

113TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

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

\_\_\_\_\_  
introduced the following bill; which was read twice  
and referred to the Committee on \_\_\_\_\_

## **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”.

### 7       **SEC. 2. TABLE OF CONTENTS; REFERENCES IN ACT.**

8       (a) TABLE OF CONTENTS.—The table of contents of  
9       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.

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

## 6       **TITLE I—FEES RELATING TO** 7                                   **ANIMAL DRUGS**

### 8       **SEC. 101. SHORT TITLE; FINDING.**

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

11       (b) FINDING.—Congress finds that the fees author-  
12 ized by the amendments made in this title will be dedi-  
13 cated toward expediting the animal drug development  
14 process and the review of new and supplemental animal  
15 drug applications and investigational animal drug submis-  
16 sions as set forth in the goals identified, for purposes of

1 part 4 of subchapter C of chapter VII of the Federal Food,  
2 Drug, and Cosmetic Act, in the letters from the Secretary  
3 of Health and Human Services to the Chairman of the  
4 Committee on Energy and Commerce of the House of  
5 Representatives and the Chairman of the Committee on  
6 Health, Education, Labor, and Pensions of the Senate as  
7 set forth in the Congressional Record.

8 **SEC. 102. DEFINITIONS.**

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

11 **“SEC. 739. DEFINITIONS.**

12 “For purposes of this part:

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

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

21 “(A) a request to the Secretary to approve  
22 a change in an animal drug application which  
23 has been approved; or

24 “(B) a request to the Secretary to approve  
25 a change to an application approved under sec-

1           tion 512(c)(2) for which data with respect to  
2           safety or effectiveness are required.

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

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

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

20                 “(A) the filing of a claim for an investiga-  
21                 tional exemption under section 512(j) for a new  
22                 animal drug intended to be the subject of an  
23                 animal drug application or a supplemental ani-  
24                 mal drug application; or

1           “(B) the submission of information for the  
2           purpose of enabling the Secretary to evaluate  
3           the safety or effectiveness of an animal drug  
4           application or supplemental animal drug appli-  
5           cation in the event of their filing.

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

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

20          “(8) The term ‘process for the review of animal  
21          drug applications’ means the following activities of  
22          the Secretary with respect to the review of animal  
23          drug applications, supplemental animal drug applica-  
24          tions, and investigational animal drug submissions:

1           “(A) The activities necessary for the re-  
2           view of animal drug applications, supplemental  
3           animal drug applications, and investigational  
4           animal drug submissions.

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

14          “(C) The inspection of animal drug estab-  
15          lishments and other facilities undertaken as  
16          part of the Secretary’s review of pending animal  
17          drug applications, supplemental animal drug  
18          applications, and investigational animal drug  
19          submissions.

20          “(D) Monitoring of research conducted in  
21          connection with the review of animal drug ap-  
22          plications, supplemental animal drug applica-  
23          tions, and investigational animal drug submis-  
24          sions.

1           “(E) The development of regulations and  
2           policy related to the review of animal drug ap-  
3           plications, supplemental animal drug applica-  
4           tions, and investigational animal drug submis-  
5           sions.

6           “(F) Development of standards for prod-  
7           ucts subject to review.

8           “(G) Meetings between the agency and the  
9           animal drug sponsor.

10          “(H) Review of advertising and labeling  
11          prior to approval of an animal drug application  
12          or supplemental animal drug application, but  
13          not after such application has been approved.

14          “(9) The term ‘costs of resources allocated for  
15          the process for the review of animal drug applica-  
16          tions’ means the expenses in connection with the  
17          process for the review of animal drug applications  
18          for—

19               “(A) officers and employees of the Food  
20               and Drug Administration, contractors of the  
21               Food and Drug Administration, advisory com-  
22               mittees consulted with respect to the review of  
23               specific animal drug applications, supplemental  
24               animal drug applications, or investigational ani-  
25               mal drug submissions, and costs related to such

1 officers, employees, committees, and contrac-  
2 tors, including costs for travel, education, and  
3 recruitment and other personnel activities;

4 “(B) management of information and the  
5 acquisition, maintenance, and repair of com-  
6 puter resources;

7 “(C) leasing, maintenance, renovation, and  
8 repair of facilities and acquisition, maintenance,  
9 and repair of fixtures, furniture, scientific  
10 equipment, and other necessary materials and  
11 supplies; and

12 “(D) collecting fees under section 740 and  
13 accounting for resources allocated for the re-  
14 view of animal drug applications, supplemental  
15 animal drug applications, and investigational  
16 animal drug submissions.

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

21 “(11) The term ‘person’ includes an affiliate  
22 thereof.

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



1   **SEC. 103. AUTHORITY TO ASSESS AND USE ANIMAL DRUG**  
2                   **FEES.**

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

5   **“SEC. 740. AUTHORITY TO ASSESS AND USE ANIMAL DRUG**  
6                   **FEES.**

7           “(a) TYPES OF FEES.—Beginning in fiscal year  
8   2004, the Secretary shall assess and collect fees in accord-  
9   ance with this section as follows:

10           “(1) ANIMAL DRUG APPLICATION AND SUPPLE-  
11       MENT FEE.—

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

16           “(i) A fee established in subsection (c)  
17       for an animal drug application, except an  
18       animal drug application subject to the cri-  
19       teria set forth in section 512(d)(4).

20           “(ii) A fee established in subsection  
21       (c), in an amount that is equal to 50 per-  
22       cent of the amount of the fee under clause  
23       (i), for—

24           “(I) a supplemental animal drug  
25       application for which safety or effec-  
26       tiveness data are required; and

1 “(II) an animal drug application  
2 subject to the criteria set forth in sec-  
3 tion 512(d)(4).

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

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

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

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

14          “(2) ANIMAL DRUG PRODUCT FEE.—

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

16                         “(i) who is named as the applicant in  
17                         an animal drug application or supple-  
18                         mental animal drug application for an ani-  
19                         mal drug product which has been sub-  
20                         mitted for listing under section 510; and

21                         “(ii) who, after September 1, 2003,  
22                         had pending before the Secretary an ani-  
23                         mal drug application or supplemental ani-  
24                         mal drug application,

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

3           “(B) PAYMENT; FEE DUE DATE.—Such fee  
4           shall be payable for the fiscal year in which the  
5           animal drug product is first submitted for list-  
6           ing under section 510, or is submitted for re-  
7           listing under section 510 if the animal drug  
8           product has been withdrawn from listing and  
9           relisted. After such fee is paid for that fiscal  
10          year, such fee shall be due each subsequent fis-  
11          cal year that the product remains listed, upon  
12          the 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.—Such fee shall be paid  
20          only once for each animal drug product for a  
21          fiscal year in which the fee is payable.

22          “(3) ANIMAL DRUG ESTABLISHMENT FEE.—

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

1 “(i) who owns or operates, directly or  
2 through an affiliate, an animal drug estab-  
3 lishment;

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

9 “(iii) who, after September 1, 2003,  
10 had pending before the Secretary an ani-  
11 mal drug application or supplemental ani-  
12 mal drug application,

13 shall be assessed an annual establishment fee as  
14 established in subsection (c) for each animal  
15 drug establishment listed in its approved animal  
16 drug application as an establishment that man-  
17 ufactures the animal drug product named in the  
18 application.

19 “(B) PAYMENT; FEE DUE DATE.—The an-  
20 nual establishment fee shall be assessed in each  
21 fiscal year in which the animal drug product  
22 named in the application is assessed a fee under  
23 paragraph (2) unless the animal drug establish-  
24 ment listed in the application does not engage  
25 in the manufacture of the animal drug product

1 during the fiscal year. The fee under this para-  
2 graph for a fiscal year shall be due upon the  
3 later of—

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

9 “(ii) January 31 of each year.

10 “(C) LIMITATION.—

11 “(i) IN GENERAL.—An establishment  
12 shall be assessed only one fee per fiscal  
13 year under this section, subject to clause  
14 (ii).

15 “(ii) CERTAIN MANUFACTURERS.—If  
16 a single establishment manufactures both  
17 animal drug products and prescription  
18 drug products, as defined in section  
19 735(3), such establishment shall be as-  
20 sessed both the animal drug establishment  
21 fee and the prescription drug establish-  
22 ment fee, as set forth in section 736(a)(2),  
23 within a single fiscal year.

24 “(4) ANIMAL DRUG SPONSOR FEE.—

25 “(A) IN GENERAL.—Each person—

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

4 “(ii) who, after September 1, 2003,  
5 had pending before the Secretary an ani-  
6 mal drug application, a supplemental ani-  
7 mal drug application, or an investigational  
8 animal drug submission,  
9 shall be assessed an annual sponsor fee as es-  
10 tablished under subsection (c).

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

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

19 “(ii) January 31 of each year.

20 “(C) LIMITATION.—Each animal drug  
21 sponsor shall pay only one such fee each fiscal  
22 year.

23 “(b) FEE REVENUE AMOUNTS.—

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

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

5           “(B) for each of fiscal years 2015 through  
6           2018, the fees required under subsection (a)  
7           shall be established to generate a total revenue  
8           amount of \$21,600,000.

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

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

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

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

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

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



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

10           “(2) INFLATION ADJUSTMENT.—For fiscal year  
11           2015 and subsequent fiscal years, the revenue  
12           amounts established in subsection (b) shall be ad-  
13           justed by the Secretary by notice, published in the  
14           Federal Register, for a fiscal year, by an amount  
15           equal to the sum of—

16                   “(A) one;

17                   “(B) the average annual percent change in  
18           the cost, per full-time equivalent position of the  
19           Food and Drug Administration, of all personnel  
20           compensation and benefits paid with respect to  
21           such positions for the first 3 of the preceding  
22           4 fiscal years for which data are available, mul-  
23           tiplied by the average proportion of personnel  
24           compensation and benefits costs to total Food  
25           and Drug Administration costs for the first 3

1 years of the preceding 4 fiscal years for which  
2 data are available; and

3 “(C) the average annual percent change  
4 that occurred in the Consumer Price Index for  
5 urban consumers (Washington-Baltimore, DC-  
6 MD-VA-WV; not seasonally adjusted; all items  
7 less food and energy; annual index) for the first  
8 3 years of the preceding 4 years for which data  
9 are available multiplied by the average propor-  
10 tion of all costs other than personnel compensa-  
11 tion and benefits costs to total Food and Drug  
12 Administration costs for the first 3 years of the  
13 preceding 4 fiscal years for which data are  
14 available.

15 The adjustment made each fiscal year under this  
16 paragraph shall be added on a compounded basis to  
17 the sum of all adjustments made each fiscal year  
18 after fiscal year 2014 under this paragraph.

19 “(3) WORKLOAD ADJUSTMENT.—For fiscal  
20 year 2015 and subsequent fiscal years, after the rev-  
21 enue amounts established in subsection (b) are ad-  
22 justed for inflation in accordance with paragraph  
23 (2), the revenue amounts shall be further adjusted  
24 for such fiscal year to reflect changes in the work-  
25 load of the Secretary for the process for the review

1 of animal drug applications. With respect to such  
2 adjustment—

3 “(A) such adjustment shall be determined  
4 by the Secretary based on a weighted average  
5 of the change in the total number of animal  
6 drug applications, supplemental animal drug  
7 applications for which data with respect to safe-  
8 ty or effectiveness are required, manufacturing  
9 supplemental animal drug applications, inves-  
10 tigational animal drug study submissions, and  
11 investigational animal drug protocol submis-  
12 sions submitted to the Secretary;

13 “(B) the Secretary shall publish in the  
14 Federal Register the fees resulting from such  
15 adjustment and the supporting methodologies;  
16 and

17 “(C) under no circumstances shall such ad-  
18 justment result in fee revenues for a fiscal year  
19 that are less than the fee revenues for that fis-  
20 cal year established in subsection (b), as ad-  
21 justed for inflation under paragraph (2).

22 “(4) FINAL YEAR ADJUSTMENT.—For fiscal  
23 year 2018, the Secretary may, in addition to other  
24 adjustments under this subsection, further increase  
25 the fees under this section, if such an adjustment is

1       necessary, to provide for up to 3 months of oper-  
2       ating reserves of carryover user fees for the process  
3       for the review of animal drug applications for the  
4       first 3 months of fiscal year 2019. If the Food and  
5       Drug Administration has carryover balances for the  
6       process for the review of animal drug applications in  
7       excess of 3 months of such operating reserves, then  
8       this adjustment will not be made. If this adjustment  
9       is necessary, then the rationale for the amount of  
10      the increase shall be contained in the annual notice  
11      setting fees for fiscal year 2018.

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

17      “(d) FEE WAIVER OR REDUCTION.—

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

22           “(A) the assessment of the fee would  
23           present a significant barrier to innovation be-  
24           cause of limited resources available to such per-  
25           son or other circumstances;

## 21

1           “(B) the fees to be paid by such person  
2 will exceed the anticipated present and future  
3 costs incurred by the Secretary in conducting  
4 the process for the review of animal drug appli-  
5 cations for such person;

6           “(C) the animal drug application or sup-  
7 plemental animal drug application is intended  
8 solely to provide for use of the animal drug  
9 in—

10           “(i) a Type B medicated feed (as de-  
11 fined in section 558.3(b)(3) of title 21,  
12 Code of Federal Regulations (or any suc-  
13 cessor regulation)) intended for use in the  
14 manufacture of Type C free-choice medi-  
15 cated feeds; or

16           “(ii) a Type C free-choice medicated  
17 feed (as defined in section 558.3(b)(4) of  
18 title 21, Code of Federal Regulations (or  
19 any successor regulation));

20           “(D) the animal drug application or sup-  
21 plemental animal drug application is intended  
22 solely to provide for a minor use or minor spe-  
23 cies indication; or

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

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

7           “(3) RULES FOR SMALL BUSINESSES.—

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

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

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

7                   “(e) EFFECT OF FAILURE TO PAY FEES.—An ani-  
8                   mal drug application or supplemental animal drug applica-  
9                   tion submitted by a person subject to fees under sub-  
10                  section (a) shall be considered incomplete and shall not  
11                  be accepted for filing by the Secretary until all fees owed  
12                  by such person have been paid. An investigational animal  
13                  drug submission under section 739(5)(B) that is sub-  
14                  mitted by a person subject to fees under subsection (a)  
15                  shall be considered incomplete and shall not be accepted  
16                  for review by the Secretary until all fees owed by such  
17                  person have been paid. The Secretary may discontinue re-  
18                  view of any animal drug application, supplemental animal  
19                  drug application or investigational animal drug submission  
20                  from a person if such person has not submitted for pay-  
21                  ment all fees owed under this section by 30 days after  
22                  the date upon which they are due.

23                  “(f) ASSESSMENT OF FEES.—

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

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

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

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

24           “(1) IN GENERAL.—Subject to paragraph  
25      (2)(C), fees authorized under subsection (a) shall be



1 collected and available for obligation only to the ex-  
2 tent and in the amount provided in advance in ap-  
3 propriations Acts. Such fees are authorized to be ap-  
4 propriated to remain available until expended. Such  
5 sums as may be necessary may be transferred from  
6 the Food and Drug Administration salaries and ex-  
7 penses appropriation account without fiscal year lim-  
8 itation to such appropriation account for salary and  
9 expenses with such fiscal year limitation. The sums  
10 transferred shall be available solely for the process  
11 for the review of animal drug applications.

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

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

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

22 “(ii) shall be available to defray in-  
23 creases in the costs of the resources allo-  
24 cated for the process for the review of ani-  
25 mal drug applications (including increases

1 in such costs for an additional number of  
2 full-time equivalent positions in the De-  
3 partment of Health and Human Services  
4 to be engaged in such process) over such  
5 costs, excluding costs paid from fees col-  
6 lected under this section, for fiscal year  
7 2003 multiplied by the adjustment factor.

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

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

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

1                   “(II) such costs are not more than 5  
2                   percent below the level specified in sub-  
3                   paragraph (A)(ii).

4                   “(C) PROVISION FOR EARLY PAYMENTS.—  
5                   Payment of fees authorized under this section  
6                   for a fiscal year, prior to the due date for such  
7                   fees, may be accepted by the Secretary in ac-  
8                   cordance with authority provided in advance in  
9                   a prior year appropriations Act.

10                  “(3) AUTHORIZATION OF APPROPRIATIONS.—  
11                  For each of the fiscal years 2014 through 2018,  
12                  there is authorized to be appropriated for fees under  
13                  this section an amount equal to the total revenue  
14                  amount determined under subsection (b) for the fis-  
15                  cal year, as adjusted or otherwise affected under  
16                  subsection (c) and paragraph (4).

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

19                  “(A) OFFSET OF OVERCOLLECTIONS.—If  
20                  the sum of the cumulative amount of fees col-  
21                  lected under this section for fiscal years 2014  
22                  through 2016 and the amount of fees estimated  
23                  to be collected under this section for fiscal year  
24                  2017 (including any increased fee collections at-  
25                  tributable to subparagraph (B)), exceeds the

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

10 “(B) RECOVERY OF COLLECTION SHORT-  
11 FALLS.—

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

21 “(ii) FISCAL YEAR 2017.—For fiscal  
22 year 2017, the amount of fees otherwise  
23 authorized to be collected under this sec-  
24 tion shall be increased by the amount, if  
25 any, by which the amount collected under

1           this section and appropriated for fiscal  
2           year 2015 falls below the amount of fees  
3           authorized for fiscal year 2015 under para-  
4           graph (3).

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

18          “(h) COLLECTION OF UNPAID FEES.—In any case  
19          where the Secretary does not receive payment of a fee as-  
20          sessed under subsection (a) within 30 days after it is due,  
21          such fee shall be treated as a claim of the United States  
22          Government subject to subchapter II of chapter 37 of title  
23          31, United States Code.

24          “(i) WRITTEN REQUESTS FOR WAIVERS, REDUC-  
25          TIONS, AND REFUNDS.—To qualify for consideration for

1 a waiver or reduction under subsection (d), or for a refund  
2 of any fee collected in accordance with subsection (a), a  
3 person shall submit to the Secretary a written request for  
4 such waiver, reduction, or refund not later than 180 days  
5 after such fee is due.

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

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

15 “(1) to the extent practicable, segregate the re-  
16 view of abbreviated new animal drug applications  
17 from the process for the review of animal drug appli-  
18 cations; and

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

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

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

5 **“SEC. 740A. REAUTHORIZATION; REPORTING REQUIRE-**  
6 **MENTS.**

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

1 from their current level due to activities under the user  
2 fee program.

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

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

18 “(d) REAUTHORIZATION.—

19 “(1) CONSULTATION.—In developing rec-  
20 ommendations to present to the Congress with re-  
21 spect to the goals, and plans for meeting the goals,  
22 for the process for the review of animal drug appli-  
23 cations for the first 5 fiscal years after fiscal year  
24 2018, and for the reauthorization of this part for  
25 such fiscal years, the Secretary shall consult with—



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

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

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. 105. SAVINGS CLAUSE.**

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

14   **SEC. 106. 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 4 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 animal drug applications and supplemental animal  
21   drug applications received on or after October 1, 2013,  
22   regardless of the date of the enactment of this Act.

23   **SEC. 107. SUNSET DATES.**

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

1 (b) REPORTING REQUIREMENTS.—Section 740A of  
2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
3 379j–13) shall cease to be effective January 31, 2019.

4 (c) PREVIOUS SUNSET PROVISION.—

5 (1) IN GENERAL.—Section 108 of the Animal  
6 Drug User Fee Amendments of 2008 (Public Law  
7 110–316) is repealed.

8 (2) CONFORMING AMENDMENT.—The Animal  
9 Drug User Fee Amendments of 2008 (Public Law  
10 110–316) is amended in the table of contents in sec-  
11 tion 1, by striking the item relating to section 108.

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

## 15 **TITLE II—FEES RELATING TO** 16 **GENERIC ANIMAL DRUGS**

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

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

20 (b) FINDING.—The fees authorized by this title will  
21 be dedicated toward expediting the generic new animal  
22 drug development process and the review of abbreviated  
23 applications for generic new animal drugs, supplemental  
24 abbreviated applications for generic new animal drugs,  
25 and investigational submissions for generic new animal

1 drugs as set forth in the goals identified in the letters from  
2 the Secretary of Health and Human Services to the Chair-  
3 man of the Committee on Energy and Commerce of the  
4 House of Representatives and the Chairman of the Com-  
5 mittee on Health, Education, Labor, and Pensions of the  
6 Senate as set forth in the Congressional Record.

7 **SEC. 202. AUTHORITY TO ASSESS AND USE GENERIC NEW**  
8 **ANIMAL DRUG FEES.**

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

11 **“SEC. 741. AUTHORITY TO ASSESS AND USE GENERIC NEW**  
12 **ANIMAL DRUG FEES.**

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

16 “(1) ABBREVIATED APPLICATION FEE.—

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

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

25 “(C) EXCEPTIONS.—

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

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

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

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

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

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

15                         “(i) who is named as the applicant in  
16                         an abbreviated application or supplemental  
17                         abbreviated application for a generic new  
18                         animal drug product which has been sub-  
19                         mitted for listing under section 510; and

20                         “(ii) who, after September 1, 2008,  
21                         had pending before the Secretary an abbrev-  
22                         viated application or supplemental abbrev-  
23                         viated application,



1 shall pay for each such generic new animal  
2 drug product the annual fee established in sub-  
3 section (c).

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

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

19 “(ii) January 31 of each year.

20 “(C) LIMITATION.—Such fee shall be paid  
21 only once for each generic new animal drug  
22 product for a fiscal year in which the fee is pay-  
23 able.

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

1 “(A) IN GENERAL.—Each person—

2 “(i) who meets the definition of a ge-  
3 neric new animal drug sponsor within a  
4 fiscal year; and

5 “(ii) who, after September 1, 2008,  
6 had pending before the Secretary an abbre-  
7 viated application, a supplemental abbre-  
8 viated application, or an investigational  
9 submission,

10 shall be assessed an annual generic new animal  
11 drug sponsor fee as established under sub-  
12 section (c).

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

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

20 “(ii) January 31 of each year.

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

24 “(i) 100 percent of the amount of the  
25 generic new animal drug sponsor fee pub-

1                   lished for that fiscal year under subsection  
2                   (c) for an applicant with more than 6 ap-  
3                   proved abbreviated applications.

4                   “(ii) 75 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 1 and  
8                   fewer than 7 approved abbreviated applica-  
9                   tions.

10                  “(iii) 50 percent of the amount of the  
11                  generic new animal drug sponsor fee pub-  
12                  lished for that fiscal year under subsection  
13                  (c) for an applicant with 1 or fewer ap-  
14                  proved abbreviated applications.

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

18                  “(1) TOTAL FEE REVENUES FOR APPLICATION  
19 FEES.—The total fee revenues to be collected in ab-  
20 breviated application fees under subsection (a)(1)  
21 shall be \$1,832,000 for fiscal year 2014, \$1,736,000  
22 for fiscal year 2015, \$1,857,000 for fiscal year  
23 2016, \$1,984,000 for fiscal year 2017, and  
24 \$2,117,000 for fiscal year 2018.

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

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

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

16           “(1) ANNUAL FEE SETTING.—The Secretary  
17      shall establish, 60 days before the start of each fis-  
18      cal year beginning after September 30, 2008, for  
19      that fiscal year, abbreviated application fees, generic  
20      new animal drug sponsor fees, and generic new ani-  
21      mal drug product fees, based on the revenue  
22      amounts established under subsection (b) and the  
23      adjustments provided under this subsection.

24           “(2) WORKLOAD ADJUSTMENT.—The fee reve-  
25      nues shall be adjusted each fiscal year after fiscal

1 year 2014 to reflect changes in review workload.

2 With respect to such adjustment:

3 “(A) This adjustment shall be determined  
4 by the Secretary based on a weighted average  
5 of the change in the total number of abbrevi-  
6 ated applications for generic new animal  
7 drugs, manufacturing supplemental abbreviated  
8 applications for generic new animal drugs, in-  
9 vestigational generic new animal drug study  
10 submissions, and investigational generic new  
11 animal drug protocol submissions submitted to  
12 the Secretary. The Secretary shall publish in  
13 the Federal Register the fees resulting from  
14 this adjustment and the supporting methodolo-  
15 gies.

16 “(B) Under no circumstances shall this  
17 workload adjustment result in fee revenues for  
18 a fiscal year that are less than the fee revenues  
19 for that fiscal year established in subsection  
20 (b).

21 “(3) FINAL YEAR ADJUSTMENT.—For fiscal  
22 year 2018, the Secretary may, in addition to other  
23 adjustments under this subsection, further increase  
24 the fees under this section, if such an adjustment is  
25 necessary, to provide for up to 3 months of oper-

1       ating reserves of carryover user fees for the process  
2       for the review of abbreviated applications for generic  
3       new animal drugs for the first 3 months of fiscal  
4       year 2019. If the Food and Drug Administration  
5       has carryover balances for the process for the review  
6       of abbreviated applications for generic new animal  
7       drugs in excess of 3 months of such operating re-  
8       serves, then this adjustment shall not be made. If  
9       this adjustment is necessary, then the rationale for  
10      the amount of the increase shall be contained in the  
11      annual notice setting fees for fiscal year 2018.

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

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

23           “(e) EFFECT OF FAILURE TO PAY FEES.—An abbre-  
24      viated application for a generic new animal drug sub-  
25      mitted by a person subject to fees under subsection (a)

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

15 “(f) ASSESSMENT OF FEES.—

16 “(1) LIMITATION.—Fees may not be assessed  
17 under subsection (a) for a fiscal year beginning after  
18 fiscal year 2008 unless appropriations for salaries  
19 and expenses of the Food and Drug Administration  
20 for such fiscal year (excluding the amount of fees  
21 appropriated for such fiscal year) are equal to or  
22 greater than the amount of appropriations for the  
23 salaries and expenses of the Food and Drug Admin-  
24 istration for the fiscal year 2003 (excluding the  
25 amount of fees appropriated for such fiscal year)

1 multiplied by the adjustment factor applicable to the  
2 fiscal year involved.

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

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

15 “(1) IN GENERAL.—Subject to paragraph  
16 (2)(C), fees authorized under subsection (a) shall be  
17 collected and available for obligation only to the ex-  
18 tent and in the amount provided in advance in ap-  
19 propriations Acts. Such fees are authorized to be ap-  
20 propriated to remain available until expended. Such  
21 sums as may be necessary may be transferred from  
22 the Food and Drug Administration salaries and ex-  
23 penses appropriation account without fiscal year lim-  
24 itation to such appropriation account for salary and  
25 expenses with such fiscal year limitation. The sums



1 transferred shall be available solely for the process  
2 for the review of abbreviated applications for generic  
3 new animal drugs.

4 “(2) COLLECTIONS AND APPROPRIATION  
5 ACTS.—

6 “(A) IN GENERAL.—The fees authorized  
7 by this section—

8 “(i) subject to subparagraph (C), shall  
9 be collected and available in each fiscal  
10 year in an amount not to exceed the  
11 amount specified in appropriation Acts, or  
12 otherwise made available for obligation for  
13 such fiscal year; and

14 “(ii) shall be available to defray in-  
15 creases in the costs of the resources allo-  
16 cated for the process for the review of ab-  
17 breviated applications for generic new ani-  
18 mal drugs (including increases in such  
19 costs for an additional number of full-time  
20 equivalent positions in the Department of  
21 Health and Human Services to be engaged  
22 in such process) over such costs, excluding  
23 costs paid from fees collected under this  
24 section, for fiscal year 2008 multiplied by  
25 the adjustment factor.

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

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

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

17                   “(II) such costs are not more than 5  
18                   percent below the level specified in sub-  
19                   paragraph (A)(ii).

20           “(C) PROVISION FOR EARLY PAYMENTS.—  
21           Payment of fees authorized under this section  
22           for a fiscal year, prior to the due date for such  
23           fees, may be accepted by the Secretary in ac-  
24           cordance with authority provided in advance in  
25           a prior year appropriations Act.

1           “(3) AUTHORIZATION OF APPROPRIATIONS.—

2           There are authorized to be appropriated for fees  
3           under this section—

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

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

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

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

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

9           as adjusted to reflect adjustments in the total fee  
10          revenues made under this section and changes in the  
11          total amounts collected by abbreviated application  
12          fees, generic new animal drug sponsor fees, and ge-  
13          neric new animal drug product fees.

14          “(4) OFFSET.—If the sum of the cumulative  
15          amount of fees collected under this section for the  
16          fiscal years 2014 through 2016 and the amount of  
17          fees estimated to be collected under this section for  
18          fiscal year 2017 exceeds the cumulative amount ap-  
19          propriated under paragraph (3) for the fiscal years  
20          2014 through 2017, the excess amount shall be  
21          credited to the appropriation account of the Food  
22          and Drug Administration as provided in paragraph  
23          (1), and shall be subtracted from the amount of fees  
24          that would otherwise be authorized to be collected

1       under this section pursuant to appropriation Acts  
2       for fiscal year 2018.

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

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

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

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

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

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

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

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

18          “(3) COSTS OF RESOURCES ALLOCATED FOR  
19          THE PROCESS FOR THE REVIEW OF ABBREVIATED  
20          APPLICATIONS FOR GENERIC NEW ANIMAL DRUGS.—  
21          The term ‘costs of resources allocated for the proc-  
22          ess for the review of abbreviated applications for ge-  
23          neric new animal drugs’ means the expenses in con-  
24          nection with the process for the review of abbre-

1 viated applications for generic new animal drugs  
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 abbreviated applications, supplemental  
8 abbreviated applications, or investigational sub-  
9 missions, and costs related to such officers, em-  
10 ployees, committees, and contractors, including  
11 costs for travel, education, and recruitment and  
12 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 this section and  
22 accounting for resources allocated for the re-  
23 view of abbreviated applications, supplemental  
24 abbreviated applications, and investigational  
25 submissions.

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

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

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

21           “(7) GENERIC NEW ANIMAL DRUG SPONSOR.—  
22 The term ‘generic new animal drug sponsor’ means  
23 either an applicant named in an abbreviated applica-  
24 tion for a generic new animal drug that has not been  
25 withdrawn by the applicant and for which approval

1       has not been withdrawn by the Secretary, or a per-  
2       son who has submitted an investigational submission  
3       for a generic new animal drug that has not been ter-  
4       minated or otherwise rendered inactive by the Sec-  
5       retary.

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

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

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

21              “(9) PERSON.—The term ‘person’ includes an  
22       affiliate thereof (as such term is defined in section  
23       735(11)).

24              “(10) PROCESS FOR THE REVIEW OF ABBRE-  
25       VIATED APPLICATIONS FOR GENERIC NEW ANIMAL



1       DRUGS.—The term ‘process for the review of abbrev-  
2       viated applications for generic new animal drugs’  
3       means the following activities of the Secretary with  
4       respect to the review of abbreviated applications,  
5       supplemental abbreviated applications, and inves-  
6       tigational submissions:

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

11              “(B) The issuance of action letters which  
12      approve abbreviated applications or supple-  
13      mental abbreviated applications or which set  
14      forth in detail the specific deficiencies in abbrev-  
15      viated applications, supplemental abbreviated  
16      applications, or investigational submissions and,  
17      where appropriate, the actions necessary to  
18      place such applications, supplemental applica-  
19      tions, or submissions in condition for approval.

20              “(C) The inspection of generic new animal  
21      drug establishments and other facilities under-  
22      taken as part of the Secretary’s review of pend-  
23      ing abbreviated applications, supplemental ab-  
24      breviated applications, and investigational sub-  
25      missions.

1           “(D) Monitoring of research conducted in  
2           connection with the review of abbreviated appli-  
3           cations, supplemental abbreviated applications,  
4           and investigational submissions.

5           “(E) The development of regulations and  
6           policy related to the review of abbreviated appli-  
7           cations, supplemental abbreviated applications,  
8           and investigational submissions.

9           “(F) Development of standards for prod-  
10          ucts subject to review.

11          “(G) Meetings between the agency and the  
12          generic new animal drug sponsor.

13          “(H) Review of advertising and labeling  
14          prior to approval of an abbreviated application  
15          or supplemental abbreviated application, but  
16          not after such application has been approved.

17          “(11) SUPPLEMENTAL ABBREVIATED APPLICA-  
18          TION FOR GENERIC NEW ANIMAL DRUG.—The terms  
19          ‘supplemental abbreviated application for a generic  
20          new animal drug’ and ‘supplemental abbreviated ap-  
21          plication’ mean a request to the Secretary to ap-  
22          prove a change in an approved abbreviated applica-  
23          tion.”.

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

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

4 **“SEC. 742. REAUTHORIZATION; REPORTING REQUIRE-**  
5 **MENTS.**

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

22 “(b) FISCAL REPORT.—Beginning with fiscal year  
23 2014, not later than 120 days after the end of each fiscal  
24 year during which fees are collected under this part, the  
25 Secretary shall prepare and submit to Committee on  
26 Health, Education, Labor, and Pensions of the Senate and

1 the Committee on Energy and Commerce of the House  
2 of Representatives a report on the implementation of the  
3 authority for such fees during such fiscal year and the  
4 use, by the Food and Drug Administration, of the fees  
5 collected during such fiscal year for which the report is  
6 made.

7 “(c) PUBLIC AVAILABILITY.—The Secretary shall  
8 make the reports required under subsections (a) and (b)  
9 available to the public on the Internet Web site of the  
10 Food and Drug Administration.

11 “(d) REAUTHORIZATION.—

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

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

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

24 “(C) scientific and academic experts;

25 “(D) veterinary professionals;

1                   “(E) representatives of patient and con-  
2                   sumer advocacy groups; and

3                   “(F) the regulated industry.

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

7                   “(A) publish a notice in the Federal Reg-  
8                   ister requesting public input on the reauthoriza-  
9                   tion;

10                  “(B) hold a public meeting at which the  
11                  public may present its views on the reauthoriza-  
12                  tion, including specific suggestions for changes  
13                  to the goals referred to in subsection (a);

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

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

19                  “(3) PERIODIC CONSULTATION.—Not less fre-  
20                  quently than once every 4 months during negotia-  
21                  tions with the regulated industry, the Secretary shall  
22                  hold discussions with representatives of veterinary,  
23                  patient, and consumer advocacy groups to continue  
24                  discussions of their views on the reauthorization and

1       their suggestions for changes to this part as ex-  
2       pressed under paragraph (2).

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

6               “(A) present the recommendations devel-  
7       oped under paragraph (1) to the congressional  
8       committees specified in such paragraph;

9               “(B) publish such recommendations in the  
10       Federal Register;

11              “(C) provide for a period of 30 days for  
12       the public to provide written comments on such  
13       recommendations;

14              “(D) hold a meeting at which the public  
15       may present its views on such recommenda-  
16       tions; and

17              “(E) after consideration of such public  
18       views and comments, revise such recommenda-  
19       tions as necessary.

20              “(5) TRANSMITTAL OF RECOMMENDATIONS.—  
21       Not later than January 15, 2018, the Secretary  
22       shall transmit to Congress the revised recommenda-  
23       tions under paragraph (4), a summary of the views  
24       and comments received under such paragraph, and

1       any changes made to the recommendations in re-  
2       sponse to such views and comments.

3           “(6) MINUTES OF NEGOTIATION MEETINGS.—

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

13           “(B) CONTENT.—The minutes described  
14      under subparagraph (A) shall summarize any  
15      substantive proposal made by any party to the  
16      negotiations as well as significant controversies  
17      or differences of opinion during the negotiations  
18      and their resolution.”.

19   **SEC. 204. SAVINGS CLAUSE.**

20       Notwithstanding the amendments made by this title,  
21   part 5 of subchapter C of chapter VII of the Federal Food,  
22   Drug, and Cosmetic Act, as in effect on the day before  
23   the date of enactment of this title, shall continue to be  
24   in effect with respect to abbreviated applications for a ge-  
25   neric new animal drug and supplemental abbreviated ap-

1 plications for a generic new animal drug (as defined in  
2 such part as of such day) that on or after October 1, 2008,  
3 but before October 1, 2013, were accepted by the Food  
4 and Drug Administration for filing with respect to assess-  
5 ing and collecting any fee required by such part for a fiscal  
6 year prior to fiscal year 2014.

7 **SEC. 205. EFFECTIVE DATE.**

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

17 **SEC. 206. SUNSET DATES.**

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

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

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



1           (1) IN GENERAL.—Section 204 of the Animal  
2       Generic Drug User Fee Act of 2008 (Public Law  
3       110–316) is repealed.

4           (2) CONFORMING AMENDMENT.—The Animal  
5       Generic Drug User Fee Act of 2008 (Public Law  
6       110–316) is amended in the table of contents in sec-  
7       tion 1, by striking the item relating to section 204.