

115TH CONGRESS
2D SESSION

H. R. 5554

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

IN THE HOUSE OF REPRESENTATIVES

APRIL 18, 2018

Mr. MULLIN (for himself, Mr. SCHRADER, Mr. WALDEN, Mr. PALLONE, Mr. BURGESS, and Mr. GENE GREEN of Texas) introduced the following bill; which was referred to the Committee on Energy and Commerce

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”.

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

7 (a) TABLE OF CONTENTS.—The table of contents for
8 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.

1 (b) REFERENCES IN ACT.—Except as otherwise spec-
 2 ified, 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
 5 (21 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 author-
 12 ized by the amendments made in this title will be dedi-
 13 cated toward expediting the animal drug development
 14 process and the review of new and supplemental animal

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

10 **SEC. 102. DEFINITIONS.**

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

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

14 “(1)(A) The term ‘animal drug application’
15 means—

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

19 “(ii) an application for conditional ap-
20 proval of a new animal drug submitted under
21 section 571.

22 “(B) Such term does not include either a new
23 animal drug application submitted under section
24 512(b)(2) or a supplemental animal drug applica-
25 tion.”; and

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

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

10 **SEC. 103. AUTHORITY TO ASSESS AND USE ANIMAL DRUG**
 11 **FEES.**

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

14 (1) in paragraph (1)—

15 (A) in subparagraph (A)—

16 (i) by striking “2014” and inserting
 17 “2019”; and

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

20 (B) in subparagraph (B)—

21 (i) by striking “2015 through 2018”
 22 and inserting “2020 through 2023”; and

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

(2) in paragraph (2), in the matter preceding subparagraph (A), by striking “determined” and inserting “established”.

(b) ANNUAL FEE SETTING; ADJUSTMENTS.—

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

(A) in the matter preceding subparagraph

(A)—

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

and

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

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

(C) by striking the flush text at the end;

and

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

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

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

“(3) WORKLOAD ADJUSTMENTS.—

“(A) IN GENERAL.—For fiscal year 2020 and subsequent fiscal years, after the fee revenue amounts established under subsection (b) are adjusted for inflation in accordance with paragraph (2), the fee revenue amounts shall be further adjusted for such fiscal year to reflect changes in the workload of the Secretary for the process for the review of animal drug applications, subject to subparagraphs (B) and (C).

With respect to such adjustment—

“(i) such adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of animal drug applications, supplemental animal drug applications for which data with respect to safety or effectiveness are required, manufacturing supplemental animal drug applications, investigational animal drug study submissions, and investigational animal drug protocol submissions submitted to the Secretary; and

1 “(ii) the Secretary shall publish in the
2 Federal Register the fees resulting from
3 such adjustment and the supporting meth-
4 odologies.

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

18 “(C) RULE OF APPLICATION.—Under no
19 circumstances shall the workload adjustments
20 under this paragraph result in fee revenues for
21 a fiscal year that are less than the fee revenues
22 for that fiscal year established under subsection
23 (b), as adjusted for inflation under paragraph
24 (2).”.

1 (3) FINAL YEAR ADJUSTMENT.—Section
2 740(c)(4) (21 U.S.C. 379j–12(c)(4)) is amended—

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

5 (B) by striking “2019” and inserting
6 “2024”.

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

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

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

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

14 “(4) EXEMPTIONS FROM FEES.—

15 “(A) CERTAIN LABELING SUPPLEMENTS
16 TO ADD NUMBER OF APPROVED APPLICA-
17 TION.—Fees under this section shall not apply
18 with respect to any person who—

19 “(i) not later than September 30,
20 2023, submits a supplemental animal drug
21 application relating to a new animal drug
22 application approved under section 512,
23 solely to add the new animal drug applica-
24 tion number to the labeling of the drug in

1 the manner specified in section 502(w)(3);
2 and

3 “(ii) otherwise would be subject to
4 fees under this section solely on the basis
5 of such supplemental application.

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

18 (d) CREDITING AND AVAILABILITY OF FEES.—

19 (1) AUTHORIZATION OF APPROPRIATIONS.—
20 Section 740(g)(3) (21 U.S.C. 379j–12(g)(3)) is
21 amended—

22 (A) by striking “2014 through 2018” and
23 inserting “2019 through 2023”;

24 (B) by striking “determined” and inserting
25 “established”; and

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

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

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

13 “(5) RECOVERY OF COLLECTION SHORT-
14 FALLS.—

15 “(A) IN GENERAL.—Subject to subpara-
16 graph (B)—

17 “(i) for fiscal year 2021, the amount
18 of fees otherwise authorized to be collected
19 under this section shall be increased by the
20 amount, if any, by which the amount col-
21 lected under this section and appropriated
22 for fiscal year 2019 falls below the amount
23 of fees authorized for fiscal year 2019
24 under paragraph (3);

1 “(ii) for fiscal year 2022, 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 2020 falls below the amount
7 of fees authorized for fiscal year 2020
8 under paragraph (3); and

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

19 “(B) REDUCTION OF SHORTFALL-BASED
20 FEE INCREASE BY PRIOR YEAR EXCESS COL-
21 LECTIONS.—

22 “(i) IN GENERAL.—Subject to clause
23 (ii), the Secretary shall, in such manner as
24 the Secretary determines appropriate, re-
25 duce any fee increase otherwise applicable

1 for a fiscal year under subparagraph (A)
2 by the amount of any excess collections
3 under this section for preceding fiscal
4 years (after fiscal year 2018).

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

16 “(C) RULE OF APPLICATION.—Under no
17 circumstances shall adjustments under this
18 paragraph result in fee revenues for a fiscal
19 year that are less than the fee revenues for that
20 fiscal year established in subsection (b), as ad-
21 justed or otherwise affected under subsection
22 (c).”.

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

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

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

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

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

7 **SEC. 105. SAVINGS CLAUSE.**

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

19 **SEC. 106. 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 4 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 animal drug applications and supplemental ani-

mal drug applications received on or after October 1, 2018, regardless of the date of the enactment of this Act.

SEC. 107. SUNSET DATES.

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

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

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

TITLE II—FEES RELATING TO GENERIC ANIMAL DRUGS

SEC. 201. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the “Animal Generic 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 generic new animal drug development process and the review of abbreviated applications for generic new animal drugs, supplemental abbreviated applications for generic new animal drugs, and investigational submissions for generic new animal drugs as

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

9 **SEC. 202. AUTHORITY TO ASSESS AND USE GENERIC NEW**
 10 **ANIMAL DRUG FEES.**

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

14 “(b) FEE REVENUE AMOUNTS.—

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

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

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

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

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

7 (b) ANNUAL FEE SETTING; ADJUSTMENTS.—

8 (1) INFLATION ADJUSTMENT.—Section 741(c)
 9 (21 U.S.C. 379j–21(c)) is amended—

10 (A) by redesignating paragraphs (2)
 11 through (4) as paragraphs (3) through (5), re-
 12 spectively; and

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

15 “(2) INFLATION ADJUSTMENT.—

16 “(A) IN GENERAL.—For fiscal year 2020
 17 and subsequent fiscal years, the revenue
 18 amounts established under subsection (b) shall
 19 be adjusted by the Secretary by notice, pub-
 20 lished in the Federal Register, for a fiscal year,
 21 by multiplying such revenue amounts by an
 22 amount equal to the sum of—

23 “(i) one;

24 “(ii) the average annual percent
 25 change in the cost, per full-time equivalent

1 position of the Food and Drug Administra-
2 tion, of all personnel compensation and
3 benefits paid with respect to such positions
4 for the first three of the preceding 4 fiscal
5 years for which data are available, multi-
6 plied by the average proportion of per-
7 sonnel compensation and benefits costs to
8 total Food and Drug Administration costs
9 for the first three of the preceding 4 fiscal
10 years for which data are available; and

11 “(iii) the average annual percent
12 change that occurred in the Consumer
13 Price Index for urban consumers (Wash-
14 ington-Baltimore, DC–MD–VA–WV; not
15 seasonally adjusted; all items less food and
16 energy; annual index) for the first three of
17 the preceding 4 years for which data are
18 available multiplied by the average propor-
19 tion of all costs other than personnel com-
20 pensation and benefits costs to total Food
21 and Drug Administration costs for the
22 first three of the preceding 4 fiscal years
23 for which data are available.

24 “(B) COMPOUNDED BASIS.—The adjust-
25 ment made each fiscal year after fiscal year

1 2020 under this paragraph shall be applied on
2 a compounded basis to the revenue amount cal-
3 culated under this paragraph for the most re-
4 cent previous fiscal year.”.

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

8 “(3) WORKLOAD ADJUSTMENTS.—

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

20 “(i) this 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 abbreviated applications for generic
24 new animal drugs, manufacturing supple-
25 mental abbreviated applications for generic

1 new animal drugs, investigational generic
2 new animal drug study submissions, and
3 investigational generic new animal drug
4 protocol submissions submitted to the Sec-
5 retary; and

6 “(ii) the Secretary shall publish in the
7 Federal Register the fees resulting from
8 this 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 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.—Paragraph (4)
 6 of section 741(c) (21 U.S.C. 379j–21(c)), as redesign-
 7 nated, is amended by—

8 (A) striking “2018” each place it appears
 9 and inserting “2023”; and

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

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

14 “(d) FEE WAIVER OR REDUCTION; EXEMPTION
 15 FROM FEES.—

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

22 “(2) EXEMPTION FROM FEES.—Fees under this
 23 section shall not apply with respect to any person
 24 who—

“(A) not later than September 30, 2023, submits a supplemental abbreviated application for a generic new animal drug approved under section 512, solely to add the application number to the labeling of the drug in the manner specified in section 502(w)(3); and

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

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

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

“(4) EXCESS COLLECTIONS.—If the sum total of fees collected under this section for a fiscal year exceeds the amount of fees authorized to be appropriated for such year under paragraph (3), the excess collections shall be credited to the appropria-

1 tions account of the Food and Drug Administration
2 as described in paragraph (1).”.

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

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

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

7 (2) in subsection (b), by striking “Committee
8 on Health, Education, Labor, and Pensions” and in-
9 serting “the Committee on Health, Education,
10 Labor and Pensions”;

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

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

15 **SEC. 204. SAVINGS CLAUSE.**

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

1 filing with respect to assessing and collecting any fee re-
2 quired by such part for a fiscal year prior to fiscal year
3 2019.

4 **SEC. 205. EFFECTIVE DATE.**

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

14 **SEC. 206. SUNSET DATES.**

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

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

21 (c) PREVIOUS SUNSET PROVISION.—Effective Octo-
22 ber 1, 2018, subsections (a) and (b) of section 206 of the
23 Animal Generic Drug User Fee Amendments of 2013
24 (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 subparagraph (1), by striking “; or” and
 14 inserting “;”;

15 (2) in subparagraph (2), by striking the period
 16 and 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.

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