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(Original Signature of Member)

118TH CONGRESS  
1ST SESSION

**H. R.**

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 HOUSE OF REPRESENTATIVES

M. \_\_\_\_\_ introduced the following bill; which was referred to the  
Committee on \_\_\_\_\_

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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 User Fee  
5 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.
- Sec. 102. Definitions.
- Sec. 103. Authority to assess and use animal drug fees.
- Sec. 104. Reauthorization; reporting requirements.
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TITLE II—FEES RELATING TO GENERIC ANIMAL DRUGS

- Sec. 201. Short title; finding.
- Sec. 202. Authority to assess and use generic new animal drug fees.
- Sec. 203. Reauthorization; reporting requirements.
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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, in the letters from the Secretary  
14  of Health and Human Services to the Chairman of the  
15  Committee on Energy and Commerce of the House of  
16  Representatives and the Chairman of the Committee on

1 Health, Education, Labor, and Pensions of the Senate as  
2 set forth in the Congressional Record.

3 **SEC. 102. DEFINITIONS.**

4 Section 739(8)(I) of the Federal Food, Drug, and  
5 Cosmetic Act (21 U.S.C. 379j–11(8)(I)) is amended to  
6 read as follows:

7 “(I) The activities necessary for implemen-  
8 tation of the United States and European  
9 Union Mutual Recognition Agreement for Phar-  
10 maceutical Good Manufacturing Practice In-  
11 spections, and the United States and United  
12 Kingdom Recognition Agreement Sectoral  
13 Annex for Pharmaceutical Good Manufacturing  
14 Practices, and future mutual recognition agree-  
15 ments, with respect to animal drug products  
16 subject to review, including implementation ac-  
17 tivities prior to and following product ap-  
18 proval.”.

19 **SEC. 103. AUTHORITY TO ASSESS AND USE ANIMAL DRUG**  
20 **FEEES.**

21 (a) TYPES OF FEES.—Section 740(a)(1)(A)(ii) of the  
22 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–  
23 12(a)(1)(A)(ii)) is amended—

24 (1) in subelause (I), by striking “and” at the  
25 end;

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

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

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

11          (b) FEE REVENUE AMOUNTS.—Section 740(b)(1) of  
12          the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
13          379j–12(b)(1)) is amended to read as follows:

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

19          (c) ANNUAL FEE SETTING; ADJUSTMENTS.—

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

23                       “(1) ANNUAL FEE SETTING.—Not later than  
24                       60 days before the start of each fiscal year begin-

1           ning after September 30, 2023, the Secretary  
2           shall—

3                   “(A) establish for that fiscal year animal  
4                   drug application fees, supplemental animal drug  
5                   application fees, animal drug sponsor fees, ani-  
6                   mal drug establishment fees, and animal drug  
7                   product fees based on the revenue amounts es-  
8                   tablished under subsection (b) and the adjust-  
9                   ments provided under this subsection; and

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

12           (2)       INFLATION       ADJUSTMENT.—Section  
13           740(c)(2) of the Federal Food, Drug, and Cosmetic  
14           Act (21 U.S.C. 379j–12(c)(2)) is amended—

15                   (A) in subparagraph (A)—

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

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

22                   (B) in subparagraph (B), by striking  
23                   “2020” and inserting “2025”.

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

4           (A) in subparagraph (A)—

5           (i) in the matter preceding clause

6           (i)—

7           (I) by striking “2020” and in-  
8 sserting “2025”; and

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

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

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

16           “(ii) such adjustment shall be made  
17 for each fiscal year that the adjustment de-  
18 termined by the Secretary is greater than  
19 3 percent, except for the first fiscal year  
20 that the adjustment is greater than 3 per-  
21 cent; and

22           “(iii) the Secretary shall publish in  
23 the Federal Register notice under para-  
24 graph (1) the amount of such adjustment  
25 and the supporting methodologies.”;

1 (B) by striking subparagraph (B); and  
2 (C) by redesignating subparagraph (C) as  
3 subparagraph (B).

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

8 “(4) OPERATING RESERVE ADJUSTMENT.—

9 “(A) IN GENERAL.—For fiscal year 2025  
10 and each subsequent fiscal year, after the fee  
11 revenue amount established under subsection  
12 (b) is adjusted in accordance with paragraphs  
13 (2) and (3), the Secretary shall—

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

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

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

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

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

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

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

13                   and

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

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

21           (d) EXEMPTION FROM FEES.—Section 740(d)(4) of  
22           the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
23           379j–12(d)(4)) is amended to read as follows:

24                   “(4) EXEMPTION FROM FEES FOR CERTAIN  
25           ANIMAL DRUG APPLICATIONS.—Fees under para-

1 graphs (2), (3), and (4) of subsection (a) shall not  
2 apply with respect to any person who is the named  
3 applicant or sponsor of an animal drug application,  
4 supplemental animal drug application, or investiga-  
5 tional animal drug submission if such application or  
6 submission involves the intentional genomic alter-  
7 ation of an animal that is intended to produce a  
8 drug, device, or biological product subject to fees  
9 under section 736, 738, 744B, or 744H.”.

10 (e) CREDITING AND AVAILABILITY OF FEES.—

11 (1) AUTHORIZATION OF APPROPRIATIONS.—

12 Section 740(g)(3) of the Federal Food, Drug, and  
13 Cosmetic Act (21 U.S.C. 379j–12(g)(3)) is amended  
14 by striking “2019 through 2023” and inserting  
15 “2024 through 2028”.

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

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

21 (B) by striking paragraph (5).

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

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

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

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

5 (3) in subsection (d)—

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

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

10 **SEC. 105. SAVINGS CLAUSE.**

11 Notwithstanding the amendments made by this title,  
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.), as  
14 in effect on the day before the date of enactment of this  
15 title, shall continue to be in effect with respect to animal  
16 drug applications and supplemental animal drug applica-  
17 tions (as defined in such part as of such day) that on or  
18 after October 1, 2018, but before October 1, 2023, were  
19 accepted by the Food and Drug Administration for filing  
20 with respect to assessing and collecting any fee required  
21 by such part for a fiscal year prior to fiscal year 2024.

22 **SEC. 106. EFFECTIVE DATE.**

23 The amendments made by this title shall take effect  
24 on October 1, 2023, or the date of the enactment of this  
25 Act, whichever is later, except that fees under part 4 of

1 subchapter C of chapter VII of the Federal Food, Drug,  
2 and Cosmetic Act, as amended by this title, shall be as-  
3 sessed for animal drug applications and supplemental ani-  
4 mal drug applications received on or after October 1,  
5 2023, regardless of the date of the enactment of this Act.

6 **SEC. 107. SUNSET DATES.**

7 (a) AUTHORIZATION.—Sections 739 and 740 of the  
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–  
9 12) shall cease to be effective October 1, 2028.

10 (b) REPORTING REQUIREMENTS.—Section 740A of  
11 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
12 379j–13) shall cease to be effective January 31, 2029.

13 (c) PREVIOUS SUNSET PROVISION.—Effective Octo-  
14 ber 1, 2023, subsections (a) and (b) of section 107 of the  
15 Animal Drug User Fee Amendments of 2018 (Public Law  
16 115–234) are repealed.

17 **TITLE II—FEES RELATING TO**  
18 **GENERIC ANIMAL DRUGS**

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

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

22 (b) FINDING.—Congress finds that the fees author-  
23 ized by the amendments made in this title will be dedi-  
24 cated toward expediting the generic new animal drug de-  
25 velopment process and the review of abbreviated applica-

1 tions for generic new animal drugs, supplemental abbreviations for generic new animal drugs, and investigational submissions for generic new animal drugs as set forth in the goals identified for purposes of part 5 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Energy and Commerce of the House of Representatives and the Chairman of the Committee on Health, Education, Labor and Pensions of the Senate as set forth in the Congressional Record.

12 **SEC. 202. AUTHORITY TO ASSESS AND USE GENERIC NEW**  
13 **ANIMAL DRUG FEES.**

14 (a) TYPES OF FEES.—Section 741(a) of the Federal  
15 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21(a)) is  
16 amended by adding at the end the following:

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

19 “(A) IN GENERAL.—

20 “(i) ASSESSMENT OF FEE.—Each person that submits a request to establish a  
21 generic investigational new animal drug  
22 file on or after October 1, 2023, shall be  
23 assessed a fee as established under sub-  
24 section (c).  
25

1           “(ii) EXISTING FILES.—In the case of  
2           a generic investigational new animal drug  
3           file established prior to October 1, 2023,  
4           each person that makes a submission to  
5           such a file on or after October 1, 2023,  
6           shall be assessed a fee for the first submis-  
7           sion on or after October 1, 2023, as estab-  
8           lished under subsection (c).

9           “(B) PAYMENT.—The fee required by sub-  
10          paragraph (A)(i) shall be due upon submission  
11          of the request to establish the generic investiga-  
12          tional new animal drug file. The fee required by  
13          subparagraph (A)(ii) shall be due upon the first  
14          submission to the generic investigational new  
15          animal drug file.

16          “(C) EXCEPTIONS.—

17                 “(i) TERMINATION.—If a person  
18                 makes a submission to the generic inves-  
19                 tigational new animal drug file to termi-  
20                 nate that file, the person shall not be sub-  
21                 ject to a fee under subparagraph (A)(ii)  
22                 for that submission.

23                 “(ii) TRANSFERS.—If a person makes  
24                 a submission to the generic investigational  
25                 new animal drug file to transfer that file

1 to a different generic new animal drug  
2 sponsor, the person shall not be subject to  
3 a fee under subparagraph (A)(ii) for that  
4 submission.”.

5 (b) FEE REVENUE AMOUNTS.—Section 741(b) of the  
6 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–  
7 21(b)) is amended—

8 (1) in paragraph (1)—

9 (A) by striking “2019 through 2023” and  
10 inserting “2024 through 2028”; and

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

13 (2) in paragraph (2)—

14 (A) in subparagraph (A)—

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

17 (ii) by inserting before the semicolon  
18 at the end the following: “and subsection  
19 (a)(4) (relating to generic investigational  
20 new animal drug files)”;

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

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

25 (c) ANNUAL FEE SETTING; ADJUSTMENTS.—

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

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

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

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

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

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

25           (A) in subparagraph (A)—

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

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

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

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

12 (A) in subparagraph (A)—

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

15 (ii) in clause (i)—

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

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

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

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

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

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

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

18 (A) striking “2023” each place it appears  
19 and inserting “2028”; and

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

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

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

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

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

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

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

1 (2) by striking the following:

2 “(4) OFFSET.—If the sum of the cumulative  
3 amount of fees collected under this section for the  
4 fiscal years 2014 through 2016 and the amount of  
5 fees estimated to be collected under this section for  
6 fiscal year 2017 exceeds the cumulative amount ap-  
7 propriated under paragraph (3) for the fiscal years  
8 2014 through 2017, the excess amount shall be  
9 credited to the appropriation account of the Food  
10 and Drug Administration as provided in paragraph  
11 (1), and shall be subtracted from the amount of fees  
12 that would otherwise be authorized to be collected  
13 under this section pursuant to appropriation Acts  
14 for fiscal year 2018.”; and

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

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

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

24 “(B) for fiscal year 2027, by the amount,  
25 if any, by which the amount collected under this

1 section and appropriated for fiscal year 2025  
2 falls below the amount of fees authorized for  
3 fiscal year 2025 under paragraph (3); and

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

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

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

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

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

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

3 “(I) The activities necessary for explo-  
4 ration and implementation of the United States  
5 and European Union Mutual Recognition  
6 Agreement for Pharmaceutical Good Manufac-  
7 turing Practice Inspections, and the United  
8 States and United Kingdom Recognition Agree-  
9 ment Sectoral Annex for Pharmaceutical Good  
10 Manufacturing Practices, and future mutual  
11 recognition agreements, with respect to generic  
12 new animal drug products subject to review, in-  
13 cluding implementation activities prior to and  
14 following product approval.”; and

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

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

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

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

10 **SEC. 204. SAVINGS CLAUSE.**

11 Notwithstanding the amendments made by this title,  
12 part 5 of subchapter C of chapter VII of the Federal Food,  
13 Drug, and Cosmetic Act (21 U.S.C. 379j–21 et seq.), as  
14 in effect on the day before the date of enactment of this  
15 title, shall continue to be in effect with respect to abbrevi-  
16 ated applications for a generic new animal drug and sup-  
17 plemental abbreviated applications for a generic new ani-  
18 mal drug (as defined in such part as of such day) that  
19 on or after October 1, 2018, but before October 1, 2023,  
20 were accepted by the Food and Drug Administration for  
21 filing with respect to assessing and collecting any fee re-  
22 quired by such part for a fiscal year prior to fiscal year  
23 2024.

24 **SEC. 205. EFFECTIVE DATE.**

25 The amendments made by this title shall take effect  
26 on October 1, 2023, or the date of the enactment of this

1 Act, whichever is later, except that fees under part 5 of  
2 subchapter C of chapter VII of the Federal Food, Drug,  
3 and Cosmetic Act, as amended by this title, shall be as-  
4 sessed for abbreviated applications for a generic new ani-  
5 mal drug and supplemental abbreviated applications for  
6 a generic new animal drug received on or after October  
7 1, 2023, regardless of the date of enactment of this Act.

8 **SEC. 206. SUNSET DATES.**

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

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

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