

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 1418
OFFERED BY M. _____**

Strike all after the enacting clause and insert the following:

1 SECTION 1. SHORT TITLE.

2 This Act may be cited as the “Animal Drug and Ani-
3 mal Generic Drug User Fee Amendments of 2023”.

4 SEC. 2. TABLE OF CONTENTS.

5 The table of contents for this Act is the following:

- Sec. 1. Short title.
- Sec. 2. Table of contents.

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.
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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.
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TITLE III—SUPPORTING ANIMAL AND HUMAN HEALTH

- Sec. 301. Reporting requirements.
- Sec. 302. Definition of major species.
- Sec. 303. Antimicrobial resistance.

1 **TITLE I—FEES RELATING TO**
2 **ANIMAL DRUGS**

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

4 (a) **SHORT TITLE.**—This title may be cited as the
5 “Animal Drug User Fee Amendments of 2023”.

6 (b) **FINDING.**—Congress finds that the fees author-
7 ized by the amendments made in this title will be dedi-
8 cated toward expediting the animal drug development
9 process and the review of new and supplemental animal
10 drug applications and investigational animal drug submis-
11 sions as set forth in the goals identified for purposes of
12 part 4 of subchapter C of chapter VII of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 379j–11 et seq.), in
14 the letters from the Secretary of Health and Human Serv-
15 ices to the Chairman of the Committee on Energy and
16 Commerce of the House of Representatives and the Chair-
17 man of the Committee on Health, Education, Labor, and
18 Pensions of the Senate as set forth in the Congressional
19 Record.

20 **SEC. 102. DEFINITIONS.**

21 Section 739 of the Federal Food, Drug, and Cosmetic
22 Act (21 U.S.C. 379j–11) is amended—

23 (1) in paragraph (3), by striking “national drug
24 code” and inserting “National Drug Code”; and

1 (2) by amending paragraph (8)(I) to read as
2 follows:

3 “(I) The activities necessary for implemen-
4 tation of the United States and European
5 Union Mutual Recognition Agreement for Phar-
6 maceutical Good Manufacturing Practice In-
7 spections, and the United States and United
8 Kingdom Mutual Recognition Agreement Sec-
9 toral Annex for Pharmaceutical Good Manufac-
10 turing Practices, and other mutual recognition
11 agreements, with respect to animal drug prod-
12 ucts subject to review, including implementation
13 activities prior to and following product ap-
14 proval.”.

15 **SEC. 103. AUTHORITY TO ASSESS AND USE ANIMAL DRUG**
16 **FEEES.**

17 (a) IN GENERAL.—Section 740(a)(1)(A)(ii) of the
18 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
19 12(a)(1)(A)(ii)) is amended—

20 (1) in subclause (I), by striking “and” at the
21 end;

22 (2) in subclause (II), by striking the period at
23 the end and inserting “; and”; and

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

1 “(III) an application for condi-
2 tional approval under section 571 of a
3 new animal drug for which an animal
4 drug application submitted under sec-
5 tion 512(b)(1) has been previously ap-
6 proved under section 512(d)(1) for
7 another intended use.”.

8 (b) FEE REVENUE AMOUNTS.—Section 740(b)(1) of
9 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
10 379j–12(b)(1)) is amended to read as follows:

11 “(1) IN GENERAL.—Subject to subsections (c),
12 (d), (f), and (g), for each of fiscal years 2024
13 through 2028, the fees required under subsection (a)
14 shall be established to generate a total revenue
15 amount of \$33,500,000.”.

16 (c) ANNUAL FEE SETTING; ADJUSTMENTS.—

17 (1) ANNUAL FEE SETTING.—Section 740(c)(1)
18 of the Federal Food, Drug, and Cosmetic Act (21
19 U.S.C. 379j–12(c)(1)) is amended to read as follows:

20 “(1) ANNUAL FEE SETTING.—Not later than
21 60 days before the start of each fiscal year begin-
22 ning after September 30, 2023, the Secretary
23 shall—

24 “(A) establish for that fiscal year animal
25 drug application fees, supplemental animal drug

1 application fees, animal drug sponsor fees, ani-
2 mal drug establishment fees, and animal drug
3 product fees based on the revenue amounts es-
4 tablished under subsection (b) and the adjust-
5 ments provided under this subsection; and

6 “(B) publish such fee revenue amounts
7 and fees in the Federal Register.”.

8 (2) INFLATION ADJUSTMENT.—Section
9 740(c)(2) of the Federal Food, Drug, and Cosmetic
10 Act (21 U.S.C. 379j–12(c)(2)) is amended—

11 (A) in subparagraph (A)—

12 (i) in the matter preceding clause (i),
13 by striking “2020” and inserting “2025”;
14 and

15 (ii) in clause (iii), by striking “Balti-
16 more” and inserting “Arlington-Alexan-
17 dria”; and

18 (B) in subparagraph (B), by striking
19 “2020” and inserting “2025”.

20 (3) WORKLOAD ADJUSTMENTS.—Section
21 740(c)(3) of the Federal Food, Drug, and Cosmetic
22 Act (21 U.S.C. 379j–12(c)(3)) is amended—

23 (A) in subparagraph (A)—

24 (i) in the matter preceding clause

25 (i)—

1 (I) by striking “2020” and in-
2 serring “2025”; and

3 (II) by striking “subparagraphs
4 (B) and (C)” and inserting “subpara-
5 graph (B)”;

6 (ii) in clause (i) by striking “and” at
7 the end; and

8 (iii) by striking clause (ii) and insert-
9 ing the following:

10 “(ii) such adjustment shall be made
11 for each fiscal year that the adjustment de-
12 termined by the Secretary is greater than
13 3 percent, except for the first fiscal year
14 that the adjustment is greater than 3 per-
15 cent; and

16 “(iii) the Secretary shall publish in
17 the Federal Register notice under para-
18 graph (1) the amount of such adjustment
19 and the supporting methodologies.”;

20 (B) by striking subparagraph (B); and

21 (C) by redesignating subparagraph (C) as
22 subparagraph (B).

23 (4) FINAL YEAR ADJUSTMENT.—Section
24 740(c)(4) of the Federal Food, Drug, and Cosmetic

1 Act (21 U.S.C. 379j-12(c)(4)) is amended to read
2 as follows:

3 “(4) OPERATING RESERVE ADJUSTMENT.—

4 “(A) IN GENERAL.—For fiscal year 2025
5 and each subsequent fiscal year, after the fee
6 revenue amount established under subsection
7 (b) is adjusted in accordance with paragraphs
8 (2) and (3), the Secretary shall—

9 “(i) increase the fee revenue amount
10 for such fiscal year, if necessary to provide
11 an operating reserve of not less than 12
12 weeks; or

13 “(ii) if the Secretary has an operating
14 reserve in excess of the number of weeks
15 specified in subparagraph (C) for that fis-
16 cal year, the Secretary shall decrease the
17 fee revenue amount to provide not more
18 than the number of weeks specified in sub-
19 paragraph (C) for that fiscal year.

20 “(B) CARRYOVER USER FEES.—For pur-
21 poses of this paragraph, the operating reserve
22 of carryover user fees for the process for the re-
23 view of animal drug applications does not in-
24 clude carryover user fees that have not been ap-
25 propriated.

1 “(C) NUMBER OF WEEKS OF OPERATING
2 RESERVES.—The number of weeks of operating
3 reserves specified in this subparagraph is—

4 “(i) 22 weeks for fiscal year 2025;

5 “(ii) 20 weeks for fiscal year 2026;

6 “(iii) 18 weeks for fiscal year 2027;

7 and

8 “(iv) 16 weeks for fiscal year 2028.

9 “(D) PUBLICATION.—If an adjustment to
10 the operating reserve is made under this para-
11 graph, the Secretary shall publish in the Fed-
12 eral Register notice under paragraph (1) the ra-
13 tionale for the amount of the adjustment and
14 the supporting methodologies.”.

15 (d) EXEMPTION FROM FEES.—Section 740(d)(4) of
16 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 379j–12(d)(4)) is amended to read as follows:

18 “(4) EXEMPTION FROM FEES.—Fees under
19 paragraphs (2), (3), and (4) of subsection (a) shall
20 not apply with respect to any person who is the
21 named applicant or sponsor of an animal drug appli-
22 cation, supplemental animal drug application, or in-
23 vestigational animal drug submission if such applica-
24 tion or submission involves the intentional genomic
25 alteration of an animal that is intended to produce

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

3 (e) CREDITING AND AVAILABILITY OF FEES.—

4 (1) AUTHORIZATION OF APPROPRIATIONS.—

5 Section 740(g)(3) of the Federal Food, Drug, and
6 Cosmetic Act (21 U.S.C. 379j–12(g)(3)) is amended
7 by striking “2019 through 2023” and inserting
8 “2024 through 2028”.

9 (2) COLLECTION SHORTFALLS.—Section 740(g)
10 of the Federal Food, Drug, and Cosmetic Act (21
11 U.S.C. 379j–12(g)) is amended—

12 (A) in paragraph (3), by striking “and
13 paragraph (5)”;

14 (B) by striking paragraph (5).

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

16 Section 740A of the Federal Food, Drug, and Cos-
17 metic Act (21 U.S.C. 379j–13) is amended—

18 (1) in subsection (a), by striking “2018” and
19 inserting “2023”;

20 (2) by striking “2019” each place it appears in
21 subsections (a) and (b) and inserting “2024”; and

22 (3) in subsection (d)—

23 (A) in paragraph (1), by striking “2023”
24 and inserting “2028”; and

1 (B) in paragraph (5), by striking “2023”
2 and inserting “2028”.

3 **SEC. 105. SAVINGS CLAUSE.**

4 Notwithstanding the amendments made by this title,
5 part 4 of subchapter C of chapter VII of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 379j–11 et seq.), as
7 in effect on the day before the date of enactment of this
8 title, shall continue to be in effect with respect to animal
9 drug applications and supplemental animal drug applica-
10 tions (as defined in such part as of such day) that on or
11 after October 1, 2018, but before October 1, 2023, were
12 accepted by the Food and Drug Administration for filing
13 with respect to assessing and collecting any fee required
14 by such part for a fiscal year prior to fiscal year 2024.

15 **SEC. 106. EFFECTIVE DATE.**

16 The amendments made by this title shall take effect
17 on October 1, 2023, or the date of the enactment of this
18 Act, whichever is later, except that fees under part 4 of
19 subchapter C of chapter VII of the Federal Food, Drug,
20 and Cosmetic Act (21 U.S.C. 379j–11 et seq.), as amended
21 by this title, shall be assessed for animal drug applications
22 and supplemental animal drug applications received on or
23 after October 1, 2023, regardless of the date of the enact-
24 ment of this Act.

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

2 (a) AUTHORIZATION.—Sections 739 and 740 of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 21
4 U.S.C. 379j–11; 379j–12) shall cease to be effective Octo-
5 ber 1, 2028.

6 (b) REPORTING REQUIREMENTS.—Section 740A of
7 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
8 379j–13) shall cease to be effective January 31, 2029.

9 (c) PREVIOUS SUNSET PROVISION.—Effective Octo-
10 ber 1, 2023, subsections (a) and (b) of section 107 of the
11 Animal Drug User Fee Amendments of 2018 (Public Law
12 115–234) are repealed.

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

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

16 (a) SHORT TITLE.—This title may be cited as the
17 “Animal Generic Drug User Fee Amendments of 2023”.

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

1 and Cosmetic Act (21 U.S.C. 379j–21 et seq.), in the let-
2 ters from the Secretary of Health and Human Services
3 to the Chairman of the Committee on Energy and Com-
4 merce of the House of Representatives and the Chairman
5 of the Committee on Health, Education, Labor and Pen-
6 sions of the Senate as set forth in the Congressional
7 Record.

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

10 (a) **GENERIC INVESTIGATIONAL NEW ANIMAL DRUG**
11 **FILE FEE.**—Section 741(a) of the Federal Food, Drug,
12 and Cosmetic Act (21 U.S.C. 379j–21(a)) is amended by
13 adding at the end the following:

14 “(4) **GENERIC INVESTIGATIONAL NEW ANIMAL**
15 **DRUG FILE FEE.**—

16 “(A) **IN GENERAL.**—

17 “(i) **NEW FILE REQUEST.**—Each per-
18 son that submits a request to establish a
19 generic investigational new animal drug
20 file on or after October 1, 2023, shall be
21 assessed a fee as established under sub-
22 section (c).

23 “(ii) **NEW SUBMISSION TO ESTAB-**
24 **LISHED FILE.**—Each person that makes a
25 submission to a generic investigational new

1 animal drug file on or after October 1,
2 2023, where such file was established prior
3 to October 1, 2023, shall be assessed a fee
4 for the first submission on or after October
5 1, 2023, as established under subsection
6 (c).

7 “(B) PAYMENT.—

8 “(i) NEW FILE REQUEST.—The fee
9 required by subparagraph (A)(i) shall be
10 due upon submission of the request to es-
11 tablish the generic investigational new ani-
12 mal drug file.

13 “(ii) NEW SUBMISSION TO ESTAB-
14 LISHED FILE.—The fee required by sub-
15 paragraph (A)(ii) shall be due upon the
16 first submission to the generic investiga-
17 tional new animal drug file.

18 “(C) EXCEPTIONS.—

19 “(i) TERMINATING AN EXISTING GE-
20 NERIC INVESTIGATIONAL NEW ANIMAL
21 DRUG FILE.—If a person makes a submis-
22 sion to the generic investigational new ani-
23 mal drug file to terminate that file, the
24 person shall not be subject to a fee under
25 subparagraph (A)(ii) for that submission.

1 “(ii) TRANSFERRING AN EXISTING GE-
2 NERIC INVESTIGATIONAL NEW ANIMAL
3 DRUG FILE.—If a person makes a submis-
4 sion to the generic investigational new ani-
5 mal drug file to transfer that file to a dif-
6 ferent generic new animal drug sponsor,
7 the person shall not be subject to a fee
8 under subparagraph (A)(ii) for that sub-
9 mission.”.

10 (b) FEE REVENUE AMOUNTS.—Section 741(b) of the
11 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-
12 21(b)) is amended—

13 (1) in paragraph (1)—

14 (A) by striking “2019 through 2023” and
15 inserting “2024 through 2028”; and

16 (B) by striking “\$18,336,340” and insert-
17 ing “\$25,000,000”; and

18 (2) in paragraph (2)—

19 (A) in subparagraph (A)—

20 (i) by striking “25 percent” and in-
21 serting “20 percent”; and

22 (ii) by inserting before the semicolon
23 at the end the following: “and fees under
24 subsection (a)(4) (relating to generic inves-
25 tigational new animal drug files)”;

1 (B) in subparagraph (B), by striking “37.5
2 percent” and inserting “40 percent”; and

3 (C) in subparagraph (C), by striking “37.5
4 percent” and inserting “40 percent”.

5 (c) ANNUAL FEE SETTING; ADJUSTMENTS.—

6 (1) ANNUAL FEE SETTING.— Section 741(c)(1)
7 of the Federal Food, Drug, and Cosmetic Act (21
8 U.S.C. 379j–21(c)(1)) is amended to read as follows:

9 “(1) ANNUAL FEE SETTING.—The Secretary
10 shall establish, not later than 60 days before the
11 start of each fiscal year beginning after September
12 30, 2023, for that fiscal year—

13 “(A) abbreviated application fees that are
14 based on the revenue amounts established
15 under subsection (b), the adjustments provided
16 under this subsection, and the amount of fees
17 anticipated to be collected under subsection
18 (a)(4) during that fiscal year;

19 “(B) generic new animal drug sponsor
20 fees, and generic new animal drug product fees,
21 based on the revenue amounts established
22 under subsection (b) and the adjustments pro-
23 vided under this subsection; and

1 “(C) a generic investigational new animal
2 drug file fee of \$50,000 for each request or
3 submission described in subsection (a)(4)(A).”.

4 (2) INFLATION ADJUSTMENT.—Section
5 741(c)(2) of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 379j–21(c)(2)) is amended—

7 (A) in subparagraph (A)—

8 (i) in the matter preceding clause (i),
9 by striking “2020” and inserting “2025”;
10 and

11 (ii) in clause (iii), by striking “Balti-
12 more” and inserting “Arlington-Alexan-
13 dria”; and

14 (B) in subparagraph (B), by striking
15 “2020” and inserting “2025”.

16 (3) WORKLOAD ADJUSTMENT.—Section
17 741(c)(3) of the Federal Food, Drug, and Cosmetic
18 Act (21 U.S.C. 379j–21(c)(3)) is amended—

19 (A) in subparagraph (A)—

20 (i) in the matter preceding clause (i),
21 by striking “2020” and inserting “2025”;

22 (ii) in clause (i)—

23 (I) by striking “and investiga-
24 tional generic new animal drug pro-
25 tocol submissions” and inserting “in-

1 vestigational generic new animal drug
2 protocol submissions, requests to es-
3 tablish a generic investigational new
4 animal drug file, and generic inves-
5 tigational new animal drug meeting
6 requests”; and

7 (II) by striking “; and” and in-
8 serting a semicolon;

9 (iii) by redesignating clause (ii) as
10 clause (iii); and

11 (iv) by inserting after clause (i) the
12 following:

13 “(ii) if the workload adjustment cal-
14 culated by the Secretary under clause (i)
15 exceeds 25 percent, the Secretary shall use
16 25 percent for the adjustment; and”; and

17 (B) in subparagraph (B), by striking
18 “2021 through 2023” and inserting “2026
19 through 2028”.

20 (4) FINAL YEAR ADJUSTMENT.—Section
21 741(c)(4) of the Federal Food, Drug, and Cosmetic
22 Act (21 U.S.C. 379j–21(c)(4)) is amended—

23 (A) by striking “2023” each place it ap-
24 pears and inserting “2028”; and

1 (B) by striking “2024” and inserting
2 “2029”.

3 (d) FEE WAIVER OR REDUCTION; EXEMPTION FROM
4 FEES.—Subsection (d) of section 741 of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21) is
6 amended to read as follows:

7 “(d) FEE WAIVER OR REDUCTION.—The Secretary
8 shall grant a waiver from, or a reduction of, one or more
9 fees assessed under subsection (a) where the Secretary
10 finds that the generic new animal drug is intended solely
11 to provide for a minor use or minor species indication.”.

12 (e) EFFECT OF FAILURE TO PAY FEES.—Section
13 741(e) of the Federal Food, Drug, and Cosmetic Act (21
14 U.S.C. 379j–21(e)) is amended by striking “The Secretary
15 may discontinue” and inserting “A request to establish a
16 generic investigational new animal drug file that is sub-
17 mitted by a person subject to fees under subsection (a)
18 shall be considered incomplete and shall not be accepted
19 for action by the Secretary until all fees owed by such per-
20 son have been paid. The Secretary may discontinue”.

21 (f) ASSESSMENT OF FEES.—Section 741(f)(2) of the
22 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
23 21(f)(2)) is amended by striking “sponsors, and generic
24 new animal drug products at any time” and inserting

1 “products, generic new animal drug sponsors, and generic
2 investigational new animal drug files at any time”.

3 (g) CREDITING AND AVAILABILITY OF FEES.—Sec-
4 tion 741(g) of the Federal Food, Drug, and Cosmetic Act
5 (21 U.S.C. 379j–21(g)) is amended—

6 (1) in paragraph (3), by striking “2019
7 through 2023” and inserting “2024 through 2028”;

8 (2) by striking the second paragraph (4) (relat-
9 ing to Offset), as added by section 202 of the Ani-
10 mal Generic Drug User Fee Amendments of 2013
11 (Public Law 113–14); and

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

13 “(5) RECOVERY OF COLLECTION SHORT-
14 FALLS.—The amount of fees otherwise authorized to
15 be collected under this section shall be increased—

16 “(A) for fiscal year 2026, by the amount,
17 if any, by which the amount collected under this
18 section and appropriated for fiscal year 2024
19 falls below the amount of fees authorized for
20 fiscal year 2024 under paragraph (3);

21 “(B) for fiscal year 2027, by the amount,
22 if any, by which the amount collected under this
23 section and appropriated for fiscal year 2025
24 falls below the amount of fees authorized for
25 fiscal year 2025 under paragraph (3); and

1 “(C) for fiscal year 2028, by the amount,
2 if any, by which the amount collected under this
3 section and appropriated for fiscal years 2026
4 and 2027 (including estimated collections for
5 fiscal year 2027) falls below the amount of fees
6 authorized for such fiscal years under para-
7 graph (3).”.

8 (h) DEFINITIONS.—Section 741(k) of the Federal
9 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21(k)) is
10 amended—

11 (1) by redesignating paragraphs (8), (9), (10),
12 and (11) as paragraphs (9), (10), (11), and (13), re-
13 spectively;

14 (2) by inserting after paragraph (7) the fol-
15 lowing:

16 “(8) GENERIC INVESTIGATIONAL NEW ANIMAL
17 DRUG MEETING REQUEST.—The term ‘generic inves-
18 tigational new animal drug meeting request’ means
19 a request submitted by a generic new animal drug
20 sponsor to meet with the Secretary to discuss an in-
21 vestigational submission for a generic new animal
22 drug.”;

23 (3) in paragraph (11) (as so redesignated), by
24 adding at the end the following:

1 “(I) The activities necessary for explo-
2 ration and implementation of the United States
3 and European Union Mutual Recognition
4 Agreement for Pharmaceutical Good Manufac-
5 turing Practice Inspections, and the United
6 States and United Kingdom Mutual Recogni-
7 tion Agreement Sectoral Annex for Pharma-
8 ceutical Good Manufacturing Practices, and
9 other mutual recognition agreements, with re-
10 spect to generic new animal drug products sub-
11 ject to review, including implementation activi-
12 ties prior to and following product approval.”;
13 and

14 (4) by inserting after paragraph (11) (as so re-
15 designated) the following:

16 “(12) REQUEST TO ESTABLISH A GENERIC IN-
17 VESTIGATIONAL NEW ANIMAL DRUG FILE.—The
18 term ‘request to establish a generic investigational
19 new animal drug file’ means the submission to the
20 Secretary of a request to establish a generic inves-
21 tigational new animal drug file to contain investiga-
22 tional submissions for a generic new animal drug.”.

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

24 Section 742 of the Federal Food, Drug, and Cosmetic
25 Act (21 U.S.C. 379j–22) is amended—

1 (1) in subsection (a), by striking “2018” and
2 inserting “2023”;

3 (2) by striking “2019” each place it appears in
4 subsections (a) and (b) and inserting “2024”; and

5 (3) in subsection (d), by striking “2023” each
6 place it appears and inserting “2028”.

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, 2018, but before October 1, 2023,
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 2024.

21 **SEC. 205. EFFECTIVE DATE.**

22 The amendments made by this title shall take effect
23 on October 1, 2023, 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 (21 U.S.C. 379j–21 et seq.), as amend-
2 ed by this title, shall be assessed for abbreviated applica-
3 tions for a generic new animal drug and supplemental ab-
4 breviated applications for a generic new animal drug re-
5 ceived on or after October 1, 2023, regardless of the date
6 of enactment of this Act.

7 **SEC. 206. SUNSET DATES.**

8 (a) AUTHORIZATION.—Section 741 of the Federal
9 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21) shall
10 cease to be effective October 1, 2028.

11 (b) REPORTING REQUIREMENTS.—Section 742 of the
12 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
13 22) shall cease to be effective January 31, 2029.

14 (c) PREVIOUS SUNSET PROVISION.—Effective Octo-
15 ber 1, 2023, subsections (a) and (b) of section 206 of the
16 Animal Generic Drug User Fee Amendments of 2018
17 (Public Law 115–234) are repealed.

18 **TITLE III—SUPPORTING ANIMAL**
19 **AND HUMAN HEALTH**

20 **SEC. 301. REPORTING REQUIREMENTS.**

21 Section 740A of the Federal Food, Drug, and Cos-
22 metic Act (21 U.S.C. 379j–13), as amended by section
23 104, is further amended—

24 (1) in subsection (a)—

1 (A) by striking “Beginning with” and in-
2 serting the following:

3 “(1) IN GENERAL.—Beginning with”; and

4 (B) by adding at the end the following:

5 “(2) CONTENTS.—The report under paragraph
6 (1) shall include the following:

7 “(A) Data, analysis and discussion of the
8 changes in the number of individuals hired and
9 funded by fees collected pursuant to section
10 740, and data, analysis, and discussion of the
11 number of full-time equivalents in the animal
12 drug review program, including a breakdown by
13 funding from fees collected pursuant to section
14 740 versus budget authority, and by each divi-
15 sion within the Center for Veterinary Medicine,
16 the Office of Regulatory Affairs, and the Office
17 of the Commissioner.

18 “(B) Data, analysis, and discussion of the
19 changes in the fee revenue amounts and costs
20 for the process for the review of new animal
21 drug applications, including identifying—

22 “(i) the drivers of such changes; and

23 “(ii) changes in the total cost per full-
24 time equivalent in the animal drug review
25 program.

1 “(C) Data, analysis, and discussion of
2 changes in the average full-time equivalent
3 hours required to complete review of each type
4 of animal drug application.

5 “(D) For fiscal years 2024 and 2025, of
6 the meeting requests from new animal drug
7 sponsors for which the Secretary has deter-
8 mined that a face-to-face meeting is appro-
9 priate, the number of face-to-face meetings re-
10 quested by sponsors to be conducted in person
11 (in such manner as the Secretary shall pre-
12 scribe on the website of the Food and Drug Ad-
13 ministration), and the number of such in-person
14 meetings granted by the Secretary.”; and

15 (2) in subsection (d)—

16 (A) in paragraph (5), by inserting a
17 comma after “paragraph (4)”;

18 (B) by redesignating paragraph (6) as
19 paragraph (7);

20 (C) by inserting after paragraph (5) the
21 following:

22 “(6) UPDATES TO CONGRESS.—The Secretary,
23 in consultation with regulated industry, shall provide
24 regular updates on negotiations on the reauthoriza-
25 tion of this part to the Committee on Health, Edu-

1 cation, Labor, and Pensions of the Senate and the
2 Committee on Energy and Commerce of the House
3 of Representatives.”; and

4 (D) in paragraph (7) (as so redesign-
5 nated)—

6 (i) in subparagraph (A)—

7 (I) by striking “Before pre-
8 senting the recommendations devel-
9 oped under paragraphs (1) through
10 (5) to Congress, the Secretary” and
11 inserting “The Secretary”; and

12 (II) by inserting before the pe-
13 riod at the end the following: “, not
14 later than 30 days after each such ne-
15 gotiation meeting”; and

16 (ii) in subparagraph (B), by inserting
17 “, in sufficient detail,” after “shall sum-
18 marize”.

19 **SEC. 302. DEFINITION OF MAJOR SPECIES.**

20 Section 201(n) of the Federal Food, Drug, and Cos-
21 metic Act (21 U.S.C. 321(n)) is amended by inserting
22 “, or remove species from,” after “add species to”.

23 **SEC. 303. ANTIMICROBIAL RESISTANCE.**

24 (a) REPORT ON ANTIMICROBIAL STEWARDSHIP.—

25 Not later than December 31, 2023, the Secretary of

1 Health and Human Services, acting through the Commis-
2 sioner of Food and Drugs, shall submit to the Committee
3 on Energy and Commerce of the House of Representatives
4 and the Committee on Health, Education, Labor, and
5 Pensions of the Senate a report describing—

6 (1) activities conducted by the Center for Vet-
7 erinary Medicine of the Food and Drug Administra-
8 tion (referred to in this section as “the Center”)
9 during the period of fiscal years 2019 through 2023
10 to support antimicrobial stewardship in veterinary
11 settings, including ongoing activities and the tar-
12 geted completion date of such activities; and

13 (2) with respect to antimicrobial stewardship in
14 veterinary settings—

15 (A) the goals of the Center regarding sup-
16 porting antimicrobial stewardship in veterinary
17 settings;

18 (B) activities the Center plans to execute
19 during the period of fiscal years 2024 through
20 2028 to support such goals, including targeted
21 completion dates for such activities; and

22 (C) metrics the Center agency plans to use
23 to evaluate progress toward its goals regarding
24 supporting antimicrobial stewardship in veteri-
25 nary settings.

1 (b) ANNUAL PROGRESS REPORTS.—Not later than
2 120 days after the end of each fiscal year during which
3 fees are collected under section 740, the Secretary shall
4 submit to the Committee on Energy and Commerce of the
5 House of Representatives and the Committee on Health,
6 Education, Labor, and Pensions of the Senate a report
7 that includes—

8 (1) a description of activities conducted by the
9 Center in the prior fiscal year to support anti-
10 microbial stewardship in veterinary settings, includ-
11 ing progress made toward goals and activities speci-
12 fied in subsection (a)(2);

13 (2) in the case of an incomplete activity de-
14 scribed in subsection (a)(2)(B) for which the target
15 completion date has passed—

16 (A) an explanation for why such target
17 completion date was not met; and

18 (B) if applicable, the updated expected
19 completion date for such activity;

20 (3) a description of emerging challenges related
21 to antimicrobial stewardship in veterinary settings
22 that impact Center activities; and

23 (4) a description of activities undertaken to
24 incentivize the development of new drugs for the

1 treatment, prevention, or control of bacterial dis-
2 eases in animals.

Amend the long title so as to read: “To amend the Federal Food, Drug, and Cosmetic Act to reauthorize user fee programs relating to new animal drugs and generic new animal drugs, and for other purposes.”.

