  
9 mal drug applications and supplemental animal drug ap-  
10 plications (as defined in such part as of such day) that  
11 on or after October 1, 2008, but before October 1, 2013,  
12 were accepted by the Food and Drug Administration for  
13 filing with respect to assessing and collecting any fee re-  
14 quired by such part for a fiscal year prior to fiscal year  
15 2014.

16 **SEC. 106. EFFECTIVE DATE.**

17           The amendments made by this title shall take effect  
18 on October 1, 2013, or the date of enactment of this Act,  
19 whichever is later, except that fees under part 4 of sub-  
20 chapter C of chapter VII of the Federal Food, Drug, and  
21 Cosmetic Act, as amended by this title, shall be assessed  
22 for all animal drug applications and supplemental animal  
23 drug applications received on or after October 1, 2013,  
24 regardless of the date of the enactment of this Act.

1 **SEC. 107. SUNSET DATES.**

2 (a) AUTHORIZATION.—Section 740 of the Federal  
3 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–12) shall  
4 cease to be effective October 1, 2018.

5 (b) REPORTING REQUIREMENTS.—Section 740A of  
6 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
7 379j–13) shall cease to be effective January 31, 2019.

8 (c) PREVIOUS SUNSET PROVISION.—

9 (1) IN GENERAL.—Section 108 of the Animal  
10 Drug User Fee Amendments of 2008 (Public Law  
11 110–316) is repealed.

12 (2) CONFORMING AMENDMENT.—The Animal  
13 Drug User Fee Amendments of 2008 (Public Law  
14 110–316) is amended in the table of contents in sec-  
15 tion 1, by striking the item relating to section 108.

16 (d) TECHNICAL CLARIFICATION.—Effective Novem-  
17 ber 18, 2003, section 5 of the Animal Drug User Fee Act  
18 of 2003 (Public Law 108–130) is repealed.

19 **TITLE II—FEES RELATING TO**  
20 **GENERIC ANIMAL DRUGS**

21 **SEC. 201. SHORT TITLE; FINDING.**

22 (a) SHORT TITLE.—This title may be cited as the  
23 “Animal Generic Drug User Fee Amendments of 2013”.

24 (b) FINDING.—The fees authorized by this title will  
25 be dedicated toward expediting the generic new animal  
26 drug development process and the review of abbreviated

1 applications for generic new animal drugs, supplemental  
 2 abbreviated applications for generic new animal drugs,  
 3 and investigational submissions for generic new animal  
 4 drugs as set forth in the goals identified in the letters from  
 5 the Secretary of Health and Human Services to the Chair-  
 6 man of the Committee on Energy and Commerce of the  
 7 House of Representatives and the Chairman of the Com-  
 8 mittee on Health, Education, Labor, and Pensions of the  
 9 Senate as set forth in the Congressional Record.

10 **SEC. 202. AUTHORITY TO ASSESS AND USE GENERIC NEW**  
 11 **ANIMAL DRUG FEES.**

12 Section 741 of the Federal Food, Drug, and Cosmetic  
 13 Act (21 U.S.C. 379j–21) is amended to read as follows:

14 **“SEC. 741. AUTHORITY TO ASSESS AND USE GENERIC NEW**  
 15 **ANIMAL DRUG FEES.**

16 “(a) TYPES OF FEES.—Beginning with respect to fis-  
 17 cal year 2009, the Secretary shall assess and collect fees  
 18 in accordance with this section as follows:

19 “(1) ABBREVIATED APPLICATION FEE.—

20 “(A) IN GENERAL.—Each person that sub-  
 21 mits, on or after July 1, 2008, an abbreviated  
 22 application for a generic new animal drug shall  
 23 be subject to a fee as established in subsection  
 24 (c) for such an application.

1           “(B) PAYMENT.—The fee required by sub-  
2 paragraph (A) shall be due upon submission of  
3 the abbreviated application.

4           “(C) EXCEPTIONS.—

5           “(i) PREVIOUSLY FILED APPLICA-  
6 TION.—If an abbreviated application was  
7 submitted by a person that paid the fee for  
8 such application, was accepted for filing,  
9 and was not approved or was withdrawn  
10 (without a waiver or refund), the submis-  
11 sion of an abbreviated application for the  
12 same product by the same person (or the  
13 person’s licensee, assignee, or successor)  
14 shall not be subject to a fee under sub-  
15 paragraph (A).

16           “(ii) CERTAIN ABBREVIATED APPLICA-  
17 TIONS INVOLVING COMBINATION ANIMAL  
18 DRUGS.—An abbreviated application which  
19 is subject to the criteria in section  
20 512(d)(4) and submitted on or after Octo-  
21 ber 1, 2013 shall be subject to a fee equal  
22 to 50 percent of the amount of the abbrevi-  
23 ated application fee established in sub-  
24 section (c).

1           “(D) REFUND OF FEE IF APPLICATION RE-  
 2           FUSED FOR FILING.—The Secretary shall re-  
 3           fund 75 percent of the fee paid under subpara-  
 4           graph (B) for any abbreviated application which  
 5           is refused for filing.

6           “(E) REFUND OF FEE IF APPLICATION  
 7           WITHDRAWN.—If an abbreviated application is  
 8           withdrawn after the application was filed, the  
 9           Secretary may refund the fee or portion of the  
 10          fee paid under subparagraph (B) if no substan-  
 11          tial work was performed on the application  
 12          after the application was filed. The Secretary  
 13          shall have the sole discretion to refund the fee  
 14          under this subparagraph. A determination by  
 15          the Secretary concerning a refund under this  
 16          subparagraph shall not be reviewable.

17          “(2) GENERIC NEW ANIMAL DRUG PRODUCT  
 18          FEE.—

19               “(A) IN GENERAL.—Each person—

20                   “(i) who is named as the applicant in  
 21                   an abbreviated application or supplemental  
 22                   abbreviated application for a generic new  
 23                   animal drug product which has been sub-  
 24                   mitted for listing under section 510; and



1                   “(ii) who, after September 1, 2008,  
2                   had pending before the Secretary an abbrevi-  
3                   ated application or supplemental abbrevi-  
4                   ated application,  
5                   shall pay for each such generic new animal  
6                   drug product the annual fee established in sub-  
7                   section (c).

8                   “(B) PAYMENT; FEE DUE DATE.—Such fee  
9                   shall be payable for the fiscal year in which the  
10                  generic new animal drug product is first sub-  
11                  mitted for listing under section 510, or is sub-  
12                  mitted for relisting under section 510 if the ge-  
13                  neric new animal drug product has been with-  
14                  drawn from listing and relisted. After such fee  
15                  is paid for that fiscal year, such fee shall be due  
16                  each subsequent fiscal year that the product re-  
17                  mains listed, upon the later of—

18                  “(i) the first business day after the  
19                  date of enactment of an appropriations Act  
20                  providing for the collection and obligation  
21                  of fees for such fiscal year under this sec-  
22                  tion; or

23                  “(ii) January 31 of each year.

24                  “(C) LIMITATION.—Such fee shall be paid  
25                  only once for each generic new animal drug

1 product for a fiscal year in which the fee is pay-  
2 able.

3 “(3) GENERIC NEW ANIMAL DRUG SPONSOR  
4 FEE.—

5 “(A) IN GENERAL.—Each person—

6 “(i) who meets the definition of a ge-  
7 neric new animal drug sponsor within a  
8 fiscal year; and

9 “(ii) who, after September 1, 2008,  
10 had pending before the Secretary an abbrevi-  
11 ated application, a supplemental abbrevi-  
12 ated application, or an investigational  
13 submission,

14 shall be assessed an annual generic new animal  
15 drug sponsor fee as established under sub-  
16 section (c).

17 “(B) PAYMENT; FEE DUE DATE.—Such fee  
18 shall be due each fiscal year upon the later of—

19 “(i) the first business day after the  
20 date of enactment of an appropriations Act  
21 providing for the collection and obligation  
22 of fees for such fiscal year under this sec-  
23 tion; or

24 “(ii) January 31 of each year.

1           “(C) AMOUNT OF FEE.—Each generic new  
2           animal drug sponsor shall pay only 1 such fee  
3           each fiscal year, as follows:

4                   “(i) 100 percent of the amount of the  
5                   generic new animal drug sponsor fee pub-  
6                   lished for that fiscal year under subsection  
7                   (c) for an applicant with more than 6 ap-  
8                   proved abbreviated applications.

9                   “(ii) 75 percent of the amount of the  
10                  generic new animal drug sponsor fee pub-  
11                  lished for that fiscal year under subsection  
12                  (c) for an applicant with more than 1 and  
13                  fewer than 7 approved abbreviated applica-  
14                  tions.

15                  “(iii) 50 percent of the amount of the  
16                  generic new animal drug sponsor fee pub-  
17                  lished for that fiscal year under subsection  
18                  (c) for an applicant with 1 or fewer ap-  
19                  proved abbreviated applications.

20           “(b) FEE AMOUNTS.—Subject to subsections (c), (d),  
21           (f), and (g), the fees required under subsection (a) shall  
22           be established to generate fee revenue amounts as follows:

23                   “(1) TOTAL FEE REVENUES FOR APPLICATION  
24                   FEES.—The total fee revenues to be collected in ab-  
25                   breviated application fees under subsection (a)(1)

1 shall be \$1,832,000 for fiscal year 2014, \$1,736,000  
2 for fiscal year 2015, \$1,857,000 for fiscal year  
3 2016, \$1,984,000 for fiscal year 2017, and  
4 \$2,117,000 for fiscal year 2018.

5 “(2) TOTAL FEE REVENUES FOR PRODUCT  
6 FEES.—The total fee revenues to be collected in ge-  
7 neric new animal drug product fees under subsection  
8 (a)(2) shall be \$2,748,000 for fiscal year 2014,  
9 \$2,604,000 for fiscal year 2015, \$2,786,000 for fis-  
10 cal year 2016, \$2,976,000 for fiscal year 2017, and  
11 \$3,175,000 for fiscal year 2018.

12 “(3) TOTAL FEE REVENUES FOR SPONSOR  
13 FEES.—The total fee revenues to be collected in ge-  
14 neric new animal drug sponsor fees under subsection  
15 (a)(3) shall be \$2,748,000 for fiscal year 2014,  
16 \$2,604,000 for fiscal year 2015, \$2,786,000 for fis-  
17 cal year 2016, \$2,976,000 for fiscal year 2017, and  
18 \$3,175,000 for fiscal year 2018.

19 “(c) ANNUAL FEE SETTING; ADJUSTMENTS.—

20 “(1) ANNUAL FEE SETTING.—The Secretary  
21 shall establish, 60 days before the start of each fis-  
22 cal year beginning after September 30, 2008, for  
23 that fiscal year, abbreviated application fees, generic  
24 new animal drug sponsor fees, and generic new ani-  
25 mal drug product fees, based on the revenue

1 amounts established under subsection (b) and the  
2 adjustments provided under this subsection.

3 “(2) WORKLOAD ADJUSTMENT.—The fee reve-  
4 nues shall be adjusted each fiscal year after fiscal  
5 year 2014 to reflect changes in review workload.

6 With respect 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 abbrevi-  
10 ated applications for generic new animal  
11 drugs, manufacturing supplemental abbreviated  
12 applications for generic new animal drugs, in-  
13 vestigational generic new animal drug study  
14 submissions, and investigational generic new  
15 animal drug protocol submissions submitted to  
16 the Secretary. The Secretary shall publish in  
17 the Federal Register the fees resulting from  
18 this adjustment and the supporting methodolo-  
19 gies.

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).

1           “(3) FINAL YEAR ADJUSTMENT.—For fiscal  
2       year 2018, the Secretary may, in addition to other  
3       adjustments under this subsection, further increase  
4       the fees under this section, if such an adjustment is  
5       necessary, to provide for up to 3 months of oper-  
6       ating reserves of carryover user fees for the process  
7       for the review of abbreviated applications for generic  
8       new animal drugs for the first 3 months of fiscal  
9       year 2019. If the Food and Drug Administration  
10      has carryover balances for the process for the review  
11      of abbreviated applications for generic new animal  
12      drugs in excess of 3 months of such operating re-  
13      serves, then this adjustment shall not be made. If  
14      this adjustment is necessary, then the rationale for  
15      the amount of the increase shall be contained in the  
16      annual notice setting fees for fiscal year 2018.

17           “(4) LIMIT.—The total amount of fees charged,  
18      as adjusted under this subsection, for a fiscal year  
19      may not exceed the total costs for such fiscal year  
20      for the resources allocated for the process for the re-  
21      view of abbreviated applications for generic new ani-  
22      mal drugs.

23           “(d) FEE WAIVER OR REDUCTION.—The Secretary  
24      shall grant a waiver from or a reduction of 1 or more fees  
25      assessed under subsection (a) where the Secretary finds

1 that the generic new animal drug is intended solely to pro-  
2 vide for a minor use or minor species indication.

3 “(e) EFFECT OF FAILURE TO PAY FEES.—An abbreve-  
4 viated application for a generic new animal drug sub-  
5 mitted by a person subject to fees under subsection (a)  
6 shall be considered incomplete and shall not be accepted  
7 for filing by the Secretary until all fees owed by such per-  
8 son have been paid. An investigational submission for a  
9 generic new animal drug that is submitted by a person  
10 subject to fees under subsection (a) shall be considered  
11 incomplete and shall not be accepted for review by the Sec-  
12 retary until all fees owed by such person have been paid.  
13 The Secretary may discontinue review of any abbreviated  
14 application for a generic new animal drug, supplemental  
15 abbreviated application for a generic new animal drug, or  
16 investigational submission for a generic new animal drug  
17 from a person if such person has not submitted for pay-  
18 ment all fees owed under this section by 30 days after  
19 the date upon which they are due.

20 “(f) ASSESSMENT OF FEES.—

21 “(1) LIMITATION.—Fees may not be assessed  
22 under subsection (a) for a fiscal year beginning after  
23 fiscal year 2008 unless appropriations for salaries  
24 and expenses of the Food and Drug Administration  
25 for such fiscal year (excluding the amount of fees

1       appropriated for such fiscal year) are equal to or  
2       greater than the amount of appropriations for the  
3       salaries and expenses of the Food and Drug Admin-  
4       istration for the fiscal year 2003 (excluding the  
5       amount of fees appropriated for such fiscal year)  
6       multiplied by the adjustment factor applicable to the  
7       fiscal year involved.

8               “(2) AUTHORITY.—If the Secretary does not  
9       assess fees under subsection (a) during any portion  
10      of a fiscal year because of paragraph (1) and if at  
11      a later date in such fiscal year the Secretary may as-  
12      sess such fees, the Secretary may assess and collect  
13      such fees, without any modification in the rate, for  
14      abbreviated applications, generic new animal drug  
15      sponsors, and generic new animal drug products at  
16      any time in such fiscal year notwithstanding the pro-  
17      visions of subsection (a) relating to the date fees are  
18      to be paid.

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

20               “(1) IN GENERAL.—Subject to paragraph  
21      (2)(C), fees authorized under subsection (a) shall be  
22      collected and available for obligation only to the ex-  
23      tent and in the amount provided in advance in ap-  
24      propriations Acts. Such fees are authorized to be ap-  
25      propriated to remain available until expended. Such



1 sums as may be necessary may be transferred from  
 2 the Food and Drug Administration salaries and ex-  
 3 penses appropriation account without fiscal year lim-  
 4 itation to such appropriation account for salary and  
 5 expenses with such fiscal year limitation. The sums  
 6 transferred shall be available solely for the process  
 7 for the review of abbreviated applications for generic  
 8 new animal drugs.

9 “(2) COLLECTIONS AND APPROPRIATION  
 10 ACTS.—

11 “(A) IN GENERAL.—The fees authorized  
 12 by this section—

13 “(i) subject to subparagraph (C), shall  
 14 be collected and available in each fiscal  
 15 year in an amount not to exceed the  
 16 amount specified in appropriation Acts, or  
 17 otherwise made available for obligation for  
 18 such fiscal year; and

19 “(ii) shall be available to defray in-  
 20 creases in the costs of the resources allo-  
 21 cated for the process for the review of ab-  
 22 breviated applications for generic new ani-  
 23 mal drugs (including increases in such  
 24 costs for an additional number of full-time  
 25 equivalent positions in the Department of

1 Health and Human Services to be engaged  
 2 in such process) over such costs, excluding  
 3 costs paid from fees collected under this  
 4 section, for fiscal year 2008 multiplied by  
 5 the adjustment factor.

6 “(B) COMPLIANCE.—The Secretary shall  
 7 be considered to have met the requirements of  
 8 subparagraph (A)(ii) in any fiscal year if the  
 9 costs funded by appropriations and allocated for  
 10 the process for the review of abbreviated appli-  
 11 cations for generic new animal drugs—

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

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

22 “(II) such costs are not more than 5  
 23 percent below the level specified in sub-  
 24 paragraph (A)(ii).

1           “(C) PROVISION FOR EARLY PAYMENTS.—

2           Payment of fees authorized under this section  
3           for a fiscal year, prior to the due date for such  
4           fees, may be accepted by the Secretary in ac-  
5           cordance with authority provided in advance in  
6           a prior year appropriations Act.

7           “(3) AUTHORIZATION OF APPROPRIATIONS.—

8           There are authorized to be appropriated for fees  
9           under this section—

10                 “(A) \$7,328,000 for fiscal year 2014;

11                 “(B) \$6,944,000 for fiscal year 2015;

12                 “(C) \$7,429,000 for fiscal year 2016;

13                 “(D) \$7,936,000 for fiscal year 2017; and

14                 “(E) \$8,467,000 for fiscal year 2018;

15           as adjusted to reflect adjustments in the total fee  
16           revenues made under this section and changes in the  
17           total amounts collected by abbreviated application  
18           fees, generic new animal drug sponsor fees, and ge-  
19           neric new animal drug product fees.

20           “(4) OFFSET.—If the sum of the cumulative  
21           amount of fees collected under this section for the  
22           fiscal years 2014 through 2016 and the amount of  
23           fees estimated to be collected under this section for  
24           fiscal year 2017 exceeds the cumulative amount ap-  
25           propriated under paragraph (3) for the fiscal years

1       2014 through 2017, the excess amount shall be  
2       credited to the appropriation account of the Food  
3       and Drug Administration as provided in paragraph  
4       (1), and shall be subtracted from the amount of fees  
5       that would otherwise be authorized to be collected  
6       under this section pursuant to appropriation Acts  
7       for fiscal year 2018.

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 abbreviated appli-

1 cations for generic new animal drugs, be reduced to offset  
 2 the number of officers, employees, and advisory commit-  
 3 tees so engaged.

4 “(k) DEFINITIONS.—In this section and section 742:

5 “(1) ABBREVIATED APPLICATION FOR A GE-  
 6 NERIC NEW ANIMAL DRUG.—The terms ‘abbreviated  
 7 application for a generic new animal drug’ and ‘ab-  
 8 breviated application’ mean an abbreviated applica-  
 9 tion for the approval of any generic new animal drug  
 10 submitted under section 512(b)(2). Such term does  
 11 not include a supplemental abbreviated application  
 12 for a generic new animal drug.

13 “(2) ADJUSTMENT FACTOR.—The term ‘adjust-  
 14 ment factor’ applicable to a fiscal year is the Con-  
 15 sumer Price Index for all urban consumers (all  
 16 items; United States city average) for October of the  
 17 preceding fiscal year divided by—

18 “(A) for purposes of subsection (f)(1),  
 19 such Index for October 2002; and

20 “(B) for purposes of subsection  
 21 (g)(2)(A)(ii), such Index for October 2007.

22 “(3) COSTS OF RESOURCES ALLOCATED FOR  
 23 THE PROCESS FOR THE REVIEW OF ABBREVIATED  
 24 APPLICATIONS FOR GENERIC NEW ANIMAL DRUGS.—

25 The term ‘costs of resources allocated for the proc-

1       ess for the review of abbreviated applications for ge-  
2       neric new animal drugs’ means the expenses in con-  
3       nection with the process for the review of abbrev-  
4       viated applications for generic new animal drugs  
5       for—

6               “(A) officers and employees of the Food  
7       and Drug Administration, contractors of the  
8       Food and Drug Administration, advisory com-  
9       mittees consulted with respect to the review of  
10      specific abbreviated applications, supplemental  
11      abbreviated applications, or investigational sub-  
12      missions, and costs related to such officers, em-  
13      ployees, committees, and contractors, including  
14      costs for travel, education, and recruitment and  
15      other personnel activities;

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

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

24              “(D) collecting fees under this section and  
25      accounting for resources allocated for the re-

1 view of abbreviated applications, supplemental  
2 abbreviated applications, and investigational  
3 submissions.

4 “(4) FINAL DOSAGE FORM.—The term ‘final  
5 dosage form’ means, with respect to a generic new  
6 animal drug product, a finished dosage form which  
7 is approved for administration to an animal without  
8 substantial further manufacturing. Such term in-  
9 cludes generic new animal drug products intended  
10 for mixing in animal feeds.

11 “(5) GENERIC NEW ANIMAL DRUG.—The term  
12 ‘generic new animal drug’ means a new animal drug  
13 that is the subject of an abbreviated application.

14 “(6) GENERIC NEW ANIMAL DRUG PRODUCT.—  
15 The term ‘generic new animal drug product’ means  
16 each specific strength or potency of a particular ac-  
17 tive ingredient or ingredients in final dosage form  
18 marketed by a particular manufacturer or dis-  
19 tributor, which is uniquely identified by the labeler  
20 code and product code portions of the national drug  
21 code, and for which an abbreviated application for a  
22 generic new animal drug or a supplemental abbrevi-  
23 ated application has been approved.

24 “(7) GENERIC NEW ANIMAL DRUG SPONSOR.—  
25 The term ‘generic new animal drug sponsor’ means

1       either an applicant named in an abbreviated applica-  
2       tion for a generic new animal drug that has not been  
3       withdrawn by the applicant and for which approval  
4       has not been withdrawn by the Secretary, or a per-  
5       son who has submitted an investigational submission  
6       for a generic new animal drug that has not been ter-  
7       minated or otherwise rendered inactive by the Sec-  
8       retary.

9               “(8) INVESTIGATIONAL SUBMISSION FOR A GE-  
10       NERIC NEW ANIMAL DRUG.—The terms ‘investiga-  
11       tional submission for a generic new animal drug’  
12       and ‘investigational submission’ mean—

13               “(A) the filing of a claim for an investiga-  
14       tional exemption under section 512(j) for a ge-  
15       neric new animal drug intended to be the sub-  
16       ject of an abbreviated application or a supple-  
17       mental abbreviated application; or

18               “(B) the submission of information for the  
19       purpose of enabling the Secretary to evaluate  
20       the safety or effectiveness of a generic new ani-  
21       mal drug in the event of the filing of an abbrevi-  
22       ated application or supplemental abbreviated  
23       application for such drug.



1           “(9) PERSON.—The term ‘person’ includes an  
2       affiliate thereof (as such term is defined in section  
3       735(11)).

4           “(10) PROCESS FOR THE REVIEW OF ABBRE-  
5       VIATED APPLICATIONS FOR GENERIC NEW ANIMAL  
6       DRUGS.—The term ‘process for the review of abbrevi-  
7       ated applications for generic new animal drugs’  
8       means the following activities of the Secretary with  
9       respect to the review of abbreviated applications,  
10      supplemental abbreviated applications, and inves-  
11      tigational submissions:

12           “(A) The activities necessary for the re-  
13      view of abbreviated applications, supplemental  
14      abbreviated applications, and investigational  
15      submissions.

16           “(B) The issuance of action letters which  
17      approve abbreviated applications or supple-  
18      mental abbreviated applications or which set  
19      forth in detail the specific deficiencies in abbrevi-  
20      ated applications, supplemental abbreviated  
21      applications, or investigational submissions and,  
22      where appropriate, the actions necessary to  
23      place such applications, supplemental applica-  
24      tions, or submissions in condition for approval.

1           “(C) The inspection of generic new animal  
2           drug establishments and other facilities under-  
3           taken as part of the Secretary’s review of pend-  
4           ing abbreviated applications, supplemental ab-  
5           breviated applications, and investigational sub-  
6           missions.

7           “(D) Monitoring of research conducted in  
8           connection with the review of abbreviated appli-  
9           cations, supplemental abbreviated applications,  
10          and investigational submissions.

11          “(E) The development of regulations and  
12          policy related to the review of abbreviated appli-  
13          cations, supplemental abbreviated applications,  
14          and investigational submissions.

15          “(F) Development of standards for prod-  
16          ucts subject to review.

17          “(G) Meetings between the agency and the  
18          generic new animal drug sponsor.

19          “(H) Review of advertising and labeling  
20          prior to approval of an abbreviated application  
21          or supplemental abbreviated application, but  
22          not after such application has been approved.

23          “(11) SUPPLEMENTAL ABBREVIATED APPLICA-  
24          TION FOR GENERIC NEW ANIMAL DRUG.—The terms  
25          ‘supplemental abbreviated application for a generic

1 new animal drug’ and ‘supplemental abbreviated ap-  
 2 plication’ mean a request to the Secretary to ap-  
 3 prove a change in an approved abbreviated applica-  
 4 tion.”.

5 **SEC. 203. REAUTHORIZATION; REPORTING REQUIREMENTS.**

6 Section 742 of the Federal Food, Drug, and Cosmetic  
 7 Act (21 U.S.C. 379j–22) is amended to read as follows:

8 **“SEC. 742. REAUTHORIZATION; REPORTING REQUIRE-**  
 9 **MENTS.**

10 “(a) PERFORMANCE REPORTS.—Beginning with fis-  
 11 cal year 2014, not later than 120 days after the end of  
 12 each fiscal year during which fees are collected under this  
 13 part, the Secretary shall prepare and submit to the Com-  
 14 mittee on Health, Education, Labor, and Pensions of the  
 15 Senate, and the Committee on Energy and Commerce of  
 16 the House of Representatives a report concerning the  
 17 progress of the Food and Drug Administration in achiev-  
 18 ing the goals identified in the letters described in section  
 19 201(b) of the Animal Generic Drug User Fee Amend-  
 20 ments of 2013 toward expediting the generic new animal  
 21 drug development process and the review of abbreviated  
 22 applications for generic new animal drugs, supplemental  
 23 abbreviated applications for generic new animal drugs,  
 24 and investigational submissions for generic new animal  
 25 drugs during such fiscal year.

1       “(b) FISCAL REPORT.—Beginning with fiscal year  
2 2014, not later than 120 days after the end of each fiscal  
3 year during which fees are collected under this part, the  
4 Secretary shall prepare and submit to Committee on  
5 Health, Education, Labor, and Pensions of the Senate and  
6 the Committee on Energy and Commerce of the House  
7 of Representatives a report on the implementation of the  
8 authority for such fees during such fiscal year and the  
9 use, by the Food and Drug Administration, of the fees  
10 collected during such fiscal year for which the report is  
11 made.

12       “(c) PUBLIC AVAILABILITY.—The Secretary shall  
13 make the reports required under subsections (a) and (b)  
14 available to the public on the Internet Web site of the  
15 Food and Drug Administration.

16       “(d) REAUTHORIZATION.—

17               “(1) CONSULTATION.—In developing rec-  
18 ommendations to present to Congress with respect to  
19 the goals, and plans for meeting the goals, for the  
20 process for the review of abbreviated applications for  
21 generic new animal drugs for the first 5 fiscal years  
22 after fiscal year 2018, and for the reauthorization of  
23 this part for such fiscal years, the Secretary shall  
24 consult with—

1           “(A) the Committee on Energy and Com-  
2 merce of the House of Representatives;

3           “(B) the Committee on Health, Education,  
4 Labor, and Pensions of the Senate;

5           “(C) scientific and academic experts;

6           “(D) veterinary professionals;

7           “(E) representatives of patient and con-  
8 sumer advocacy groups; and

9           “(F) the regulated industry.

10          “(2) PRIOR PUBLIC INPUT.—Prior to beginning  
11 negotiations with the regulated industry on the reau-  
12 thorization of this part, the Secretary shall—

13           “(A) publish a notice in the Federal Reg-  
14 ister requesting public input on the reauthoriza-  
15 tion;

16           “(B) hold a public meeting at which the  
17 public may present its views on the reauthoriza-  
18 tion, including specific suggestions for changes  
19 to the goals referred to in subsection (a);

20           “(C) provide a period of 30 days after the  
21 public meeting to obtain written comments from  
22 the public suggesting changes to this part; and

23           “(D) publish the comments on the Food  
24 and Drug Administration’s Internet Web site.

1           “(3) PERIODIC CONSULTATION.—Not less fre-  
2           quently than once every 4 months during negotia-  
3           tions with the regulated industry, the Secretary shall  
4           hold discussions with representatives of veterinary,  
5           patient, and consumer advocacy groups to continue  
6           discussions of their views on the reauthorization and  
7           their suggestions for changes to this part as ex-  
8           pressed under paragraph (2).

9           “(4) PUBLIC REVIEW OF RECOMMENDA-  
10          TIONS.—After negotiations with the regulated indus-  
11          try, the Secretary shall—

12               “(A) present the recommendations devel-  
13               oped under paragraph (1) to the congressional  
14               committees specified in such paragraph;

15               “(B) publish such recommendations in the  
16               Federal Register;

17               “(C) provide for a period of 30 days for  
18               the public to provide written comments on such  
19               recommendations;

20               “(D) hold a meeting at which the public  
21               may present its views on such recommenda-  
22               tions; and

23               “(E) after consideration of such public  
24               views and comments, revise such recommenda-  
25               tions as necessary.

1           “(5) TRANSMITTAL OF RECOMMENDATIONS.—

2           Not later than January 15, 2018, the Secretary  
3           shall transmit to Congress the revised recommenda-  
4           tions under paragraph (4), a summary of the views  
5           and comments received under such paragraph, and  
6           any changes made to the recommendations in re-  
7           sponse to such views and comments.

8           “(6) MINUTES OF NEGOTIATION MEETINGS.—

9           “(A) PUBLIC AVAILABILITY.—Before pre-  
10          senting the recommendations developed under  
11          paragraphs (1) through (5) to Congress, the  
12          Secretary shall make publicly available, on the  
13          Internet Web site of the Food and Drug Ad-  
14          ministration, minutes of all negotiation meet-  
15          ings conducted under this subsection between  
16          the Food and Drug Administration and the reg-  
17          ulated industry.

18          “(B) CONTENT.—The minutes described  
19          under subparagraph (A) shall summarize any  
20          substantive proposal made by any party to the  
21          negotiations as well as significant controversies  
22          or differences of opinion during the negotiations  
23          and their resolution.”.

1 **SEC. 204. SAVINGS CLAUSE.**

2       Notwithstanding the amendments made by this title,  
3 part 5 of subchapter C of chapter VII of the Federal Food,  
4 Drug, and Cosmetic Act, as in effect on the day before  
5 the date of enactment of this title, shall continue to be  
6 in effect with respect to abbreviated applications for a ge-  
7 neric new animal drug and supplemental abbreviated ap-  
8 plications for a generic new animal drug (as defined in  
9 such part as of such day) that on or after October 1, 2008,  
10 but before October 1, 2013, were accepted by the Food  
11 and Drug Administration for filing with respect to assess-  
12 ing and collecting any fee required by such part for a fiscal  
13 year prior to fiscal year 2014.

14 **SEC. 205. EFFECTIVE DATE.**

15       The amendments made by this title shall take effect  
16 on October 1, 2013, or the date of enactment of this Act,  
17 whichever is later, except that fees under part 5 of sub-  
18 chapter C of chapter VII of the Federal Food, Drug, and  
19 Cosmetic Act, as amended by this title, shall be assessed  
20 for all abbreviated applications for a generic new animal  
21 drug and supplemental abbreviated applications for a ge-  
22 neric new animal drug received on or after October 1,  
23 2013, regardless of the date of enactment of this Act.



1   **SEC. 206. SUNSET DATES.**

2           (a) AUTHORIZATION.—Section 741 of the Federal  
3 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21) shall  
4 cease to be effective October 1, 2018.

5           (b) REPORTING REQUIREMENTS.—Section 742 of the  
6 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–  
7 22) shall cease to be effective January 31, 2019.

8           (c) PREVIOUS SUNSET PROVISION.—

9               (1) IN GENERAL.—Section 204 of the Animal  
10 Generic Drug User Fee Act of 2008 (Public Law  
11 110–316) is repealed.

12              (2) CONFORMING AMENDMENT.—The Animal  
13 Generic Drug User Fee Act of 2008 (Public Law  
14 110–316) is amended in the table of contents in sec-  
15 tion 1, by striking the item relating to section 204.

**Calendar No. 31**

113<sup>TH</sup> CONGRESS  
1<sup>ST</sup> Session  
**S. 622**

**A BILL**

To amend the Federal Food, Drug, and Cosmetic Act to reauthorize user fee programs relating to new animal drugs and generic new animal drugs.

MARCH 20, 2013

Read twice and placed on the calendar