

113TH CONGRESS
1ST SESSION

S. 622

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 sented 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.

113TH CONGRESS
1ST SESSION

S. 622

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.