

118TH CONGRESS
1ST SESSION

H. R. 1418

AN ACT

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,*

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.

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—SUPPORTING ANIMAL AND HUMAN HEALTH

Sec. 301. Reporting requirements.

Sec. 302. Definition of major species.

Sec. 303. Antimicrobial resistance.

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 2023”.

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

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 (21 U.S.C. 379j–11 et seq.), in
6 the letters from the Secretary of Health and Human Serv-
7 ices to the Chairman of the Committee on Energy and
8 Commerce of the House of Representatives and the Chair-
9 man of the Committee on Health, Education, Labor, and
10 Pensions of the Senate as set forth in the Congressional
11 Record.

12 **SEC. 102. DEFINITIONS.**

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

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

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

19 “(I) The activities necessary for implemen-
20 tation of the United States and European
21 Union Mutual Recognition Agreement for Phar-
22 maceutical Good Manufacturing Practice In-
23 spections, and the United States and United
24 Kingdom Mutual Recognition Agreement Sec-
25 toral Annex for Pharmaceutical Good Manufac-

turing Practices, and other mutual recognition agreements, with respect to animal drug products subject to review, including implementation activities prior to and following product approval.”.

SEC. 103. AUTHORITY TO ASSESS AND USE ANIMAL DRUG FEES.

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

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

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

(3) by adding at the end the following:

“(III) an application for conditional approval under section 571 of a new animal drug for which an animal drug application submitted under section 512(b)(1) has been previously approved under section 512(d)(1) for another intended use.”.

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

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

6 (c) ANNUAL FEE SETTING; ADJUSTMENTS.—

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

10 “(1) ANNUAL FEE SETTING.—Not later than
11 60 days before the start of each fiscal year begin-
12 ning after September 30, 2023, the Secretary
13 shall—

14 “(A) establish for that fiscal year animal
15 drug application fees, supplemental animal drug
16 application fees, animal drug sponsor fees, ani-
17 mal drug establishment fees, and animal drug
18 product fees based on the revenue amounts es-
19 tablished under subsection (b) and the adjust-
20 ments provided under this subsection; and

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

23 (2) INFLATION ADJUSTMENT.—Section
24 740(c)(2) of the Federal Food, Drug, and Cosmetic
25 Act (21 U.S.C. 379j–12(c)(2)) is amended—

1 (A) in subparagraph (A)—

2 (i) in the matter preceding clause (i),
3 by striking “2020” and inserting “2025”;
4 and

5 (ii) in clause (iii), by striking “Balti-
6 more” and inserting “Arlington-Alexan-
7 dria”; and

8 (B) in subparagraph (B), by striking
9 “2020” and inserting “2025”.

10 (3) WORKLOAD ADJUSTMENTS.—Section
11 740(c)(3) of the Federal Food, Drug, and Cosmetic
12 Act (21 U.S.C. 379j–12(c)(3)) is amended—

13 (A) in subparagraph (A)—

14 (i) in the matter preceding clause
15 (i)—

16 (I) by striking “2020” and in-
17 serting “2025”; and

18 (II) by striking “subparagraphs
19 (B) and (C)” and inserting “subpara-
20 graph (B)”;

21 (ii) in clause (i) by striking “and” at
22 the end; and

23 (iii) by striking clause (ii) and insert-
24 ing the following:

1 “(ii) such adjustment shall be made
 2 for each fiscal year that the adjustment de-
 3 termined by the Secretary is greater than
 4 3 percent, except for the first fiscal year
 5 that the adjustment is greater than 3 per-
 6 cent; and

7 “(iii) the Secretary shall publish in
 8 the Federal Register notice under para-
 9 graph (1) the amount of such adjustment
 10 and the supporting methodologies.”;

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

12 (C) by redesignating subparagraph (C) as
 13 subparagraph (B).

14 (4) FINAL YEAR ADJUSTMENT.—Section
 15 740(c)(4) of the Federal Food, Drug, and Cosmetic
 16 Act (21 U.S.C. 379j–12(c)(4)) is amended to read
 17 as follows:

18 “(4) OPERATING RESERVE ADJUSTMENT.—

19 “(A) IN GENERAL.—For fiscal year 2025
 20 and each subsequent fiscal year, after the fee
 21 revenue amount established under subsection
 22 (b) is adjusted in accordance with paragraphs
 23 (2) and (3), the Secretary shall—

24 “(i) increase the fee revenue amount
 25 for such fiscal year, if necessary to provide

1 an operating reserve of not less than 12
2 weeks; or

3 “(ii) if the Secretary has an operating
4 reserve in excess of the number of weeks
5 specified in subparagraph (C) for that fis-
6 cal year, the Secretary shall decrease the
7 fee revenue amount to provide not more
8 than the number of weeks specified in sub-
9 paragraph (C) for that fiscal year.

10 “(B) CARRYOVER USER FEES.—For pur-
11 poses of this paragraph, the operating reserve
12 of carryover user fees for the process for the re-
13 view of animal drug applications does not in-
14 clude carryover user fees that have not been ap-
15 propriated.

16 “(C) NUMBER OF WEEKS OF OPERATING
17 RESERVES.—The number of weeks of operating
18 reserves specified in this subparagraph is—

19 “(i) 22 weeks for fiscal year 2025;

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

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

22 and

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

24 “(D) PUBLICATION.—If an adjustment to
25 the operating reserve is made under this para-

1 graph, the Secretary shall publish in the Fed-
2 eral Register notice under paragraph (1) the ra-
3 tionale for the amount of the adjustment and
4 the supporting methodologies.”.

5 (d) EXEMPTION FROM FEES.—Section 740(d)(4) of
6 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
7 379j–12(d)(4)) is amended to read as follows:

8 “(4) EXEMPTION FROM FEES.—Fees under
9 paragraphs (2), (3), and (4) of subsection (a) shall
10 not apply with respect to any person who is the
11 named applicant or sponsor of an animal drug appli-
12 cation, supplemental animal drug application, or in-
13 vestigational animal drug submission if such applica-
14 tion or submission involves the intentional genomic
15 alteration of an animal that is intended to produce
16 a drug, device, or biological product subject to fees
17 under section 736, 738, 744B, or 744H.”.

18 (e) CREDITING AND AVAILABILITY OF FEES.—

19 (1) AUTHORIZATION OF APPROPRIATIONS.—
20 Section 740(g)(3) of the Federal Food, Drug, and
21 Cosmetic Act (21 U.S.C. 379j–12(g)(3)) is amended
22 by striking “2019 through 2023” and inserting
23 “2024 through 2028”.

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

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

6 (B) by striking paragraph (5).

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

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

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

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

14 (3) in subsection (d)—

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

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

19 **SEC. 105. SAVINGS CLAUSE.**

20 Notwithstanding the amendments made by this title,
21 part 4 of subchapter C of chapter VII of the Federal Food,
22 Drug, and Cosmetic Act (21 U.S.C. 379j–11 et seq.), as
23 in effect on the day before the date of enactment of this
24 title, shall continue to be in effect with respect to animal
25 drug applications and supplemental animal drug applica-

1 tions (as defined in such part as of such day) that on or
2 after October 1, 2018, but before October 1, 2023, were
3 accepted by the Food and Drug Administration for filing
4 with respect to assessing and collecting any fee required
5 by such part for a fiscal year prior to fiscal year 2024.

6 **SEC. 106. EFFECTIVE DATE.**

7 The amendments made by this title shall take effect
8 on October 1, 2023, or the date of the enactment of this
9 Act, whichever is later, except that fees under part 4 of
10 subchapter C of chapter VII of the Federal Food, Drug,
11 and Cosmetic Act (21 U.S.C. 379j–11 et seq.), as amend-
12 ed by this title, shall be assessed for animal drug applica-
13 tions and supplemental animal drug applications received
14 on or after October 1, 2023, regardless of the date of the
15 enactment of this Act.

16 **SEC. 107. SUNSET DATES.**

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

21 (b) **REPORTING REQUIREMENTS.**—Section 740A of
22 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
23 379j–13) shall cease to be effective January 31, 2029.

24 (c) **PREVIOUS SUNSET PROVISION.**—Effective Octo-
25 ber 1, 2023, subsections (a) and (b) of section 107 of the

1 Animal Drug User Fee Amendments of 2018 (Public Law
2 115–234) are repealed.

3 **TITLE II—FEES RELATING TO**
4 **GENERIC ANIMAL DRUGS**

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

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

8 (b) FINDING.—Congress finds that the fees author-
9 ized by the amendments made in this title will be dedi-
10 cated toward expediting the generic new animal drug de-
11 velopment process and the review of abbreviated applica-
12 tions for generic new animal drugs, supplemental abbrevi-
13 ated applications for generic new animal drugs, and in-
14 vestigational submissions for generic new animal drugs as
15 set forth in the goals identified for purposes of part 5 of
16 subchapter C of chapter VII of the Federal Food, Drug,
17 and Cosmetic Act (21 U.S.C. 379j–21 et seq.), in the let-
18 ters from the Secretary of Health and Human Services
19 to the Chairman of the Committee on Energy and Com-
20 merce of the House of Representatives and the Chairman
21 of the Committee on Health, Education, Labor and Pen-
22 sions of the Senate as set forth in the Congressional
23 Record.

1 **SEC. 202. AUTHORITY TO ASSESS AND USE GENERIC NEW**
2 **ANIMAL DRUG FEES.**

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

7 “(4) GENERIC INVESTIGATIONAL NEW ANIMAL
8 DRUG FILE FEE.—

9 “(A) IN GENERAL.—

10 “(i) NEW FILE REQUEST.—Each per-
11 son that submits a request to establish a
12 generic investigational new animal drug
13 file on or after October 1, 2023, shall be
14 assessed a fee as established under sub-
15 section (c).

16 “(ii) NEW SUBMISSION TO ESTAB-
17 LISHED FILE.—Each person that makes a
18 submission to a generic investigational new
19 animal drug file on or after October 1,
20 2023, where such file was established prior
21 to October 1, 2023, shall be assessed a fee
22 for the first submission on or after October
23 1, 2023, as established under subsection
24 (c).

25 “(B) PAYMENT.—

1 “(i) NEW FILE REQUEST.—The fee
2 required by subparagraph (A)(i) shall be
3 due upon submission of the request to es-
4 tablish the generic investigational new ani-
5 mal drug file.

6 “(ii) NEW SUBMISSION TO ESTAB-
7 LISHED FILE.—The fee required by sub-
8 paragraph (A)(ii) shall be due upon the
9 first submission to the generic investiga-
10 tional new animal drug file.

11 “(C) EXCEPTIONS.—

12 “(i) TERMINATING AN EXISTING GE-
13 NERIC INVESTIGATIONAL NEW ANIMAL
14 DRUG FILE.—If a person makes a submis-
15 sion to the generic investigational new ani-
16 mal drug file to terminate that file, the
17 person shall not be subject to a fee under
18 subparagraph (A)(ii) for that submission.

19 “(ii) TRANSFERRING 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 transfer that file to a dif-
24 ferent generic new animal drug sponsor,
25 the person shall not be subject to a fee

1 under subparagraph (A)(ii) for that sub-
2 mission.”.

3 (b) FEE REVENUE AMOUNTS.—Section 741(b) of the
4 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
5 21(b)) is amended—

6 (1) in paragraph (1)—

7 (A) by striking “2019 through 2023” and
8 inserting “2024 through 2028”; and

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

11 (2) in paragraph (2)—

12 (A) in subparagraph (A)—

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

15 (ii) by inserting before the semicolon
16 at the end the following: “and fees under
17 subsection (a)(4) (relating to generic inves-
18 tigational new animal drug files)”;

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

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

23 (c) ANNUAL FEE SETTING; ADJUSTMENTS.—

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

4 “(1) ANNUAL FEE SETTING.—The Secretary
5 shall establish, not later than 60 days before the
6 start of each fiscal year beginning after September
7 30, 2023, for that fiscal year—

8 “(A) abbreviated application fees that are
9 based on the revenue amounts established
10 under subsection (b), the adjustments provided
11 under this subsection, and the amount of fees
12 anticipated to be collected under subsection
13 (a)(4) during that fiscal year;

14 “(B) generic new animal drug sponsor
15 fees, and generic new animal drug product fees,
16 based on the revenue amounts established
17 under subsection (b) and the adjustments pro-
18 vided under this subsection; and

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

22 (2) INFLATION ADJUSTMENT.—Section
23 741(c)(2) of the Federal Food, Drug, and Cosmetic
24 Act (21 U.S.C. 379j–21(c)(2)) is amended—

25 (A) in subparagraph (A)—

1 (i) in the matter preceding clause (i),
2 by striking “2020” and inserting “2025”;
3 and

4 (ii) in clause (iii), by striking “Balti-
5 more” and inserting “Arlington-Alexan-
6 dria”; and

7 (B) in subparagraph (B), by striking
8 “2020” and inserting “2025”.

9 (3) WORKLOAD ADJUSTMENT.—Section
10 741(c)(3) of the Federal Food, Drug, and Cosmetic
11 Act (21 U.S.C. 379j–21(c)(3)) is amended—

12 (A) in subparagraph (A)—

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

15 (ii) in clause (i)—

16 (I) by striking “and investiga-
17 tional generic new animal drug pro-
18 tocol submissions” and inserting “in-
19 vestigational generic new animal drug
20 protocol submissions, requests to es-
21 tablish a generic investigational new
22 animal drug file, and generic inves-
23 tigational new animal drug meeting
24 requests”; and

1 (II) by striking “; and” and in-
2 serting a semicolon;

3 (iii) by redesignating clause (ii) as
4 clause (iii); and

5 (iv) by inserting after clause (i) the
6 following:

7 “(ii) if the workload adjustment cal-
8 culated by the Secretary under clause (i)
9 exceeds 25 percent, the Secretary shall use
10 25 percent for the adjustment; and”; and

11 (B) in subparagraph (B), by striking
12 “2021 through 2023” and inserting “2026
13 through 2028”.

14 (4) FINAL YEAR ADJUSTMENT.—Section
15 741(c)(4) of the Federal Food, Drug, and Cosmetic
16 Act (21 U.S.C. 379j–21(c)(4)) is amended—

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

19 (B) by striking “2024” and inserting
20 “2029”.

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

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

6 (e) EFFECT OF FAILURE TO PAY FEES.—Section
7 741(e) of the Federal Food, Drug, and Cosmetic Act (21
8 U.S.C. 379j–21(e)) is amended by striking “The Secretary
9 may discontinue” and inserting “A request to establish a
10 generic investigational new animal drug file that is sub-
11 mitted by a person subject to fees under subsection (a)
12 shall be considered incomplete and shall not be accepted
13 for action by the Secretary until all fees owed by such per-
14 son have been paid. The Secretary may discontinue”.

15 (f) ASSESSMENT OF FEES.—Section 741(f)(2) of the
16 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
17 21(f)(2)) is amended by striking “sponsors, and generic
18 new animal drug products at any time” and inserting
19 “products, generic new animal drug sponsors, and generic
20 investigational new animal drug files at any time”.

21 (g) CREDITING AND AVAILABILITY OF FEES.—Sec-
22 tion 741(g) of the Federal Food, Drug, and Cosmetic Act
23 (21 U.S.C. 379j–21(g)) is amended—

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

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

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

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

9 “(A) for fiscal year 2026, by the amount,
10 if any, by which the amount collected under this
11 section and appropriated for fiscal year 2024
12 falls below the amount of fees authorized for
13 fiscal year 2024 under paragraph (3);

14 “(B) for fiscal year 2027, by the amount,
15 if any, by which the amount collected under this
16 section and appropriated for fiscal year 2025
17 falls below the amount of fees authorized for
18 fiscal year 2025 under paragraph (3); and

19 “(C) for fiscal year 2028, by the amount,
20 if any, by which the amount collected under this
21 section and appropriated for fiscal years 2026
22 and 2027 (including estimated collections for
23 fiscal year 2027) falls below the amount of fees
24 authorized for such fiscal years under para-
25 graph (3).”.

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

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

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

9 “(8) GENERIC INVESTIGATIONAL NEW ANIMAL
10 DRUG MEETING REQUEST.—The term ‘generic inves-
11 tigational new animal drug meeting request’ means
12 a request submitted by a generic new animal drug
13 sponsor to meet with the Secretary to discuss an in-
14 vestigational submission for a generic new animal
15 drug.”;

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

18 “(I) The activities necessary for explo-
19 ration and implementation of the United States
20 and European Union Mutual Recognition
21 Agreement for Pharmaceutical Good Manufac-
22 turing Practice Inspections, and the United
23 States and United Kingdom Mutual Recogni-
24 tion Agreement Sectoral Annex for Pharma-
25 ceutical Good Manufacturing Practices, and

1 other mutual recognition agreements, with re-
2 spect to generic new animal drug products sub-
3 ject to review, including implementation activi-
4 ties prior to and following product approval.”;
5 and

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

8 “(12) REQUEST TO ESTABLISH A GENERIC IN-
9 VESTIGATIONAL NEW ANIMAL DRUG FILE.—The
10 term ‘request to establish a generic investigational
11 new animal drug file’ means the submission to the
12 Secretary of a request to establish a generic inves-
13 tigational new animal drug file to contain investiga-
14 tional submissions for a generic new animal drug.”.

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

16 Section 742 of the Federal Food, Drug, and Cosmetic
17 Act (21 U.S.C. 379j–22) 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), by striking “2023” each
23 place it appears and inserting “2028”.

1 **SEC. 204. SAVINGS CLAUSE.**

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

15 **SEC. 205. 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 5 of
19 subchapter C of chapter VII of the Federal Food, Drug,
20 and Cosmetic Act (21 U.S.C. 379j–21 et seq.), as amend-
21 ed by this title, shall be assessed for abbreviated applica-
22 tions for a generic new animal drug and supplemental ab-
23 breviated applications for a generic new animal drug re-
24 ceived on or after October 1, 2023, regardless of the date
25 of enactment of this Act.

1 **SEC. 206. SUNSET DATES.**

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

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

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

12 **TITLE III—SUPPORTING ANIMAL**
13 **AND HUMAN HEALTH**

14 **SEC. 301. REPORTING REQUIREMENTS.**

15 Section 740A of the Federal Food, Drug, and Cos-
16 metic Act (21 U.S.C. 379j–13), as amended by section
17 104, is further amended—

18 (1) in subsection (a)—

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

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

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

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

25 “(A) Data, analysis and discussion of the
26 changes in the number of individuals hired and

1 funded by fees collected pursuant to section
2 740, and data, analysis, and discussion of the
3 number of full-time equivalents in the animal
4 drug review program, including a breakdown by
5 funding from fees collected pursuant to section
6 740 versus budget authority, and by each divi-
7 sion within the Center for Veterinary Medicine,
8 the Office of Regulatory Affairs, and the Office
9 of the Commissioner.

10 “(B) Data, analysis, and discussion of the
11 changes in the fee revenue amounts and costs
12 for the process for the review of animal drug
13 applications, including identifying—

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

15 “(ii) changes in the total cost per full-
16 time equivalent in the animal drug review
17 program.

18 “(C) Data, analysis, and discussion of
19 changes in the average full-time equivalent
20 hours required to complete review of each type
21 of animal drug application.

22 “(D) For fiscal years 2024 and 2025, of
23 the meeting requests from animal drug spon-
24 sors for which the Secretary has determined
25 that a face-to-face meeting is appropriate, the

1 number of face-to-face meetings requested by
2 sponsors to be conducted in person (in such
3 manner as the Secretary shall prescribe on the
4 website of the Food and Drug Administration),
5 and the number of such in-person meetings
6 granted by the Secretary.”; and

7 (2) in subsection (d)—

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

10 (B) by redesignating paragraph (6) as
11 paragraph (7);

12 (C) by inserting after paragraph (5) the
13 following:

14 “(6) UPDATES TO CONGRESS.—The Secretary,
15 in consultation with regulated industry, shall provide
16 regular updates on negotiations on the reauthoriza-
17 tion of this part to the Committee on Health, Edu-
18 cation, Labor, and Pensions of the Senate and the
19 Committee on Energy and Commerce of the House
20 of Representatives.”; and

21 (D) in paragraph (7) (as so redesign-
22 nated)—

23 (i) in subparagraph (A)—

24 (I) by striking “Before pre-
25 senting the recommendations devel-

1 oped under paragraphs (1) through
 2 (5) to Congress, the Secretary” and
 3 inserting “The Secretary”; and

4 (II) by inserting before the pe-
 5 riod at the end the following: “, not
 6 later than 30 days after each such ne-
 7 gotiation meeting”; and

8 (ii) in subparagraph (B), by inserting
 9 “, in sufficient detail,” after “shall sum-
 10 marize”.

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

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

15 **SEC. 303. ANTIMICROBIAL RESISTANCE.**

16 (a) REPORT ON ANTIMICROBIAL STEWARDSHIP.—
 17 Not later than December 31, 2023, the Secretary of
 18 Health and Human Services, acting through the Commis-
 19 sioner of Food and Drugs, shall submit to the Committee
 20 on Energy and Commerce of the House of Representatives
 21 and the Committee on Health, Education, Labor, and
 22 Pensions of the Senate a report describing—

23 (1) activities conducted by the Center for Vet-
 24 erinary Medicine of the Food and Drug Administra-
 25 tion (referred to in this section as “the Center”)

1 during the period of fiscal years 2019 through 2023
2 to support antimicrobial stewardship in veterinary
3 settings, including ongoing activities and the tar-
4 geted completion date of such activities; and

5 (2) with respect to antimicrobial stewardship in
6 veterinary settings—

7 (A) the goals of the Center regarding sup-
8 porting antimicrobial stewardship in veterinary
9 settings;

10 (B) activities the Center plans to execute
11 during the period of fiscal years 2024 through
12 2028 to support such goals, including targeted
13 completion dates for such activities; and

14 (C) metrics the Center plans to use to
15 evaluate progress toward its goals regarding
16 supporting antimicrobial stewardship in veteri-
17 nary settings.

18 (b) ANNUAL PROGRESS REPORTS.—Not later than
19 120 days after the end of each fiscal year during which
20 fees are collected under section 740, the Secretary shall
21 submit to the Committee on Energy and Commerce of the
22 House of Representatives and the Committee on Health,
23 Education, Labor, and Pensions of the Senate a report
24 that includes—

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

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

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

11 (B) if applicable, the updated expected
12 completion date for such activity;

13 (3) a description of emerging challenges related
14 to antimicrobial stewardship in veterinary settings
15 that impact Center activities; and

16 (4) a description of activities undertaken to
17 incentivize the development of new drugs for the
18 treatment, prevention, or control of bacterial dis-
19 eases in animals.

Passed the House of Representatives July 17, 2023.

Attest:

Clerk.

118TH CONGRESS
1ST SESSION

H. R. 1418

AN ACT

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