

## Calendar No. 174

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.

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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

JULY 26, 2023

Reported by Mr. SANDERS, with an amendment

[Insert the part printed in *italic*]

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**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”.

1 **SEC. 2. TABLE OF CONTENTS.**

2 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.  
Sec. 304. *Regulation of zootechnical animal food substances.*

3 **TITLE I—FEES RELATING TO**  
4 **ANIMAL DRUGS**

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

6 (a) SHORT TITLE.—This title may be cited as the  
7 “Animal 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 animal drug development  
11 process and the review of new and supplemental animal  
12 drug applications and investigational animal drug submis-  
13 sions as set forth in the goals identified for purposes of

1 part 4 of subchapter C of chapter VII of the Federal Food,  
2 Drug, and Cosmetic Act (21 U.S.C. 379j–11 et seq.), in  
3 the letters from the Secretary of Health and Human Serv-  
4 ices to the Chairman of the Committee on Energy and  
5 Commerce of the House of Representatives and the Chair-  
6 man of the Committee on Health, Education, Labor, and  
7 Pensions of the Senate as set forth in the Congressional  
8 Record.

9 **SEC. 102. DEFINITIONS.**

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

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

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

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

1 activities prior to and following product ap-  
 2 proval.”.

3 **SEC. 103. AUTHORITY TO ASSESS AND USE ANIMAL DRUG**  
 4 **FEES.**

5 (a) IN GENERAL.—Section 740(a)(1)(A)(ii) of the  
 6 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–  
 7 12(a)(1)(A)(ii)) is amended—

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

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

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

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

20 (b) FEE REVENUE AMOUNTS.—Section 740(b)(1) of  
 21 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
 22 379j–12(b)(1)) is amended to read as follows:

23 “(1) IN GENERAL.—Subject to subsections (c),  
 24 (d), (f), and (g), for each of fiscal years 2024  
 25 through 2028, the fees required under subsection (a)

1 shall be established to generate a total revenue  
 2 amount of \$33,500,000.”.

3 (c) ANNUAL FEE SETTING; ADJUSTMENTS.—

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

7 “(1) ANNUAL FEE SETTING.—Not later than  
 8 60 days before the start of each fiscal year begin-  
 9 ning after September 30, 2023, the Secretary  
 10 shall—

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

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

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

23 (A) in subparagraph (A)—

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

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

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

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

(A) in subparagraph (A)—

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

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

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

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

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

“(ii) such adjustment shall be made  
for each fiscal year that the adjustment de-

1           terminated by the Secretary is greater than  
 2           3 percent, except for the first fiscal year  
 3           that the adjustment is greater than 3 per-  
 4           cent; and

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

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

10          (C) by redesignating subparagraph (C) as  
 11          subparagraph (B).

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

16          “(4) OPERATING RESERVE ADJUSTMENT.—

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

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

“(ii) if the Secretary has an operating reserve in excess of the number of weeks specified in subparagraph (C) for that fiscal year, the Secretary shall decrease the fee revenue amount to provide not more than the number of weeks specified in subparagraph (C) for that fiscal year.

“(B) CARRYOVER USER FEES.—For purposes of this paragraph, the operating reserve of carryover user fees for the process for the review of animal drug applications does not include carryover user fees that have not been appropriated.

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

“(i) 22 weeks for fiscal year 2025;

“(ii) 20 weeks for fiscal year 2026;

“(iii) 18 weeks for fiscal year 2027;

and

“(iv) 16 weeks for fiscal year 2028.

“(D) PUBLICATION.—If an adjustment to the operating reserve is made under this paragraph, the Secretary shall publish in the Federal Register notice under paragraph (1) the ra-

1           tionale for the amount of the adjustment and  
2           the supporting methodologies.”.

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

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

16          (e) CREDITING AND AVAILABILITY OF FEES.—

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

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

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

3 (B) by striking paragraph (5).

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

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

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

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

11 (3) in subsection (d)—

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

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

16 **SEC. 105. SAVINGS CLAUSE.**

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

1 with respect to assessing and collecting any fee required  
2 by such part for a fiscal year prior to fiscal year 2024.

3 **SEC. 106. EFFECTIVE DATE.**

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

13 **SEC. 107. SUNSET DATES.**

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

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

21 (c) **PREVIOUS SUNSET PROVISION.**—Effective Octo-  
22 ber 1, 2023, subsections (a) and (b) of section 107 of the  
23 Animal Drug User Fee Amendments of 2018 (Public Law  
24 115–234) 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

1 website of the Food and Drug Administration),  
2 and the number of such in-person meetings  
3 granted by the Secretary.”; 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  
10 following:

11 “(6) UPDATES TO CONGRESS.—The Secretary,  
12 in 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  
17 of Representatives.”; and

18 (D) in paragraph (7) (as so redesign-  
19 nated)—

20 (i) in subparagraph (A)—

21 (I) by striking “Before pre-  
22 senting the recommendations devel-  
23 oped under paragraphs (1) through  
24 (5) to Congress, the Secretary” and  
25 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.

17 **SEC. 304. REGULATION OF ZOOTECHNICAL ANIMAL FOOD**  
 18 **SUBSTANCES.**

19 (a) *DEFINITION.*—Section 201 of the Federal Food,  
 20 Drug, and Cosmetic Act (21 U.S.C. 321) is amended by  
 21 adding at the end the following:

22 “(tt)(1) The term ‘zootechnical animal food substance’  
 23 means a substance that—

24 “(A) is added to the food or drinking water of  
 25 animals;

1           “(B) is intended to—

2                   “(i) affect the byproducts of the digestive  
3           process of an animal;

4                   “(ii) reduce the presence of foodborne patho-  
5           gens of human health significance in an animal  
6           intended to be used for food; or

7                   “(iii) affect the structure or function of the  
8           body of the animal, other than by providing nu-  
9           tritive value, by altering the animal’s gastro-  
10          intestinal microbiome; and

11           “(C) achieves its intended effect by acting solely  
12          within the gastrointestinal tract of the animal.

13          “(2) Such term does not include a substance that—

14                   “(A) is intended for use in the diagnosis, cure,  
15          mitigation, treatment, or prevention of disease in an  
16          animal;

17                   “(B) is a hormone;

18                   “(C) is an active moiety in an animal drug,  
19          which, prior to the filing of a petition under section  
20          409 was approved under section 512, conditionally  
21          approved under section 571, or indexed under section  
22          572, or for which substantial clinical investigations  
23          have been instituted and for which the existence of  
24          such investigations has been made public;

25                   “(D) is an ionophore; or

1           “(E) is otherwise excluded from the definition  
2       based on criteria established by the Secretary through  
3       notice and comment rulemaking.

4       “(3) A zootechnical animal food substance shall be  
5       deemed to be a food additive within the meaning of para-  
6       graph (s) and its introduction into interstate commerce  
7       shall be in accordance with a regulation issued under sec-  
8       tion 409. A zootechnical animal food substance shall not  
9       be considered a drug under paragraph (g)(1)(C) solely be-  
10      cause the substance has an intended effect described in sub-  
11      paragraph (1).”.

12       (b) *FOOD ADDITIVES*.—Section 409 of the Federal  
13      Food, Drug, and Cosmetic Act (21 U.S.C. 348) is amend-  
14      ed—

15           (1) in subsection (b)—

16               (A) by redesignating paragraphs (3)  
17               through (5) as paragraphs (4) through (6), re-  
18               spectively; and

19               (B) by inserting after paragraph (2) the fol-  
20               lowing:

21           “(3) In the case of a zootechnical animal food  
22       substance, such petition shall, in addition to any ex-  
23       planatory or supporting data, contain—

24               “(A) all relevant data bearing on the effect  
25       the zootechnical animal food substance is in-

1        *tended to have and the quantity of such sub-*  
 2        *stance required to produce the intended effect;*  
 3        *and*

4                *“(B) full reports of investigations made*  
 5        *with respect to the intended use of such sub-*  
 6        *stance, including full information as to the*  
 7        *methods and controls used in conducting such*  
 8        *investigations.”;*

9        *(2) in subsection (c)—*

10                *(A) by amending subparagraph (A) of*  
 11        *paragraph (1) to read as follows:*

12                *“(A)(i) by order establish a regulation (whether*  
 13        *or not in accord with that proposed by the petitioner)*  
 14        *prescribing—*

15                *“(I) with respect to one or more proposed*  
 16        *uses of the food additive involved, the conditions*  
 17        *under which such additive may be safely used*  
 18        *(including specifications as to the particular*  
 19        *food or classes of food in or on which such addi-*  
 20        *tive may be used, the maximum quantity which*  
 21        *may be used or permitted to remain in or on*  
 22        *such food, the manner in which such additive*  
 23        *may be added to or used in or on such food, and*  
 24        *any directions or other labeling or packaging re-*  
 25        *quirements for such additive as the Secretary de-*

1 *termines necessary to assure the safety of such*  
 2 *use); and*

3 *“(II) in the case of a zootechnical animal*  
 4 *food substance, the conditions under which such*  
 5 *substance may be used to achieve the intended ef-*  
 6 *fect; and*

7 *“(ii) notify the petitioner of such order and the*  
 8 *reasons for such action; or”; and*

9 *(B) in paragraph (3)—*

10 *(i) in subparagraph (A), by striking “;*  
 11 *or” and inserting a semicolon;*

12 *(ii) in subparagraph (B), by striking*  
 13 *the period and inserting “; or”; and*

14 *(iii) by adding at the end the fol-*  
 15 *lowing:*

16 *“(C) in the case of a zootechnical animal food*  
 17 *substance, fails to establish that the proposed use of*  
 18 *the substance, under the conditions of use to be speci-*  
 19 *fied in the regulation, will achieve the intended ef-*  
 20 *fect.”; and*

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

22 *“(l) ZOOTECHNICAL ANIMAL FOOD SUBSTANCES.—*  
 23 *The labeling of a zootechnical animal food substance—*

1           “(1) shall include the statement: ‘Not for use in  
2       the diagnosis, cure, mitigation, treatment, or preven-  
3       tion of disease in animals.’; and

4           “(2) may include statements regarding the in-  
5       tended effect of the substance on the structure or func-  
6       tion of the body of animals, as set forth in section  
7       201(tt)(1).”.

8       (c) MISBRANDED FOOD.—Section 403 of the Federal  
9       Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended  
10      by adding at the end the following:

11       “(z) If it is a zootechnical animal food substance and  
12      the labeling of the food does not include the statement re-  
13      quired by section 409(l)(1).”.

14       (d) RULE OF CONSTRUCTION.—Nothing in this sec-  
15      tion, or the amendments made by this section, shall be con-  
16      strued to authorize the Secretary of Health and Human  
17      Services to require the use of any zootechnical food sub-  
18      stance or food additive (as those terms are defined in section  
19      201 of the Federal Food, Drug, and Cosmetic Act, as  
20      amended by subsection (a)).



Calendar No. 174

118TH CONGRESS  
1ST Session  
**S. 1844**

**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.

JULY 26, 2023

Reported with an amendment