

115TH CONGRESS
2D SESSION

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.

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.).

TITLE I—FEES RELATING TO ANIMAL DRUGS

SEC. 101. SHORT TITLE; FINDING.

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

(b) FINDING.—Congress finds that the fees authorized by the amendments made in this title will be dedicated toward expediting the animal drug development process and the review of new and supplemental animal drug applications and investigational animal drug submissions as set forth in the goals identified for purposes of part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Energy and Commerce of the House of Representatives and the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate as set forth in the Congressional Record.

SEC. 102. DEFINITIONS.

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

(1) by amending paragraph (1) to read as follows:

“(1)(A) The term ‘animal drug application’ 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

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

“(2) INFLATION ADJUSTMENT.—

“(A) IN GENERAL.—For fiscal year 2020 and subsequent fiscal years, the revenue amounts established under subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year, by multiplying such revenue amounts by an amount equal to the sum of—

“(i) one;

“(ii) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 of the preceding 4 fiscal years for which data are available, multiplied by the average proportion of personnel compensation and benefits costs to total Food and Drug Administration costs for the first 3 of the preceding 4 fiscal years for which data are available; and

“(iii) the average annual percent 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 metric 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.

115TH CONGRESS
2^D SESSION

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.