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118TH CONGRESS
1ST SESSION

H. R. 1418

[Report No. 118-104]

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

MARCH 7, 2023

Mr. PENCE (for himself and Ms. SCHRIER) introduced the following bill; which was referred to the Committee on Energy and Commerce

JUNE 9, 2023

Additional sponsor: Ms. Lee of Nevada

JUNE 9, 2023

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in *italie*]

[For text of introduced bill, see copy of bill as introduced on March 7, 2023]

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 2023”.*

6 **SEC. 2. TABLE OF CONTENTS.**

7 *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.

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TITLE II—FEES RELATING TO GENERIC ANIMAL DRUGS

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TITLE III—SUPPORTING ANIMAL AND HUMAN HEALTH

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Sec. 302. Definition of major species.

Sec. 303. Antimicrobial resistance.

8 **TITLE I—FEES RELATING TO**
 9 **ANIMAL DRUGS**

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

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

1 (b) *FINDING.*—Congress finds that the fees authorized
2 by the amendments made in this title will be dedicated to-
3 ward expediting the animal drug development process and
4 the review of new and supplemental animal drug applica-
5 tions and investigational animal drug submissions as set
6 forth in the goals identified for purposes of part 4 of sub-
7 chapter C of chapter VII of the Federal Food, Drug, and
8 Cosmetic Act (21 U.S.C. 379j–11 et seq.), in the letters from
9 the Secretary of Health and Human Services to the Chair-
10 man of the Committee on Energy and Commerce of the
11 House of Representatives and the Chairman of the Com-
12 mittee on Health, Education, Labor, and Pensions of the
13 Senate as set forth in the Congressional Record.

14 **SEC. 102. DEFINITIONS.**

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

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

19 (2) by amending paragraph (8)(I) to read as fol-
20 lows:

21 “(I) The activities necessary for implemen-
22 tation of the United States and European Union
23 Mutual Recognition Agreement for Pharma-
24 ceutical Good Manufacturing Practice Inspec-
25 tions, and the United States and United King-

1 *dom Mutual Recognition Agreement Sectoral*
2 *Annex for Pharmaceutical Good Manufacturing*
3 *Practices, and other mutual recognition agree-*
4 *ments, with respect to animal drug products sub-*
5 *ject to review, including implementation activi-*
6 *ties prior to and following product approval.”.*

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

9 *(a) IN GENERAL.—Section 740(a)(1)(A)(ii) of the Fed-*
10 *eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j–*
11 *12(a)(1)(A)(ii)) is amended—*

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

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

16 *(3) by adding at the end the following:*

17 *“(III) an application for condi-*
18 *tional approval under section 571 of a*
19 *new animal drug for which an animal*
20 *drug application submitted under sec-*
21 *tion 512(b)(1) has been previously ap-*
22 *proved under section 512(d)(1) for an-*
23 *other intended use.”.*

1 (b) *FEE REVENUE AMOUNTS.*—Section 740(b)(1) of
2 *the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–*
3 *12(b)(1)) is amended to read as follows:*

4 “(1) *IN GENERAL.*—Subject to subsections (c),
5 (d), (f), and (g), for each of fiscal years 2024 through
6 2028, the fees required under subsection (a) shall be
7 established to generate a total revenue amount of
8 \$33,500,000.”.

9 (c) *ANNUAL FEE SETTING; ADJUSTMENTS.*—

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

13 “(1) *ANNUAL FEE SETTING.*—Not later than 60
14 days before the start of each fiscal year beginning
15 after September 30, 2023, the Secretary shall—

16 “(A) establish for that fiscal year animal
17 drug application fees, supplemental animal drug
18 application fees, animal drug sponsor fees, ani-
19 mal drug establishment fees, and animal drug
20 product fees based on the revenue amounts estab-
21 lished under subsection (b) and the adjustments
22 provided under this subsection; and

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

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

4 (A) in subparagraph (A)—

5 (i) in the matter preceding clause (i),
6 by striking “2020” and inserting “2025”;
7 and

8 (ii) in clause (iii), by striking “Balti-
9 more” and inserting “Arlington-Alexan-
10 dria”; and

11 (B) in subparagraph (B), by striking
12 “2020” and inserting “2025”.

13 (3) *WORKLOAD ADJUSTMENTS.*—Section
14 740(c)(3) of the Federal Food, Drug, and Cosmetic
15 Act (21 U.S.C. 379j–12(c)(3)) is amended—

16 (A) in subparagraph (A)—

17 (i) in the matter preceding clause (i)—

18 (I) by striking “2020” and insert-
19 ing “2025”; and

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

23 (ii) in clause (i) by striking “and” at
24 the end; and

1 (iii) by striking clause (ii) and insert-
2 ing the following:

3 “(ii) such adjustment shall be made for
4 each fiscal year that the adjustment deter-
5 mined by the Secretary is greater than 3
6 percent, except for the first fiscal year that
7 the adjustment is greater than 3 percent;
8 and

9 “(iii) the Secretary shall publish in the
10 Federal Register notice under paragraph
11 (1) the amount of such adjustment and the
12 supporting methodologies.”;

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

14 (C) by redesignating subparagraph (C) as
15 subparagraph (B).

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

20 “(4) OPERATING RESERVE ADJUSTMENT.—

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

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

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

12 “(B) CARRYOVER USER FEES.—For pur-
13 poses of this paragraph, the operating reserve of
14 carryover user fees for the process for the review
15 of animal drug applications does not include
16 carryover user fees that have not been appro-
17 priated.

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

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

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

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

24 and

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

1 “(D) *PUBLICATION.*—If an adjustment to
2 the operating reserve is made under this para-
3 graph, the Secretary shall publish in the Federal
4 Register notice under paragraph (1) the ration-
5 ale for the amount of the adjustment and the
6 supporting methodologies.”.

7 (d) *EXEMPTION FROM FEES.*—Section 740(d)(4) of the
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
9 12(d)(4)) is amended to read as follows:

10 “(4) *EXEMPTION FROM FEES.*—Fees under para-
11 graphs (2), (3), and (4) of subsection (a) shall not
12 apply with respect to any person who is the named
13 applicant or sponsor of an animal drug application,
14 supplemental animal drug application, or investiga-
15 tional animal drug submission if such application or
16 submission involves the intentional genomic alter-
17 ation of an animal that is intended to produce a
18 drug, device, or biological product subject to fees
19 under section 736, 738, 744B, or 744H.”.

20 (e) *CREDITING AND AVAILABILITY OF FEES.*—

21 (1) *AUTHORIZATION OF APPROPRIATIONS.*—Sec-
22 tion 740(g)(3) of the Federal Food, Drug, and Cos-
23 metic Act (21 U.S.C. 379j–12(g)(3)) is amended by
24 striking “2019 through 2023” and inserting “2024
25 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 Cosmetic
9 Act (21 U.S.C. 379j–13) is amended—

10 (1) in subsection (a), by striking “2018” and in-
11 serting “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 in
23 effect on the day before the date of enactment of this title,
24 shall continue to be in effect with respect to animal drug
25 applications and supplemental animal drug applications

1 *(as defined in such part as of such day) that on or after*
2 *October 1, 2018, but before October 1, 2023, were accepted*
3 *by the Food and Drug Administration for filing with re-*
4 *spect to assessing and collecting any fee required by such*
5 *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 sub-*
10 *chapter C of chapter VII of the Federal Food, Drug, and*
11 *Cosmetic Act (21 U.S.C. 379j-11 et seq.), as amended by*
12 *this title, shall be assessed for animal drug applications and*
13 *supplemental animal drug applications received on or after*
14 *October 1, 2023, regardless of the date of the enactment of*
15 *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 U.S.C.*
19 *379j-11; 379j-12) shall cease to be effective October 1, 2028.*

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

23 *(c) PREVIOUS SUNSET PROVISION.—Effective October*
24 *1, 2023, subsections (a) and (b) of section 107 of the Animal*

1 *Drug User Fee Amendments of 2018 (Public Law 115–234)*
2 *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 authorized*
9 *by the amendments made in this title will be dedicated to-*
10 *ward expediting the generic new animal drug development*
11 *process and the review of abbreviated applications for ge-*
12 *neric new animal drugs, supplemental abbreviated applica-*
13 *tions for generic new animal drugs, and investigational*
14 *submissions for generic new animal drugs as set forth in*
15 *the goals identified for purposes of part 5 of subchapter C*
16 *of chapter VII of the Federal Food, Drug, and Cosmetic Act*
17 *(21 U.S.C. 379j–21 et seq.), in the letters from the Secretary*
18 *of Health and Human Services to the Chairman of the*
19 *Committee on Energy and Commerce of the House of Rep-*
20 *resentatives and the Chairman of the Committee on Health,*
21 *Education, Labor and Pensions of the Senate as set forth*
22 *in the Congressional 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, and
5 *Cosmetic Act (21 U.S.C. 379j–21(a)) is amended by adding*
6 *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 ge-*
12 *neric investigational new animal drug file*
13 *on or after October 1, 2023, shall be assessed*
14 *a fee as established under subsection (c).*

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

23 “(B) *PAYMENT.*—

24 “(i) *NEW FILE REQUEST.*—*The fee re-*
25 *quired by subparagraph (A)(i) shall be due*
26 *upon submission of the request to establish*

1 *the generic investigational new animal drug*
2 *file.*

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

8 “(C) *EXCEPTIONS.—*

9 “(i) *TERMINATING AN EXISTING GE-*
10 *NERIC INVESTIGATIONAL NEW ANIMAL DRUG*
11 *FILE.—If a person makes a submission to*
12 *the generic investigational new animal drug*
13 *file to terminate that file, the person shall*
14 *not be subject to a fee under subparagraph*
15 *(A)(ii) for that submission.*

16 “(i) *TRANSFERRING AN EXISTING GE-*
17 *NERIC INVESTIGATIONAL NEW ANIMAL DRUG*
18 *FILE.—If a person makes a submission to*
19 *the generic investigational new animal drug*
20 *file to transfer that file to a different ge-*
21 *neric new animal drug sponsor, the person*
22 *shall not be subject to a fee under subpara-*
23 *graph (A)(ii) for that submission.”.*

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

4 (1) in paragraph (1)—

5 (A) by striking “2019 through 2023” and
6 inserting “2024 through 2028”; and

7 (B) by striking “\$18,336,340” and inserting
8 “\$25,000,000”; and

9 (2) in paragraph (2)—

10 (A) in subparagraph (A)—

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

13 (ii) by inserting before the semicolon at
14 the end the following: “and fees under sub-
15 section (a)(4) (relating to generic investiga-
16 tional new animal drug files)”;

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

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

21 (c) *ANNUAL FEE SETTING; ADJUSTMENTS.*—

22 (1) *ANNUAL FEE SETTING.*— Section 741(c)(1) of
23 the *Federal Food, Drug, and Cosmetic Act* (21 U.S.C.
24 379j–21(c)(1)) is amended to read as follows:

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

5 “(A) *abbreviated application fees that are*
6 *based on the revenue amounts established under*
7 *subsection (b), the adjustments provided under*
8 *this subsection, and the amount of fees antici-*
9 *pated to be collected under subsection (a)(4) dur-*
10 *ing that fiscal year;*

11 “(B) *generic new animal drug sponsor fees,*
12 *and generic new animal drug product fees, based*
13 *on the revenue amounts established under sub-*
14 *section (b) and the adjustments provided under*
15 *this subsection; and*

16 “(C) *a generic investigational new animal*
17 *drug file fee of \$50,000 for each request or sub-*
18 *mission described in subsection (a)(4)(A).”.*

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

22 (A) *in subparagraph (A)—*

23 (i) *in the matter preceding clause (i),*
24 *by striking “2020” and inserting “2025”;*
25 *and*

1 (ii) in clause (iii), by striking “Balti-
2 more” and inserting “Arlington-Alexan-
3 dria”; and

4 (B) in subparagraph (B), by striking
5 “2020” and inserting “2025”.

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

9 (A) in subparagraph (A)—

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

12 (ii) in clause (i)—

13 (I) by striking “and investiga-
14 tional generic new animal drug pro-
15 tocol submissions” and inserting “in-
16 vestigational generic new animal drug
17 protocol submissions, requests to estab-
18 lish a generic investigational new ani-
19 mal drug file, and generic investiga-
20 tional new animal drug meeting re-
21 quests”; and

22 (II) by striking “; and” and in-
23 serting a semicolon;

24 (iii) by redesignating clause (ii) as
25 clause (iii); and

1 (iv) by inserting after clause (i) the
2 following:

3 “(ii) if the workload adjustment cal-
4 culated by the Secretary under clause (i) ex-
5 ceeds 25 percent, the Secretary shall use 25
6 percent for the adjustment; and”;

7 (B) in subparagraph (B), by striking “2021
8 through 2023” and inserting “2026 through
9 2028”.

10 (4) *FINAL YEAR ADJUSTMENT.*—Section
11 741(c)(4) of the Federal Food, Drug, and Cosmetic
12 Act (21 U.S.C. 379j–21(c)(4)) is amended—

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

15 (B) by striking “2024” and inserting
16 “2029”.

17 (d) *FEE WAIVER OR REDUCTION; EXEMPTION FROM*
18 *FEEES.*—Subsection (d) of section 741 of the Federal Food,
19 Drug, and Cosmetic Act (21 U.S.C. 379j–21) is amended
20 to read as follows:

21 “(d) *FEE WAIVER OR REDUCTION.*—The Secretary
22 shall grant a waiver from, or a reduction of, one or more
23 fees assessed under subsection (a) where the Secretary finds
24 that the generic new animal drug is intended solely to pro-
25 vide for a minor use or minor species indication.”.

1 (e) *EFFECT OF FAILURE TO PAY FEES.*—Section
2 741(e) of the Federal Food, Drug, and Cosmetic Act (21
3 U.S.C. 379j–21(e)) is amended by striking “The Secretary
4 may discontinue” and inserting “A request to establish a
5 generic investigational new animal drug file that is sub-
6 mitted by a person subject to fees under subsection (a) shall
7 be considered incomplete and shall not be accepted for ac-
8 tion by the Secretary until all fees owed by such person
9 have been paid. The Secretary may discontinue”.

10 (f) *ASSESSMENT OF FEES.*—Section 741(f)(2) of the
11 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
12 21(f)(2)) is amended by striking “sponsors, and generic new
13 animal drug products at any time” and inserting “prod-
14 ucts, generic new animal drug sponsors, and generic inves-
15 tigational new animal drug files at any time”.

16 (g) *CREDITING AND AVAILABILITY OF FEES.*—Section
17 741(g) of the Federal Food, Drug, and Cosmetic Act (21
18 U.S.C. 379j–21(g)) is amended—

19 (1) in paragraph (3), by striking “2019 through
20 2023” and inserting “2024 through 2028”;

21 (2) by striking the second paragraph (4) (relat-
22 ing to Offset), as added by section 202 of the Animal
23 Generic Drug User Fee Amendments of 2013 (Public
24 Law 113–14); and

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

1 “(5) *RECOVERY OF COLLECTION SHORTFALLS.*—
2 *The amount of fees otherwise authorized to be collected*
3 *under this section shall be increased—*

4 “(A) *for fiscal year 2026, by the amount, if*
5 *any, by which the amount collected under this*
6 *section and appropriated for fiscal year 2024*
7 *falls below the amount of fees authorized for fis-*
8 *cal year 2024 under paragraph (3);*

9 “(B) *for fiscal year 2027, by the amount, if*
10 *any, by which the amount collected under this*
11 *section and appropriated for fiscal year 2025*
12 *falls below the amount of fees authorized for fis-*
13 *cal year 2025 under paragraph (3); and*

14 “(C) *for fiscal year 2028, by the amount, if*
15 *any, by which the amount collected under this*
16 *section and appropriated for fiscal years 2026*
17 *and 2027 (including estimated collections for fis-*
18 *cal year 2027) falls below the amount of fees au-*
19 *thorized for such fiscal years under paragraph*
20 *(3).”.*

21 (h) *DEFINITIONS.*—*Section 741(k) of the Federal Food,*
22 *Drug, and Cosmetic Act (21 U.S.C. 379j–21(k)) is amend-*
23 *ed—*

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

4 (2) *by inserting after paragraph (7) the fol-*
5 *lowing:*

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

13 (3) *in paragraph (11) (as so redesignated), by*
14 *adding at the end the following:*

15 “(I) *The activities necessary for exploration*
16 *and implementation of the United States and*
17 *European Union Mutual Recognition Agreement*
18 *for Pharmaceutical Good Manufacturing Prac-*
19 *tice Inspections, and the United States and*
20 *United Kingdom Mutual Recognition Agreement*
21 *Sectoral Annex for Pharmaceutical Good Manu-*
22 *facturing Practices, and other mutual recogni-*
23 *tion agreements, with respect to generic new ani-*
24 *mal drug products subject to review, including*

1 *implementation activities prior to and following*
2 *product approval.”; and*

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

5 “(12) *REQUEST TO ESTABLISH A GENERIC IN-*
6 *VESTIGATIONAL NEW ANIMAL DRUG FILE.—The term*
7 *‘request to establish a generic investigational new ani-*
8 *mal drug file’ means the submission to the Secretary*
9 *of a request to establish a generic investigational new*
10 *animal drug file to contain investigational submis-*
11 *sions for a generic new animal drug.”.*

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

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

15 (1) *in subsection (a), by striking “2018” and in-*
16 *serting “2023”;*

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

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

21 **SEC. 204. SAVINGS CLAUSE.**

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

1 *shall continue to be in effect with respect to abbreviated ap-*
2 *plications for a generic new animal drug and supplemental*
3 *abbreviated applications for a generic new animal drug (as*
4 *defined in such part as of such day) that on or after October*
5 *1, 2018, but before October 1, 2023, were accepted by the*
6 *Food and Drug Administration for filing with respect to*
7 *assessing and collecting any fee required by such part for*
8 *a fiscal year prior to fiscal year 2024.*

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

10 *The amendments made by this title shall take effect*
11 *on October 1, 2023, or the date of the enactment of this*
12 *Act, whichever is later, except that fees under part 5 of sub-*
13 *chapter C of chapter VII of the Federal Food, Drug, and*
14 *Cosmetic Act (21 U.S.C. 379j–21 et seq.), as amended by*
15 *this title, shall be assessed for abbreviated applications for*
16 *a generic new animal drug and supplemental abbreviated*
17 *applications for a generic new animal drug received on or*
18 *after October 1, 2023, regardless of the date of enactment*
19 *of this Act.*

20 **SEC. 206. SUNSET DATES.**

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

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

4 (c) *PREVIOUS SUNSET PROVISION.*—Effective October
 5 1, 2023, subsections (a) and (b) of section 206 of the *Animal*
 6 *Generic Drug User Fee Amendments of 2018* (Public Law
 7 115–234) are repealed.

8 ***TITLE III—SUPPORTING ANIMAL***
 9 ***AND HUMAN HEALTH***

10 ***SEC. 301. REPORTING REQUIREMENTS.***

11 Section 740A of the *Federal Food, Drug, and Cosmetic*
 12 *Act* (21 U.S.C. 379j–13), as amended by section 104, is fur-
 13 *ther amended—*

14 (1) *in subsection (a)—*

15 (A) *by striking “Beginning with” and in-*
 16 *serting the following:*

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

18 (B) *by adding at the end the following:*

19 “(2) *CONTENTS.*—*The report under paragraph*
 20 *(1) shall include the following:*

21 “(A) *Data, analysis and discussion of the*
 22 *changes in the number of individuals hired and*
 23 *funded by fees collected pursuant to section 740,*
 24 *and data, analysis, and discussion of the number*
 25 *of full-time equivalents in the animal drug re-*

1 view program, including a breakdown by fund-
2 ing from fees collected pursuant to section 740
3 versus budget authority, and by each division
4 within the Center for Veterinary Medicine, the
5 Office of Regulatory Affairs, and the Office of the
6 Commissioner.

7 “(B) Data, analysis, and discussion of the
8 changes in the fee revenue amounts and costs for
9 the process for the review of animal drug appli-
10 cations, including identifying—

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

12 “(ii) changes in the total cost per full-
13 time equivalent in the animal drug review
14 program.

15 “(C) Data, analysis, and discussion of
16 changes in the average full-time equivalent hours
17 required to complete review of each type of ani-
18 mal drug application.

19 “(D) For fiscal years 2024 and 2025, of the
20 meeting requests from animal drug sponsors for
21 which the Secretary has determined that a face-
22 to-face meeting is appropriate, the number of
23 face-to-face meetings requested by sponsors to be
24 conducted in person (in such manner as the Sec-
25 retary shall prescribe on the website of the Food

1 *and Drug Administration), and the number of*
2 *such in-person meetings granted by the Sec-*
3 *retary.”; and*

4 *(2) in subsection (d)—*

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

7 *(B) by redesignating paragraph (6) as*
8 *paragraph (7);*

9 *(C) by inserting after paragraph (5) the fol-*
10 *lowing:*

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

18 *(D) in paragraph (7) (as so redesignated)—*

19 *(i) in subparagraph (A)—*

20 *(I) by striking “Before presenting*
21 *the recommendations developed under*
22 *paragraphs (1) through (5) to Con-*
23 *gress, the Secretary” and inserting*
24 *“The Secretary”; and*

1 (II) by inserting before the period
2 at the end the following: “, not later
3 than 30 days after each such negotia-
4 tion meeting”; and

5 (ii) in subparagraph (B), by inserting
6 “, in sufficient detail,” after “shall summa-
7 rize”.

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

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

12 **SEC. 303. ANTIMICROBIAL RESISTANCE.**

13 (a) *REPORT ON ANTIMICROBIAL STEWARDSHIP.*—Not
14 later than December 31, 2023, the Secretary of Health and
15 Human Services, acting through the Commissioner of Food
16 and Drugs, shall submit to the Committee on Energy and
17 Commerce of the House of Representatives and the Com-
18 mittee on Health, Education, Labor, and Pensions of the
19 Senate a report describing—

20 (1) activities conducted by the Center for Veteri-
21 nary Medicine of the Food and Drug Administration
22 (referred to in this section as “the Center”) during the
23 period of fiscal years 2019 through 2023 to support
24 antimicrobial stewardship in veterinary settings, in-

1 *cluding ongoing activities and the targeted completion*
2 *date of such activities; and*

3 *(2) with respect to antimicrobial stewardship in*
4 *veterinary settings—*

5 *(A) the goals of the Center regarding sup-*
6 *porting antimicrobial stewardship in veterinary*
7 *settings;*

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

12 *(C) metrics the Center plans to use to evalu-*
13 *ate progress toward its goals regarding sup-*
14 *porting antimicrobial stewardship in veterinary*
15 *settings.*

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

22 *(1) a description of activities conducted by the*
23 *Center in the prior fiscal year to support anti-*
24 *microbial stewardship in veterinary settings, includ-*

1 *ing progress made toward goals and activities speci-*
2 *fied in subsection (a)(2);*

3 *(2) in the case of an incomplete activity de-*
4 *scribed in subsection (a)(2)(B) for which the target*
5 *completion date has passed—*

6 *(A) an explanation for why such target*
7 *completion date was not met; and*

8 *(B) if applicable, the updated expected com-*
9 *pletion date for such activity;*

10 *(3) a description of emerging challenges related*
11 *to antimicrobial stewardship in veterinary settings*
12 *that impact Center activities; and*

13 *(4) a description of activities undertaken to*
14 *incentivize the development of new drugs for the treat-*
15 *ment, prevention, or control of bacterial diseases in*
16 *animals.*

Union Calendar No. 80

118TH CONGRESS
1ST Session

H. R. 1418

[Report No. 118-104]

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.

JUNE 9, 2023

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed