

# Calendar No. 341

115TH CONGRESS  
2D SESSION

# S. 2434

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

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## IN THE SENATE OF THE UNITED STATES

FEBRUARY 15, 2018

Mr. ALEXANDER introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

MARCH 7, 2018

Reported by Mr. ALEXANDER, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

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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 and generic new animal drugs.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Animal Drug and Ani-  
5 mal Generic Drug User Fee Amendments of 2018”.

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

2 (a) **TABLE OF CONTENTS.**—The table of contents for  
 3 this Act is as follows:

Sec. 1. Short title.

Sec. 2. Table of contents; references in Act.

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

Sec. 101. Short title; finding.

Sec. 102. Definitions.

Sec. 103. Authority to assess and use animal drug fees.

Sec. 104. Reauthorization; reporting requirements.

Sec. 105. Savings clause.

Sec. 106. Effective date.

Sec. 107. Sunset dates.

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

Sec. 201. Short title; finding.

Sec. 202. Authority to assess and use generic new animal drug fees.

Sec. 203. Reauthorization; reporting requirements.

Sec. 204. Savings clause.

Sec. 205. Effective date.

Sec. 206. Sunset dates.

**TITLE III—MISCELLANEOUS PROVISIONS**

Sec. 301. Electronic submissions.

Sec. 302. Index of legally marketed unapproved new animal drugs for minor  
 species.

Sec. 303. Misbranded drugs and devices.

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

9 **TITLE I—FEES RELATING TO**  
 10 **ANIMAL DRUGS**

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

12 (a) **SHORT TITLE.**—This title may be cited as the  
 13 “Animal Drug User Fee Amendments of 2018”.

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

14 **SEC. 102. DEFINITIONS.**

15           Section 739 (21 U.S.C. 379j-11) is amended—

16           (1) by amending paragraph (1) to read as fol-  
17 lows:

18           “(1)(A) The term ‘animal drug application’  
19 means—

20           “(i) an application for approval of any new  
21 animal drug submitted under section 512(b)(1);

22           or

23           “(ii) an application for conditional ap-  
24 proval of a new animal drug submitted under  
25 section 571.

1           “(B) Such term does not include either a new  
2 animal drug application submitted under section  
3 512(b)(2) or a supplemental animal drug applica-  
4 tion.”; and

5           (2) in paragraph (8), by adding at the end the  
6 following:

7           “(I) The activities necessary for implemen-  
8 tation of the United States and European  
9 Union Good Manufacturing Practice Mutual In-  
10 spection Agreement with respect to animal drug  
11 products subject to review, including implemen-  
12 tation activities prior to and following product  
13 approval.”.

14 **SEC. 103. AUTHORITY TO ASSESS AND USE ANIMAL DRUG**  
15 **FEEES.**

16           (a) **FEE REVENUE AMOUNTS.**—Section 740(b) (21  
17 U.S.C. 379j-12(b)) is amended—

18           (1) in paragraph (1)—

19           (A) in subparagraph (A)—

20           (i) by striking “2014” and inserting  
21 “2019”; and

22           (ii) by striking “\$23,600,000” and in-  
23 serting “\$30,331,240”; and

24           (B) in subparagraph (B)—

1 (i) by striking “2015 through 2018”  
2 and inserting “2020 through 2023”; and

3 (ii) by striking “\$21,600,000” and in-  
4 serting “\$29,931,240”; and

5 (2) in paragraph (2), in the matter preceding  
6 subparagraph (A), by striking “determined” and in-  
7 serting “established”.

8 (b) ANNUAL FEE SETTING; ADJUSTMENTS.—

9 (1) INFLATION ADJUSTMENT.—Section  
10 740(c)(2) (21 U.S.C. 379j-12(c)(2)) is amended—

11 (A) in the matter preceding subparagraph  
12 (A)—

13 (i) by striking “For fiscal year 2015”  
14 and inserting “(A) For fiscal year 2020”;  
15 and

16 (ii) by inserting “multiplying such  
17 revenue amounts by” before “an amount”;

18 (B) by redesignating subparagraphs (A),  
19 (B), and (C) as clauses (i), (ii), and (iii), re-  
20 spectively;

21 (C) by striking the flush text at the end;  
22 and

23 (D) by adding at the end the following new  
24 subparagraph:

1           “~~(B)~~ COMPOUNDED BASIS.—The adjustment  
2           made each fiscal year after fiscal year 2020 under  
3           this paragraph shall be applied on a compounded  
4           basis to the revenue amount calculated under this  
5           paragraph for the most recent previous fiscal year.”.

6           ~~(2)~~ WORKLOAD ADJUSTMENTS.—Paragraph ~~(3)~~  
7           of section 740(c) (~~21 U.S.C. 379j-12(c)~~) is amended  
8           to read as follows:

9           “~~(3)~~ WORKLOAD ADJUSTMENTS.—

10           “~~(A)~~ IN GENERAL.—For fiscal year 2020  
11           and subsequent fiscal years, after the fee rev-  
12           enue amounts established under subsection (b)  
13           are adjusted for inflation in accordance with  
14           paragraph ~~(2)~~, the fee revenue amounts shall be  
15           further adjusted for such fiscal year to reflect  
16           changes in the workload of the Secretary for  
17           the process for the review of animal drug appli-  
18           cations, subject to subparagraphs ~~(B)~~ and ~~(C)~~.

19           With respect to such adjustment—

20           “~~(i)~~ such adjustment shall be deter-  
21           mined by the Secretary based on a weight-  
22           ed average of the change in the total num-  
23           ber of animal drug applications, supple-  
24           mental animal drug applications for which  
25           data with respect to safety or effectiveness

1 are required; manufacturing supplemental  
2 animal drug applications; investigational  
3 animal drug study submissions; and inves-  
4 tigational animal drug protocol submis-  
5 sions submitted to the Secretary; and

6 “(ii) the Secretary shall publish in the  
7 Federal Register the fees resulting from  
8 such adjustment and the supporting meth-  
9 odologies.

10 “(B) REDUCTION OF WORKLOAD-BASED  
11 INCREASE BY AMOUNT OF CERTAIN EXCESS  
12 COLLECTIONS.—For each of fiscal years 2021  
13 through 2023, if application of the workload ad-  
14 justment under subparagraph (A) increases the  
15 fee revenue amounts otherwise established for  
16 the fiscal year under subsection (b), as adjusted  
17 for inflation under paragraph (2), such fee rev-  
18 enue increase shall be reduced by the amount of  
19 any excess collections, as described in sub-  
20 section (g)(4), for the second preceding fiscal  
21 year, up to the amount of such fee revenue in-  
22 crease.

23 “(C) RULE OF APPLICATION.—Under no  
24 circumstances shall the workload adjustments  
25 under this paragraph result in fee revenues for

1 a fiscal year that are less than the fee revenues  
 2 for that fiscal year established under subsection  
 3 (b), as adjusted for inflation under paragraph  
 4 (2).”.

5 (3) FINAL YEAR ADJUSTMENT.—Section  
 6 740(c)(4) (21 U.S.C. 379j-12(c)(4)) is amended—

7 (A) by striking “2018” each place it ap-  
 8 pears and inserting “2023”; and

9 (B) by striking “2019” and inserting  
 10 “2024”.

11 (e) EXEMPTIONS FROM FEES.—Section 740(d) (21  
 12 U.S.C. 379j-12(d)) is amended—

13 (1) in the subsection heading, by inserting “;  
 14 EXEMPTIONS FROM FEES” after “REDUCTION”;

15 (2) by striking the heading of paragraph (1)  
 16 and inserting “WAIVER OR REDUCTION”; and

17 (3) by adding at the end the following:

18 “(4) EXEMPTIONS FROM FEES.—

19 “(A) CERTAIN LABELING SUPPLEMENTS  
 20 TO ADD NUMBER OF APPROVED APPLICA-  
 21 TION.—Fees under this section shall not apply  
 22 with respect to any person who—

23 “(i) not later than September 30,  
 24 2023, submits a supplemental animal drug  
 25 application relating to a new animal drug



1 application approved under section 512,  
 2 solely to add the new animal drug applica-  
 3 tion number to the labeling of the drug in  
 4 the manner specified in section 502(w)(3);  
 5 and

6 “(ii) otherwise would be subject to  
 7 fees under this section solely on the basis  
 8 of such supplemental application.

9 “(B) CERTAIN ANIMAL DRUG APPLICA-  
 10 TIONS.—Fees under paragraphs (2), (3), and  
 11 (4) of subsection (a) shall not apply with re-  
 12 spect to any person who is the named applicant  
 13 or sponsor of an animal drug application, sup-  
 14 plemental animal drug application, or investiga-  
 15 tional animal drug submission if such applica-  
 16 tion or submission involves the intentional  
 17 genomic alteration of an animal that is in-  
 18 tended to produce a drug, device, or biological  
 19 product subject to fees under section 736, 738,  
 20 744B, or 744H.”.

21 (d) CREDITING AND AVAILABILITY OF FEES.—

22 (1) AUTHORIZATION OF APPROPRIATIONS.—

23 Section 740(g)(3) (21 U.S.C. 379j-12(g)(3)) is  
 24 amended—

1 (A) by striking “2014 through 2018” and  
 2 inserting “2019 through 2023”;

3 (B) by striking “determined” and inserting  
 4 “established”; and

5 (C) by striking “paragraph (4)” and in-  
 6 serting “paragraph (5)”.

7 (2) EXCESS COLLECTIONS.—Section 740(g) (21  
 8 U.S.C. 379j-12(g)) is amended by striking para-  
 9 graph (4) and inserting the following:

10 “(4) EXCESS COLLECTIONS.—If the sum total  
 11 of fees collected under this section for a fiscal year  
 12 exceeds the amount of fees authorized to be appro-  
 13 priated for such year under paragraph (3), the ex-  
 14 cess collections shall be credited to the appropria-  
 15 tions account of the Food and Drug Administration  
 16 as described in paragraph (1).

17 “(5) RECOVERY OF COLLECTION SHORT-  
 18 FALLS.—

19 “(A) IN GENERAL.—Subject to subpara-  
 20 graph (B)—

21 “(i) for fiscal year 2021, the amount  
 22 of fees otherwise authorized to be collected  
 23 under this section shall be increased by the  
 24 amount, if any, by which the amount col-  
 25 lected under this section and appropriated

1 for fiscal year 2019 falls below the amount  
2 of fees authorized for fiscal year 2019  
3 under paragraph (3);

4 “(ii) for fiscal year 2022, the amount  
5 of fees otherwise authorized to be collected  
6 under this section shall be increased by the  
7 amount, if any, by which the amount col-  
8 lected under this section and appropriated  
9 for fiscal year 2020 falls below the amount  
10 of fees authorized for fiscal year 2020  
11 under paragraph (3); and

12 “(iii) for fiscal year 2023, the amount  
13 of fees otherwise authorized to be collected  
14 under this section shall be increased by the  
15 cumulative amount, if any, by which the  
16 amount collected under this section and  
17 appropriated for fiscal years 2021 and  
18 2022 (including estimated collections for  
19 fiscal year 2022) falls below the cumulative  
20 amount of fees authorized for such fiscal  
21 years under paragraph (3).

22 “(B) REDUCTION OF SHORTFALL-BASED  
23 FEE INCREASE BY PRIOR YEAR EXCESS COL-  
24 LECTIONS.—

1           “(i) IN GENERAL.—Subject to clause  
2           (ii), the Secretary shall, in such manner as  
3           the Secretary determines appropriate, re-  
4           duce any fee increase otherwise applicable  
5           for a fiscal year under subparagraph (A)  
6           by the amount of any excess collections  
7           under this section for preceding fiscal  
8           years (after fiscal year 2018).

9           “(ii) ~~WORKLOAD-BASED FEE AC-~~  
10          ~~COUNTING.~~—In applying clause (i), the  
11          Secretary shall account for the reduction of  
12          workload-based fee revenue increases by  
13          excess collections under subsection  
14          (e)(3)(B), in such manner as needed to  
15          provide that no portion of any excess col-  
16          lections described in clause (i) is applied  
17          for purposes of reducing fee increases  
18          under both such subsection (e)(3)(B) and  
19          this paragraph.

20          “(C) RULE OF APPLICATION.—Under no  
21          circumstances shall adjustments under this  
22          paragraph result in fee revenues for a fiscal  
23          year that are less than the fee revenues for that  
24          fiscal year established in subsection (b), as ad-

1           justed or otherwise affected under subsection  
2           (e).”.

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

4           Section 740A (21 U.S.C. 379j-13) is amended—

5           (1) in subsection (a), by striking “2013” and  
6           inserting “2018”;

7           (2) by striking “2014” each place it appears in  
8           subsections (a) and (b) and inserting “2019”; and

9           (3) in subsection (d), by striking “2018” each  
10          place it appears and inserting “2023”.

11 **SEC. 105. SAVINGS CLAUSE.**

12          Notwithstanding the amendments made by this title,  
13 part 4 of subchapter C of chapter VII of the Federal Food,  
14 Drug, and Cosmetic Act (21 U.S.C. 379j-11 et seq.), as  
15 in effect on the day before the date of enactment of this  
16 title, shall continue to be in effect with respect to animal  
17 drug applications and supplemental animal drug applica-  
18 tions (as defined in such part as of such day) that on or  
19 after October 1, 2013, but before October 1, 2018, were  
20 accepted by the Food and Drug Administration for filing  
21 with respect to assessing and collecting any fee required  
22 by such part for a fiscal year prior to fiscal year 2019.

23 **SEC. 106. EFFECTIVE DATE.**

24          The amendments made by this title shall take effect  
25 on October 1, 2018, or the date of the enactment of this

1 Act, whichever is later, except that fees under part 4 of  
2 subchapter C of chapter VII of the Federal Food, Drug,  
3 and Cosmetic Act, as amended by this title, shall be as-  
4 sessed for animal drug applications and supplemental ani-  
5 mal drug applications received on or after October 1,  
6 2018, regardless of the date of the enactment of this Act.

7 **SEC. 107. SUNSET DATES.**

8 (a) **AUTHORIZATION.**—Section 740 of the Federal  
9 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–12) shall  
10 cease to be effective October 1, 2023.

11 (b) **REPORTING REQUIREMENTS.**—Section 740A of  
12 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
13 379j–13) shall cease to be effective January 31, 2024.

14 (c) **PREVIOUS SUNSET PROVISION.**—Effective Octo-  
15 ber 1, 2018, subsections (a) and (b) of section 107 of the  
16 Animal Drug User Fee Amendments of 2013 (Public Law  
17 113–14) are repealed.

18 **TITLE II—FEES RELATING TO**  
19 **GENERIC ANIMAL DRUGS**

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

21 (a) **SHORT TITLE.**—This title may be cited as the  
22 “Animal Generic Drug User Fee Amendments of 2018”.

23 (b) **FINDING.**—Congress finds that the fees author-  
24 ized by the amendments made in this title will be dedi-  
25 cated toward expediting the generic new animal drug de-

1 velopment process and the review of abbreviated applica-  
2 tions for generic new animal drugs; supplemental abbrevi-  
3 ated applications for generic new animal drugs; and in-  
4 vestigational submissions for generic new animal drugs as  
5 set forth in the goals identified for purposes of part 5 of  
6 subchapter C of chapter VII of the Federal Food, Drug,  
7 and Cosmetic Act, in the letters from the Secretary of  
8 Health and Human Services to the Chairman of the Com-  
9 mittee on Energy and Commerce of the House of Rep-  
10 resentatives and the Chairman of the Committee on  
11 Health, Education, Labor, and Pensions of the Senate as  
12 set forth in the Congressional Record.

13 **SEC. 202. AUTHORITY TO ASSESS AND USE GENERIC NEW**  
14 **ANIMAL DRUG FEES.**

15 (a) FEE REVENUE AMOUNTS.—Subsection (b) of sec-  
16 tion 741 (21 U.S.C. 379j–21) is amended to read as fol-  
17 lows:

18 “(b) FEE REVENUE AMOUNTS.—

19 “(1) IN GENERAL.—Subject to subsections (c),  
20 (d), (f), and (g), for each of fiscal years 2019  
21 through 2023, the fees required under subsection (a)  
22 shall be established to generate a total revenue  
23 amount of \$18,336,340.

1           “(2) TYPES OF FEES.—Of the total revenue  
2 amount established for a fiscal year under para-  
3 graph (1)—

4           “(A) 25 percent shall be derived from fees  
5 under subsection (a)(1) (relating to abbreviated  
6 applications for a generic new animal drug);

7           “(B) 37.5 percent shall be derived from  
8 fees under subsection (a)(2) (relating to generic  
9 new animal drug products); and

10          “(C) 37.5 percent shall be derived from  
11 fees under subsection (a)(3) (relating to generic  
12 new animal drug sponsors).”.

13 (b) ANNUAL FEE SETTING; ADJUSTMENTS.—

14          (1) INFLATION ADJUSTMENT.—Section 741(e)  
15 (~~21 U.S.C. 379j-21(e)~~) is amended—

16          (A) by redesignating paragraphs (2)  
17 through (4) as paragraphs (3) through (5), re-  
18 spectively; and

19          (B) by inserting after paragraph (1) the  
20 following:

21          “(2) INFLATION ADJUSTMENT.—

22          “(A) IN GENERAL.—For fiscal year 2020  
23 and subsequent fiscal years, the revenue  
24 amounts established under subsection (b) shall  
25 be adjusted by the Secretary by notice, pub-



1 lished in the Federal Register, for a fiscal year,  
2 by multiplying such revenue amounts by an  
3 amount equal to the sum of—

4 “(i) one;

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

17 “(iii) the average annual percent  
18 change that occurred in the Consumer  
19 Price Index for urban consumers (Wash-  
20 ington-Baltimore, DC-MD-VA-WV; not  
21 seasonally adjusted; all items less food and  
22 energy; annual index) for the first 3 of the  
23 preceding 4 years for which data are avail-  
24 able multiplied by the average proportion  
25 of all costs other than personnel compensa-

1           tion and benefits costs to total Food and  
2           Drug Administration costs for the first 3  
3           of the preceding 4 fiscal years for which  
4           data are available.

5           “(B) COMPOUNDED BASIS.—The adjust-  
6           ment made each fiscal year after fiscal year  
7           2020 under this paragraph shall be applied on  
8           a compounded basis to the revenue amount cal-  
9           culated under this paragraph for the most re-  
10          cent previous fiscal year.”.

11          (2) WORKLOAD ADJUSTMENTS.—Paragraph (3)  
12          of section 741(e) (21 U.S.C. 379j-21(e)), as redesign-  
13          ated, is amended to read as follows:

14          “(3) WORKLOAD ADJUSTMENTS.—

15                 “(A) IN GENERAL.—For fiscal year 2020  
16                 and subsequent fiscal years, after the fee rev-  
17                 enue amounts established under subsection (b)  
18                 are adjusted for inflation in accordance with  
19                 paragraph (2), the fee revenue amounts shall be  
20                 further adjusted for each such fiscal year to re-  
21                 flect changes in the workload of the Secretary  
22                 for the process for the review of abbreviated ap-  
23                 plications for generic new animal drugs, subject  
24                 to subparagraphs (B) and (C). With respect to  
25                 such adjustment—

1           “(i) this adjustment shall be deter-  
2           mined by the Secretary based on a weight-  
3           ed average of the change in the total num-  
4           ber of abbreviated applications for generic  
5           new animal drugs, manufacturing supple-  
6           mental abbreviated applications for generic  
7           new animal drugs, investigational generic  
8           new animal drug study submissions, and  
9           investigational generic new animal drug  
10          protocol submissions submitted to the Sec-  
11          retary; and

12          “(ii) the Secretary shall publish in the  
13          Federal Register the fees resulting from  
14          this adjustment and the supporting meth-  
15          odologies.

16          “(B) REDUCTION OF WORKLOAD-BASED  
17          INCREASE BY AMOUNT OF CERTAIN EXCESS  
18          COLLECTIONS.—For each of fiscal years 2021  
19          through 2023, if application of the workload ad-  
20          justment under subparagraph (A) increases the  
21          fee revenue amounts otherwise established for  
22          the fiscal year under subsection (b), as adjusted  
23          for inflation under paragraph (2), such fee rev-  
24          enue increase shall be reduced by the amount of  
25          any excess collections, as described in sub-

1 section (g)(4), for the second preceding fiscal  
 2 year, up to the amount of such fee revenue in-  
 3 crease.

4 “(C) RULE OF APPLICATION.—Under no  
 5 circumstances shall workload adjustments  
 6 under this paragraph result in fee revenues for  
 7 a fiscal year that are less than the fee revenues  
 8 for that fiscal year established under subsection  
 9 (b), as adjusted for inflation under paragraph  
 10 (2).”.

11 (3) FINAL YEAR ADJUSTMENT.—Paragraph (4)  
 12 of section 741(e) (21 U.S.C. 379j-21(e)), as redesign-  
 13 nated, is amended by—

14 (A) striking “2018” each place it appears  
 15 and inserting “2023”; and

16 (B) striking “2019” and inserting “2024”.

17 (e) FEE WAIVER OR REDUCTION; EXEMPTION FROM  
 18 FEES.—Subsection (d) of section 741 (21 U.S.C. 379j-  
 19 21) is amended to read as follows:

20 “(d) FEE WAIVER OR REDUCTION; EXEMPTION  
 21 FROM FEES.—

22 “(1) FEE WAIVER OR REDUCTION.—The Sec-  
 23 retary shall grant a waiver from or a reduction of  
 24 1 or more fees assessed under subsection (a) where  
 25 the Secretary finds that the generic new animal drug

1 is intended solely to provide for a minor use or  
2 minor species indication.

3 ~~“(2) EXEMPTION FROM FEES.—Fees under this~~  
4 ~~section shall not apply with respect to any person~~  
5 ~~who—~~

6 ~~“(A) not later than September 30, 2023,~~  
7 ~~submits a supplemental abbreviated application~~  
8 ~~for a generic new animal drug approved under~~  
9 ~~section 512, solely to add the application num-~~  
10 ~~ber to the labeling of the drug in the manner~~  
11 ~~specified in section 502(w)(3); and~~

12 ~~“(B) otherwise would be subject to fees~~  
13 ~~under this section solely on the basis of such~~  
14 ~~supplemental abbreviated application.”.~~

15 ~~(d) CREDITING AND AVAILABILITY OF FEES.—Sec-~~  
16 ~~tion 741(g) (21 U.S.C. 379j–21) is amended by striking~~  
17 ~~paragraph (3) and inserting the following paragraphs:~~

18 ~~“(3) AUTHORIZATION OF APPROPRIATIONS.—~~  
19 ~~For each of the fiscal years 2019 through 2023,~~  
20 ~~there is authorized to be appropriated for fees under~~  
21 ~~this section an amount equal to the total revenue~~  
22 ~~amount established under subsection (b) for the fis-~~  
23 ~~cal year, as adjusted or otherwise affected under~~  
24 ~~subsection (c).~~

1           “(4) **EXCESS COLLECTIONS.**—If the sum total  
2 of fees collected under this section for a fiscal year  
3 exceeds the amount of fees authorized to be appro-  
4 priated for such year under paragraph (3), the ex-  
5 cess collections shall be credited to the appropria-  
6 tions account of the Food and Drug Administration  
7 as described in paragraph (1).”.

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

9 Section 742 (21 U.S.C. 379j–22) is amended—

10           (1) in subsection (a), by striking “2013” and  
11 inserting “2018”;

12           (2) by striking “2014” each place it appears in  
13 subsections (a) and (b) and inserting “2019”; and

14           (3) in subsection (d), by striking “2018” each  
15 place it appears and inserting “2023”.

16 **SEC. 204. SAVINGS CLAUSE.**

17 Notwithstanding the amendments made by this title,  
18 part 5 of subchapter C of chapter VII of the Federal Food,  
19 Drug, and Cosmetic Act (21 U.S.C. 379j–21 et seq.), as  
20 in effect on the day before the date of enactment of this  
21 title, shall continue to be in effect with respect to abbre-  
22 viated applications for a generic new animal drug and sup-  
23 plemental abbreviated applications for a generic new ani-  
24 mal drug (as defined in such part as of such day) that  
25 on or after October 1, 2013, but before October 1, 2018,

1 were accepted by the Food and Drug Administration for  
2 filing with respect to assessing and collecting any fee re-  
3 quired by such part for a fiscal year prior to fiscal year  
4 2019.

5 **SEC. 205. EFFECTIVE DATE.**

6 The amendments made by this title shall take effect  
7 on ~~October 1, 2018,~~ or the date of the enactment of this  
8 Act, whichever is later, except that fees under part 5 of  
9 subchapter C of chapter VII of the Federal Food, Drug,  
10 and Cosmetic Act, as amended by this title, shall be as-  
11 sessed for abbreviated applications for a generic new ani-  
12 mal drug and supplemental abbreviated applications for  
13 a generic new animal drug received on or after October  
14 1, 2018, regardless of the date of enactment of this Act.

15 **SEC. 206. SUNSET DATES.**

16 (a) **AUTHORIZATION.**—~~Section 741 of the Federal~~  
17 ~~Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21)~~ shall  
18 cease to be effective ~~October 1, 2023.~~

19 (b) **REPORTING REQUIREMENTS.**—~~Section 742 of the~~  
20 ~~Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–~~  
21 ~~22)~~ shall cease to be effective ~~January 31, 2024.~~

22 (c) **PREVIOUS SUNSET PROVISION.**—Effective Octo-  
23 ber 1, 2018, subsections (a) and (b) of section 206 of the  
24 Animal Generic Drug User Fee Amendments of 2013  
25 (Public Law 113–14) are repealed.

1           **TITLE III—MISCELLANEOUS**  
 2                                   **PROVISIONS**

3   **SEC. 301. ELECTRONIC SUBMISSIONS.**

4           (a) **NEW ANIMAL DRUG APPLICATIONS AND ABBRE-**  
 5 **VIATED APPLICATIONS FOR A GENERIC NEW ANIMAL**  
 6 **DRUG.**—Section 512(b) (21 U.S.C. 360b(b)) is amended  
 7 by adding at the end the following:

8           “(4) Beginning on October 1, 2018, all applications  
 9 or submissions pursuant to this subsection shall be sub-  
 10 mitted by electronic means in such format as the Sec-  
 11 retary may require.”.

12          (b) **CONDITIONAL APPROVAL OF NEW ANIMAL**  
 13 **DRUGS FOR MINOR USE AND MINOR SPECIES.**—Section  
 14 571(a) (21 U.S.C. 360ccc(a)) is amended by adding at  
 15 the end the following:

16          “(4) Beginning on October 1, 2018, all applications  
 17 or submissions pursuant to this subsection shall be sub-  
 18 mitted by electronic means in such format as the Sec-  
 19 retary may require.”.

20   **SEC. 302. INDEX OF LEGALLY MARKETED UNAPPROVED**  
 21                                   **NEW ANIMAL DRUGS FOR MINOR SPECIES.**

22          Effective on October 1, 2018, section 572(h) (21  
 23 U.S.C. 360ccc–1(h)) is amended—

24                   (1) by amending paragraph (1) to read as fol-  
 25                   lows:



1           “(1) ‘LEGAL STATUS—In order to be legally  
 2 marketed, a new animal drug intended for a minor  
 3 species must be Approved, Conditionally Approved,  
 4 or Indexed by the Food and Drug Administration.  
 5 THIS PRODUCT IS INDEXED—MIF.’ (followed  
 6 by the applicable minor species index file number  
 7 and a period) ‘Extra-label use is prohibited.’;” and  
 8           (2) in paragraph (2), by striking “other ani-  
 9 mals” and inserting “food-producing animals”.

10 **SEC. 303. MISBRANDED DRUGS AND DEVICES.**

11       (a) IN GENERAL.—Section 502(w) (21 U.S.C.  
 12 352(w)) is amended—

13           (1) in paragraph (1), by striking “; or” and in-  
 14 serting “;”,

15           (2) in paragraph (2), by striking the period and  
 16 inserting “; or”, and

17           (3) by adding at the end the following:

18           “(3) for which an application has been ap-  
 19 proved under section 512 and the labeling of such  
 20 drug does not include the application number in the  
 21 format: ‘Approved by FDA under (A)NADA # xxx-  
 22 xxx’, except that this subparagraph shall not apply  
 23 to representative labeling required under section  
 24 514.1(b)(3)(v)(b) of title 21, Code of Federal Regu-

1       lations (or any successor regulation) for animal feed  
2       bearing or containing a new animal drug.”.

3       (b) **APPLICABILITY.**—Section 502(w)(3) of the Fed-  
4       eral Food, Drug, and Cosmetic Act, as added by sub-  
5       section (a), shall apply beginning on September 30, 2023.

6       **SECTION 1. SHORT TITLE.**

7       *This Act may be cited as the “Animal Drug and Ani-  
8       mal Generic Drug User Fee Amendments of 2018”.*

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

10       (a) *TABLE OF CONTENTS.*—*The table of contents for  
11       this Act is as follows:*

*Sec. 1. Short title.*

*Sec. 2. Table of contents; references in Act.*

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

*Sec. 101. Short title; finding.*

*Sec. 102. Definitions.*

*Sec. 103. Authority to assess and use animal drug fees.*

*Sec. 104. Reauthorization; reporting requirements.*

*Sec. 105. Savings clause.*

*Sec. 106. Effective date.*

*Sec. 107. Sunset dates.*

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

*Sec. 201. Short title; finding.*

*Sec. 202. Authority to assess and use generic new animal drug fees.*

*Sec. 203. Reauthorization; reporting requirements.*

*Sec. 204. Savings clause.*

*Sec. 205. Effective date.*

*Sec. 206. Sunset dates.*

**TITLE III—MISCELLANEOUS PROVISIONS**

*Sec. 301. Electronic submissions.*

*Sec. 302. Index of legally marketed unapproved new animal drugs for minor spe-  
cies.*

*Sec. 303. Misbranded drugs and devices.*

*Sec. 304. Issuance of recommendations.*

*Sec. 305. Guidance addressing investigation designs.*

*Sec. 306. Food additives intended for use in animal food.*

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

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

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

9       (a) *SHORT TITLE.*—*This title may be cited as the*  
10 *“Animal Drug User Fee Amendments of 2018”.*

11       (b) *FINDING.*—*Congress finds that the fees authorized*  
12 *by the amendments made in this title will be dedicated to-*  
13 *ward expediting the animal drug development process and*  
14 *the review of new and supplemental animal drug applica-*  
15 *tions and investigational animal drug submissions as set*  
16 *forth in the goals identified for purposes of part 4 of sub-*  
17 *chapter C of chapter VII of the Federal Food, Drug, and*  
18 *Cosmetic Act, in the letters from the Secretary of Health*  
19 *and Human Services to the Chairman of the Committee on*  
20 *Energy and Commerce of the House of Representatives and*  
21 *the Chairman of the Committee on Health, Education,*  
22 *Labor, and Pensions of the Senate as set forth in the Con-*  
23 *gressional Record.*

24   **SEC. 102. DEFINITIONS.**

25       *Section 739 (21 U.S.C. 379j–11) is amended—*

1           (1) *by amending paragraph (1) to read as fol-*  
2 *lows:*

3           “(1)(A) *The term ‘animal drug application’*  
4 *means—*

5                   “(i) *an application for approval of any new*  
6 *animal drug submitted under section 512(b)(1);*  
7 *or*

8                   “(ii) *an application for conditional ap-*  
9 *proval of a new animal drug submitted under*  
10 *section 571.*

11           “(B) *Such term does not include either a new*  
12 *animal drug application submitted under section*  
13 *512(b)(2) or a supplemental animal drug applica-*  
14 *tion.”; and*

15           (2) *in paragraph (8), by adding at the end the*  
16 *following:*

17                   “(I) *The activities necessary for implemen-*  
18 *tation of the United States and European Union*  
19 *Good Manufacturing Practice Mutual Inspection*  
20 *Agreement with respect to animal drug products*  
21 *subject to review, including implementation ac-*  
22 *tivities prior to and following product ap-*  
23 *proval.”.*

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

2 **FEES.**

3 (a) *FEE REVENUE AMOUNTS.*—Section 740(b) (21  
4 U.S.C. 379j–12(b)) is amended—

5 (1) in paragraph (1)—

6 (A) in subparagraph (A)—

7 (i) by striking “2014” and inserting  
8 “2019”; and

9 (ii) by striking “\$23,600,000” and in-  
10 serting “\$30,331,240”; and

11 (B) in subparagraph (B)—

12 (i) by striking “2015 through 2018”  
13 and inserting “2020 through 2023”; and

14 (ii) by striking “\$21,600,000” and in-  
15 serting “\$29,931,240”; and

16 (2) in paragraph (2), in the matter preceding  
17 subparagraph (A), by striking “determined” and in-  
18 serting “established”.

19 (b) *ANNUAL FEE SETTING; ADJUSTMENTS.*—

20 (1) *INFLATION ADJUSTMENT.*—Section 740(c)(2)  
21 (21 U.S.C. 379j–12(c)(2)) is amended—

22 (A) in the matter preceding subparagraph

23 (A)—

24 (i) by striking “For fiscal year 2015”  
25 and inserting “(A) For fiscal year 2020”;

26 and

1                   (ii) by inserting “multiplying such  
2                   revenue amounts by” before “an amount”;

3                   (B) by redesignating subparagraphs (A),  
4                   (B), and (C) as clauses (i), (ii), and (iii), respec-  
5                   tively;

6                   (C) by striking the flush text at the end;  
7                   and

8                   (D) by adding at the end the following new  
9                   subparagraph:

10                  “(B) *COMPOUNDED BASIS.*—The adjustment  
11                  made each fiscal year after fiscal year 2020 under  
12                  this paragraph shall be applied on a compounded  
13                  basis to the revenue amount calculated under this  
14                  paragraph for the most recent previous fiscal year.”.

15                  (2) *WORKLOAD ADJUSTMENTS.*—Paragraph (3)  
16                  of section 740(c) (21 U.S.C. 379j–12(c)) is amended  
17                  to read as follows:

18                  “(3) *WORKLOAD ADJUSTMENTS.*—

19                  “(A) *IN GENERAL.*—For fiscal year 2020  
20                  and subsequent fiscal years, after the fee revenue  
21                  amounts established under subsection (b) are ad-  
22                  justed for inflation in accordance with para-  
23                  graph (2), the fee revenue amounts shall be fur-  
24                  ther adjusted for such fiscal year to reflect  
25                  changes in the workload of the Secretary for the

1 process for the review of animal drug applica-  
2 tions, subject to subparagraphs (B) and (C).

3 With respect to such adjustment—

4 “(i) such adjustment shall be deter-  
5 mined by the Secretary based on a weighted  
6 average of the change in the total number of  
7 animal drug applications, supplemental  
8 animal drug applications for which data  
9 with respect to safety or effectiveness are re-  
10 quired, manufacturing supplemental ani-  
11 mal drug applications, investigational ani-  
12 mal drug study submissions, and investiga-  
13 tional animal drug protocol submissions  
14 submitted to the Secretary; and

15 “(ii) the Secretary shall publish in the  
16 Federal Register the fees resulting from such  
17 adjustment and the supporting methodolo-  
18 gies.

19 “(B) REDUCTION OF WORKLOAD-BASED IN-  
20 CREASE BY AMOUNT OF CERTAIN EXCESS COL-  
21 LECTIONS.—For each of fiscal years 2021  
22 through 2023, if application of the workload ad-  
23 justment under subparagraph (A) increases the  
24 fee revenue amounts otherwise established for the  
25 fiscal year under subsection (b), as adjusted for

1           inflation under paragraph (2), such fee revenue  
 2           increase shall be reduced by the amount of any  
 3           excess collections, as described in subsection  
 4           (g)(4), for the second preceding fiscal year, up to  
 5           the amount of such fee revenue increase.

6           “(C) *RULE OF APPLICATION.*—Under no  
 7           circumstances shall the workload adjustments  
 8           under this paragraph result in fee revenues for  
 9           a fiscal year that are less than the fee revenues  
 10          for that fiscal year established under subsection  
 11          (b), as adjusted for inflation under paragraph  
 12          (2).”.

13          (3) *FINAL YEAR ADJUSTMENT.*—Section  
 14          740(c)(4) (21 U.S.C. 379j–12(c)(4)) is amended—

15                (A) by striking “2018” each place it ap-  
 16                pears and inserting “2023”; and

17                (B) by striking “2019” and inserting  
 18                “2024”.

19          (c) *EXEMPTIONS FROM FEES.*—Section 740(d) (21  
 20          U.S.C. 379j–12(d)) is amended—

21                (1) in the subsection heading, by inserting “;  
 22                *EXEMPTIONS FROM FEES*” after “*REDUCTION*”;

23                (2) by striking the heading of paragraph (1) and  
 24                inserting “*WAIVER OR REDUCTION*”; and

25                (3) by adding at the end the following:



1           “(4) *EXEMPTIONS FROM FEES.*—

2                   “(A) *CERTAIN LABELING SUPPLEMENTS TO*  
3 *ADD NUMBER OF APPROVED APPLICATION.*—*Fees*  
4 *under this section shall not apply with respect to*  
5 *any person who—*

6                           “(i) *not later than September 30, 2023,*  
7 *submits a supplemental animal drug appli-*  
8 *cation relating to a new animal drug appli-*  
9 *cation approved under section 512, solely to*  
10 *add the new animal drug application num-*  
11 *ber to the labeling of the drug in the man-*  
12 *ner specified in section 502(w)(3); and*

13                           “(ii) *otherwise would be subject to fees*  
14 *under this section solely on the basis of such*  
15 *supplemental application.*

16                   “(B) *CERTAIN ANIMAL DRUG APPLICA-*  
17 *TIONS.*—*Fees under paragraphs (2), (3), and (4)*  
18 *of subsection (a) shall not apply with respect to*  
19 *any person who is the named applicant or spon-*  
20 *sor of an animal drug application, supplemental*  
21 *animal drug application, or investigational ani-*  
22 *mal drug submission if such application or sub-*  
23 *mission involves the intentional genomic alter-*  
24 *ation of an animal that is intended to produce*

1           *a drug, device, or biological product subject to*  
 2           *fees under section 736, 738, 744B, or 744H.”.*

3           *(d) CREDITING AND AVAILABILITY OF FEES.—*

4           *(1) AUTHORIZATION OF APPROPRIATIONS.—Section*  
 5           *740(g)(3) (21 U.S.C. 379j–12(g)(3)) is amend-*  
 6           *ed—*

7                   *(A) by striking “2014 through 2018” and*  
 8                   *inserting “2019 through 2023”;*

9                   *(B) by striking “determined” and inserting*  
 10                   *“established”; and*

11                   *(C) by striking “paragraph (4)” and insert-*  
 12                   *ing “paragraph (5)”.*

13           *(2) EXCESS COLLECTIONS.—Section 740(g) (21*  
 14           *U.S.C. 379j–12(g)) is amended by striking paragraph*  
 15           *(4) and inserting the following:*

16                   *“(4) EXCESS COLLECTIONS.—If the sum total of*  
 17                   *fees collected under this section for a fiscal year ex-*  
 18                   *ceeds the amount of fees authorized to be appropriated*  
 19                   *for such year under paragraph (3), the excess collec-*  
 20                   *tions shall be credited to the appropriations account*  
 21                   *of the Food and Drug Administration as provided in*  
 22                   *paragraph (1).*

23           *“(5) RECOVERY OF COLLECTION SHORTFALLS.—*

24                   *“(A) IN GENERAL.—Subject to subpara-*  
 25                   *graph (B)—*

1           “(i) for fiscal year 2021, the amount of  
2           fees otherwise authorized to be collected  
3           under this section shall be increased by the  
4           amount, if any, by which the amount col-  
5           lected under this section and appropriated  
6           for fiscal year 2019 falls below the amount  
7           of fees authorized for fiscal year 2019 under  
8           paragraph (3);

9           “(ii) for fiscal year 2022, the amount  
10          of fees otherwise authorized to be collected  
11          under this section shall be increased by the  
12          amount, if any, by which the amount col-  
13          lected under this section and appropriated  
14          for fiscal year 2020 falls below the amount  
15          of fees authorized for fiscal year 2020 under  
16          paragraph (3); and

17          “(iii) for fiscal year 2023, the amount  
18          of fees otherwise authorized to be collected  
19          under this section shall be increased by the  
20          cumulative amount, if any, by which the  
21          amount collected under this section and ap-  
22          propriated for fiscal years 2021 and 2022  
23          (including estimated collections for fiscal  
24          year 2022) falls below the cumulative

1           *amount of fees authorized for such fiscal*  
2           *years under paragraph (3).*

3           “(B) *REDUCTION OF SHORTFALL-BASED*  
4           *FEE INCREASE BY PRIOR YEAR EXCESS COLLEC-*  
5           *TIONS.—*

6                   “(i) *IN GENERAL.—Subject to clause*  
7                   *(ii), the Secretary shall, in such manner as*  
8                   *the Secretary determines appropriate, re-*  
9                   *duce any fee increase otherwise applicable*  
10                  *for a fiscal year under subparagraph (A) by*  
11                  *the amount of any excess collections under*  
12                  *this section for preceding fiscal years (after*  
13                  *fiscal year 2018).*

14                   “(ii) *WORKLOAD-BASED FEE ACCOUNT-*  
15                   *ING.—In applying clause (i), the Secretary*  
16                   *shall account for the reduction of workload-*  
17                   *based fee revenue increases by excess collec-*  
18                   *tions under subsection (c)(3)(B), in such*  
19                   *manner as needed to provide that no por-*  
20                   *tion of any excess collections described in*  
21                   *clause (i) is applied for purposes of reduc-*  
22                   *ing fee increases under both such subsection*  
23                   *(c)(3)(B) and this paragraph.*

24                   “(C) *RULE OF APPLICATION.—Under no*  
25                   *circumstances shall adjustments under this para-*

1           *graph result in fee revenues for a fiscal year that*  
2           *are less than the fee revenues for that fiscal year*  
3           *established in subsection (b), as adjusted or oth-*  
4           *erwise affected under subsection (c).”.*

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

6           *Section 740A (21 U.S.C. 379j–13) is amended—*

7           (1) *in subsection (a), by striking “2013” and in-*  
8           *serting “2018”;*

9           (2) *by striking “2014” each place it appears in*  
10          *subsections (a) and (b) and inserting “2019”; and*

11          (3) *in subsection (d), by striking “2018” each*  
12          *place it appears and inserting “2023”.*

13 **SEC. 105. SAVINGS CLAUSE.**

14          *Notwithstanding the amendments made by this title,*  
15          *part 4 of subchapter C of chapter VII of the Federal Food,*  
16          *Drug, and Cosmetic Act (21 U.S.C. 379j–11 et seq.), as in*  
17          *effect on the day before the date of enactment of this title,*  
18          *shall continue to be in effect with respect to animal drug*  
19          *applications and supplemental animal drug applications*  
20          *(as defined in such part as of such day) that on or after*  
21          *October 1, 2013, but before October 1, 2018, were accepted*  
22          *by the Food and Drug Administration for filing with re-*  
23          *spect to assessing and collecting any fee required by such*  
24          *part for a fiscal year prior to fiscal year 2019.*

1 **SEC. 106. EFFECTIVE DATE.**

2       *The amendments made by this title shall take effect*  
 3 *on October 1, 2018, or the date of the enactment of this*  
 4 *Act, whichever is later, except that fees under part 4 of sub-*  
 5 *chapter C of chapter VII of the Federal Food, Drug, and*  
 6 *Cosmetic Act, as amended by this title, shall be assessed for*  
 7 *animal drug applications and supplemental animal drug*  
 8 *applications received on or after October 1, 2018, regardless*  
 9 *of the date of the enactment of this Act.*

10 **SEC. 107. SUNSET DATES.**

11       *(a) AUTHORIZATION.—Section 740 of the Federal*  
 12 *Food, Drug, and Cosmetic Act (21 U.S.C. 379j–12) shall*  
 13 *cease to be effective October 1, 2023.*

14       *(b) REPORTING REQUIREMENTS.—Section 740A of the*  
 15 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–*  
 16 *13) shall cease to be effective January 31, 2024.*

17       *(c) PREVIOUS SUNSET PROVISION.—Effective October*  
 18 *1, 2018, subsections (a) and (b) of section 107 of the Animal*  
 19 *Drug User Fee Amendments of 2013 (Public Law 113–14)*  
 20 *are repealed.*

21       **TITLE II—FEES RELATING TO**  
 22       **GENERIC ANIMAL DRUGS**

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

24       *(a) SHORT TITLE.—This title may be cited as the*  
 25 *“Animal Generic Drug User Fee Amendments of 2018”.*

1           (b) *FINDING.*—Congress finds that the fees authorized  
2 by the amendments made in this title will be dedicated to-  
3 ward expediting the generic new animal drug development  
4 process and the review of abbreviated applications for ge-  
5 neric new animal drugs, supplemental abbreviated applica-  
6 tions for generic new animal drugs, and investigational  
7 submissions for generic new animal drugs as set forth in  
8 the goals identified for purposes of part 5 of subchapter C  
9 of chapter VII of the Federal Food, Drug, and Cosmetic Act,  
10 in the letters from the Secretary of Health and Human  
11 Services to the Chairman of the Committee on Energy and  
12 Commerce of the House of Representatives and the Chair-  
13 man of the Committee on Health, Education, Labor, and  
14 Pensions of the Senate as set forth in the Congressional  
15 Record.

16 **SEC. 202. AUTHORITY TO ASSESS AND USE GENERIC NEW**  
17 **ANIMAL DRUG FEES.**

18           (a) *FEE REVENUE AMOUNTS.*—Subsection (b) of sec-  
19 tion 741 (21 U.S.C. 379j–21) is amended to read as follows:

20           “(b) *FEE REVENUE AMOUNTS.*—

21                   “(1) *IN GENERAL.*—Subject to subsections (c),  
22 (d), (f), and (g), for each of fiscal years 2019 through  
23 2023, the fees required under subsection (a) shall be  
24 established to generate a total revenue amount of  
25 \$18,336,340.

1           “(2) *TYPES OF FEES.*—Of the total revenue  
2           *amount established for a fiscal year under paragraph*  
3           *(1)—*

4                   “(A) *25 percent shall be derived from fees*  
5                   *under subsection (a)(1) (relating to abbreviated*  
6                   *applications for a generic new animal drug);*

7                   “(B) *37.5 percent shall be derived from fees*  
8                   *under subsection (a)(2) (relating to generic new*  
9                   *animal drug products); and*

10                   “(C) *37.5 percent shall be derived from fees*  
11                   *under subsection (a)(3) (relating to generic new*  
12                   *animal drug sponsors).”.*

13           **(b) ANNUAL FEE SETTING; ADJUSTMENTS.**—

14                   **(1) INFLATION ADJUSTMENT.**—Section 741(c)  
15                   *(21 U.S.C. 379j–21(c)) is amended—*

16                           (A) *by redesignating paragraphs (2)*  
17                           *through (4) as paragraphs (3) through (5), re-*  
18                           *spectively; and*

19                           (B) *by inserting after paragraph (1) the fol-*  
20                           *lowing:*

21                   **“(2) INFLATION ADJUSTMENT.**—

22                           “(A) *IN GENERAL.*—*For fiscal year 2020*  
23                           *and subsequent fiscal years, the revenue amounts*  
24                           *established under subsection (b) shall be adjusted*  
25                           *by the Secretary by notice, published in the Fed-*



1            *eral Register, for a fiscal year, by multiplying*  
2            *such revenue amounts by an amount equal to the*  
3            *sum of—*

4                    *“(i) one;*

5                    *“(ii) the average annual percent*  
6                    *change in the cost, per full-time equivalent*  
7                    *position of the Food and Drug Administra-*  
8                    *tion, of all personnel compensation and ben-*  
9                    *efits paid with respect to such positions for*  
10                   *the first 3 of the preceding 4 fiscal years for*  
11                   *which data are available, multiplied by the*  
12                   *average proportion of personnel compensa-*  
13                   *tion and benefits costs to total Food and*  
14                   *Drug Administration costs for the first 3 of*  
15                   *the preceding 4 fiscal years for which data*  
16                   *are available; and*

17                   *“(iii) the average annual percent*  
18                   *change that occurred in the Consumer Price*  
19                   *Index for urban consumers (Washington-*  
20                   *Baltimore, DC–MD–VA–WV; not seasonally*  
21                   *adjusted; all items less food and energy; an-*  
22                   *annual index) for the first 3 of the preceding*  
23                   *4 years for which data are available multi-*  
24                   *plied by the average proportion of all costs*  
25                   *other than personnel compensation and ben-*

1            *efits costs to total Food and Drug Adminis-*  
2            *tration costs for the first 3 years of the pre-*  
3            *ceding 4 fiscal years for which data are*  
4            *available.*

5            *“(B) COMPOUNDED BASIS.—The adjustment*  
6            *made each fiscal year after fiscal year 2020*  
7            *under this paragraph shall be applied on a com-*  
8            *pounded basis to the revenue amount calculated*  
9            *under this paragraph for the most recent pre-*  
10           *vious fiscal year.”.*

11           *(2) WORKLOAD ADJUSTMENTS.—Paragraph (3)*  
12           *of section 741(c) (21 U.S.C. 379j–21(c)), as redesign-*  
13           *ated, is amended to read as follows:*

14           *“(3) WORKLOAD ADJUSTMENTS.—*

15           *“(A) IN GENERAL.—For fiscal year 2020*  
16           *and subsequent fiscal years, after the fee revenue*  
17           *amounts established under subsection (b) are ad-*  
18           *justed for inflation in accordance with para-*  
19           *graph (2), the fee revenue amounts shall be fur-*  
20           *ther adjusted for each such fiscal year to reflect*  
21           *changes in the workload of the Secretary for the*  
22           *process for the review of abbreviated applications*  
23           *for generic new animal drugs, subject to sub-*  
24           *paragraphs (B) and (C). With respect to such*  
25           *adjustment—*

1           “(i) this adjustment shall be deter-  
2           mined by the Secretary based on a weighted  
3           average of the change in the total number of  
4           abbreviated applications for generic new  
5           animal drugs, manufacturing supplemental  
6           abbreviated applications for generic new  
7           animal drugs, investigational generic new  
8           animal drug study submissions, and inves-  
9           tigational generic new animal drug protocol  
10          submissions submitted to the Secretary; and

11           “(ii) the Secretary shall publish in the  
12          *Federal Register* the fees resulting from this  
13          adjustment and the supporting methodolo-  
14          gies.

15          “(B) *REDUCTION OF WORKLOAD-BASED IN-*  
16          *CREASE BY AMOUNT OF CERTAIN EXCESS COL-*  
17          *LECTIONS.—For each of fiscal years 2021*  
18          *through 2023, if application of the workload ad-*  
19          *justment under subparagraph (A) increases the*  
20          *fee revenue amounts otherwise established for the*  
21          *fiscal year under subsection (b), as adjusted for*  
22          *inflation under paragraph (2), such fee revenue*  
23          *increase shall be reduced by the amount of any*  
24          *excess collections, as described in subsection*

1           (g)(4), for the second preceding fiscal year, up to  
2           the amount of such fee revenue increase.

3           “(C) *RULE OF APPLICATION.*—Under no  
4           circumstances shall workload adjustments under  
5           this paragraph result in fee revenues for a fiscal  
6           year that are less than the fee revenues for that  
7           fiscal year established under subsection (b), as  
8           adjusted for inflation under paragraph (2).”.

9           (3) *FINAL YEAR ADJUSTMENT.*—Paragraph (4)  
10          of section 741(c) (21 U.S.C. 379j–21(c)), as redesign-  
11          ated, is amended by—

12                 (A) striking “2018” each place it appears  
13                 and inserting “2023”; and

14                 (B) striking “2019” and inserting “2024”.

15          (c) *FEE WAIVER OR REDUCTION; EXEMPTION FROM*  
16          *FEEES.*—Subsection (d) of section 741 (21 U.S.C. 379j–21)  
17          is amended to read as follows:

18                 “(d) *FEE WAIVER OR REDUCTION; EXEMPTION FROM*  
19          *FEEES.*—

20                 “(1) *FEE WAIVER OR REDUCTION.*—The Sec-  
21                 retary shall grant a waiver from or a reduction of 1  
22                 or more fees assessed under subsection (a) where the  
23                 Secretary finds that the generic new animal drug is  
24                 intended solely to provide for a minor use or minor  
25                 species indication.

1           “(2) *EXEMPTION FROM FEES.*—Fees under this  
2 section shall not apply with respect to any person  
3 who—

4                   “(A) not later than September 30, 2023,  
5 submits a supplemental abbreviated application  
6 for a generic new animal drug approved under  
7 section 512, solely to add the application number  
8 to the labeling of the drug in the manner speci-  
9 fied in section 502(w)(3); and

10                   “(B) otherwise would be subject to fees  
11 under this section solely on the basis of such sup-  
12 plemental abbreviated application.”.

13           (d) *CREDITING AND AVAILABILITY OF FEES.*—Section  
14 741(g) (21 U.S.C. 379j–21) is amended by striking para-  
15 graph (3) and inserting the following paragraphs:

16                   “(3) *AUTHORIZATION OF APPROPRIATIONS.*—For  
17 each of the fiscal years 2019 through 2023, there is  
18 authorized to be appropriated for fees under this sec-  
19 tion an amount equal to the total revenue amount es-  
20 tablished under subsection (b) for the fiscal year, as  
21 adjusted or otherwise affected under subsection (c).

22                   “(4) *EXCESS COLLECTIONS.*—If the sum total of  
23 fees collected under this section for a fiscal year ex-  
24 ceeds the amount of fees authorized to be appropriated  
25 for such year under paragraph (3), the excess collec-

1        *tions shall be credited to the appropriations account*  
2        *of the Food and Drug Administration as provided in*  
3        *paragraph (1).”.*

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

5        *Section 742 (21 U.S.C. 379j–22) is amended—*

6                *(1) in subsection (a), by striking “2013” and in-*  
7                *serting “2018”;*

8                *(2) by striking “2014” each place it appears in*  
9                *subsections (a) and (b) and inserting “2019”; and*

10                *(3) in subsection (d), by striking “2018” each*  
11                *place it appears and inserting “2023”.*

12        **SEC. 204. SAVINGS CLAUSE.**

13        *Notwithstanding the amendments made by this title,*  
14        *part 5 of subchapter C of chapter VII of the Federal Food,*  
15        *Drug, and Cosmetic Act (21 U.S.C. 379j–21 et seq.), as in*  
16        *effect on the day before the date of enactment of this title,*  
17        *shall continue to be in effect with respect to abbreviated ap-*  
18        *plications for a generic new animal drug and supplemental*  
19        *abbreviated applications for a generic new animal drug (as*  
20        *defined in such part as of such day) that on or after October*  
21        *1, 2013, but before October 1, 2018, were accepted by the*  
22        *Food and Drug Administration for filing with respect to*  
23        *assessing and collecting any fee required by such part for*  
24        *a fiscal year prior to fiscal year 2019.*

1 **SEC. 205. EFFECTIVE DATE.**

2       *The amendments made by this title shall take effect*  
 3 *on October 1, 2018, or the date of the enactment of this*  
 4 *Act, whichever is later, except that fees under part 5 of sub-*  
 5 *chapter C of chapter VII of the Federal Food, Drug, and*  
 6 *Cosmetic Act, as amended by this title, shall be assessed for*  
 7 *abbreviated applications for a generic new animal drug and*  
 8 *supplemental abbreviated applications for a generic new*  
 9 *animal drug received on or after October 1, 2018, regardless*  
 10 *of the date of enactment of this Act.*

11 **SEC. 206. SUNSET DATES.**

12       *(a) AUTHORIZATION.—Section 741 of the Federal*  
 13 *Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21) shall*  
 14 *cease to be effective October 1, 2023.*

15       *(b) REPORTING REQUIREMENTS.—Section 742 of the*  
 16 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–*  
 17 *22) shall cease to be effective January 31, 2024.*

18       *(c) PREVIOUS SUNSET PROVISION.—Effective October*  
 19 *1, 2018, subsections (a) and (b) of section 206 of the Animal*  
 20 *Generic Drug User Fee Amendments of 2013 (Public Law*  
 21 *113–14) are repealed.*

22       **TITLE III—MISCELLANEOUS**  
 23       **PROVISIONS**

24 **SEC. 301. ELECTRONIC SUBMISSIONS.**

25       *(a) NEW ANIMAL DRUG APPLICATIONS AND ABBRE-*  
 26 *VIATED APPLICATIONS FOR A GENERIC NEW ANIMAL*

1 *DRUG.—Section 512(b) (21 U.S.C. 360b(b)) is amended by*  
 2 *adding at the end the following:*

3 “(4) *Beginning on October 1, 2018, all applications*  
 4 *or submissions pursuant to this subsection shall be sub-*  
 5 *mitted by electronic means in such format as the Secretary*  
 6 *may require.”.*

7 (b) *CONDITIONAL APPROVAL OF NEW ANIMAL DRUGS*  
 8 *FOR MINOR USE AND MINOR SPECIES.—Section 571(a) (21*  
 9 *U.S.C. 360ccc(a)) is amended by adding at the end the fol-*  
 10 *lowing:*

11 “(4) *Beginning on October 1, 2018, all applications*  
 12 *or submissions pursuant to this subsection shall be sub-*  
 13 *mitted by electronic means in such format as the Secretary*  
 14 *may require.”.*

15 **SEC. 302. INDEX OF LEGALLY MARKETED UNAPPROVED**  
 16 **NEW ANIMAL DRUGS FOR MINOR SPECIES.**

17 *Effective on October 1, 2018, section 572(h) (21 U.S.C.*  
 18 *360ccc–1(h)) is amended—*

19 (1) *by amending paragraph (1) to read as fol-*  
 20 *lows:*

21 “(1) ‘*LEGAL STATUS—In order to be legally*  
 22 *marketed, a new animal drug intended for a minor*  
 23 *species must be Approved, Conditionally Approved, or*  
 24 *Indexed by the Food and Drug Administration. THIS*  
 25 *PRODUCT IS INDEXED—MIF.’ (followed by the*



1 applicable minor species index file number and a pe-  
2 riod) ‘Extra-label use is prohibited.’;’; and

3 (2) in paragraph (2), by striking “other ani-  
4 mals” and inserting “food-producing animals”.

5 **SEC. 303. MISBRANDED DRUGS AND DEVICES.**

6 (a) *IN GENERAL.*—Section 502(w) (21 U.S.C. 352(w))  
7 is amended—

8 (1) in paragraph (1), by striking “; or” and in-  
9 serting “;”;

10 (2) in paragraph (2), by striking the period and  
11 inserting “; or”; and

12 (3) by adding at the end the following:

13 “(3) for which an application has been approved  
14 under section 512 and the labeling of such drug does  
15 not include the application number in the format:  
16 ‘Approved by FDA under (A)NADA # xxx-xxx’, ex-  
17 cept that this subparagraph shall not apply to rep-  
18 resentative labeling required under section  
19 514.1(b)(3)(v)(b) of title 21, Code of Federal Regula-  
20 tions (or any successor regulation) for animal feed  
21 bearing or containing a new animal drug.”.

22 (b) *APPLICABILITY.*—Section 502(w)(3) of the Federal  
23 Food, Drug, and Cosmetic Act, as added by subsection (a),  
24 shall apply beginning on September 30, 2023.

1 **SEC. 304. ISSUANCE OF RECOMMENDATIONS.**

2 *Not later than September 30, 2019, the Secretary of*  
3 *Health and Human Services (referred to in this section as*  
4 *the “Secretary”)* shall issue recommendations that the Sec-  
5 *retary, in the letters described in section 101(b) of the Ani-*  
6 *mal Drug User Fee Amendments of 2013 (Public Law 113–*  
7 *14), agreed to develop regarding the feasibility of pursuing*  
8 *statutory revisions that may expand the use of conditional*  
9 *approval of new animal drugs under section 571 of the Fed-*  
10 *eral Food, Drug, and Cosmetic Act (21 U.S.C. 360ccc) to*  
11 *appropriate categories of new animal drugs.*

12 **SEC. 305. GUIDANCE ADDRESSING INVESTIGATION DE-**  
13 **SIGNS.**

14 *(a) IN GENERAL.—For purposes of assisting sponsors*  
15 *in incorporating complex adaptive and other novel inves-*  
16 *tigation designs, data from foreign countries, real world*  
17 *evidence (including ongoing surveillance activities, observa-*  
18 *tional studies, and registry data), biomarkers, and surro-*  
19 *gate endpoints (referred to in this section as “elements of*  
20 *investigations”)* into proposed clinical investigation proto-  
21 *cols and applications for new animal drugs under sections*  
22 *512 and 571 of the Federal Food, Drug, and Cosmetic Act*  
23 *(21 U.S.C. 360b; 360ccc), the Secretary of Health and*  
24 *Human Services (referred to in this section as the “Sec-*  
25 *retary”)* shall issue guidance addressing the use of such ele-

1 *ments of investigations in the development and regulatory*  
2 *review of such new animal drugs.*

3       **(b) CONTENTS.**—*The guidance under subsection (a)*  
4 *shall address how the Secretary will evaluate the elements*  
5 *of investigations proposed or submitted pursuant to section*  
6 *512(b)(1)(A) of the Federal Food, Drug, and Cosmetic Act*  
7 *or to meet the commitment under section 571(a)(2)(F) of*  
8 *such Act, and how sponsors of such applications may obtain*  
9 *feedback from the Secretary on technical issues related to*  
10 *such investigations prior to the submission of an applica-*  
11 *tion to the Secretary.*

12       **(c) MEETING.**—*Prior to issuing the guidance under*  
13 *subsection (a), the Secretary shall consult with stakeholders,*  
14 *including representatives of regulated industry, consumer*  
15 *groups, academia, veterinarians, and food producers,*  
16 *through a public meeting to be held not later than 1 year*  
17 *after the date of enactment of this Act.*

18       **(d) TIMING.**—*The Secretary shall issue a draft guid-*  
19 *ance under subsection (a) not later than 1 year after the*  
20 *date of the public meeting under subsection (c), and shall*  
21 *finalize such guidance not later than 1 year after the date*  
22 *on which the public comment period on such draft guidance*  
23 *ends.*

1 **SEC. 306. FOOD ADDITIVES INTENDED FOR USE IN ANIMAL**  
2 **FOOD.**

3 (a) *FOOD ADDITIVE PETITIONS FOR ANIMAL FOOD.*—  
4 *Section 409 of the Federal Food, Drug, and Cosmetic Act*  
5 *(21 U.S.C. 348) is amended by adding at the end the fol-*  
6 *lowing:*

7 “(k) *FOOD ADDITIVES INTENDED FOR USE IN ANIMAL*  
8 *FOOD.*—(1) *In taking action on a petition under subsection*  
9 *(c) for, or for recognition of, a food additive intended for*  
10 *use in animal food, the Secretary shall review reports of*  
11 *investigations conducted in foreign countries, provided by*  
12 *the petitioner.*

13 “(2) *The Secretary shall post on the internet website*  
14 *of the Food and Drug Administration, no later than March*  
15 *1 of each year, on—*

16 “(A) *the number of petitions for food additives*  
17 *intended for use in animal food filed under subsection*  
18 *(b) that are pending;*

19 “(B) *how long each such petition submitted*  
20 *under subsection (b) has been pending, including such*  
21 *petitions the Secretary has extended under subsection*  
22 *(c)(2); and*

23 “(C) *the number of study protocols that have*  
24 *been pending review for over 50 days, and the number*  
25 *that have received an extension.*

1       “(3) *In the case of a food additive petition intended*  
 2 *for use in animal food, the Secretary shall provide informa-*  
 3 *tion to the petitioner on the required contents of such peti-*  
 4 *tion. If the Secretary requires additional studies beyond*  
 5 *what the petitioner proposed, the Secretary shall provide*  
 6 *the scientific rationale for such requirement.”.*

7       (b) *ENSURING THE SAFETY OF PET FOOD.—Section*  
 8 *1002(a) of the Food and Drug Administration Amendments*  
 9 *Act of 2007 (21 U.S.C. 2102(a)) is amended—*

10           (1) *by striking paragraph (1); and*

11           (2) *by redesignating paragraphs (2) and (3) as*  
 12 *paragraphs (1) and (2), respectively.*

13       (c) *GUIDANCE ON PRE-PETITION CONSULTATION*  
 14 *PROCESS FOR ANIMAL FOOD ADDITIVES.—*

15           (1) *IN GENERAL.—Not later than 18 months*  
 16 *after the date of enactment of this Act, the Secretary*  
 17 *of Health and Human Services (referred to in this*  
 18 *subsection as the “Secretary”) shall publish draft*  
 19 *guidance relating to the voluntary pre-petition con-*  
 20 *sultation process for food additives intended for use in*  
 21 *animal food.*

22           (2) *CONTENTS.—The guidance under paragraph*  
 23 *(1) shall include—*

24           (A) *the recommended format to submit to*  
 25 *the Food and Drug Administration existing*

1           *data, including any applicable foreign data, for*  
2           *assessment prior to submission of a food additive*  
3           *petition for animal food under section 409(b) of*  
4           *the Federal Food, Drug, and Cosmetic Act;*

5                     *(B) the manner and the number of days by*  
6           *which the Food and Drug Administration in-*  
7           *tends to review and respond to such existing*  
8           *data, including with respect to providing a sci-*  
9           *entific rationale for any additional data request;*

10                    *(C) circumstances under which the submis-*  
11           *sion of study protocols is recommended prior to*  
12           *submission of a food additive petition under such*  
13           *section 409(b);*

14                    *(D) the manner in which the Secretary in-*  
15           *tends to inform the person submitting a study*  
16           *protocol for a food additive if the review of such*  
17           *study protocol will take longer than 50 days; and*

18                    *(E) best practices for communication be-*  
19           *tween the Food and Drug Administration and*  
20           *industry on the development of pre-petition sub-*  
21           *missions of study protocols and existing data for*  
22           *food additives.*

23                    *(3) FINAL GUIDANCE.—The guidance under*  
24           *paragraph (1) shall be finalized, withdrawn, or re-*

- 1 *issued not later than 1 year after the close of the com-*
- 2 *ment period on the draft guidance.*

**Calendar No. 341**

115<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

**S. 2434**

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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 and generic new animal drugs.

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MARCH 7, 2018

Reported with an amendment