

Calendar No. 341

115TH CONGRESS
2D SESSION**S. 2434**

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

IN THE SENATE OF THE UNITED STATES

FEBRUARY 15, 2018

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

MARCH 7, 2018

Reported by Mr. ALEXANDER, with an amendment

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

A BILL

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

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

3 **SECTION 1. SHORT TITLE.**

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

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

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

Sec. 1. Short title.

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

TITLE I—FEES RELATING TO ANIMAL DRUGS

Sec. 101. Short title; finding.

Sec. 102. Definitions.

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

Sec. 104. Reauthorization; reporting requirements.

Sec. 105. Savings clause.

Sec. 106. Effective date.

Sec. 107. Sunset dates.

TITLE II—FEES RELATING TO GENERIC ANIMAL DRUGS

Sec. 201. Short title; finding.

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

Sec. 203. Reauthorization; reporting requirements.

Sec. 204. Savings clause.

Sec. 205. Effective date.

Sec. 206. Sunset dates.

TITLE III—MISCELLANEOUS PROVISIONS

Sec. 301. Electronic submissions.

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

Sec. 303. Misbranded drugs and devices.

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

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

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

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

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

14 **SEC. 102. DEFINITIONS.**

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

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

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

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

22 or

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

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

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

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

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

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

18 (1) in paragraph (1)—

19 (A) in subparagraph (A)—

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

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

24 (B) in subparagraph (B)—

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

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

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

8 (b) ANNUAL FEE SETTING; ADJUSTMENTS.—

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

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

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

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

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

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

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

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

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

9 ~~“(3) WORKLOAD ADJUSTMENTS.—~~

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

19 With respect to such adjustment—

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

are required; manufacturing supplemental animal drug applications; investigational animal drug study submissions; and investigational animal drug protocol submissions submitted to the Secretary; and

“(ii) the Secretary shall publish in the Federal Register the fees resulting from such adjustment and the supporting methodologies.

“(B) REDUCTION OF WORKLOAD-BASED INCREASE BY AMOUNT OF CERTAIN EXCESS COLLECTIONS.—For each of fiscal years 2021 through 2023, if application of the workload adjustment under subparagraph (A) increases the fee revenue amounts otherwise established for the fiscal year under subsection (b), as adjusted for inflation under paragraph (2), such fee revenue increase shall be reduced by the amount of any excess collections, as described in subsection (g)(4), for the second preceding fiscal year, up to the amount of such fee revenue increase.

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

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

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

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

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

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

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

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

(3) by adding at the end the following:

“(4) EXEMPTIONS FROM FEES.—

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

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

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

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

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

21 (d) CREDITING AND AVAILABILITY OF FEES.—

22 (1) AUTHORIZATION OF APPROPRIATIONS.—

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

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

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

(C) by striking “paragraph (4)” and inserting “paragraph (5)”.

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

“(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 appropriations account of the Food and Drug Administration as described in paragraph (1).

“(5) RECOVERY OF COLLECTION SHORTFALLS.—

“(A) IN GENERAL.—Subject to subparagraph (B)—

“(i) for fiscal year 2021, the amount of fees otherwise authorized to be collected under this section shall be increased by the amount, if any, by which the amount collected under this section and appropriated

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18 “(b) FEE REVENUE AMOUNTS.—

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

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

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

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

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

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

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

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

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

21 ~~“(2) INFLATION ADJUSTMENT.—~~

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

lished 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 Administra-
tion, 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; multi-
plied by the average proportion of per-
sonnel 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
Price Index for urban consumers (Wash-
ington-Baltimore, DC-MD-VA-WV; not
seasonally adjusted; all items less food and
energy; annual index) for the first 3 of the
preceding 4 years for which data are avail-
able multiplied by the average proportion
of all costs other than personnel compensa-

tion 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.

“(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 741(c) (21 U.S.C. 379j-21(c)), as redesignated, 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 each such fiscal year to reflect changes in the workload of the Secretary for the process for the review of abbreviated applications for generic new animal drugs, subject to subparagraphs (B) and (C). With respect to such adjustment—

“(i) this adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of abbreviated applications for generic new animal drugs, manufacturing supplemental abbreviated applications for generic new animal drugs, investigational generic new animal drug study submissions, and investigational generic new animal drug protocol submissions submitted to the Secretary; and

“(ii) the Secretary shall publish in the Federal Register the fees resulting from this adjustment and the supporting methodologies.

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

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

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

(3) FINAL YEAR ADJUSTMENT.—Paragraph (4) of section 741(c) (21 U.S.C. 379j-21(c)), as redesignated, is amended by—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6 **SECTION 1. SHORT TITLE.**

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

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

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

Sec. 1. Short title.

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

TITLE I—FEES RELATING TO ANIMAL DRUGS

Sec. 101. Short title; finding.

Sec. 102. Definitions.

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

Sec. 104. Reauthorization; reporting requirements.

Sec. 105. Savings clause.

Sec. 106. Effective date.

Sec. 107. Sunset dates.

TITLE II—FEES RELATING TO GENERIC ANIMAL DRUGS

Sec. 201. Short title; finding.

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

Sec. 203. Reauthorization; reporting requirements.

Sec. 204. Savings clause.

Sec. 205. Effective date.

Sec. 206. Sunset dates.

TITLE III—MISCELLANEOUS PROVISIONS

Sec. 301. Electronic submissions.

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

Sec. 303. Misbranded drugs and devices.

Sec. 304. Issuance of recommendations.

Sec. 305. Guidance addressing investigation designs.

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

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

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

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

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

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

24 **SEC. 102. DEFINITIONS.**

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

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

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

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

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

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

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

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

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

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

5 (1) in paragraph (1)—

6 (A) in subparagraph (A)—

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

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

11 (B) in subparagraph (B)—

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

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

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

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

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

22 (A) in the matter preceding subparagraph
 23 (A)—

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

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

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

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

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

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

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

18 “(3) WORKLOAD ADJUSTMENTS.—

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

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

3 *With respect to such adjustment—*

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

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

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

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

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

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

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

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

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

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

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

(3) by adding at the end the following:

1 “(4) *EXEMPTIONS FROM FEES.*—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20 “(b) *FEE REVENUE AMOUNTS.*—

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

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

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

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

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

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

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

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

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

21 “(2) *INFLATION ADJUSTMENT.*—

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

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

4 “(i) one;

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

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

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

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

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

14 “(3) WORKLOAD ADJUSTMENTS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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115TH CONGRESS
2^D Session

S. 2434

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.

MARCH 7, 2018

Reported with an amendment