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(Original Signature of Member)

113TH CONGRESS  
1ST SESSION

# H. R.

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

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## IN THE HOUSE OF REPRESENTATIVES

Mr. SHIMKUS introduced the following bill; which was referred to the Committee on \_\_\_\_\_

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# A BILL

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

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; FINDING.**

4 (a) SHORT TITLE.—This Act 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 Act will be dedicated  
8 toward expediting the animal drug development process  
9 and the review of new and supplemental animal drug ap-

1 plications and investigational animal drug submissions as  
2 set forth in the goals identified, for purposes of part 4  
3 of subchapter C of chapter VII of the Federal Food, Drug,  
4 and Cosmetic Act, in the letters from the Secretary of  
5 Health and Human Services to the Chairman of the Com-  
6 mittee on Energy and Commerce of the House of Rep-  
7 resentatives and the Chairman of the Committee on  
8 Health, Education, Labor, and Pensions of the Senate as  
9 set forth in the Congressional Record.

10 **SEC. 2. DEFINITIONS.**

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

13 **“SEC. 739. DEFINITIONS.**

14 “For purposes of this part:

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

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

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

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

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

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

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

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

1 animal drug application or a supplemental ani-  
2 mal drug application; or

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

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

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

22 “(8) The term ‘process for the review of animal  
23 drug applications’ means the following activities of  
24 the Secretary with respect to the review of animal

1 drug applications, supplemental animal drug applica-  
2 tions, and investigational animal drug submissions:

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

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

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

22 “(D) Monitoring of research conducted in  
23 connection with the review of animal drug ap-  
24 plications, supplemental animal drug applica-

1           tions, and investigational animal drug submis-  
2           sions.

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

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

10          “(G) Meetings between the agency and the  
11          animal drug sponsor.

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

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

21          “(A) officers and employees of the Food  
22          and Drug Administration, contractors of the  
23          Food and Drug Administration, advisory com-  
24          mittees consulted with respect to the review of  
25          specific animal drug applications, supplemental

1 animal drug applications, or investigational ani-  
2 mal drug submissions, and costs related to such  
3 officers, employees, committees, and contrac-  
4 tors, including costs for travel, education, and  
5 recruitment and other personnel activities;

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

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

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

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

23 “(11) The term ‘person’ includes an affiliate  
24 thereof.

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

3   **SEC. 3. AUTHORITY TO ASSESS AND USE ANIMAL DRUG**  
4           **FEES.**

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

7   **“SEC. 740. AUTHORITY TO ASSESS AND USE ANIMAL DRUG**  
8           **FEES.**

9           “(a) TYPES OF FEES.—Beginning in fiscal year  
10 2004, the Secretary shall assess and collect fees in accord-  
11 ance with this section as follows:

12           “(1) ANIMAL DRUG APPLICATION AND SUPPLE-  
13           MENT FEE.—

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

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

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

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

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

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

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

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

1 supplemental animal drug application which is  
2 refused for filing.

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

16 “(2) ANIMAL DRUG PRODUCT FEE.—

17 “(A) IN GENERAL.—Each person—

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

23 “(ii) who, after September 1, 2003,  
24 had pending before the Secretary an ani-

1           mal drug application or supplemental ani-  
2           mal drug application,  
3           shall pay for each such animal drug product the  
4           annual fee established in subsection (c).

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

24          “(3) ANIMAL DRUG ESTABLISHMENT FEE.—

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

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

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

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

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

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

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

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

9 “(ii) January 31 of each year.

10 “(C) LIMITATION.—

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

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

24 “(4) ANIMAL DRUG SPONSOR FEE.—

25 “(A) IN GENERAL.—Each person—

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

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

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

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

19                 “(ii) January 31 of each year.

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

23          “(b) FEE REVENUE AMOUNTS.—

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

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

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

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

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

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

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

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

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

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

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

16                   “(A) one;

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

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

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

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

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

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

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

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

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

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

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

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

17 “(d) FEE WAIVER OR REDUCTION.—

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

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

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

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

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

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

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

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

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

7           “(3) RULES FOR SMALL BUSINESSES.—

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

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

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

7                   “(e) EFFECT OF FAILURE TO PAY FEES.—An ani-  
8                   mal drug application or supplemental animal drug applica-  
9                   tion submitted by a person subject to fees under sub-  
10                  section (a) shall be considered incomplete and shall not  
11                  be accepted for filing by the Secretary until all fees owed  
12                  by such person have been paid. An investigational animal  
13                  drug submission under section 739(5)(B) that is sub-  
14                  mitted by a person subject to fees under subsection (a)  
15                  shall be considered incomplete and shall not be accepted  
16                  for review by the Secretary until all fees owed by such  
17                  person have been paid. The Secretary may discontinue re-  
18                  view of any animal drug application, supplemental animal  
19                  drug application, or investigational animal drug 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. 4. 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 1(b) of  
16 the Animal Drug User Fee Amendments of 2013 toward  
17 expediting the animal drug development process and the  
18 review of the new and supplemental animal drug applica-  
19 tions and investigational animal drug submissions during  
20 such fiscal year, the future plans of the Food and Drug  
21 Administration for meeting the goals, the review times for  
22 abbreviated new animal drug applications, and the admin-  
23 istrative procedures adopted by the Food and Drug Ad-  
24 ministration to ensure that review times for abbreviated  
25 new animal drug applications are not increased from their  
26 current level due to activities under the user fee program.

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

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

16       “(d) REAUTHORIZATION.—

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

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

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

3                   “(C) scientific and academic experts;

4                   “(D) veterinary professionals;

5                   “(E) representatives of patient and con-  
6                   sumer advocacy groups; and

7                   “(F) the regulated industry.

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

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

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

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

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

23                  “(3) PERIODIC CONSULTATION.—Not less fre-  
24                  quently than once every 4 months during negotia-  
25                  tions with the regulated industry, the Secretary shall

1 hold discussions with representatives of veterinary,  
2 patient, and consumer advocacy groups to continue  
3 discussions of their views on the reauthorization and  
4 their suggestions for changes to this part as ex-  
5 pressed under paragraph (2).

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

9 “(A) present the recommendations devel-  
10 oped under paragraph (1) to the congressional  
11 committees specified in such paragraph;

12 “(B) publish such recommendations in the  
13 Federal Register;

14 “(C) provide for a period of 30 days for  
15 the public to provide written comments on such  
16 recommendations;

17 “(D) hold a meeting at which the public  
18 may present its views on such recommenda-  
19 tions; and

20 “(E) after consideration of such public  
21 views and comments, revise such recommenda-  
22 tions as necessary.

23 “(5) TRANSMITTAL OF RECOMMENDATIONS.—  
24 Not later than January 15, 2018, the Secretary  
25 shall transmit to Congress the revised recommenda-

1 tions under paragraph (4), a summary of the views  
2 and comments received under such paragraph, and  
3 any changes made to the recommendations in re-  
4 sponse to such views and comments.

5 “(6) MINUTES OF NEGOTIATION MEETINGS.—

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

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

21 **SEC. 5. SAVINGS CLAUSE.**

22 Notwithstanding the amendments made by this Act,  
23 part 4 of subchapter C of chapter VII of the Federal Food,  
24 Drug, and Cosmetic Act (21 U.S.C. 379j–11 et seq.), as  
25 in effect on the day before the date of the enactment of

1 this Act, shall continue to be in effect with respect to ani-  
2 mal drug applications and supplemental animal drug ap-  
3 plications (as defined in such part as of such day) that  
4 on or after October 1, 2008, but before October 1, 2013,  
5 were accepted by the Food and Drug Administration for  
6 filing with respect to assessing and collecting any fee re-  
7 quired by such part for a fiscal year prior to fiscal year  
8 2014.

9 **SEC. 6. EFFECTIVE DATE.**

10 The amendments made by this Act shall take effect  
11 on October 1, 2013, or the date of enactment of this Act,  
12 whichever is later, except that fees under part 4 of sub-  
13 chapter C of chapter VII of the Federal Food, Drug, and  
14 Cosmetic Act, as amended by this Act, shall be assessed  
15 for all animal drug applications and supplemental animal  
16 drug applications received on or after October 1, 2013,  
17 regardless of the date of the enactment of this Act.

18 **SEC. 7. SUNSET DATES.**

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

22 (b) **REPORTING REQUIREMENTS.**—Section 740A of  
23 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
24 379j–13) shall cease to be effective January 31, 2019.

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

1           (1) IN GENERAL.—Section 108 of the Animal  
2 Drug User Fee Amendments of 2008 (Public Law  
3 110–316) is repealed.

4           (2) CONFORMING AMENDMENT.—The Animal  
5 Drug User Fee Amendments 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 108.

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