

113TH CONGRESS  
1ST SESSION

# S. 622

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## AN ACT

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Animal Drug and Ani-  
3 mal Generic Drug User Fee Reauthorization Act of  
4 2013”.

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

6 (a) **TABLE OF CONTENTS.**—The table of contents of  
7 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.

8 (b) **REFERENCES IN ACT.**—Except as otherwise spec-  
9 ified, amendments made by this Act to a section or other  
10 provision of law are amendments to such section or other  
11 provision of the Federal Food, Drug, and Cosmetic Act  
12 (21 U.S.C. 301 et seq.).

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

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

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

6       (b) **FINDING.**—Congress finds that the fees author-  
7 ized by the amendments made in this title will be dedi-  
8 cated toward expediting the animal drug development  
9 process and the review of new and supplemental animal  
10 drug applications and investigational animal drug submis-  
11 sions as set forth in the goals identified, for purposes of  
12 part 4 of subchapter C of chapter VII of the Federal Food,  
13 Drug, and Cosmetic Act, in the letters from the Secretary  
14 of Health and Human Services to the Chairman of the  
15 Committee on Energy and Commerce of the House of  
16 Representatives and the Chairman of the Committee on  
17 Health, Education, Labor, and Pensions of the Senate as  
18 set forth in the Congressional Record.

19   **SEC. 102. DEFINITIONS.**

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

22   **“SEC. 739. DEFINITIONS.**

23       “For purposes of this part:

24               “(1) The term ‘animal drug application’ means  
25       an application for approval of any new animal drug

1 submitted under section 512(b)(1). Such term does  
2 not include either a new animal drug application  
3 submitted under section 512(b)(2) or a supplemental  
4 animal drug application.

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

7 “(A) a request to the Secretary to approve  
8 a change in an animal drug application which  
9 has been approved; or

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

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

23 “(4) The term ‘animal drug establishment’  
24 means a foreign or domestic place of business which  
25 is at one general physical location consisting of one

1 or more buildings all of which are within 5 miles of  
2 each other, at which one or more animal drug prod-  
3 ucts are manufactured in final dosage form.

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

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

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

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

24 “(7) The term ‘final dosage form’ means, with  
25 respect to an animal drug product, a finished dosage

1 form which is approved for administration to an ani-  
2 mal without substantial further manufacturing. Such  
3 term includes animal drug products intended for  
4 mixing in animal feeds.

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

10 “(A) The activities necessary for the re-  
11 view of animal drug applications, supplemental  
12 animal drug applications, and investigational  
13 animal drug submissions.

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

23 “(C) The inspection of animal drug estab-  
24 lishments and other facilities undertaken as  
25 part of the Secretary’s review of pending animal

1 drug applications, supplemental animal drug  
2 applications, and investigational animal drug  
3 submissions.

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

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

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

16 “(G) Meetings between the agency and the  
17 animal drug sponsor.

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

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

1 process for the review of animal drug applications  
2 for—

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

13 “(B) management of information and the  
14 acquisition, maintenance, and repair of com-  
15 puter resources;

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

21 “(D) collecting fees under section 740 and  
22 accounting for resources allocated for the re-  
23 view of animal drug applications, supplemental  
24 animal drug applications, and investigational  
25 animal drug submissions.

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

5           “(11) The term ‘person’ includes an affiliate  
6           thereof.

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

9   **SEC. 103. AUTHORITY TO ASSESS AND USE ANIMAL DRUG**

10                   **FEES.**

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

13   **“SEC. 740. AUTHORITY TO ASSESS AND USE ANIMAL DRUG**

14                   **FEES.**

15           “(a) TYPES OF FEES.—Beginning in fiscal year  
16 2004, the Secretary shall assess and collect fees in accord-  
17 ance with this section as follows:

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

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

24                                   “(i) A fee established in subsection (c)  
25                                   for an animal drug application, except an

1 animal drug application subject to the cri-  
2 teria set forth in section 512(d)(4).

3 “(ii) A fee established in subsection  
4 (c), in an amount that is equal to 50 per-  
5 cent of the amount of the fee under clause  
6 (i), for—

7 “(I) a supplemental animal drug  
8 application for which safety or effec-  
9 tiveness data are required; and

10 “(II) an animal drug application  
11 subject to the criteria set forth in sec-  
12 tion 512(d)(4).

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

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

1 same product by the same person (or the per-  
2 son's licensee, assignee, or successor) shall not  
3 be subject to a fee under subparagraph (A).

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

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

23 “(2) ANIMAL DRUG PRODUCT FEE.—

24 “(A) IN GENERAL.—Each person—

1           “(i) who is named as the applicant in  
2           an animal drug application or supple-  
3           mental animal drug application for an ani-  
4           mal drug product which has been sub-  
5           mitted for listing under section 510; and

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

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

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

22                 “(i) the first business day after the  
23                 date of enactment of an appropriations Act  
24                 providing for the collection and obligation

1 of fees for such fiscal year under this sec-  
2 tion; or

3 “(ii) January 31 of each year.

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

7 “(3) ANIMAL DRUG ESTABLISHMENT FEE.—

8 “(A) IN GENERAL.—Each person—

9 “(i) who owns or operates, directly or  
10 through an affiliate, an animal drug estab-  
11 lishment;

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

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

21 shall be assessed an annual establishment fee as  
22 established in subsection (c) for each animal  
23 drug establishment listed in its approved animal  
24 drug application as an establishment that man-

1 manufactures the animal drug product named in the  
2 application.

3 “(B) PAYMENT; FEE DUE DATE.—The an-  
4 nual establishment fee shall be assessed in each  
5 fiscal year in which the animal drug product  
6 named in the application is assessed a fee under  
7 paragraph (2) unless the animal drug establish-  
8 ment listed in the application does not engage  
9 in the manufacture of the animal drug product  
10 during the fiscal year. The fee under this para-  
11 graph for a fiscal year shall be due upon the  
12 later of—

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

18 “(ii) January 31 of each year.

19 “(C) LIMITATION.—

20 “(i) IN GENERAL.—An establishment  
21 shall be assessed only one fee per fiscal  
22 year under this section, subject to clause  
23 (ii).

24 “(ii) CERTAIN MANUFACTURERS.—If  
25 a single establishment manufactures both

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

8 “(4) ANIMAL DRUG SPONSOR FEE.—

9 “(A) IN GENERAL.—Each person—

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

13 “(ii) who, after September 1, 2003,  
14 had pending before the Secretary an ani-  
15 mal drug application, a supplemental ani-  
16 mal drug application, or an investigational  
17 animal drug submission,

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

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

23 “(i) the first business day after the  
24 date of enactment of an appropriations Act  
25 providing for the collection and obligation

1 of fees for such fiscal year under this sec-  
2 tion; or

3 “(ii) January 31 of each year.

4 “(C) LIMITATION.—Each animal drug  
5 sponsor shall pay only one such fee each fiscal  
6 year.

7 “(b) FEE REVENUE AMOUNTS.—

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

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

14 “(B) for each of fiscal years 2015 through  
15 2018, the fees required under subsection (a)  
16 shall be established to generate a total revenue  
17 amount of \$21,600,000.

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

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

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

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

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

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

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

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

1           “(A) one;

2           “(B) the average annual percent change in  
3 the cost, per full-time equivalent position of the  
4 Food and Drug Administration, of all personnel  
5 compensation and benefits paid with respect to  
6 such positions for the first 3 of the preceding  
7 4 fiscal years for which data are available, mul-  
8 tiplied by the average proportion of personnel  
9 compensation and benefits costs to total Food  
10 and Drug Administration costs for the first 3  
11 years of the preceding 4 fiscal years for which  
12 data are available; and

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

1 The adjustment made each fiscal year under this  
2 paragraph shall be added on a compounded basis to  
3 the sum of all adjustments made each fiscal year  
4 after fiscal year 2014 under this paragraph.

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

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

24 “(B) the Secretary shall publish in the  
25 Federal Register the fees resulting from such

1 adjustment and the supporting methodologies;  
2 and

3 “(C) under no circumstances shall such ad-  
4 justment result in fee revenues for a fiscal year  
5 that are less than the fee revenues for that fis-  
6 cal year established in subsection (b), as ad-  
7 justed for inflation under paragraph (2).

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

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) FREE WAIVER OR REDUCTION.—

4 “(1) IN GENERAL.—The Secretary shall grant a  
5 waiver from or a reduction of one 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, animal drug sponsors, animal drug establish-  
4 ments and animal drug products at any time in such  
5 fiscal year notwithstanding the provisions of sub-  
6 section (a) relating to the date fees are to be paid.

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

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

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

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

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

7           “(ii) shall be available to defray in-  
8           creases in the costs of the resources allo-  
9           cated for the process for the review of ani-  
10          mal drug applications (including increases  
11          in such costs for an additional number of  
12          full-time equivalent positions in the De-  
13          partment of Health and Human Services  
14          to be engaged in such process) over such  
15          costs, excluding costs paid from fees col-  
16          lected under this section, for fiscal year  
17          2003 multiplied by the adjustment 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           “(C) PROVISION FOR EARLY PAYMENTS.—  
15 Payment of fees authorized under this section  
16 for a fiscal year, prior to the due date for such  
17 fees, may be accepted by the Secretary in ac-  
18 cordance with authority provided in advance in  
19 a prior year appropriations Act.

20           “(3) AUTHORIZATION OF APPROPRIATIONS.—  
21 For each of the fiscal years 2014 through 2018,  
22 there is authorized to be appropriated for fees under  
23 this section an amount equal to the total revenue  
24 amount determined under subsection (b) for the fis-

1 cal year, as adjusted or otherwise affected under  
2 subsection (c) and paragraph (4).

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

5 “(A) OFFSET OF OVERCOLLECTIONS.—If  
6 the sum of the cumulative amount of fees col-  
7 lected under this section for fiscal years 2014  
8 through 2016 and the amount of fees estimated  
9 to be collected under this section for fiscal year  
10 2017 (including any increased fee collections at-  
11 tributable to subparagraph (B)), exceeds the  
12 cumulative amount appropriated pursuant to  
13 paragraph (3) for the fiscal years 2014 through  
14 2017, the excess amount shall be credited to  
15 the appropriation account of the Food and  
16 Drug Administration as provided in paragraph  
17 (1), and shall be subtracted from the amount of  
18 fees that would otherwise be authorized to be  
19 collected under this section pursuant to appro-  
20 priation Acts for fiscal year 2018.

21 “(B) RECOVERY OF COLLECTION SHORT-  
22 FALLS.—

23 “(i) FISCAL YEAR 2016.—For fiscal  
24 year 2016, the amount of fees otherwise  
25 authorized to be collected under this sec-

1           tion shall be increased by the amount, if  
2           any, by which the amount collected under  
3           this section and appropriated for fiscal  
4           year 2014 falls below the amount of fees  
5           authorized for fiscal year 2014 under para-  
6           graph (3).

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

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

1 falls below the cumulative amount of fees  
2 authorized under paragraph (3) for fiscal  
3 years 2016 and 2017.

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

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

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

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

1           “(1) to the extent practicable, segregate the re-  
2 view of abbreviated new animal drug applications  
3 from the process for the review of animal drug appli-  
4 cations; and

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

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

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

13 **“SEC. 740A. REAUTHORIZATION; REPORTING REQUIRE-**  
14 **MENTS.**

15       “(a) PERFORMANCE REPORT.—Beginning with fiscal  
16 year 2014, not later than 120 days after the end of each  
17 fiscal year during which fees are collected under this part,  
18 the Secretary shall prepare and submit to the Committee  
19 on Health, Education, Labor, and Pensions of the Senate  
20 and the Committee on Energy and Commerce of the  
21 House of Representatives a report concerning the progress  
22 of the Food and Drug Administration in achieving the  
23 goals identified in the letters described in section 101(b)  
24 of the Animal Drug User Fee Amendments of 2013 to-  
25 ward expediting the animal drug development process and

1 the review of the new and supplemental animal drug appli-  
2 cations and investigational animal drug submissions dur-  
3 ing such fiscal year, the future plans of the Food and  
4 Drug Administration for meeting the goals, the review  
5 times for abbreviated new animal drug applications, and  
6 the administrative procedures adopted by the Food and  
7 Drug Administration to ensure that review times for ab-  
8 breviated new animal drug applications are not increased  
9 from their current level due to activities under the user  
10 fee program.

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

22 “(c) PUBLIC AVAILABILITY.—The Secretary shall  
23 make the reports required under subsections (a) and (b)  
24 available to the public on the Internet Web site of the  
25 Food and Drug Administration.

1 “(d) REAUTHORIZATION.—

2 “(1) CONSULTATION.—In developing rec-  
3 ommendations to present to the Congress with re-  
4 spect to the goals, and plans for meeting the goals,  
5 for the process for the review of animal drug appli-  
6 cations for the first 5 fiscal years after fiscal year  
7 2018, and for the reauthorization of this part for  
8 such fiscal years, the Secretary shall consult with—

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

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

13 “(C) scientific and academic experts;

14 “(D) veterinary professionals;

15 “(E) representatives of patient and con-  
16 sumer advocacy groups; and

17 “(F) the regulated industry.

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

21 “(A) publish a notice in the Federal Reg-  
22 ister requesting public input on the reauthoriza-  
23 tion;

24 “(B) hold a public meeting at which the  
25 public may present its views on the reauthoriza-

1           tion, including specific suggestions for changes  
2           to the goals referred to in subsection (a);

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

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

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

16          “(4) PUBLIC REVIEW OF RECOMMENDA-  
17          TIONS.—After negotiations with the regulated indus-  
18          try, the Secretary shall—

19                 “(A) present the recommendations devel-  
20                 oped under paragraph (1) to the Congressional  
21                 committees specified in such paragraph;

22                 “(B) publish such recommendations in the  
23                 Federal Register;

1           “(C) provide for a period of 30 days for  
2 the public to provide written comments on such  
3 recommendations;

4           “(D) hold a meeting at which the public  
5 may present its views on such recommenda-  
6 tions; and

7           “(E) after consideration of such public  
8 views and comments, revise such recommenda-  
9 tions as necessary.

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

17          “(6) MINUTES OF NEGOTIATION MEETINGS.—

18           “(A) PUBLIC AVAILABILITY.—Before pre-  
19 senting the recommendations developed under  
20 paragraphs (1) through (5) to Congress, the  
21 Secretary shall make publicly available, on the  
22 Internet Web site of the Food and Drug Ad-  
23 ministration, minutes of all negotiation meet-  
24 ings conducted under this subsection between

1 the Food and Drug Administration and the reg-  
2 ulated industry.

3 “(B) CONTENT.—The minutes described  
4 under subparagraph (A) shall summarize any  
5 substantive proposal made by any party to the  
6 negotiations as well as significant controversies  
7 or differences of opinion during the negotiations  
8 and their resolution.”.

9 **SEC. 105. SAVINGS CLAUSE.**

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

22 **SEC. 106. EFFECTIVE DATE.**

23 The amendments made by this title shall take effect  
24 on October 1, 2013, or the date of enactment of this Act,  
25 whichever is later, except that fees under part 4 of sub-

1 chapter C of chapter VII of the Federal Food, Drug, and  
2 Cosmetic Act, as amended by this title, shall be assessed  
3 for all animal drug applications and supplemental animal  
4 drug applications received on or after October 1, 2013,  
5 regardless of the date of the enactment of this Act.

6 **SEC. 107. SUNSET DATES.**

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

10 (b) **REPORTING REQUIREMENTS.**—Section 740A of  
11 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
12 379j–13) shall cease to be effective January 31, 2019.

13 (c) **PREVIOUS SUNSET PROVISION.**—

14 (1) **IN GENERAL.**—Section 108 of the Animal  
15 Drug User Fee Amendments of 2008 (Public Law  
16 110–316) is repealed.

17 (2) **CONFORMING AMENDMENT.**—The Animal  
18 Drug User Fee Amendments of 2008 (Public Law  
19 110–316) is amended in the table of contents in sec-  
20 tion 1, by striking the item relating to section 108.

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

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

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

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

6           (b) **FINDING.**—The fees authorized by this title will  
7       be dedicated toward expediting the generic new animal  
8       drug development process and the review of abbreviated  
9       applications for generic new animal drugs, supplemental  
10       abbreviated applications for generic new animal drugs,  
11       and investigational submissions for generic new animal  
12       drugs as set forth in the goals identified in the letters from  
13       the Secretary of Health and Human Services to the Chair-  
14       man of the Committee on Energy and Commerce of the  
15       House of Representatives and the Chairman of the Com-  
16       mittee on Health, Education, Labor, and Pensions of the  
17       Senate as set forth in the Congressional Record.

18       **SEC. 202. AUTHORITY TO ASSESS AND USE GENERIC NEW**  
19               **ANIMAL DRUG FEES.**

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

1 **“SEC. 741. AUTHORITY TO ASSESS AND USE GENERIC NEW**  
2 **ANIMAL DRUG FEES.**

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

6 “(1) ABBREVIATED APPLICATION FEE.—

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

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

15 “(C) EXCEPTIONS.—

16 “(i) PREVIOUSLY FILED APPLICA-  
17 TION.—If an abbreviated application was  
18 submitted by a person that paid the fee for  
19 such application, was accepted for filing,  
20 and was not approved or was withdrawn  
21 (without a waiver or refund), the submis-  
22 sion of an abbreviated application for the  
23 same product by the same person (or the  
24 person’s licensee, assignee, or successor)  
25 shall not be subject to a fee under sub-  
26 paragraph (A).

1           “(ii) CERTAIN ABBREVIATED APPLICA-  
2           TIONS INVOLVING COMBINATION ANIMAL  
3           DRUGS.—An abbreviated application which  
4           is subject to the criteria in section  
5           512(d)(4) and submitted on or after Octo-  
6           ber 1, 2013 shall be subject to a fee equal  
7           to 50 percent of the amount of the abbre-  
8           viated application fee established in sub-  
9           section (c).

10           “(D) REFUND OF FEE IF APPLICATION RE-  
11           FUSED FOR FILING.—The Secretary shall re-  
12           fund 75 percent of the fee paid under subpara-  
13           graph (B) for any abbreviated application which  
14           is refused for filing.

15           “(E) REFUND OF FEE IF APPLICATION  
16           WITHDRAWN.—If an abbreviated application is  
17           withdrawn after the application was filed, the  
18           Secretary may refund the fee or portion of the  
19           fee paid under subparagraph (B) if no substan-  
20           tial work was performed on the application  
21           after the application was filed. The Secretary  
22           shall have the sole discretion to refund the fee  
23           under this subparagraph. A determination by  
24           the Secretary concerning a refund under this  
25           subparagraph shall not be reviewable.

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

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

4                   “(i) who is named as the applicant in  
5 an abbreviated application or supplemental  
6 abbreviated application for a generic new  
7 animal drug product which has been sub-  
8 mitted for listing under section 510; and

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

13 shall pay for each such generic new animal  
14 drug product the annual fee established in sub-  
15 section (c).

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

1           “(i) the first business day after the  
2           date of enactment of an appropriations Act  
3           providing for the collection and obligation  
4           of fees for such fiscal year under this sec-  
5           tion; or

6           “(ii) January 31 of each year.

7           “(C) LIMITATION.—Such fee shall be paid  
8           only once for each generic new animal drug  
9           product for a fiscal year in which the fee is pay-  
10          able.

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

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

14                 “(i) who meets the definition of a ge-  
15                 neric new animal drug sponsor within a  
16                 fiscal year; and

17                 “(ii) who, after September 1, 2008,  
18                 had pending before the Secretary an abbrevi-  
19                 ated application, a supplemental abbrevi-  
20                 ated application, or an investigational  
21                 submission,

22                 shall be assessed an annual generic new animal  
23                 drug sponsor fee as established under sub-  
24                 section (c).

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

3           “(i) the first business day after the  
4 date of enactment of an appropriations Act  
5 providing for the collection and obligation  
6 of fees for such fiscal year under this sec-  
7 tion; or

8           “(ii) January 31 of each year.

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

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

17           “(ii) 75 percent of the amount of the  
18 generic new animal drug sponsor fee pub-  
19 lished for that fiscal year under subsection  
20 (c) for an applicant with more than 1 and  
21 fewer than 7 approved abbreviated applica-  
22 tions.

23           “(iii) 50 percent of the amount of the  
24 generic new animal drug sponsor fee pub-  
25 lished for that fiscal year under subsection

1 (c) for an applicant with 1 or fewer ap-  
2 proved abbreviated applications.

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

6 “(1) **TOTAL FEE REVENUES FOR APPLICATION**  
7 **FEES.**—The total fee revenues to be collected in ab-  
8 breviated application fees under subsection (a)(1)  
9 shall be \$1,832,000 for fiscal year 2014, \$1,736,000  
10 for fiscal year 2015, \$1,857,000 for fiscal year  
11 2016, \$1,984,000 for fiscal year 2017, and  
12 \$2,117,000 for fiscal year 2018.

13 “(2) **TOTAL FEE REVENUES FOR PRODUCT**  
14 **FEES.**—The total fee revenues to be collected in ge-  
15 neric new animal drug product fees under subsection  
16 (a)(2) shall be \$2,748,000 for fiscal year 2014,  
17 \$2,604,000 for fiscal year 2015, \$2,786,000 for fis-  
18 cal year 2016, \$2,976,000 for fiscal year 2017, and  
19 \$3,175,000 for fiscal year 2018.

20 “(3) **TOTAL FEE REVENUES FOR SPONSOR**  
21 **FEES.**—The total fee revenues to be collected in ge-  
22 neric new animal drug sponsor fees under subsection  
23 (a)(3) shall be \$2,748,000 for fiscal year 2014,  
24 \$2,604,000 for fiscal year 2015, \$2,786,000 for fis-

1 cal year 2016, \$2,976,000 for fiscal year 2017, and  
2 \$3,175,000 for fiscal year 2018.

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

4 “(1) ANNUAL FEE SETTING.—The Secretary  
5 shall establish, 60 days before the start of each fis-  
6 cal year beginning after September 30, 2008, for  
7 that fiscal year, abbreviated application fees, generic  
8 new animal drug sponsor fees, and generic new ani-  
9 mal drug product fees, based on the revenue  
10 amounts established under subsection (b) and the  
11 adjustments provided under this subsection.

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

15 With respect to such adjustment:

16 “(A) This adjustment shall be determined  
17 by the Secretary based on a weighted average  
18 of the change in the total number of abbrevi-  
19 ated applications for generic new animal  
20 drugs, manufacturing supplemental abbreviated  
21 applications for generic new animal drugs, in-  
22 vestigational generic new animal drug study  
23 submissions, and investigational generic new  
24 animal drug protocol submissions submitted to  
25 the Secretary. The Secretary shall publish in

1 the Federal Register the fees resulting from  
2 this adjustment and the supporting methodolo-  
3 gies.

4 “(B) Under no circumstances shall this  
5 workload adjustment result in fee revenues for  
6 a fiscal year that are less than the fee revenues  
7 for that fiscal year established in subsection  
8 (b).

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

1           “(4) LIMIT.—The total amount of fees charged,  
2           as adjusted under this subsection, for a fiscal year  
3           may not exceed the total costs for such fiscal year  
4           for the resources allocated for the process for the re-  
5           view of abbreviated applications for generic new ani-  
6           mal drugs.

7           “(d) FEE WAIVER OR REDUCTION.—The Secretary  
8           shall grant a waiver from or a reduction of 1 or more fees  
9           assessed under subsection (a) where the Secretary finds  
10          that the generic new animal drug is intended solely to pro-  
11          vide for a minor use or minor species indication.

12          “(e) EFFECT OF FAILURE TO PAY FEES.—An abbre-  
13          viated application for a generic new animal drug sub-  
14          mitted by a person subject to fees under subsection (a)  
15          shall be considered incomplete and shall not be accepted  
16          for filing by the Secretary until all fees owed by such per-  
17          son have been paid. An investigational submission for a  
18          generic new animal drug that is submitted by a person  
19          subject to fees under subsection (a) shall be considered  
20          incomplete and shall not be accepted for review by the Sec-  
21          retary until all fees owed by such person have been paid.  
22          The Secretary may discontinue review of any abbreviated  
23          application for a generic new animal drug, supplemental  
24          abbreviated application for a generic new animal drug, or  
25          investigational submission for a generic new animal drug

1 from a person if such person has not submitted for pay-  
2 ment all fees owed under this section by 30 days after  
3 the date upon which they are due.

4 “(f) ASSESSMENT OF FEES.—

5 “(1) LIMITATION.—Fees may not be assessed  
6 under subsection (a) for a fiscal year beginning after  
7 fiscal year 2008 unless appropriations for salaries  
8 and expenses of the Food and Drug Administration  
9 for such fiscal year (excluding the amount of fees  
10 appropriated for such fiscal year) are equal to or  
11 greater than the amount of appropriations for the  
12 salaries and expenses of the Food and Drug Admin-  
13 istration for the fiscal year 2003 (excluding the  
14 amount of fees appropriated for such fiscal year)  
15 multiplied by the adjustment factor applicable to the  
16 fiscal year involved.

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

1       visions of subsection (a) relating to the date fees are  
2       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 abbreviated applications for generic  
17       new animal drugs.

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

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

22                       “(i) subject to subparagraph (C), shall  
23       be collected and available in each fiscal  
24       year in an amount not to exceed the  
25       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 ab-  
6 breviated applications for generic new ani-  
7 mal drugs (including increases in such  
8 costs for an additional number of full-time  
9 equivalent positions in the Department of  
10 Health and Human Services to be engaged  
11 in such process) over such costs, excluding  
12 costs paid from fees collected under this  
13 section, for fiscal year 2008 multiplied by  
14 the adjustment factor.

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

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

24 “(ii)(I) are more than 3 percent below  
25 the level specified in subparagraph (A)(ii),

1 and fees assessed for the fiscal year fol-  
2 lowing the subsequent fiscal year are de-  
3 creased by the amount in excess of 3 per-  
4 cent by which such costs fell below the  
5 level specified in subparagraph (A)(ii); and

6 “(II) such costs are not more than 5  
7 percent below the level specified in sub-  
8 paragraph (A)(ii).

9 “(C) PROVISION FOR EARLY PAYMENTS.—

10 Payment of fees authorized under this section  
11 for a fiscal year, prior to the due date for such  
12 fees, may be accepted by the Secretary in ac-  
13 cordance with authority provided in advance in  
14 a prior year appropriations Act.

15 “(3) AUTHORIZATION OF APPROPRIATIONS.—

16 There are authorized to be appropriated for fees  
17 under this section—

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

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

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

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

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

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 abbreviated application

1 fees, generic new animal drug sponsor fees, and ge-  
2 neric new animal drug product fees.

3 “(4) OFFSET.—If the sum of the cumulative  
4 amount of fees collected under this section for the  
5 fiscal years 2014 through 2016 and the amount of  
6 fees estimated to be collected under this section for  
7 fiscal year 2017 exceeds the cumulative amount ap-  
8 propriated under paragraph (3) for the fiscal years  
9 2014 through 2017, the excess amount shall be  
10 credited to the appropriation account of the Food  
11 and Drug Administration as provided in paragraph  
12 (1), and shall be subtracted from the amount of fees  
13 that would otherwise be authorized to be collected  
14 under this section pursuant to appropriation Acts  
15 for fiscal year 2018.

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

22 “(i) WRITTEN REQUESTS FOR WAIVERS, REDUC-  
23 TIONS, AND REFUNDS.—To qualify for consideration for  
24 a waiver or reduction under subsection (d), or for a refund  
25 of any fee collected in accordance with subsection (a), a

1 person shall submit to the Secretary a written request for  
2 such waiver, reduction, or refund not later than 180 days  
3 after such fee is due.

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

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

13 “(1) ABBREVIATED APPLICATION FOR A GE-  
14 NERIC NEW ANIMAL DRUG.—The terms ‘abbreviated  
15 application for a generic new animal drug’ and ‘ab-  
16 breviated application’ mean an abbreviated applica-  
17 tion for the approval of any generic new animal drug  
18 submitted under section 512(b)(2). Such term does  
19 not include a supplemental abbreviated application  
20 for a generic new animal drug.

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

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

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

5           “(3) COSTS OF RESOURCES ALLOCATED FOR  
6           THE PROCESS FOR THE REVIEW OF ABBREVIATED  
7           APPLICATIONS FOR GENERIC NEW ANIMAL DRUGS.—  
8           The term ‘costs of resources allocated for the proc-  
9           ess for the review of abbreviated applications for ge-  
10          neric new animal drugs’ means the expenses in con-  
11          nection with the process for the review of abbre-  
12          viated applications for generic new animal drugs  
13          for—

14           “(A) officers and employees of the Food  
15           and Drug Administration, contractors of the  
16           Food and Drug Administration, advisory com-  
17           mittees consulted with respect to the review of  
18           specific abbreviated applications, supplemental  
19           abbreviated applications, or investigational sub-  
20           missions, and costs related to such officers, em-  
21           ployees, committees, and contractors, including  
22           costs for travel, education, and recruitment and  
23           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 this section and  
10          accounting for resources allocated for the re-  
11          view of abbreviated applications, supplemental  
12          abbreviated applications, and investigational  
13          submissions.

14          “(4) FINAL DOSAGE FORM.—The term ‘final  
15          dosage form’ means, with respect to a generic new  
16          animal drug product, a finished dosage form which  
17          is approved for administration to an animal without  
18          substantial further manufacturing. Such term in-  
19          cludes generic new animal drug products intended  
20          for mixing in animal feeds.

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

24          “(6) GENERIC NEW ANIMAL DRUG PRODUCT.—  
25          The term ‘generic new animal drug product’ means

1 each specific strength or potency of a particular ac-  
2 tive ingredient or ingredients in final dosage form  
3 marketed by a particular manufacturer or dis-  
4 tributor, which is uniquely identified by the labeler  
5 code and product code portions of the national drug  
6 code, and for which an abbreviated application for a  
7 generic new animal drug or a supplemental abbrevi-  
8 ated application has been approved.

9 “(7) GENERIC NEW ANIMAL DRUG SPONSOR.—

10 The term ‘generic new animal drug sponsor’ means  
11 either an applicant named in an abbreviated applica-  
12 tion for a generic new animal drug that has not been  
13 withdrawn by the applicant and for which approval  
14 has not been withdrawn by the Secretary, or a per-  
15 son who has submitted an investigational submission  
16 for a generic new animal drug that has not been ter-  
17 minated or otherwise rendered inactive by the Sec-  
18 retary.

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

23 “(A) the filing of a claim for an investiga-  
24 tional exemption under section 512(j) for a ge-  
25 neric new animal drug intended to be the sub-

1           ject of an abbreviated application or a supple-  
2           mental abbreviated application; or

3           “(B) the submission of information for the  
4           purpose of enabling the Secretary to evaluate  
5           the safety or effectiveness of a generic new ani-  
6           mal drug in the event of the filing of an abbrevi-  
7           ated application or supplemental abbreviated  
8           application for such drug.

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

12          “(10) PROCESS FOR THE REVIEW OF ABBRE-  
13          VIATED APPLICATIONS FOR GENERIC NEW ANIMAL  
14          DRUGS.—The term ‘process for the review of abbrevi-  
15          ated applications for generic new animal drugs’  
16          means the following activities of the Secretary with  
17          respect to the review of abbreviated applications,  
18          supplemental abbreviated applications, and inves-  
19          tigational submissions:

20                 “(A) The activities necessary for the re-  
21                 view of abbreviated applications, supplemental  
22                 abbreviated applications, and investigational  
23                 submissions.

24                 “(B) The issuance of action letters which  
25                 approve abbreviated applications or supple-

1           mental abbreviated applications or which set  
2           forth in detail the specific deficiencies in abbrevi-  
3           ated applications, supplemental abbreviated  
4           applications, or investigational submissions and,  
5           where appropriate, the actions necessary to  
6           place such applications, supplemental applica-  
7           tions, or submissions in condition for approval.

8           “(C) The inspection of generic new animal  
9           drug establishments and other facilities under-  
10          taken as part of the Secretary’s review of pend-  
11          ing abbreviated applications, supplemental ab-  
12          breviated applications, and investigational sub-  
13          missions.

14          “(D) Monitoring of research conducted in  
15          connection with the review of abbreviated appli-  
16          cations, supplemental abbreviated applications,  
17          and investigational submissions.

18          “(E) The development of regulations and  
19          policy related to the review of abbreviated appli-  
20          cations, supplemental abbreviated applications,  
21          and investigational submissions.

22          “(F) Development of standards for prod-  
23          ucts subject to review.

24          “(G) Meetings between the agency and the  
25          generic new animal drug sponsor.

1           “(H) Review of advertising and labeling  
2           prior to approval of an abbreviated application  
3           or supplemental abbreviated application, but  
4           not after such application has been approved.

5           “(11) SUPPLEMENTAL ABBREVIATED APPLICA-  
6           TION FOR GENERIC NEW ANIMAL DRUG.—The terms  
7           ‘supplemental abbreviated application for a generic  
8           new animal drug’ and ‘supplemental abbreviated ap-  
9           plication’ mean a request to the Secretary to ap-  
10          prove a change in an approved abbreviated applica-  
11          tion.”.

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

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

15 **“SEC. 742. REAUTHORIZATION; REPORTING REQUIRE-**  
16 **MENTS.**

17          “(a) PERFORMANCE REPORTS.—Beginning with fis-  
18 cal year 2014, not later than 120 days after the end of  
19 each fiscal year during which fees are collected under this  
20 part, the Secretary shall prepare and submit to the Com-  
21 mittee on Health, Education, Labor, and Pensions of the  
22 Senate, and the Committee on Energy and Commerce of  
23 the House of Representatives a report concerning the  
24 progress of the Food and Drug Administration in achiev-  
25 ing the goals identified in the letters described in section

1 201(b) of the Animal Generic Drug User Fee Amend-  
2 ments of 2013 toward expediting the generic new animal  
3 drug development process and the review of abbreviated  
4 applications for generic new animal drugs, supplemental  
5 abbreviated applications for generic new animal drugs,  
6 and investigational submissions for generic new animal  
7 drugs during such fiscal year.

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

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

23       “(d) REAUTHORIZATION.—

24               “(1) CONSULTATION.—In developing rec-  
25 ommendations to present to Congress with respect to

1 the goals, and plans for meeting the goals, for the  
2 process for the review of abbreviated applications for  
3 generic new animal drugs for the first 5 fiscal years  
4 after fiscal year 2018, and for the reauthorization of  
5 this part for such fiscal years, the Secretary shall  
6 consult with—

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

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

11 “(C) scientific and academic experts;

12 “(D) veterinary professionals;

13 “(E) representatives of patient and con-  
14 sumer advocacy groups; and

15 “(F) the regulated industry.

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

19 “(A) publish a notice in the Federal Reg-  
20 ister requesting public input on the reauthoriza-  
21 tion;

22 “(B) hold a public meeting at which the  
23 public may present its views on the reauthoriza-  
24 tion, including specific suggestions for changes  
25 to the goals referred to in subsection (a);

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

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

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

14           “(4) PUBLIC REVIEW OF RECOMMENDA-  
15 TIONS.—After negotiations with the regulated indus-  
16 try, the Secretary shall—

17           “(A) present the recommendations devel-  
18 oped under paragraph (1) to the congressional  
19 committees specified in such paragraph;

20           “(B) publish such recommendations in the  
21 Federal Register;

22           “(C) provide for a period of 30 days for  
23 the public to provide written comments on such  
24 recommendations;

1           “(D) hold a meeting at which the public  
2           may present its views on such recommenda-  
3           tions; and

4           “(E) after consideration of such public  
5           views and comments, revise such recommenda-  
6           tions as necessary.

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

14          “(6) MINUTES OF NEGOTIATION MEETINGS.—

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

24                 “(B) CONTENT.—The minutes described  
25                 under subparagraph (A) shall summarize any

1 substantive proposal made by any party to the  
2 negotiations as well as significant controversies  
3 or differences of opinion during the negotiations  
4 and their resolution.”.

5 **SEC. 204. SAVINGS CLAUSE.**

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

18 **SEC. 205. EFFECTIVE DATE.**

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

1 neric new animal drug received on or after October 1,  
2 2013, regardless of the date of enactment of this Act.

3 **SEC. 206. SUNSET DATES.**

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

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

10 (c) PREVIOUS SUNSET PROVISION.—

11 (1) IN GENERAL.—Section 204 of the Animal  
12 Generic Drug User Fee Act of 2008 (Public Law  
13 110–316) is repealed.

14 (2) CONFORMING AMENDMENT.—The Animal  
15 Generic Drug User Fee Act of 2008 (Public Law  
16 110–316) is amended in the table of contents in sec-  
17 tion 1, by striking the item relating to section 204.  
Passed the Senate May 8, 2013.

Attest:

*Secretary.*

113<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

**S. 622**

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**AN ACT**

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