AMENDMENT NO._____ Calendar No._____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—115th Cong., 2d Sess.

S. 2434

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

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by _____

Viz:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Animal Drug and Animal Generic Drug User Fee Amendments of 2018''.

SEC. 2. TABLE OF CONTENTS; REFERENCES IN ACT.

(a) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

(b) REFERENCES IN ACT.—Except as otherwise specified, amendments made by this Act to a section or other provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

TITLE I—FEES RELATING TO ANIMAL DRUGS

SEC. 101. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the ''Animal Drug User Fee Amendments of 2018''.

(b) FINDING.—Congress finds that the fees authorized by the amendments made in this title will be dedicated toward expediting the animal drug development process and the review of new and supplemental animal drug applications and investigational animal drug submissions as set forth in the goals identified for purposes of

part 4 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.

SEC. 102. DEFINITIONS.

Section 739 (21 U.S.C. 379j–11) is amended—

(1) by amending paragraph (1) to read as follows:

''(1)(A) The term 'animal drug application' means—

''(i) an application for approval of any new animal drug submitted under section 512(b)(1); or

''(ii) an application for conditional approval of a new animal drug submitted under section 571.

''(B) Such term does not include either a new animal drug application submitted under section 512(b)(2) or a supplemental animal drug application.''; and

(2) in paragraph (8), by adding at the end the following:

''(I) The activities necessary for implementation of the United States and European Union Good Manufacturing Practice Mutual Inspection Agreement with respect to animal drug products subject to review, including implementation activities prior to and following product approval.''.

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

(a) FEE REVENUE AMOUNTS.—Section 740(b) (21 U.S.C. 379j–12(b)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (A)—

(i) by striking ''2014'' and inserting ''2019''; and

(ii) by striking ''$23,600,000'' and inserting ''$30,331,240''; and

(B) in subparagraph (B)—

(i) by striking ''2015 through 2018'' and inserting ''2020 through 2023''; and

(ii) by striking ''$21,600,000'' and inserting ''$29,931,240''; and

(2) in paragraph (2), in the matter preceding subparagraph (A), by striking ''determined'' and inserting ''established''.

(b) ANNUAL FEE SETTING; ADJUSTMENTS.—

(1) INFLATION ADJUSTMENT.—Section 740(c)(2) (21 U.S.C. 379j–12(c)(2)) is amended—

(A) in the matter preceding subparagraph (A)—

(i) by striking ''For fiscal year 2015'' and inserting ''(A) For fiscal year 2020''; and

(ii) by inserting ''multiplying such revenue amounts by'' before ''an amount'';

(B) by redesignating subparagraphs (A), (B), and (C) as clauses (i), (ii), and (iii), respectively;

(C) by striking the flush text at the end; and

(D) by adding at the end the following new subparagraph:

''(B) COMPOUNDED BASIS.—The adjustment made each fiscal year after fiscal year 2020 under this paragraph shall be applied on a compounded basis to the revenue amount calculated under this paragraph for the most recent previous fiscal year.''.

(2) WORKLOAD ADJUSTMENTS.—Paragraph (3) of section 740(c) (21 U.S.C. 379j–12(c)) is amended to read as follows:

''(3) WORKLOAD ADJUSTMENTS.—

''(A) IN GENERAL.—For fiscal year 2020 and subsequent fiscal years, after the fee revenue amounts established under subsection (b) are adjusted for inflation in accordance with paragraph (2), the fee revenue amounts shall be further adjusted for such fiscal year to reflect changes in the workload of the Secretary for the process for the review of animal drug applications, subject to subparagraphs (B) and (C). With respect to such adjustment—

''(i) such adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of animal drug applications, supplemental animal drug applications for which data with respect to safety or effectiveness are required, manufacturing supplemental animal drug applications, investigational animal drug study submissions, and investigational animal drug protocol submissions submitted to the Secretary; and

''(ii) the Secretary shall publish in the Federal Register the fees resulting from

such adjustment and the supporting methodologies.

"(B) REDUCTION OF WORKLOAD-BASED INCREASE BY AMOUNT OF CERTAIN EXCESS COLLECTIONS.—For each of fiscal years 2021 through 2023, if application of the workload adjustment under subparagraph (A) increases the fee revenue amounts otherwise established for the fiscal year under subsection (b), as adjusted for inflation under paragraph (2), such fee revenue increase shall be reduced by the amount of any excess collections, as described in subsection (g)(4), for the second preceding fiscal year, up to the amount of such fee revenue increase.

"(C) RULE OF APPLICATION.—Under no circumstances shall the workload adjustments under this paragraph result in fee revenues for a fiscal year that are less than the fee revenues for that fiscal year established under subsection (b), as adjusted for inflation under paragraph (2).".

(3) FINAL YEAR ADJUSTMENT.—Section 740(c)(4) (21 U.S.C. 379j–12(c)(4)) is amended—

(A) by striking ''2018'' each place it appears and inserting ''2023''; and

(B) by striking ''2019'' and inserting ''2024''.

(c) EXEMPTIONS FROM FEES.—Section 740(d) (21 U.S.C. 379j–12(d)) is amended—

(1) in the subsection heading, by inserting ''; EXEMPTIONS FROM FEES'' after ''REDUCTION'';

(2) by striking the heading of paragraph (1) and inserting ''WAIVER OR REDUCTION''; and

(3) by adding at the end the following:

''(4) EXEMPTIONS FROM FEES.—

''(A) CERTAIN LABELING SUPPLEMENTS TO ADD NUMBER OF APPROVED APPLICATION.—Fees under this section shall not apply with respect to any person who—

''(i) not later than September 30, 2023, submits a supplemental animal drug application relating to a new animal drug application approved under section 512, solely to add the new animal drug application number to the labeling of the drug in the manner specified in section 502(w)(3); and

"(ii) otherwise would be subject to fees under this section solely on the basis of such supplemental application.

"(B) CERTAIN ANIMAL DRUG APPLICATIONS.—Fees under paragraphs (2), (3), and (4) of subsection (a) shall not apply with respect to any person who is the named applicant or sponsor of an animal drug application, supplemental animal drug application, or investigational animal drug submission if such application or submission involves the intentional genomic alteration of an animal that is intended to produce a drug, device, or biological product subject to fees under section 736, 738, 744B, or 744H.".

(d) CREDITING AND AVAILABILITY OF FEES.—

(1) AUTHORIZATION OF APPROPRIATIONS.—Section 740(g)(3) (21 U.S.C. 379j–12(g)(3)) is amended—

(A) by striking "2014 through 2018" and inserting "2019 through 2023";

(B) by striking "determined" and inserting "established"; and

(C) by striking "paragraph (4)" and inserting "paragraph (5)".

(2) EXCESS COLLECTIONS.—Section 740(g) (21 U.S.C. 379j–12(g)) is amended by striking paragraph (4) and inserting the following:

''(4) EXCESS COLLECTIONS.—If the sum total of fees collected under this section for a fiscal year exceeds the amount of fees authorized to be appropriated for such year under paragraph (3), the excess collections shall be credited to the appropriations account of the Food and Drug Administration as provided in paragraph (1).

''(5) RECOVERY OF COLLECTION SHORTFALLS.—

''(A) IN GENERAL.—Subject to subparagraph (B)—

''(i) for fiscal year 2021, the amount of fees otherwise authorized to be collected under this section shall be increased by the amount, if any, by which the amount collected under this section and appropriated for fiscal year 2019 falls below the amount of fees authorized for fiscal year 2019 under paragraph (3);

''(ii) for fiscal year 2022, the amount of fees otherwise authorized to be collected under this section shall be increased by the

amount, if any, by which the amount collected under this section and appropriated for fiscal year 2020 falls below the amount of fees authorized for fiscal year 2020 under paragraph (3); and

"(iii) for fiscal year 2023, the amount of fees otherwise authorized to be collected under this section shall be increased by the cumulative amount, if any, by which the amount collected under this section and appropriated for fiscal years 2021 and 2022 (including estimated collections for fiscal year 2022) falls below the cumulative amount of fees authorized for such fiscal years under paragraph (3).

"(B) REDUCTION OF SHORTFALL-BASED FEE INCREASE BY PRIOR YEAR EXCESS COLLECTIONS.—

"(i) IN GENERAL.—Subject to clause (ii), the Secretary shall, in such manner as the Secretary determines appropriate, reduce any fee increase otherwise applicable for a fiscal year under subparagraph (A) by the amount of any excess collections

under this section for preceding fiscal years (after fiscal year 2018).

''(ii) WORKLOAD-BASED FEE ACCOUNTING.—In applying clause (i), the Secretary shall account for the reduction of workload-based fee revenue increases by excess collections under subsection (c)(3)(B), in such manner as needed to provide that no portion of any excess collections described in clause (i) is applied for purposes of reducing fee increases under both such subsection (c)(3)(B) and this paragraph.

''(C) RULE OF APPLICATION.—Under no circumstances shall adjustments under this paragraph result in fee revenues for a fiscal year that are less than the fee revenues for that fiscal year established in subsection (b), as adjusted or otherwise affected under subsection (c).''.

SEC. 104. REAUTHORIZATION; REPORTING REQUIREMENTS.

Section 740A (21 U.S.C. 379j–13) is amended—

(1) in subsection (a), by striking ''2013'' and inserting ''2018'';

(2) by striking ''2014'' each place it appears in subsections (a) and (b) and inserting ''2019''; and

(3) in subsection (d), by striking ''2018'' each place it appears and inserting ''2023''.

SEC. 105. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–11 et seq.), as in effect on the day before the date of enactment of this title, shall continue to be in effect with respect to animal drug applications and supplemental animal drug applications (as defined in such part as of such day) that on or after October 1, 2013, but before October 1, 2018, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2019.

SEC. 106. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2018, or the date of the enactment of this Act, whichever is later, except that fees under part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as amended by this title, shall be assessed for animal drug applications and supplemental animal drug applications received on or after October 1, 2018, regardless of the date of the enactment of this Act.

SEC. 107. SUNSET DATES.

(a) AUTHORIZATION.—Section 740 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–12) shall cease to be effective October 1, 2023.

(b) REPORTING REQUIREMENTS.—Section 740A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–13) shall cease to be effective January 31, 2024.

(c) PREVIOUS SUNSET PROVISION.—Effective October 1, 2018, subsections (a) and (b) of section 107 of the Animal Drug User Fee Amendments of 2013 (Public Law 113–14) are repealed.

TITLE II—FEES RELATING TO GENERIC ANIMAL DRUGS

SEC. 201. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the ''Animal Generic Drug User Fee Amendments of 2018''.

(b) FINDING.—Congress finds that the fees authorized by the amendments made in this title will be dedicated toward expediting the generic new animal drug development process and the review of abbreviated applications for generic new animal drugs, supplemental abbreviated applications 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.

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

(a) FEE REVENUE AMOUNTS.—Subsection (b) of section 741 (21 U.S.C. 379j–21) is amended to read as follows:

''(b) FEE REVENUE AMOUNTS.—

''(1) IN GENERAL.—Subject to subsections (c), (d), (f), and (g), for each of fiscal years 2019 through 2023, the fees required under subsection (a) shall be established to generate a total revenue amount of $18,336,340.

''(2) TYPES OF FEES.—Of the total revenue amount established for a fiscal year under paragraph (1)—

''(A) 25 percent shall be derived from fees under subsection (a)(1) (relating to abbreviated applications for a generic new animal drug);

''(B) 37.5 percent shall be derived from fees under subsection (a)(2) (relating to generic new animal drug products); and

"(C) 37.5 percent shall be derived from fees under subsection (a)(3) (relating to generic new animal drug sponsors).".

(b) ANNUAL FEE SETTING; ADJUSTMENTS.—

(1) INFLATION ADJUSTMENT.—Section 741(c) (21 U.S.C. 379j–21(c)) is amended—

(A) by redesignating paragraphs (2) through (4) as paragraphs (3) through (5), respectively; and

(B) by inserting after paragraph (1) the following:

"(2) INFLATION ADJUSTMENT.—

"(A) IN GENERAL.—For fiscal year 2020 and subsequent fiscal years, the revenue amounts established under subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year, by multiplying such revenue amounts by an amount equal to the sum of—

"(i) one;

"(ii) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions

for the first 3 of the preceding 4 fiscal years for which data are available, multiplied by the average proportion of personnel compensation and benefits costs to total Food and Drug Administration costs for the first 3 of the preceding 4 fiscal years for which data are available; and

''(iii) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; not seasonally adjusted; all items less food and energy; annual index) for the first 3 of the preceding 4 years for which data are available multiplied by the average proportion of all costs other than personnel compensation and benefits costs to total Food and Drug Administration costs for the first 3 years of the preceding 4 fiscal years for which data are available.

''(B) COMPOUNDED BASIS.—The adjustment made each fiscal year after fiscal year 2020 under this paragraph shall be applied on a compounded basis to the revenue amount cal-

culated under this paragraph for the most recent previous fiscal year.''.

(2) WORKLOAD ADJUSTMENTS.—Paragraph (3) of section 741(c) (21 U.S.C. 379j–21(c)), as redesignated, is amended to read as follows:

''(3) WORKLOAD ADJUSTMENTS.—

''(A) IN GENERAL.—For fiscal year 2020 and subsequent fiscal years, after the fee revenue amounts established under subsection (b) are adjusted for inflation in accordance with paragraph (2), the fee revenue amounts shall be further adjusted for each such fiscal year to reflect changes in the workload of the Secretary for the process for the review of abbreviated applications for generic new animal drugs, subject to subparagraphs (B) and (C). With respect to such adjustment—

''(i) this adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of abbreviated applications for generic new animal drugs, manufacturing supplemental abbreviated applications for generic new animal drugs, investigational generic new animal drug study submissions, and

investigational generic new animal drug protocol submissions submitted to the Secretary; and

''(ii) the Secretary shall publish in the Federal Register the fees resulting from this adjustment and the supporting methodologies.

''(B) REDUCTION OF WORKLOAD-BASED INCREASE BY AMOUNT OF CERTAIN EXCESS COLLECTIONS.—For each of fiscal years 2021 through 2023, if application of the workload adjustment under subparagraph (A) increases the fee revenue amounts otherwise established for the fiscal year under subsection (b), as adjusted for inflation under paragraph (2), such fee revenue increase shall be reduced by the amount of any excess collections, as described in subsection (g)(4), for the second preceding fiscal year, up to the amount of such fee revenue increase.

''(C) RULE OF APPLICATION.—Under no circumstances shall workload adjustments under this paragraph result in fee revenues for a fiscal year that are less than the fee revenues for that fiscal year established under subsection

(b), as adjusted for inflation under paragraph (2).''.

(3) FINAL YEAR ADJUSTMENT.—Paragraph (4) of section 741(c) (21 U.S.C. 379j–21(c)), as redesignated, is amended by—

(A) striking ''2018'' each place it appears and inserting ''2023''; and

(B) striking ''2019'' and inserting ''2024''.

(c) FEE WAIVER OR REDUCTION; EXEMPTION FROM FEES.—Subsection (d) of section 741 (21 U.S.C. 379j–21) is amended to read as follows:

''(d) FEE WAIVER OR REDUCTION; EXEMPTION FROM FEES.—

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

''(2) EXEMPTION FROM FEES.—Fees under this section shall not apply with respect to any person who—

''(A) not later than September 30, 2023, submits a supplemental abbreviated application for a generic new animal drug approved under

section 512, solely to add the application number to the labeling of the drug in the manner specified in section 502(w)(3); and

''(B) otherwise would be subject to fees under this section solely on the basis of such supplemental abbreviated application.''.

(d) CREDITING AND AVAILABILITY OF FEES.—Section 741(g) (21 U.S.C. 379j–21) is amended by striking paragraph (3) and inserting the following paragraphs:

''(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2019 through 2023, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount established under subsection (b) for the fiscal year, as adjusted or otherwise affected under subsection (c).

''(4) EXCESS COLLECTIONS.—If the sum total of fees collected under this section for a fiscal year exceeds the amount of fees authorized to be appropriated for such year under paragraph (3), the excess collections shall be credited to the appropriations account of the Food and Drug Administration as provided in paragraph (1).''.

SEC. 203. REAUTHORIZATION; REPORTING REQUIREMENTS.

Section 742 (21 U.S.C. 379j–22) is amended—

(1) in subsection (a), by striking ''2013'' and inserting ''2018'';

(2) by striking ''2014'' each place it appears in subsections (a) and (b) and inserting ''2019''; and

(3) in subsection (d), by striking ''2018'' each place it appears and inserting ''2023''.

SEC. 204. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 5 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21 et seq.), as in effect on the day before the date of enactment of this title, shall continue to be in effect with respect to abbreviated applications for a generic new animal drug and supplemental abbreviated applications for a generic new animal drug (as defined in such part as of such day) that on or after October 1, 2013, but before October 1, 2018, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2019.

SEC. 205. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2018, or the date of the enactment of this Act, whichever is later, except that fees under part 5 of subchapter C of chapter VII of the Federal Food, Drug,

and Cosmetic Act, as amended by this title, shall be assessed for abbreviated applications for a generic new animal drug and supplemental abbreviated applications for a generic new animal drug received on or after October 1, 2018, regardless of the date of enactment of this Act.

SEC. 206. SUNSET DATES.

(a) AUTHORIZATION.—Section 741 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21) shall cease to be effective October 1, 2023.

(b) REPORTING REQUIREMENTS.—Section 742 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–22) shall cease to be effective January 31, 2024.

(c) PREVIOUS SUNSET PROVISION.—Effective October 1, 2018, subsections (a) and (b) of section 206 of the Animal Generic Drug User Fee Amendments of 2013 (Public Law 113–14) are repealed.

TITLE III—MISCELLANEOUS PROVISIONS

SEC. 301. ELECTRONIC SUBMISSIONS.

(a) NEW ANIMAL DRUG APPLICATIONS AND ABBREVIATED APPLICATIONS FOR A GENERIC NEW ANIMAL DRUG.—Section 512(b) (21 U.S.C. 360b(b)) is amended by adding at the end the following:

''(4) Beginning on October 1, 2018, all applications or submissions pursuant to this subsection shall be sub-

mitted by electronic means in such format as the Secretary may require.''.

(b) CONDITIONAL APPROVAL OF NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES.—Section 571(a) (21 U.S.C. 360ccc(a)) is amended by adding at the end the following:

''(4) Beginning on October 1, 2018, all applications or submissions pursuant to this subsection shall be submitted by electronic means in such format as the Secretary may require.''.

SEC. 302. INDEX OF LEGALLY MARKETED UNAPPROVED NEW ANIMAL DRUGS FOR MINOR SPECIES.

Effective on October 1, 2018, section 572(h) (21 U.S.C. 360ccc–1(h)) is amended—

(1) by amending paragraph (1) to read as follows:

''(1) 'LEGAL STATUS—In order to be legally marketed, a new animal drug intended for a minor species must be Approved, Conditionally Approved, or Indexed by the Food and Drug Administration. THIS PRODUCT IS INDEXED—MIF.' (followed by the applicable minor species index file number and a period) 'Extra-label use is prohibited.';''; and

(2) in paragraph (2), by striking ''other animals'' and inserting ''food-producing animals''.

SEC. 303. MISBRANDED DRUGS AND DEVICES.

(a) IN GENERAL.—Section 502(w) (21 U.S.C. 352(w)) is amended—

(1) in paragraph (1), by striking ''; or'' and inserting '';'';

(2) in paragraph (2), by striking the period and inserting ''; or''; and

(3) by adding at the end the following:

''(3) for which an application has been approved under section 512 and the labeling of such drug does not include the application number in the format: 'Approved by FDA under (A)NADA # xxx-xxx', except that this subparagraph shall not apply to representative labeling required under section 514.1(b)(3)(v)(b) of title 21, Code of Federal Regulations (or any successor regulation) for animal feed bearing or containing a new animal drug.''.

(b) APPLICABILITY.—Section 502(w)(3) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall apply beginning on September 30, 2023.

SEC. 304. ISSUANCE OF RECOMMENDATIONS.

Not later than September 30, 2019, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall issue recommendations that the Secretary, in the letters described in section 101(b) of the Animal Drug User Fee Amendments of 2013 (Public Law

113–14), agreed to develop regarding the feasibility of pursuing statutory revisions that may expand the use of conditional approval of new animal drugs under section 571 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ccc) to appropriate categories of new animal drugs.