

115TH CONGRESS  
2D SESSION

# S. 2434

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

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IN THE SENATE OF THE UNITED STATES

FEBRUARY 15, 2018

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

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## A BILL

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

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

3       **SECTION 1. SHORT TITLE.**

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

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

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

4 (b) ANNUAL FEE SETTING; ADJUSTMENTS.—

5           (1) INFLATION ADJUSTMENT.—Section  
6 740(c)(2) (21 U.S.C. 379j–12(c)(2)) is amended—

7           (A) in the matter preceding subparagraph

8           (A)—

9                   (i) by striking “For fiscal year 2015”

10                   and inserting “(A) For fiscal year 2020”;

11                   and

12                   (ii) by inserting “multiplying such

13                   revenue amounts by” before “an amount”;

14           (B) by redesignating subparagraphs (A),

15           (B), and (C) as clauses (i), (ii), and (iii), re-

16           spectively;

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

18           and

19           (D) by adding at the end the following new

20           subparagraph:

21           “(B) COMPOUNDED BASIS.—The adjustment

22           made each fiscal year after fiscal year 2020 under

23           this paragraph shall be applied on a compounded

24           basis to the revenue amount calculated under this

25           paragraph for the most recent previous fiscal year.”.

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

4           “(3) WORKLOAD ADJUSTMENTS.—

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

14 With respect to such adjustment—

15           “(i) such adjustment shall be deter-  
16 mined by the Secretary based on a weight-  
17 ed average of the change in the total num-  
18 ber of animal drug applications, supple-  
19 mental animal drug applications for which  
20 data with respect to safety or effectiveness  
21 are required, manufacturing supplemental  
22 animal drug applications, investigational  
23 animal drug study submissions, and inves-  
24 tigational animal drug protocol submis-  
25 sions 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-

1 mal drug applications received on or after October 1,  
2 2018, regardless of the date of the enactment of this Act.

3 **SEC. 107. SUNSET DATES.**

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

7 (b) **REPORTING REQUIREMENTS.**—Section 740A of  
8 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
9 379j–13) shall cease to be effective January 31, 2024.

10 (c) **PREVIOUS SUNSET PROVISION.**—Effective Octo-  
11 ber 1, 2018, subsections (a) and (b) of section 107 of the  
12 Animal Drug User Fee Amendments of 2013 (Public Law  
13 113–14) are repealed.

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

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

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

19 (b) **FINDING.**—Congress finds that the fees author-  
20 ized by the amendments made in this title will be dedi-  
21 cated toward expediting the generic new animal drug de-  
22 velopment process and the review of abbreviated applica-  
23 tions for generic new animal drugs, supplemental abbrevi-  
24 ated applications for generic new animal drugs, and in-  
25 vestigational 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 3 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 3 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 3 of the  
17 preceding 4 years for which data are avail-  
18 able multiplied by the average proportion  
19 of all costs other than personnel compensa-  
20 tion and benefits costs to total Food and  
21 Drug Administration costs for the first 3  
22 of the preceding 4 fiscal years for which  
23 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 1 or more fees assessed under subsection (a) where  
19 the Secretary finds that the generic new animal drug  
20 is intended solely to provide for a minor use or  
21 minor species indication.

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

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

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

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

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

20               “(4) EXCESS COLLECTIONS.—If the sum total  
21          of fees collected under this section for a fiscal year  
22          exceeds the amount of fees authorized to be appro-  
23          priated for such year under paragraph (3), the ex-  
24          cess 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) 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. 204. SAVINGS CLAUSE.**

12 Notwithstanding the amendments made by this title,  
13 part 5 of subchapter C of chapter VII of the Federal Food,  
14 Drug, and Cosmetic Act (21 U.S.C. 379j–21 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 abbrevi-  
17 ated applications for a generic new animal drug and sup-  
18 plemental abbreviated applications for a generic new ani-  
19 mal drug (as defined in such part as of such day) that  
20 on or after October 1, 2013, but before October 1, 2018,  
21 were accepted by the Food and Drug Administration for  
22 filing with respect to assessing and collecting any fee re-  
23 quired by such part for a fiscal year prior to fiscal year  
24 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  
 5 subchapter C of chapter VII of the Federal Food, Drug,  
 6 and Cosmetic Act, as amended by this title, shall be as-  
 7 sessed for abbreviated applications for a generic new ani-  
 8 mal drug and supplemental abbreviated applications for  
 9 a generic new animal drug received on or after October  
 10 1, 2018, regardless 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 Octo-  
 19 ber 1, 2018, subsections (a) and (b) of section 206 of the  
 20 Animal Generic Drug User Fee Amendments of 2013  
 21 (Public Law 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  
2 by 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 Sec-  
6 retary may require.”.

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

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 Sec-  
14 retary may require.”.

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

17 Effective on October 1, 2018, section 572(h) (21  
18 U.S.C. 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,  
24 or Indexed by the Food and Drug Administration.  
25 **THIS PRODUCT IS INDEXED—MIF.**’ (followed

1 by the applicable minor species index file number  
2 and a period) ‘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.  
7 352(w)) 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 ap-  
14 proved under section 512 and the labeling of such  
15 drug does not include the application number in the  
16 format: ‘Approved by FDA under (A)NADA # xxx-  
17 xxx’, except that this subparagraph shall not apply  
18 to representative labeling required under section  
19 514.1(b)(3)(v)(b) of title 21, Code of Federal Regu-  
20 lations (or any successor regulation) for animal feed  
21 bearing or containing a new animal drug.”.

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

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