

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

# H. R. 5554

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## AN ACT

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

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

1 **SECTION 1. SHORT TITLE.**

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

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

5       (a) TABLE OF CONTENTS.—The table of contents for  
6 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.

Sec. 304. Conditional approval of new animal drugs.

Sec. 305. Guidance addressing investigation designs.

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

7       (b) REFERENCES IN ACT.—Except as otherwise spec-  
8 ified, amendments made by this Act to a section or other  
9 provision of law are amendments to such section or other  
10 provision of the Federal Food, Drug, and Cosmetic Act  
11 (21 U.S.C. 301 et seq.).

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

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

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

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

19   **SEC. 102. DEFINITIONS.**

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

21           (1) by amending paragraph (1) to read as fol-  
22 lows:

23           “(1)(A) The term ‘animal drug application’  
24 means—

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

4 “(ii) an application for conditional ap-  
5 proval of a new animal drug submitted under  
6 section 571.

7 “(B) Such term does not include either a new  
8 animal drug application submitted under section  
9 512(b)(2) or a supplemental animal drug applica-  
10 tion.”; and

11 (2) in paragraph (8), by adding at the end the  
12 following:

13 “(I) The activities necessary for implemen-  
14 tation of the United States and European  
15 Union Good Manufacturing Practice Mutual In-  
16 spection Agreement with respect to animal drug  
17 products subject to review, including implemen-  
18 tation activities prior to and following product  
19 approval.”.

20 **SEC. 103. AUTHORITY TO ASSESS AND USE ANIMAL DRUG**  
21 **FEEES.**

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

24 (1) in paragraph (1)—

25 (A) in subparagraph (A)—

1 (i) by striking “2014” and inserting  
2 “2019”; and

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

5 (B) in subparagraph (B)—

6 (i) by striking “2015 through 2018”  
7 and inserting “2020 through 2023”; and

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

10 (2) in paragraph (2), in the matter preceding  
11 subparagraph (A), by striking “determined” and in-  
12 serting “established”.

13 (b) ANNUAL FEE SETTING; ADJUSTMENTS.—

14 (1) INFLATION ADJUSTMENT.—Section  
15 740(c)(2) (21 U.S.C. 379j–12(c)(2)) is amended—

16 (A) in the matter preceding subparagraph  
17 (A)—

18 (i) by striking “For fiscal year 2015”  
19 and inserting “(A) For fiscal year 2020”;  
20 and

21 (ii) by inserting “multiplying such  
22 revenue amounts by” before “an amount”;

23 (B) by redesignating subparagraphs (A),  
24 (B), and (C) as clauses (i), (ii), and (iii), re-  
25 spectively;

1 (C) by striking the flush text at the end;  
2 and

3 (D) by adding at the end the following new  
4 subparagraph:

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

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

13 “(3) WORKLOAD ADJUSTMENTS.—

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

23 With respect to such adjustment—

24 “(i) such adjustment shall be deter-  
25 mined by the Secretary based on a weight-

1 ed average of the change in the total num-  
2 ber of animal drug applications, supple-  
3 mental animal drug applications for which  
4 data with respect to safety or effectiveness  
5 are required, manufacturing supplemental  
6 animal drug applications, investigational  
7 animal drug study submissions, and inves-  
8 tigational animal drug protocol submis-  
9 sions submitted to the Secretary; and

10 “(ii) the Secretary shall publish in the  
11 Federal Register the fees resulting from  
12 such adjustment and the supporting meth-  
13 odologies.

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

1 year, up to the amount of such fee revenue in-  
2 crease.

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

10 (3) FINAL YEAR ADJUSTMENT.—Section  
11 740(c)(4) (21 U.S.C. 379j–12(c)(4)) is amended—

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

14 (B) by striking “2019” and inserting  
15 “2024”.

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

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

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

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

23 “(4) EXEMPTIONS FROM FEES.—

24 “(A) CERTAIN LABELING SUPPLEMENTS  
25 TO ADD NUMBER OF APPROVED APPLICA-



1 TION.—Fees under this section shall not apply  
2 with respect to any person who—

3 “(i) not later than September 30,  
4 2023, submits a supplemental animal drug  
5 application relating to a new animal drug  
6 application approved under section 512,  
7 solely to add the new animal drug applica-  
8 tion number to the labeling of the drug in  
9 the manner specified in section 502(w)(3);  
10 and

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

14 “(B) CERTAIN ANIMAL DRUG APPLICA-  
15 TIONS.—Fees under paragraphs (2), (3), and  
16 (4) of subsection (a) shall not apply with re-  
17 spect to any person who is the named applicant  
18 or sponsor of an animal drug application, sup-  
19 plemental animal drug application, or investiga-  
20 tional animal drug submission if such applica-  
21 tion or submission involves the intentional  
22 genomic alteration of an animal that is in-  
23 tended to produce a drug, device, or biological  
24 product subject to fees under section 736, 738,  
25 744B, or 744H.”.

1 (d) CREDITING AND AVAILABILITY OF FEES.—

2 (1) AUTHORIZATION OF APPROPRIATIONS.—

3 Section 740(g)(3) (21 U.S.C. 379j–12(g)(3)) is  
4 amended—

5 (A) by striking “2014 through 2018” and  
6 inserting “2019 through 2023”;

7 (B) by striking “determined” and inserting  
8 “established”; and

9 (C) by striking “paragraph (4)” and in-  
10 sserting “paragraph (5)”.

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

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

21 “(5) RECOVERY OF COLLECTION SHORT-  
22 FALLS.—

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

1           “(i) for fiscal year 2021, the amount  
2 of 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  
8 under 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  
16 under 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  
22 appropriated for fiscal years 2021 and  
23 2022 (including estimated collections for  
24 fiscal 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 COL-  
5 LECTIONS.—

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)  
11 by the amount of any excess collections  
12 under this section for preceding fiscal  
13 years (after fiscal year 2018).

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

1           “(C) RULE OF APPLICATION.—Under no  
2           circumstances shall adjustments under this  
3           paragraph result in fee revenues for a fiscal  
4           year that are less than the fee revenues for that  
5           fiscal year established in subsection (b), as ad-  
6           justed or otherwise affected under subsection  
7           (c).”.

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

9           Section 740A (21 U.S.C. 379j–13) 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. 105. SAVINGS CLAUSE.**

17           Notwithstanding the amendments made by this title,  
18           part 4 of subchapter C of chapter VII of the Federal Food,  
19           Drug, and Cosmetic Act (21 U.S.C. 379j–11 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 animal  
22           drug applications and supplemental animal drug applica-  
23           tions (as defined in such part as of such day) that on or  
24           after October 1, 2013, but before October 1, 2018, were  
25           accepted by the Food and Drug Administration for filing

1 with respect to assessing and collecting any fee required  
2 by such part for a fiscal year prior to fiscal year 2019.

3 **SEC. 106. EFFECTIVE DATE.**

4       The amendments made by this title shall take effect  
5 on October 1, 2018, or the date of the enactment of this  
6 Act, whichever is later, except that fees under part 4 of  
7 subchapter C of chapter VII of the Federal Food, Drug,  
8 and Cosmetic Act, as amended by this title, shall be as-  
9 sessed for animal drug applications and supplemental ani-  
10 mal drug applications received on or after October 1,  
11 2018, regardless of the date of the enactment of this Act.

12 **SEC. 107. SUNSET DATES.**

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

16       (b) **REPORTING REQUIREMENTS.**—Section 740A of  
17 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
18 379j–13) shall cease to be effective January 31, 2024.

19       (c) **PREVIOUS SUNSET PROVISION.**—Effective Octo-  
20 ber 1, 2018, subsections (a) and (b) of section 107 of the  
21 Animal Drug User Fee Amendments of 2013 (Public Law  
22 113–14) are repealed.

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

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

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

6           (b) **FINDING.**—Congress finds that the fees author-  
7 ized by the amendments made in this title will be dedi-  
8 cated toward expediting the generic new animal drug de-  
9 velopment process and the review of abbreviated applica-  
10 tions for generic new animal drugs, supplemental abbrevi-  
11 ated applications for generic new animal drugs, and in-  
12 vestigational submissions for generic new animal drugs as  
13 set forth in the goals identified for purposes of part 5 of  
14 subchapter C of chapter VII of the Federal Food, Drug,  
15 and Cosmetic Act, in the letters from the Secretary of  
16 Health and Human Services to the Chairman of the Com-  
17 mittee on Energy and Commerce of the House of Rep-  
18 resentatives and the Chairman of the Committee on  
19 Health, Education, Labor and Pensions of the Senate as  
20 set forth in the Congressional Record.

21       **SEC. 202. AUTHORITY TO ASSESS AND USE GENERIC NEW**  
22               **ANIMAL DRUG FEES.**

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

1 “(b) FEE REVENUE AMOUNTS.—

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

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

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

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

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

19 (b) ANNUAL FEE SETTING; ADJUSTMENTS.—

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

22 (A) by redesignating paragraphs (2)  
23 through (4) as paragraphs (3) through (5), re-  
24 spectively; and



1 (B) by inserting after paragraph (1) the  
2 following:

3 “(2) INFLATION ADJUSTMENT.—

4 “(A) IN GENERAL.—For fiscal year 2020  
5 and subsequent fiscal years, the revenue  
6 amounts established under subsection (b) shall  
7 be adjusted by the Secretary by notice, pub-  
8 lished in the Federal Register, for a fiscal year,  
9 by multiplying such revenue amounts by an  
10 amount equal to the sum of—

11 “(i) one;

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

24 “(iii) the average annual percent  
25 change that occurred in the Consumer

1 Price Index for urban consumers (Wash-  
2 ington-Baltimore, DC–MD–VA–WV; not  
3 seasonally adjusted; all items less food and  
4 energy; annual index) for the first 3 of the  
5 preceding 4 years for which data are avail-  
6 able multiplied by the average proportion  
7 of all costs other than personnel compensa-  
8 tion and benefits costs to total Food and  
9 Drug Administration costs for the first 3  
10 of the preceding 4 fiscal years for which  
11 data are available.

12 “(B) COMPOUNDED BASIS.—The adjust-  
13 ment made each fiscal year after fiscal year  
14 2020 under this paragraph shall be applied on  
15 a compounded basis to the revenue amount cal-  
16 culated under this paragraph for the most re-  
17 cent previous fiscal year.”.

18 (2) WORKLOAD ADJUSTMENTS.—Paragraph (3)  
19 of section 741(c) (21 U.S.C. 379j–21(c)), as redesign-  
20 nated, is amended to read as follows:

21 “(3) WORKLOAD ADJUSTMENTS.—

22 “(A) IN GENERAL.—For fiscal year 2020  
23 and subsequent fiscal years, after the fee rev-  
24 enue amounts established under subsection (b)  
25 are adjusted for inflation in accordance with

1 paragraph (2), the fee revenue amounts shall be  
2 further adjusted for each such fiscal year to re-  
3 flect changes in the workload of the Secretary  
4 for the process for the review of abbreviated ap-  
5 plications for generic new animal drugs, subject  
6 to subparagraphs (B) and (C). With respect to  
7 such adjustment—

8 “(i) this adjustment shall be deter-  
9 mined by the Secretary based on a weight-  
10 ed average of the change in the total num-  
11 ber of abbreviated applications for generic  
12 new animal drugs, manufacturing supple-  
13 mental abbreviated applications for generic  
14 new animal drugs, investigational generic  
15 new animal drug study submissions, and  
16 investigational generic new animal drug  
17 protocol submissions submitted to the Sec-  
18 retary; and

19 “(ii) the Secretary shall publish in the  
20 Federal Register the fees resulting from  
21 this adjustment and the supporting meth-  
22 odologies.

23 “(B) REDUCTION OF WORKLOAD-BASED  
24 INCREASE BY AMOUNT OF CERTAIN EXCESS  
25 COLLECTIONS.—For each of fiscal years 2021

1 through 2023, if application of the workload ad-  
2 justment under subparagraph (A) increases the  
3 fee revenue amounts otherwise established for  
4 the fiscal year under subsection (b), as adjusted  
5 for inflation under paragraph (2), such fee rev-  
6 enue increase shall be reduced by the amount of  
7 any excess collections, as described in sub-  
8 section (g)(4), for the second preceding fiscal  
9 year, up to the amount of such fee revenue in-  
10 crease.

11 “(C) RULE OF APPLICATION.—Under no  
12 circumstances shall workload adjustments  
13 under this paragraph result in fee revenues for  
14 a fiscal year that are less than the fee revenues  
15 for that fiscal year established under subsection  
16 (b), as adjusted for inflation under paragraph  
17 (2).”.

18 (3) FINAL YEAR ADJUSTMENT.—Paragraph (4)  
19 of section 741(c) (21 U.S.C. 379j–21(c)), as redesign-  
20 nated, is amended by—

21 (A) striking “2018” each place it appears  
22 and inserting “2023”; and

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

1 (c) FEE WAIVER OR REDUCTION; EXEMPTION FROM  
2 FEES.—Subsection (d) of section 741 (21 U.S.C. 379j—  
3 21) is amended to read as follows:

4 “(d) FEE WAIVER OR REDUCTION; EXEMPTION  
5 FROM FEES.—

6 “(1) FEE WAIVER OR REDUCTION.—The Sec-  
7 retary shall grant a waiver from or a reduction of  
8 one or more fees assessed under subsection (a)  
9 where the Secretary finds that the generic new ani-  
10 mal drug is intended solely to provide for a minor  
11 use or minor species indication.

12 “(2) EXEMPTION FROM FEES.—Fees under this  
13 section shall not apply with respect to any person  
14 who—

15 “(A) not later than September 30, 2023,  
16 submits a supplemental abbreviated application  
17 for a generic new animal drug approved under  
18 section 512, solely to add the application num-  
19 ber to the labeling of the drug in the manner  
20 specified in section 502(w)(3); and

21 “(B) otherwise would be subject to fees  
22 under this section solely on the basis of such  
23 supplemental abbreviated application.”.

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

4 “(3) AUTHORIZATION OF APPROPRIATIONS.—  
5 For each of the fiscal years 2019 through 2023,  
6 there is authorized to be appropriated for fees under  
7 this section an amount equal to the total revenue  
8 amount established under subsection (b) for the fis-  
9 cal year, as adjusted or otherwise affected under  
10 subsection (c).

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

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

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

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

22 (2) in subsection (b), by striking “Committee  
23 on Health, Education, Labor, and Pensions” and in-  
24 serting “the Committee on Health, Education,  
25 Labor and Pensions”;

1           (3) by striking “2014” each place it appears in  
2           subsections (a) and (b) and inserting “2019”; and  
3           (4) in subsection (d), by striking “2018” each  
4           place it appears and inserting “2023”.

5 **SEC. 204. SAVINGS CLAUSE.**

6           Notwithstanding the amendments made by this title,  
7           part 5 of subchapter C of chapter VII of the Federal Food,  
8           Drug, and Cosmetic Act (21 U.S.C. 379j–21 et seq.), as  
9           in effect on the day before the date of enactment of this  
10          title, shall continue to be in effect with respect to abbrevi-  
11          ated applications for a generic new animal drug and sup-  
12          plemental abbreviated applications for a generic new ani-  
13          mal drug (as defined in such part as of such day) that  
14          on or after October 1, 2013, but before October 1, 2018,  
15          were accepted by the Food and Drug Administration for  
16          filing with respect to assessing and collecting any fee re-  
17          quired by such part for a fiscal year prior to fiscal year  
18          2019.

19 **SEC. 205. EFFECTIVE DATE.**

20          The amendments made by this title shall take effect  
21          on October 1, 2018, or the date of the enactment of this  
22          Act, whichever is later, except that fees under part 5 of  
23          subchapter C of chapter VII of the Federal Food, Drug,  
24          and Cosmetic Act, as amended by this title, shall be as-  
25          sessed for abbreviated applications for a generic new ani-

1 mal drug and supplemental abbreviated applications for  
2 a generic new animal drug received on or after October  
3 1, 2018, regardless of the date of enactment of this Act.

4 **SEC. 206. SUNSET DATES.**

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

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

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

15 **TITLE III—MISCELLANEOUS**  
16 **PROVISIONS**

17 **SEC. 301. ELECTRONIC SUBMISSIONS.**

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

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



1 (b) CONDITIONAL APPROVAL OF NEW ANIMAL  
2 DRUGS FOR MINOR USE AND MINOR SPECIES.—Section  
3 571(a) (21 U.S.C. 360ccc(a)) is amended by adding at  
4 the end the following:

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

9 **SEC. 302. INDEX OF LEGALLY MARKETED UNAPPROVED**  
10 **NEW ANIMAL DRUGS FOR MINOR SPECIES.**

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

13 (1) by amending paragraph (1) to read as fol-  
14 lows:

15 “(1) ‘LEGAL STATUS—In order to be legally  
16 marketed, a new animal drug intended for a minor  
17 species must be Approved, Conditionally Approved,  
18 or Indexed by the Food and Drug Administration.  
19 THIS PRODUCT IS INDEXED—MIF #’ (fol-  
20 lowed by the applicable minor species index file num-  
21 ber and a period) ‘Extra-label use is prohibited.’;”;  
22 and

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

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

2 (a) IN GENERAL.—Section 502(w) (21 U.S.C.  
3 352(w)) is amended—

4 (1) in subparagraph (1), by striking “; or” and  
5 inserting “;”;

6 (2) in subparagraph (2), by striking the period  
7 and inserting “; or”; and

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

9 “(3) for which an application has been ap-  
10 proved under section 512 and the labeling of such  
11 drug does not include the application number in the  
12 format: ‘Approved by FDA under (A)NADA # xxx-  
13 xxx’, except that this subparagraph shall not apply  
14 to representative labeling required under section  
15 514.1(b)(3)(v)(b) of title 21, Code of Federal Regu-  
16 lations (or any successor regulation) for animal feed  
17 bearing or containing a new animal drug.”.

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

21 **SEC. 304. CONDITIONAL APPROVAL OF NEW ANIMAL**  
22 **DRUGS.**

23 (a) IN GENERAL.—Section 571 of the Federal Food,  
24 Drug, and Cosmetic Act (21 U.S.C. 360ccc) is amended—

1 (1) in the section heading, by striking “**SPE-**  
2 **CIES**” and inserting “**SPECIES AND CERTAIN**  
3 **NEW ANIMAL DRUGS**”;

4 (2) in subsection (a)—

5 (A) by amending paragraph (1) to read as  
6 follows:

7 “(1)(A) Except as provided in paragraph (3), any  
8 person may file with the Secretary an application for con-  
9 ditional approval of—

10 “(i) a new animal drug intended for a minor  
11 use or a minor species; or

12 “(ii) a new animal drug not intended for a  
13 minor use or minor species—

14 “(I) that is intended to treat a serious or  
15 life-threatening disease or condition or address-  
16 es an unmet animal or human health need; and

17 “(II) for which the Secretary determines  
18 that a demonstration of effectiveness would re-  
19 quire a complex or particularly difficult study  
20 or studies.

21 “(B) The Secretary shall, not later than September  
22 30, 2019, issue guidance or regulations further clarifying  
23 the criteria specified in subparagraph (A)(ii).

24 “(C) An application under this paragraph shall com-  
25 ply in all respects with the provisions of section 512 except

1 for subsections (a)(4), (b)(2), (c)(1), (c)(2), (c)(3), (d)(1),  
2 (e), (h), and (n) of such section unless otherwise stated  
3 in this section, and any additional provisions of this sec-  
4 tion.

5 “(D) New animal drugs for which conditional ap-  
6 proval is sought under this section are subject to the same  
7 safety standards that would be applied to new animal  
8 drugs under section 512(d) (including, for antimicrobial  
9 new animal drugs, with respect to antimicrobial resist-  
10 ance).”; and

11 (B) in paragraph (3)—

12 (i) in subparagraph (B), by striking “,  
13 or” and inserting “; or”;

14 (ii) by redesignating subparagraphs  
15 (A), (B), and (C) as clauses (i), (ii), and  
16 (iii), respectively;

17 (iii) by striking “A person may not  
18 file” and inserting “(A) A person may not  
19 file”; and

20 (iv) by adding at the end the following  
21 new subparagraph:

22 “(B) A person may not file an application under  
23 paragraph (1)(A)(ii) if the application seeks conditional  
24 approval of a new animal drug that contains an anti-  
25 microbial active ingredient.”;

1 (3) in subsection (f)—

2 (A) in paragraph (1), in the matter pre-  
3 ceding subparagraph (A), by inserting “for the  
4 conditionally approved use” after “shall”; and

5 (B) in paragraph (2)—

6 (i) by striking “An intended use” and  
7 inserting “The Secretary shall, through  
8 regulation or guidance, determine under  
9 what conditions an intended use”; and

10 (ii) by striking “shall not” and insert-  
11 ing “may”; and

12 (4) by adding at the end the following new sub-  
13 section:

14 “(k) SUNSET.—

15 “(1) The Secretary’s authority to grant condi-  
16 tional approval of new animal drugs not intended for  
17 a minor use or minor species pursuant to subsection  
18 (a)(1)(A)(ii) terminates on October 1, 2028.

19 “(2) The Secretary—

20 “(A) may not accept any new applications  
21 for such conditional approval pursuant to sub-  
22 section (a)(1)(A)(ii) on or after such date; and

23 “(B) may continue all activities under this  
24 section with respect to drugs that were condi-

1           tionally approved pursuant to (a)(1)(A)(ii) prior  
2           to such date.

3           “(3) The Secretary may, until October 1, 2032,  
4           accept applications for approval under 512 of drugs  
5           conditionally approved pursuant to (a)(1)(A)(ii).”.

6           (b) EXCEPTION FROM FEES IN CASE OF CERTAIN  
7 PREVIOUSLY SUBMITTED APPLICATIONS FOR CONDI-  
8 TIONAL APPROVAL.—Section 740(a)(1)(C) of the Federal  
9 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–  
10 12(a)(1)(C)) is amended—

11           (1) in the caption by striking “EXCEPTION”  
12           and inserting “EXCEPTIONS”;

13           (2) by striking “If an animal drug” and insert-  
14           ing the following:

15                       “(i) If an animal drug”; and

16           (3) by inserting after clause (i), as so des-  
17           ignated, the following new clause:

18                       “(ii) Beginning with fiscal year 2019,  
19                       in the case of an animal drug application  
20                       submitted by a person under section  
21                       512(b)(1), where such person (or their li-  
22                       censor, assignor, or predecessor-in-interest)  
23                       previously submitted an application for  
24                       conditional approval under section 571 for  
25                       the same product and paid the applicable

1 fee under subparagraph (A), the applica-  
2 tion under section 512(b)(1) shall not be  
3 subject to a fee under subparagraph (A) if  
4 submitted within the timeframe specified  
5 in section 571(h).”.

6 (c) REPORT ON INCORPORATING VETERINARY OVER-  
7 SIGHT.—Not later than September 30, 2019, the Sec-  
8 retary of Health and Human Services, acting through the  
9 Commissioner of Food and Drugs, shall submit a report  
10 to the Committee on Energy and Commerce of the House  
11 of Representatives and the Committee on Health, Edu-  
12 cation, Labor and Pensions of the Senate identifying how  
13 the Food and Drug Administration will incorporate veteri-  
14 nary oversight for all approved medically important anti-  
15 microbial drugs administered to animals that are not yet  
16 subject to veterinary oversight. Such report shall address  
17 requirements related to revisions of labeling to reflect that  
18 medically important antimicrobial drugs administered to  
19 animals shall be subject to veterinary oversight.

20 (d) GAO STUDY OF CONDITIONAL APPROVAL PRO-  
21 GRAMS.—

22 (1) STUDY.—The Comptroller General of the  
23 United States (referred to in this section as the  
24 “Comptroller General”) shall conduct a study on the  
25 effectiveness and overall impact of the conditional

1 approval pathway under section 571 of the Federal  
2 Food, Drug, and Cosmetic Act (21 U.S.C. 360ccc).

3 (2) ISSUANCE OF REPORT.—Not later than  
4 January 1, 2026, the Comptroller General shall sub-  
5 mit to the Committee on Health, Education, Labor  
6 and Pensions of the Senate and the Committee on  
7 Energy and Commerce of the House of Representa-  
8 tives a report containing the results of the study  
9 under paragraph (1).

10 (3) CONTENTS OF REPORTS.—The report sub-  
11 mitted under paragraph (2) shall address—

12 (A) for each drug for which a conditional  
13 approval has been awarded since October 1,  
14 2018—

15 (i) whether the drug was granted con-  
16 ditional approval pursuant to clause (i) or  
17 (ii) of section 571(a)(1)(A) of the Federal  
18 Food, Drug, and Cosmetic Act, as amend-  
19 ed by subsection (a);

20 (ii) whether the drug was dual labeled  
21 during its conditional approval;

22 (iii) the indications for which the drug  
23 was granted conditional approval under  
24 section 571 of such Act (21 U.S.C.  
25 360ccc) and whether the drug was ap-



1 proved or not approved under section 512  
2 of such Act (21 U.S.C. 360b);

3 (iv) the number of years the drug was  
4 so conditionally approved and a description  
5 of the complexity of the investigation to  
6 demonstrate the drug's effectiveness;

7 (v) whether, and to what extent, the  
8 conditional approval pathway under such  
9 section 571 (21 U.S.C. 360ccc) impacted  
10 the sponsor's decision to develop the drug  
11 or seek approval of the drug under section  
12 512 of such Act (21 U.S.C. 360b);

13 (vi) whether, and to what extent, con-  
14 ditional approval pursuant to clause (ii) of  
15 section 571(a)(1)(A) of such Act (21  
16 U.S.C. 360b(a)(1)(A)) addressed a serious  
17 or life-threatening condition; and

18 (vii) whether, and to what extent, con-  
19 ditional approval pursuant to clause (ii) of  
20 section 571(a)(1)(A) of such Act (21  
21 U.S.C. 360b(a)(1)(A)) addressed an unmet  
22 animal or human health need, and whether  
23 before such conditional approval there were  
24 available therapies for the disease or condi-  
25 tion involved;

1 (B) an analysis of the conditional approval  
2 program under section 571 of such Act (21  
3 U.S.C. 360ccc), including—

4 (i) the resources used by the Food  
5 and Drug Administration in reviewing ap-  
6 plications for conditional approval of drugs  
7 pursuant to such program and renewal of  
8 such conditional approval, including the ef-  
9 fects of the program on the Food and  
10 Drug Administration’s review of animal  
11 drugs for which conditional approval is not  
12 used;

13 (ii) whether any improvements to the  
14 program under section 512 of such Act (21  
15 U.S.C. 360b) are necessary to incentivize  
16 the development of animal drugs that  
17 would likely not otherwise be developed, or  
18 developed in as timely a manner, to ad-  
19 dress—

20 (I) serious or life-threatening  
21 conditions; and

22 (II) an unmet animal or human  
23 health need; and

24 (iii) whether the conditional approval  
25 pathway has resulted in a greater number

1 of animal drugs approved under section  
2 512 of such Act (21 U.S.C. 360b) for seri-  
3 ous or life-threatening conditions or unmet  
4 animal or human health needs than would  
5 have otherwise come to market under the  
6 practices and commitments of the Center  
7 for Veterinary Medicine of the Food and  
8 Drug Administration as such practices and  
9 commitments existed as of the day before  
10 the date of enactment of this Act; and

11 (C) how the Center for Veterinary Medi-  
12 cine of the Food and Drug Administration has  
13 utilized complex adaptive or other novel inves-  
14 tigation designs, data from foreign countries,  
15 real-world evidence (including ongoing surveil-  
16 lance activities, observational studies, and reg-  
17 istry data), biomarkers, or surrogate  
18 endpoints—

19 (i) to support the approval of products  
20 under section 512 of such Act (21 U.S.C.  
21 360b), including how many such products  
22 have been approved since October 1, 2018;  
23 and

24 (ii) to support the approval of prod-  
25 ucts under section 512 of such Act (21

1 U.S.C. 360b) that received conditional ap-  
2 proval under section 571 of such Act (21  
3 U.S.C. 360ccc), including how many such  
4 products have been approved since October  
5 1, 2018.

6 **SEC. 305. GUIDANCE ADDRESSING INVESTIGATION DE-**  
7 **SIGNS.**

8 (a) IN GENERAL.—For purposes of assisting spon-  
9 sors in incorporating complex adaptive and other novel in-  
10 vestigation designs, data from foreign countries, real world  
11 evidence (including ongoing surveillance activities, obser-  
12 vational studies, and registry data), biomarkers, and sur-  
13 rogate endpoints (referred to in this section as “elements  
14 of investigations”) into proposed clinical investigation pro-  
15 tocols and applications for new animal drugs under sec-  
16 tions 512 and 571 of the Federal Food, Drug, and Cos-  
17 metic Act (21 U.S.C. 360b; 360ccc), the Secretary of  
18 Health and Human Services (referred to in this section  
19 as the “Secretary”) shall issue guidance addressing the  
20 use of such elements of investigations in the development  
21 and regulatory review of such new animal drugs.

22 (b) CONTENTS.—The guidance under subsection (a)  
23 shall address how the Secretary will evaluate the elements  
24 of investigations proposed or submitted pursuant to sec-  
25 tion 512(b)(1)(A) of the Federal Food, Drug, and Cos-

1 metic Act or to meet the commitment under section  
2 571(a)(2)(F) of such Act, and how sponsors of such appli-  
3 cations may obtain feedback from the Secretary on tech-  
4 nical issues related to such investigations prior to the sub-  
5 mission of an application to the Secretary.

6 (c) MEETING.—Prior to issuing the guidance under  
7 subsection (a), the Secretary shall consult with stake-  
8 holders, including representatives of regulated industry,  
9 consumer groups, academia, veterinarians, and food pro-  
10 ducers, through a public meeting to be held not later than  
11 1 year after the date of enactment of this Act.

12 (d) TIMING.—The Secretary shall issue a draft guid-  
13 ance under subsection (a) not later than 1 year after the  
14 date of the public meeting under subsection (c), and shall  
15 finalize such guidance not later than 1 year after the date  
16 on which the public comment period on such draft guid-  
17 ance ends.

18 **SEC. 306. FOOD ADDITIVES INTENDED FOR USE IN ANIMAL**

19 **FOOD.**

20 (a) FOOD ADDITIVE PETITIONS FOR ANIMAL  
21 FOOD.—Section 409 of the Federal Food, Drug, and Cos-  
22 metic Act (21 U.S.C. 348) is amended by adding at the  
23 end the following:

24 “(k) FOOD ADDITIVES INTENDED FOR USE IN ANI-  
25 MAL FOOD.—(1) In taking action on a petition under sub-

1 section (c) for, or for recognition of, a food additive in-  
2 tended for use in animal food, the Secretary shall review  
3 reports of investigations conducted in foreign countries,  
4 provided by the petitioner.

5 “(2) Not later than 12 months after the date of en-  
6 actment of the Animal Drug and Animal Generic Drug  
7 Use Fee Amendments of 2018, the Secretary shall post  
8 on the internet website of the Food and Drug Administra-  
9 tion—

10 “(A) the number of petitions for food additives  
11 intended for use in animal food filed under sub-  
12 section (b) that are pending;

13 “(B) how long each such petition submitted  
14 under subsection (b) has been pending, including  
15 such petitions the Secretary has extended under sub-  
16 section (c)(2); and

17 “(C) the number of study protocols that have  
18 been pending review for over 50 days, and the num-  
19 ber that have received an extension.

20 “(3) In the case of a food additive petition intended  
21 for use in animal food, the Secretary shall provide infor-  
22 mation to the petitioner on the required contents of such  
23 petition. If the Secretary requires additional studies be-  
24 yond what the petitioner proposed, the Secretary shall pro-  
25 vide the scientific rationale for such requirement.”.

1 (b) ENSURING THE SAFETY OF PET FOOD.—Section  
2 1002(a) of the Food and Drug Administration Amend-  
3 ments Act of 2007 (21 U.S.C. 2102(a)) is amended—

4 (1) by striking paragraph (1); and

5 (2) by redesignating paragraphs (2) and (3) as  
6 paragraphs (1) and (2), respectively.

7 (c) GUIDANCE ON PRE-PETITION CONSULTATION  
8 PROCESS FOR ANIMAL FOOD ADDITIVES.—

9 (1) IN GENERAL.—Not later than 18 months  
10 after the date of enactment of this Act, the Sec-  
11 retary of Health and Human Services (referred to in  
12 this subsection as the “Secretary”) shall publish  
13 draft guidance relating to the voluntary pre-petition  
14 consultation process for food additives intended for  
15 use in animal food.

16 (2) CONTENTS.—The guidance under para-  
17 graph (1) shall include—

18 (A) the recommended format to submit to  
19 the Food and Drug Administration existing  
20 data, including any applicable foreign data, for  
21 assessment prior to submission of a food addi-  
22 tive petition for animal food under section  
23 409(b) of the Federal Food, Drug, and Cos-  
24 metic Act;

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

6           (C) circumstances under which the submis-  
7           sion of study protocols is recommended prior to  
8           submission of a food additive petition under  
9           such section 409(b);

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

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

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



1 issued not later than 1 year after the close of the  
2 comment period on the draft guidance.

Passed the House of Representatives July 16, 2018.

Attest:

*Clerk.*

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

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# H. R. 5554

## AN ACT

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