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(Original Signature of Member)

115TH CONGRESS
2D SESSION

H. R. _____

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

IN THE HOUSE OF REPRESENTATIVES

Mr. MULLIN introduced the following bill; which was referred to the Committee on _____

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:

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

11 **SEC. 102. DEFINITIONS.**

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

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

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

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

19 or

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

23 “(B) Such term does not include either a new
24 animal drug application submitted under section

1 512(b)(2) or a supplemental animal drug applica-
2 tion.”; and

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

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

12 **SEC. 103. AUTHORITY TO ASSESS AND USE ANIMAL DRUG**
13 **FEES.**

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

16 (1) in paragraph (1)—

17 (A) in subparagraph (A)—

18 (i) by striking “2014” and inserting
19 “2019”; and

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

22 (B) in subparagraph (B)—

23 (i) by striking “2015 through 2018”
24 and inserting “2020 through 2023”; and

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

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

6 (b) ANNUAL FEE SETTING; ADJUSTMENTS.—

7 (1) INFLATION ADJUSTMENT.—Section
8 740(c)(2) (21 U.S.C. 379j–12(c)(2)) is amended—

9 (A) in the matter preceding subparagraph
10 (A)—

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

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

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

19 (C) by striking the flush text at the end;
20 and

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

23 “(B) COMPOUNDED BASIS.—The adjustment
24 made each fiscal year after fiscal year 2020 under
25 this paragraph shall be applied on a compounded

1 basis to the revenue amount calculated under this
2 paragraph for the most recent previous fiscal year.”.

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

6 “(3) WORKLOAD ADJUSTMENTS.—

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

16 With respect to such adjustment—

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

1 tigation animal drug protocol submis-
2 sions submitted to the Secretary; and

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

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

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

1 (b), as adjusted for inflation under paragraph
2 (2).”.

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

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

7 (B) by striking “2019” and inserting
8 “2024”.

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

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

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

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

16 “(4) EXEMPTIONS FROM FEES.—

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

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

1 tion number to the labeling of the drug in
2 the manner specified in section 502(w)(3);
3 and

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

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

19 (d) CREDITING AND AVAILABILITY OF FEES.—

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

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

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

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

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

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

15 “(5) RECOVERY OF COLLECTION SHORT-
16 FALLS.—

17 “(A) IN GENERAL.—Subject to subpara-
18 graph (B)—

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

1 of fees authorized for fiscal year 2019
2 under paragraph (3);

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

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

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

24 “(i) IN GENERAL.—Subject to clause
25 (ii), the Secretary shall, in such manner as

1 the Secretary determines appropriate, re-
2 duce any fee increase otherwise applicable
3 for a fiscal year under subparagraph (A)
4 by the amount of any excess collections
5 under this section for preceding fiscal
6 years (after fiscal year 2018).

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

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

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

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

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

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

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

9 **SEC. 105. SAVINGS CLAUSE.**

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

21 **SEC. 106. EFFECTIVE DATE.**

22 The amendments made by this title shall take effect
23 on October 1, 2018, or the date of the enactment of this
24 Act, whichever is later, except that fees under part 4 of
25 subchapter C of chapter VII of the Federal Food, Drug,
26 and Cosmetic Act, as amended by this title, shall be as-

1 sessed for animal drug applications and supplemental ani-
2 mal drug applications received on or after October 1,
3 2018, regardless of the date of the enactment of this Act.

4 **SEC. 107. SUNSET DATES.**

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

8 (b) **REPORTING REQUIREMENTS.**—Section 740A of
9 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
10 379j–13) shall cease to be effective January 31, 2024.

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

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

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

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

20 (b) **FINDING.**—Congress finds that the fees author-
21 ized by the amendments made in this title will be dedi-
22 cated toward expediting the generic new animal drug de-
23 velopment process and the review of abbreviated applica-
24 tions for generic new animal drugs, supplemental abbrevi-
25 ated applications for generic new animal drugs, and in-

1 vestigational submissions for generic new animal drugs as
2 set forth in the goals identified for purposes of part 5 of
3 subchapter C of chapter VII of the Federal Food, Drug,
4 and Cosmetic Act, in the letters from the Secretary of
5 Health and Human Services to the Chairman of the Com-
6 mittee on Energy and Commerce of the House of Rep-
7 resentatives 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. 202. AUTHORITY TO ASSESS AND USE GENERIC NEW**
11 **ANIMAL DRUG FEES.**

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

15 “(b) **FEE REVENUE AMOUNTS.**—

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

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

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

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

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

10 (b) ANNUAL FEE SETTING; ADJUSTMENTS.—

11 (1) INFLATION ADJUSTMENT.—Section 741(c)
12 (21 U.S.C. 379j–21(c)) is amended—

13 (A) by redesignating paragraphs (2)
14 through (4) as paragraphs (3) through (5), re-
15 spectively; and

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

18 “(2) INFLATION ADJUSTMENT.—

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

1 “(i) one;

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

14 “(iii) the average annual percent
15 change that occurred in the Consumer
16 Price Index for urban consumers (Wash-
17 ington-Baltimore, DC–MD–VA–WV; not
18 seasonally adjusted; all items less food and
19 energy; annual index) for the first 3 of the
20 preceding 4 years for which data are avail-
21 able multiplied by the average proportion
22 of all costs other than personnel compensa-
23 tion and benefits costs to total Food and
24 Drug Administration costs for the first 3

1 of the preceding 4 fiscal years for which
2 data are available.

3 “(B) COMPOUNDED BASIS.—The adjust-
4 ment made each fiscal year after fiscal year
5 2020 under this paragraph shall be applied on
6 a compounded basis to the revenue amount cal-
7 culated under this paragraph for the most re-
8 cent previous fiscal year.”.

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

12 “(3) WORKLOAD ADJUSTMENTS.—

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

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

1 ed average of the change in the total num-
2 ber of abbreviated applications for generic
3 new animal drugs, manufacturing supple-
4 mental abbreviated applications for generic
5 new animal drugs, investigational generic
6 new animal drug study submissions, and
7 investigational generic new animal drug
8 protocol submissions submitted to the Sec-
9 retary; and

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

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

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

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

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

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

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

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

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

21 “(1) FEE WAIVER OR REDUCTION.—The Sec-
22 retary shall grant a waiver from or a reduction of
23 1 or more fees assessed under subsection (a) where
24 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.—Sec-
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) in subsection (b), by striking “Committee
13 on Health, Education, Labor, and Pensions” and in-
14 serting “the Committee on Health, Education,
15 Labor and Pensions”;

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

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

20 **SEC. 204. SAVINGS CLAUSE.**

21 Notwithstanding the amendments made by this title,
22 part 5 of subchapter C of chapter VII of the Federal Food,
23 Drug, and Cosmetic Act (21 U.S.C. 379j–21 et seq.), as
24 in effect on the day before the date of enactment of this
25 title, shall continue to be in effect with respect to abbre-

1 viated applications for a generic new animal drug and sup-
2 plemental abbreviated applications for a generic new ani-
3 mal drug (as defined in such part as of such day) that
4 on or after October 1, 2013, but before October 1, 2018,
5 were accepted by the Food and Drug Administration for
6 filing with respect to assessing and collecting any fee re-
7 quired by such part for a fiscal year prior to fiscal year
8 2019.

9 **SEC. 205. EFFECTIVE DATE.**

10 The amendments made by this title shall take effect
11 on October 1, 2018, or the date of the enactment of this
12 Act, whichever is later, except that fees under part 5 of
13 subchapter C of chapter VII of the Federal Food, Drug,
14 and Cosmetic Act, as amended by this title, shall be as-
15 sessed for abbreviated applications for a generic new ani-
16 mal drug and supplemental abbreviated applications for
17 a generic new animal drug received on or after October
18 1, 2018, regardless of the date of enactment of this Act.

19 **SEC. 206. SUNSET DATES.**

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

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

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

5 **TITLE III—MISCELLANEOUS**
6 **PROVISIONS**

7 **SEC. 301. ELECTRONIC SUBMISSIONS.**

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

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

16 (b) CONDITIONAL APPROVAL OF NEW ANIMAL
17 DRUGS FOR MINOR USE AND MINOR SPECIES.—Section
18 571(a) (21 U.S.C. 360ccc(a)) is amended by adding at
19 the end the following:

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

1 **SEC. 302. INDEX OF LEGALLY MARKETED UNAPPROVED**
2 **NEW ANIMAL DRUGS FOR MINOR SPECIES.**

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

5 (1) by amending paragraph (1) to read as fol-
6 lows:

7 “(1) ‘LEGAL STATUS—In order to be legally
8 marketed, a new animal drug intended for a minor
9 species must be Approved, Conditionally Approved,
10 or Indexed by the Food and Drug Administration.
11 THIS PRODUCT IS INDEXED—MIF.’ (followed
12 by the applicable minor species index file number
13 and a period) ‘Extra-label use is prohibited.’;”;

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

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

17 (a) IN GENERAL.—Section 502(w) (21 U.S.C.
18 352(w)) is amended—

19 (1) in subparagraph (1), by striking “; or” and
20 inserting “;”;

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

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

24 “(3) for which an application has been ap-
25 proved under section 512 and the labeling of such
26 drug does not include the application number in the

1 format: ‘Approved by FDA under (A)NADA # xxx-
2 xxx’, except that this subparagraph shall not apply
3 to representative labeling required under section
4 514.1(b)(3)(v)(b) of title 21, Code of Federal Regu-
5 lations (or any successor regulation) for animal feed
6 bearing or containing a new animal drug.’’.

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