

AMENDMENT NO. _____ Calendar No. _____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—115th Cong., 2d Sess.

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.

Referred to the Committee on _____ and
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended
to be proposed by _____

Viz:

1 Strike all after the enacting clause and insert the fol-

2 lowing:

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.

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

8 **SEC. 102. DEFINITIONS.**

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

10 (1) by amending paragraph (1) to read as fol-
11 lows:

12 “(1)(A) The term ‘animal drug application’
13 means—

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

16 or

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

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

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

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

8 **SEC. 103. AUTHORITY TO ASSESS AND USE ANIMAL DRUG**
9 **FEES.**

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

12 (1) in paragraph (1)—

13 (A) in subparagraph (A)—

14 (i) by striking “2014” and inserting
15 “2019”; and

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

18 (B) in subparagraph (B)—

19 (i) by striking “2015 through 2018”
20 and inserting “2020 through 2023”; and

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

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

1 (b) ANNUAL FEE SETTING; ADJUSTMENTS.—

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

4 (A) in the matter preceding subparagraph
5 (A)—

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

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

11 (B) by redesignating subparagraphs (A),
12 (B), and (C) as clauses (i), (ii), and (iii), re-
13 spectively;

14 (C) by striking the flush text at the end;
15 and

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

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

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

1 “(3) WORKLOAD ADJUSTMENTS.—

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

11 With respect to such adjustment—

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

23 “(ii) the Secretary shall publish in the
24 Federal Register the fees resulting from

1 such adjustment and the supporting meth-
2 odologies.

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

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

23 (3) FINAL YEAR ADJUSTMENT.—Section
24 740(c)(4) (21 U.S.C. 379j–12(c)(4)) is amended—

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

3 (B) by striking “2019” and inserting
4 “2024”.

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

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

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

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

12 “(4) EXEMPTIONS FROM FEES.—

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

17 “(i) not later than September 30,
18 2023, submits a supplemental animal drug
19 application relating to a new animal drug
20 application approved under section 512,
21 solely to add the new animal drug applica-
22 tion number to the labeling of the drug in
23 the manner specified in section 502(w)(3);
24 and

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

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

16 (d) CREDITING AND AVAILABILITY OF FEES.—

17 (1) AUTHORIZATION OF APPROPRIATIONS.—

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

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

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

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

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

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

11 “(5) RECOVERY OF COLLECTION SHORT-
12 FALLS.—

13 “(A) IN GENERAL.—Subject to subpara-
14 graph (B)—

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

23 “(ii) for fiscal year 2022, the amount
24 of fees otherwise authorized to be collected
25 under this section shall be increased by the

1 amount, if any, by which the amount col-
2 lected under this section and appropriated
3 for fiscal year 2020 falls below the amount
4 of fees authorized for fiscal year 2020
5 under paragraph (3); and

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

16 “(B) REDUCTION OF SHORTFALL-BASED
17 FEE INCREASE BY PRIOR YEAR EXCESS COL-
18 LECTIONS.—

19 “(i) IN GENERAL.—Subject to clause
20 (ii), the Secretary shall, in such manner as
21 the Secretary determines appropriate, re-
22 duce any fee increase otherwise applicable
23 for a fiscal year under subparagraph (A)
24 by the amount of any excess collections

1 under this section for preceding fiscal
2 years (after fiscal year 2018).

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

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

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

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

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

1 (2) by striking “2014” each place it appears in
2 subsections (a) and (b) and inserting “2019”; and
3 (3) in subsection (d), by striking “2018” each
4 place it appears and inserting “2023”.

5 **SEC. 105. SAVINGS CLAUSE.**

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

17 **SEC. 106. EFFECTIVE DATE.**

18 The amendments made by this title shall take effect
19 on October 1, 2018, or the date of the enactment of this
20 Act, whichever is later, except that fees under part 4 of
21 subchapter C of chapter VII of the Federal Food, Drug,
22 and Cosmetic Act, as amended by this title, shall be as-
23 sessed for animal drug applications and supplemental ani-
24 mal drug applications received on or after October 1,
25 2018, regardless of the date of the enactment of this Act.

1 **SEC. 107. SUNSET DATES.**

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

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

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

12 **TITLE II—FEES RELATING TO**
13 **GENERIC ANIMAL DRUGS**

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

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

17 (b) FINDING.—Congress finds that the fees author-
18 ized by the amendments made in this title will be dedi-
19 cated toward expediting the generic new animal drug de-
20 velopment process and the review of abbreviated applica-
21 tions for generic new animal drugs, supplemental abbrevi-
22 ated applications for generic new animal drugs, and in-
23 vestigational submissions for generic new animal drugs as
24 set forth in the goals identified for purposes of part 5 of
25 subchapter C of chapter VII of the Federal Food, Drug,
26 and Cosmetic Act, in the letters from the Secretary of

1 Health and Human Services to the Chairman of the Com-
2 mittee on Energy and Commerce of the House of Rep-
3 resentatives and the Chairman of the Committee on
4 Health, Education, Labor, and Pensions of the Senate as
5 set forth in the Congressional Record.

6 **SEC. 202. AUTHORITY TO ASSESS AND USE GENERIC NEW**
7 **ANIMAL DRUG FEES.**

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

11 “(b) FEE REVENUE AMOUNTS.—

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

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

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

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

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

4 (b) ANNUAL FEE SETTING; ADJUSTMENTS.—

5 (1) INFLATION ADJUSTMENT.—Section 741(c)
6 (21 U.S.C. 379j–21(c)) is amended—

7 (A) by redesignating paragraphs (2)
8 through (4) as paragraphs (3) through (5), re-
9 spectively; and

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

12 “(2) INFLATION ADJUSTMENT.—

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

20 “(i) one;

21 “(ii) the average annual percent
22 change in the cost, per full-time equivalent
23 position of the Food and Drug Administra-
24 tion, of all personnel compensation and
25 benefits paid with respect to such positions

1 for the first 3 of the preceding 4 fiscal
2 years for which data are available, multi-
3 plied by the average proportion of per-
4 sonnel compensation and benefits costs to
5 total Food and Drug Administration costs
6 for the first 3 of the preceding 4 fiscal
7 years for which data are available; and

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

21 “(B) COMPOUNDED BASIS.—The adjust-
22 ment made each fiscal year after fiscal year
23 2020 under this paragraph shall be applied on
24 a compounded basis to the revenue amount cal-

1 investigational generic new animal drug
2 protocol submissions submitted to the Sec-
3 retary; and

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

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

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

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

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

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

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

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

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

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

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

23 “(A) not later than September 30, 2023,
24 submits a supplemental abbreviated application
25 for a generic new animal drug approved under

1 section 512, solely to add the application num-
2 ber to the labeling of the drug in the manner
3 specified in section 502(w)(3); and

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

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

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

17 “(4) EXCESS COLLECTIONS.—If the sum total
18 of fees collected under this section for a fiscal year
19 exceeds the amount of fees authorized to be appro-
20 priated for such year under paragraph (3), the ex-
21 cess collections shall be credited to the appropria-
22 tions account of the Food and Drug Administration
23 as provided in paragraph (1).”.

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

25 Section 742 (21 U.S.C. 379j–22) 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. 204. SAVINGS CLAUSE.**

8 Notwithstanding the amendments made by this title,
9 part 5 of subchapter C of chapter VII of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 379j–21 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 abbrevi-
13 ated applications for a generic new animal drug and sup-
14 plemental abbreviated applications for a generic new ani-
15 mal drug (as defined in such part as of such day) that
16 on or after October 1, 2013, but before October 1, 2018,
17 were accepted by the Food and Drug Administration for
18 filing with respect to assessing and collecting any fee re-
19 quired by such part for a fiscal year prior to fiscal year
20 2019.

21 **SEC. 205. 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 5 of
25 subchapter C of chapter VII of the Federal Food, Drug,

1 and Cosmetic Act, as amended by this title, shall be as-
2 sessed for abbreviated applications for a generic new ani-
3 mal drug and supplemental abbreviated applications for
4 a generic new animal drug received on or after October
5 1, 2018, regardless of the date of enactment of this Act.

6 **SEC. 206. SUNSET DATES.**

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

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

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

17 **TITLE III—MISCELLANEOUS**
18 **PROVISIONS**

19 **SEC. 301. ELECTRONIC SUBMISSIONS.**

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

24 “(4) Beginning on October 1, 2018, all applications
25 or submissions pursuant to this subsection shall be sub-

1 mitted by electronic means in such format as the Sec-
2 retary may require.”.

3 (b) **CONDITIONAL APPROVAL OF NEW ANIMAL**
4 **DRUGS FOR MINOR USE AND MINOR SPECIES.**—Section
5 571(a) (21 U.S.C. 360ccc(a)) is amended by adding at
6 the end the following:

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

11 **SEC. 302. INDEX OF LEGALLY MARKETED UNAPPROVED**
12 **NEW ANIMAL DRUGS FOR MINOR SPECIES.**

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

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

17 “(1) ‘LEGAL STATUS—In order to be legally
18 marketed, a new animal drug intended for a minor
19 species must be Approved, Conditionally Approved,
20 or Indexed by the Food and Drug Administration.
21 **THIS PRODUCT IS INDEXED—MIF.**’ (followed
22 by the applicable minor species index file number
23 and a period) ‘Extra-label use is prohibited.’;”;

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

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

2 (a) IN GENERAL.—Section 502(w) (21 U.S.C.
3 352(w)) is amended—

4 (1) in paragraph (1), by striking “; or” and in-
5 serting “;”;

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

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

9 “(3) for which an application has been ap-
10 proved under section 512 and the labeling of such
11 drug does not include the application number in the
12 format: ‘Approved by FDA under (A)NADA # xxx-
13 xxx’, except that this subparagraph shall not apply
14 to representative labeling required under section
15 514.1(b)(3)(v)(b) of title 21, Code of Federal Regu-
16 lations (or any successor regulation) for animal feed
17 bearing or containing a new animal drug.”.

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

21 **SEC. 304. ISSUANCE OF RECOMMENDATIONS.**

22 Not later than September 30, 2019, the Secretary of
23 Health and Human Services (referred to in this section
24 as the “Secretary”) shall issue recommendations that the
25 Secretary, in the letters described in section 101(b) of the
26 Animal Drug User Fee Amendments of 2013 (Public Law

1 113–14), agreed to develop regarding the feasibility of
2 pursuing statutory revisions that may expand the use of
3 conditional approval of new animal drugs under section
4 571 of the Federal Food, Drug, and Cosmetic Act (21
5 U.S.C. 360ccc) to appropriate categories of new animal
6 drugs.