

118TH CONGRESS
1ST SESSION

S. 1844

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 SENATE OF THE UNITED STATES

JUNE 7, 2023

Ms. BALDWIN (for herself and Mr. MULLIN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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

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 Sec. 103. Authority to assess and use animal drug fees.
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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

1 Commerce of the House of Representatives and the Chair-
2 man of the Committee on Health, Education, Labor, and
3 Pensions of the Senate as set forth in the Congressional
4 Record.

5 **SEC. 102. DEFINITIONS.**

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

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

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

12 “(I) The activities necessary for implemen-
13 tation of the United States and European
14 Union Mutual Recognition Agreement for Phar-
15 maceutical Good Manufacturing Practice In-
16 spections, and the United States and United
17 Kingdom Mutual Recognition Agreement Sec-
18 toral Annex for Pharmaceutical Good Manufac-
19 turing Practices, and other mutual recognition
20 agreements, with respect to animal drug prod-
21 ucts subject to review, including implementation
22 activities prior to and following product ap-
23 proval.”.

1 **SEC. 103. AUTHORITY TO ASSESS AND USE ANIMAL DRUG**
 2 **FEES.**

3 (a) IN GENERAL.—Section 740(a)(1)(A)(ii) of the
 4 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
 5 12(a)(1)(A)(ii)) is amended—

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

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

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

11 “(III) an application for condi-
 12 tional approval under section 571 of a
 13 new animal drug for which an animal
 14 drug application submitted under sec-
 15 tion 512(b)(1) has been previously ap-
 16 proved under section 512(d)(1) for
 17 another intended use.”.

18 (b) FEE REVENUE AMOUNTS.—Section 740(b)(1) of
 19 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 20 379j–12(b)(1)) is amended to read as follows:

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

26 (c) ANNUAL FEE SETTING; ADJUSTMENTS.—

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

4 “(1) ANNUAL FEE SETTING.—Not later than
 5 60 days before the start of each fiscal year begin-
 6 ning after September 30, 2023, the Secretary
 7 shall—

8 “(A) establish for that fiscal year animal
 9 drug application fees, supplemental animal drug
 10 application fees, animal drug sponsor fees, ani-
 11 mal drug establishment fees, and animal drug
 12 product fees based on the revenue amounts es-
 13 tablished under subsection (b) and the adjust-
 14 ments provided under this subsection; and

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

17 (2) INFLATION ADJUSTMENT.—Section
 18 740(c)(2) of the Federal Food, Drug, and Cosmetic
 19 Act (21 U.S.C. 379j–12(c)(2)) is amended—

20 (A) in subparagraph (A)—

21 (i) in the matter preceding clause (i),
 22 by striking “2020” and inserting “2025”;
 23 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 ADJUSTMENTS.—Section
 7 740(c)(3) of the Federal Food, Drug, and Cosmetic
 8 Act (21 U.S.C. 379j–12(c)(3)) is amended—

9 (A) in subparagraph (A)—

10 (i) in the matter preceding clause
 11 (i)—

12 (I) by striking “2020” and in-
 13 serting “2025”; and

14 (II) by striking “subparagraphs
 15 (B) and (C)” and inserting “subpara-
 16 graph (B)”;

17 (ii) in clause (i) by striking “and” at
 18 the end; and

19 (iii) by striking clause (ii) and insert-
 20 ing the following:

21 “(ii) such adjustment shall be made
 22 for each fiscal year that the adjustment de-
 23 termined by the Secretary is greater than
 24 3 percent, except for the first fiscal year

1 that the adjustment is greater than 3 per-
2 cent; and

3 “(iii) the Secretary shall publish in
4 the Federal Register notice under para-
5 graph (1) the amount of such adjustment
6 and the supporting methodologies.”;

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

8 (C) by redesignating subparagraph (C) as
9 subparagraph (B).

10 (4) FINAL YEAR ADJUSTMENT.—Section
11 740(c)(4) of the Federal Food, Drug, and Cosmetic
12 Act (21 U.S.C. 379j–12(c)(4)) is amended to read
13 as follows:

14 “(4) OPERATING RESERVE ADJUSTMENT.—

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

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

24 “(ii) if the Secretary has an operating
25 reserve in excess of the number of weeks

1 specified in subparagraph (C) for that fis-
 2 cal year, the Secretary shall decrease the
 3 fee revenue amount to provide not more
 4 than the number of weeks specified in sub-
 5 paragraph (C) for that fiscal year.

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

12 “(C) NUMBER OF WEEKS OF OPERATING
 13 RESERVES.—The number of weeks of operating
 14 reserves specified in this subparagraph is—

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

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

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

18 and

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

20 “(D) PUBLICATION.—If an adjustment to
 21 the operating reserve is made under this para-
 22 graph, the Secretary shall publish in the Fed-
 23 eral Register notice under paragraph (1) the ra-
 24 tionale for the amount of the adjustment and
 25 the supporting methodologies.”.

1 (d) EXEMPTION FROM FEES.—Section 740(d)(4) of
 2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 3 379j–12(d)(4)) is amended to read as follows:

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

14 (e) CREDITING AND AVAILABILITY OF FEES.—

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

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

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

25 (B) by striking paragraph (5).

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

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

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

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

8 (3) in subsection (d)—

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

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

13 **SEC. 105. SAVINGS CLAUSE.**

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

1 **SEC. 106. EFFECTIVE DATE.**

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

11 **SEC. 107. SUNSET DATES.**

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

16 (b) **REPORTING REQUIREMENTS.**—Section 740A of
17 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
18 379j–13) shall cease to be effective January 31, 2029.

19 (c) **PREVIOUS SUNSET PROVISION.**—Effective Octo-
20 ber 1, 2023, subsections (a) and (b) of section 107 of the
21 Animal Drug User Fee Amendments of 2018 (Public Law
22 115–234) are repealed.

1 **TITLE II—FEES RELATING TO**
2 **GENERIC ANIMAL DRUGS**

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

4 (a) SHORT TITLE.—This title may be cited as the
5 “Animal Generic 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 generic new animal drug de-
9 velopment process and the review of abbreviated applica-
10 tions for generic new animal drugs, supplemental abbrevi-
11 ated applications for generic new animal drugs, and in-
12 vestigational submissions for generic new animal drugs as
13 set forth in the goals identified for purposes of part 5 of
14 subchapter C of chapter VII of the Federal Food, Drug,
15 and Cosmetic Act (21 U.S.C. 379j–21 et seq.), in the let-
16 ters from the Secretary of Health and Human Services
17 to the Chairman of the Committee on Energy and Com-
18 merce of the House of Representatives and the Chairman
19 of the Committee on Health, Education, Labor and Pen-
20 sions of the Senate as set forth in the Congressional
21 Record.

22 **SEC. 202. AUTHORITY TO ASSESS AND USE GENERIC NEW**
23 **ANIMAL DRUG FEES.**

24 (a) GENERIC INVESTIGATIONAL NEW ANIMAL DRUG
25 FILE FEE.—Section 741(a) of the Federal Food, Drug,

1 and Cosmetic Act (21 U.S.C. 379j–21(a)) is amended by
2 adding at the end the following:

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

5 “(A) IN GENERAL.—

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

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

21 “(B) PAYMENT.—

22 “(i) NEW FILE REQUEST.—The fee
23 required by subparagraph (A)(i) shall be
24 due upon submission of the request to es-

1 tablish the generic investigational new ani-
2 mal drug file.

3 “(ii) 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
11 DRUG FILE.—If a person makes a submis-
12 sion to the generic investigational new ani-
13 mal drug file to terminate that file, the
14 person shall not be subject to a fee under
15 subparagraph (A)(ii) for that submission.

16 “(ii) TRANSFERRING AN EXISTING GE-
17 NERIC INVESTIGATIONAL NEW ANIMAL
18 DRUG FILE.—If a person makes a submis-
19 sion to the generic investigational new ani-
20 mal drug file to transfer that file to a dif-
21 ferent generic new animal drug sponsor,
22 the person shall not be subject to a fee
23 under subparagraph (A)(ii) for that sub-
24 mission.”.

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 insert-
 8 ing “\$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
 14 at the end the following: “and fees under
 15 subsection (a)(4) (relating to generic inves-
 16 tigational 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)
 23 of the Federal Food, Drug, and Cosmetic Act (21
 24 U.S.C. 379j–21(c)(1)) is amended to read as follows:

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

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

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

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

19 (2) INFLATION ADJUSTMENT.—Section
 20 741(c)(2) of the Federal Food, Drug, and Cosmetic
 21 Act (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
 7 741(c)(3) of the Federal Food, Drug, and Cosmetic
 8 Act (21 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 es-
 18 tablish a generic investigational new
 19 animal drug file, and generic inves-
 20 tigational new animal drug meeting
 21 requests”; 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)
 5 exceeds 25 percent, the Secretary shall use
 6 25 percent for the adjustment; and”; and
 7 (B) in subparagraph (B), by striking
 8 “2021 through 2023” and inserting “2026
 9 through 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 FEES.—Subsection (d) of section 741 of the Federal
 19 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21) is
 20 amended 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
 24 finds that the generic new animal drug is intended solely
 25 to provide 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)
 7 shall be considered incomplete and shall not be accepted
 8 for action by the Secretary until all fees owed by such per-
 9 son 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
 13 new animal drug products at any time” and inserting
 14 “products, generic new animal drug sponsors, and generic
 15 investigational new animal drug files at any time”.

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

19 (1) in paragraph (3), by striking “2019
 20 through 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 Ani-
 23 mal Generic Drug User Fee Amendments of 2013
 24 (Public Law 113–14); and

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

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

4 “(A) for fiscal year 2026, by the amount,
5 if 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
8 fiscal year 2024 under paragraph (3);

9 “(B) for fiscal year 2027, by the amount,
10 if 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
13 fiscal year 2025 under paragraph (3); and

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

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

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
9 a 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 explo-
16 ration and implementation of the United States
17 and European Union Mutual Recognition
18 Agreement for Pharmaceutical Good Manufac-
19 turing Practice Inspections, and the United
20 States and United Kingdom Mutual Recogni-
21 tion Agreement Sectoral Annex for Pharma-
22 ceutical Good Manufacturing Practices, and
23 other mutual recognition agreements, with re-
24 spect to generic new animal drug products sub-
25 ject to review, including implementation activi-

1 ties prior to and following product approval.”;
2 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
7 term ‘request to establish a generic investigational
8 new animal drug file’ means the submission to the
9 Secretary of a request to establish a generic inves-
10 tigational new animal drug file to contain investiga-
11 tional submissions 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
16 inserting “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
25 in effect on the day before the date of enactment of this

1 title, shall continue to be in effect with respect to abbrevi-
2 ated applications for a generic new animal drug and sup-
3 plemental abbreviated applications for a generic new ani-
4 mal drug (as defined in such part as of such day) that
5 on or after October 1, 2018, but before October 1, 2023,
6 were accepted by the Food and Drug Administration for
7 filing with respect to assessing and collecting any fee re-
8 quired by such part for a fiscal year prior to fiscal year
9 2024.

10 **SEC. 205. EFFECTIVE DATE.**

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

21 **SEC. 206. SUNSET DATES.**

22 (a) AUTHORIZATION.—Section 741 of the Federal
23 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21) shall
24 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 Octo-
 5 ber 1, 2023, subsections (a) and (b) of section 206 of the
 6 Animal Generic Drug User Fee Amendments of 2018
 7 (Public Law 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 Cos-
 12 metic Act (21 U.S.C. 379j–13), as amended by section
 13 104, is further 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
 24 740, and data, analysis, and discussion of the
 25 number of full-time equivalents in the animal

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

7 “(B) Data, analysis, and discussion of the
8 changes in the fee revenue amounts and costs
9 for the process for the review of animal drug
10 applications, 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
17 hours required to complete review of each type
18 of animal drug application.

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

website of the Food and Drug Administration),
and the number of such in-person meetings
granted by the Secretary.”; and

(2) in subsection (d)—

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

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

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

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

(D) in paragraph (7) (as so redesign-
ated)—

(i) in subparagraph (A)—

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

1 (II) by inserting before the pe-
 2 riod at the end the following: “, not
 3 later than 30 days after each such ne-
 4 gotiation meeting”; and
 5 (ii) in subparagraph (B), by inserting
 6 “, in sufficient detail,” after “shall sum-
 7 marize”.

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

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

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

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

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

1 settings, including ongoing activities and the tar-
2 geted completion 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
13 evaluate progress toward its goals regarding
14 supporting antimicrobial stewardship in veteri-
15 nary settings.

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

23 (1) a description of activities conducted by the
24 Center in the prior fiscal year to support anti-
25 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
9 completion 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
15 treatment, prevention, or control of bacterial dis-
16 eases in animals.

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