

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 1407
OFFERED BY MR. SHIMKUS OF ILLINOIS**

Strike all after the enacting clause and insert the following:

1 SECTION 1. TABLE OF CONTENTS.

Sec. 1. Table of Contents.

TITLE I—ANIMAL DRUG USER FEE AMENDMENTS

- 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—ANIMAL GENERIC DRUG USER FEE AMENDMENTS

- 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.

**2 TITLE I—ANIMAL DRUG USER
3 FEE AMENDMENTS**

4 SEC. 101. SHORT TITLE; FINDING.

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

7 (b) **FINDING.**—Congress finds that the fees author-
8 ized by the amendments made in this title will be dedi-

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

12 **SEC. 102. DEFINITIONS.**

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

15 **“SEC. 739. DEFINITIONS.**

16 “For purposes of this part:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20 “(i) A fee established in subsection (c)
21 for an animal drug application, except an
22 animal drug application described in sec-
23 tion 512(d)(4).

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

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

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

6 “(II) an animal drug application
7 described in section 512(d)(4).

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

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

24 “(D) REFUND OF FEE IF APPLICATION RE-
25 FUSED FOR FILING.—The Secretary shall re-

1 fund 75 percent of the fee paid under subpara-
2 graph (B) for any animal drug application or
3 supplemental animal drug application which is
4 refused for filing.

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

18 “(2) ANIMAL DRUG PRODUCT FEE.—

19 “(A) IN GENERAL.—Each person—

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

1 “(ii) who, after September 1, 2003,
2 had pending before the Secretary an ani-
3 mal drug application or supplemental ani-
4 mal drug application,
5 shall pay for each such animal drug product the
6 annual fee established in subsection (c).

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

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

22 “(ii) January 31 of each year.

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

1 “(3) ANIMAL DRUG ESTABLISHMENT FEE.—

2 “(A) IN GENERAL.—Each person—

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

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

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

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

21 “(B) PAYMENT; FEE DUE DATE.—The an-
22 nual establishment fee shall be assessed in each
23 fiscal year in which the animal drug product
24 named in the application is assessed a fee under
25 paragraph (2) unless the animal drug establish-

1 ment listed in the application does not engage
2 in the manufacture of the animal drug product
3 during the fiscal year. The fee under this para-
4 graph for a fiscal year shall be due upon the
5 later of—

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

11 “(ii) January 31 of each year.

12 “(C) LIMITATION.—

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

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

1 “(4) ANIMAL DRUG SPONSOR FEE.—

2 “(A) IN GENERAL.—Each person—

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

5 and

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

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

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

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

21 “(ii) January 31 of each year.

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

25 “(b) FEE REVENUE AMOUNTS.—

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

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

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

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

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

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

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

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

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

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

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

17 “(A) one;

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

1 and Drug Administration costs for the first 3
2 years of the preceding 4 fiscal years for which
3 data are available; and

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

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

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

1 load of the Secretary for the process for the review
2 of animal drug applications. With respect to such
3 adjustment—

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

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

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

23 “(4) FINAL YEAR ADJUSTMENT.—For fiscal
24 year 2018, the Secretary may, in addition to other
25 adjustments under this subsection, further increase

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

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

18 “(d) FREE WAIVER OR REDUCTION.—

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

23 “(A) the assessment of the fee would
24 present a significant barrier to innovation be-

1 cause of limited resources available to such per-
2 son or other circumstances;

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

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

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

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

22 “(D) the animal drug application or sup-
23 plemental animal drug application is intended
24 solely to provide for a minor use or minor spe-
25 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 submis-
20 sion from a person if such person has not submitted for
21 payment 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
21 such fiscal year notwithstanding the provisions of
22 subsection (a) relating to the date fees are to be
23 paid.

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

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

14 “(2) COLLECTIONS AND APPROPRIATION
15 ACTS.—

16 “(A) IN GENERAL.—The fees authorized
17 by this section—

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

24 “(ii) shall be available to defray in-
25 creases in the costs of the resources allo-

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

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

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

19 “(ii)(I) are more than 3 percent below
20 the level specified in subparagraph (A)(ii),
21 and fees assessed for the fiscal year fol-
22 lowing the subsequent fiscal year are de-
23 creased by the amount in excess of 3 per-
24 cent by which such costs fell below the
25 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 Energy and Commerce of the House of Representatives
12 and the Committee on Health, Education, Labor, and
13 Pensions of the Senate 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 Energy and Commerce of the House of Representatives
8 and the Committee on Health, Education, Labor, and
9 Pensions of the Senate a report on the implementation
10 of the authority for such fees during such fiscal year and
11 the 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 Energy and Com-
2 merce of the House of Representatives;

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

5 “(C) scientific and academic experts;

6 “(D) veterinary professionals;

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

9 “(F) the regulated industry.

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

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

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

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

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

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

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

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

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

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

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

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

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

8 “(6) MINUTES OF NEGOTIATION MEETINGS.—

9 “(A) PUBLIC AVAILABILITY.—Before pre-
10 sented 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 title,
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 title.

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—ANIMAL GENERIC** 16 **DRUG USER FEE AMENDMENTS**

17 **SECTION 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 for an
15 animal drug described in section 512(d)(4)
16 and submitted on or after October 1, 2013,
17 shall be subject to a fee equal to 50 per-
18 cent of the amount of the abbreviated ap-
19 plication fee established in subsection (c).

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 abbreviated application which
24 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 abbrevi-
22 ated application or supplemental abbrevi-
23 ated 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 abbrev-
7 viated application, a supplemental abbrev-
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 the 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 title,
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 title.

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.

