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1ST SESSION

S. 1844

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

IN THE SENATE OF THE UNITED STATES

JUNE 7, 2023

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

JULY 26, 2023

Reported by Mr. SANDERS, with an amendment

[Insert the part printed in italic]

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Animal Drug and Animal Generic Drug User Fee Amendments of 2023''.

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is the following:

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 2023''.

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

(1) in paragraph (3), by striking ''national drug code'' and inserting ''National Drug Code''; and

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

''(I) The activities necessary for implementation of the United States and European Union Mutual Recognition Agreement for Pharmaceutical Good Manufacturing Practice Inspections, and the United States and United Kingdom Mutual Recognition Agreement Sectoral Annex for Pharmaceutical Good Manufacturing Practices, and other mutual recognition agreements, 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) IN GENERAL.—Section 740(a)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–12(a)(1)(A)(ii)) is amended—

(1) in subclause (I), by striking ''and'' at the end;

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

(3) by adding at the end the following:

''(III) an application for conditional approval under section 571 of a new animal drug for which an animal drug application submitted under section 512(b)(1) has been previously approved under section 512(d)(1) for another intended use.''.

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

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

shall be established to generate a total revenue amount of $33,500,000.''.

(c) ANNUAL FEE SETTING; ADJUSTMENTS.—

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

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

''(A) establish for that fiscal year animal drug application fees, supplemental animal drug application fees, animal drug sponsor fees, animal drug establishment fees, and animal drug product fees based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection; and

''(B) publish such fee revenue amounts and fees in the Federal Register.''.

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

(A) in subparagraph (A)—

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

(ii) in clause (iii), by striking ''Baltimore'' and inserting ''Arlington-Alexandria''; 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 inserting ''2025''; and

(II) by striking ''subparagraphs (B) and (C)'' and inserting ''subparagraph (B)'';

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

(iii) by striking clause (ii) and inserting the following:

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

termined by the Secretary is greater than 3 percent, except for the first fiscal year that the adjustment is greater than 3 percent; and

''(iii) the Secretary shall publish in the Federal Register notice under paragraph (1) the amount of such adjustment and the supporting methodologies.'';

(B) by striking subparagraph (B); and

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

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

''(4) OPERATING RESERVE ADJUSTMENT.—

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

''(i) increase the fee revenue amount for such fiscal year, if necessary to provide an operating reserve of not less than 12 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-

tionale for the amount of the adjustment and the supporting methodologies.''.

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

''(4) EXEMPTION FROM FEES.—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.''.

(e) CREDITING AND AVAILABILITY OF FEES.—

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

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

(A) in paragraph (3), by striking ''and paragraph (5)''; and

(B) by striking paragraph (5).

SEC. 104. REAUTHORIZATION; REPORTING REQUIREMENTS.

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

(1) in subsection (a), by striking ''2018'' and inserting ''2023'';

(2) by striking ''2019'' each place it appears in subsections (a) and (b) and inserting ''2024''; and

(3) in subsection (d)—

(A) in paragraph (1), by striking ''2023'' and inserting ''2028''; and

(B) in paragraph (5), by striking ''2023'' and inserting ''2028''.

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, 2018, but before October 1, 2023, 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 2024.

SEC. 106. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2023, 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 (21 U.S.C. 379j–11 et seq.), as amended by this title, shall be assessed for animal drug applications and supplemental animal drug applications received on or after October 1, 2023, regardless of the date of the enactment of this Act.

SEC. 107. SUNSET DATES.

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

(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, 2029.

(c) PREVIOUS SUNSET PROVISION.—Effective October 1, 2023, subsections (a) and (b) of section 107 of the Animal Drug User Fee Amendments of 2018 (Public Law 115–234) 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 2023''.

(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 (21 U.S.C. 379j–21 et seq.), 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) GENERIC INVESTIGATIONAL NEW ANIMAL DRUG FILE FEE.—Section 741(a) of the Federal Food, Drug,

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

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

"(A) IN GENERAL.—

"(i) NEW FILE REQUEST.—Each person that submits a request to establish a generic investigational new animal drug file on or after October 1, 2023, shall be assessed a fee as established under subsection (c).

"(ii) NEW SUBMISSION TO ESTABLISHED FILE.—Each person that makes a submission to a generic investigational new animal drug file on or after October 1, 2023, where such file was established prior to October 1, 2023, shall be assessed a fee for the first submission on or after October 1, 2023, as established under subsection (c).

"(B) PAYMENT.—

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

tablish the generic investigational new animal drug file.

''(ii) NEW SUBMISSION TO ESTABLISHED FILE.—The fee required by subparagraph (A)(ii) shall be due upon the first submission to the generic investigational new animal drug file.

''(C) EXCEPTIONS.—

''(i) TERMINATING AN EXISTING GENERIC INVESTIGATIONAL NEW ANIMAL DRUG FILE.—If a person makes a submission to the generic investigational new animal drug file to terminate that file, the person shall not be subject to a fee under subparagraph (A)(ii) for that submission.

''(ii) TRANSFERRING AN EXISTING GENERIC INVESTIGATIONAL NEW ANIMAL DRUG FILE.—If a person makes a submission to the generic investigational new animal drug file to transfer that file to a different generic new animal drug sponsor, the person shall not be subject to a fee under subparagraph (A)(ii) for that submission.''.

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

(1) in paragraph (1)—

(A) by striking ''2019 through 2023'' and inserting ''2024 through 2028''; and

(B) by striking ''$18,336,340'' and inserting ''$25,000,000''; and

(2) in paragraph (2)—

(A) in subparagraph (A)—

(i) by striking ''25 percent'' and inserting ''20 percent''; and

(ii) by inserting before the semicolon at the end the following: ''and fees under subsection (a)(4) (relating to generic investigational new animal drug files)'';

(B) in subparagraph (B), by striking ''37.5 percent'' and inserting ''40 percent''; and

(C) in subparagraph (C), by striking ''37.5 percent'' and inserting ''40 percent''.

(c) ANNUAL FEE SETTING; ADJUSTMENTS.—

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

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

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

''(B) generic new animal drug sponsor fees, and generic new animal drug product fees, based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection; and

''(C) a generic investigational new animal drug file fee of $50,000 for each request or submission described in subsection (a)(4)(A).''.

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

(A) in subparagraph (A)—

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

(ii) in clause (iii), by striking ''Baltimore'' and inserting ''Arlington-Alexandria''; and

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

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

(A) in subparagraph (A)—

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

(ii) in clause (i)—

(I) by striking ''and investigational generic new animal drug protocol submissions'' and inserting ''investigational generic new animal drug protocol submissions, requests to establish a generic investigational new animal drug file, and generic investigational new animal drug meeting requests''; and

(II) by striking ''; and'' and inserting a semicolon;

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

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

''(ii) if the workload adjustment calculated by the Secretary under clause (i) exceeds 25 percent, the Secretary shall use 25 percent for the adjustment; and''; and

(B) in subparagraph (B), by striking ''2021 through 2023'' and inserting ''2026 through 2028''.

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

(A) by striking ''2023'' each place it appears and inserting ''2028''; and

(B) by striking ''2024'' and inserting ''2029''.

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

''(d) FEE WAIVER OR REDUCTION.—The Secretary shall grant a waiver from, or a reduction of, one 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.''.

(e) EFFECT OF FAILURE TO PAY FEES.—Section 741(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21(e)) is amended by striking ''The Secretary may discontinue'' and inserting ''A request to establish a generic investigational new animal drug file that is submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for action by the Secretary until all fees owed by such person have been paid. The Secretary may discontinue''.

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

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

(1) in paragraph (3), by striking ''2019 through 2023'' and inserting ''2024 through 2028'';

(2) by striking the second paragraph (4) (relating to Offset), as added by section 202 of the Animal Generic Drug User Fee Amendments of 2013 (Public Law 113–14); and

(3) by adding at the end the following:

''(5) RECOVERY OF COLLECTION SHORTFALLS.—The amount of fees otherwise authorized to be collected under this section shall be increased—

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

''(B) for fiscal year 2027, by the amount, if any, by which the amount collected under this section and appropriated for fiscal year 2025 falls below the amount of fees authorized for fiscal year 2025 under paragraph (3); and

''(C) for fiscal year 2028, by the amount, if any, by which the amount collected under this section and appropriated for fiscal years 2026 and 2027 (including estimated collections for fiscal year 2027) falls below the amount of fees authorized for such fiscal years under paragraph (3).''.

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

(1) by redesignating paragraphs (8), (9), (10), and (11) as paragraphs (9), (10), (11), and (13), respectively;

(2) by inserting after paragraph (7) the following:

''(8) GENERIC INVESTIGATIONAL NEW ANIMAL DRUG MEETING REQUEST.—The term 'generic investigational new animal drug meeting request' means a request submitted by a generic new animal drug sponsor to meet with the Secretary to discuss an investigational submission for a generic new animal drug.'';

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

''(I) The activities necessary for exploration and implementation of the United States and European Union Mutual Recognition Agreement for Pharmaceutical Good Manufacturing Practice Inspections, and the United States and United Kingdom Mutual Recognition Agreement Sectoral Annex for Pharmaceutical Good Manufacturing Practices, and other mutual recognition agreements, with respect to generic new animal drug products subject to review, including implementation activi-

ties prior to and following product approval.''; and

(4) by inserting after paragraph (11) (as so redesignated) the following:

''(12) REQUEST TO ESTABLISH A GENERIC INVESTIGATIONAL NEW ANIMAL DRUG FILE.—The term 'request to establish a generic investigational new animal drug file' means the submission to the Secretary of a request to establish a generic investigational new animal drug file to contain investigational submissions for a generic new animal drug.''.

SEC. 203. REAUTHORIZATION; REPORTING REQUIREMENTS.

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

(1) in subsection (a), by striking ''2018'' and inserting ''2023'';

(2) by striking ''2019'' each place it appears in subsections (a) and (b) and inserting ''2024''; and

(3) in subsection (d), by striking ''2023'' each place it appears and inserting ''2028''.

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, 2018, but before October 1, 2023, 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 2024.

SEC. 205. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2023, 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 (21 U.S.C. 379j–21 et seq.), 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, 2023, 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, 2028.

(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, 2029.

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

TITLE III—SUPPORTING ANIMAL AND HUMAN HEALTH

SEC. 301. REPORTING REQUIREMENTS.

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

(1) in subsection (a)—

(A) by striking ''Beginning with'' and inserting the following:

''(1) IN GENERAL.—Beginning with''; and

(B) by adding at the end the following:

''(2) CONTENTS.—The report under paragraph (1) shall include the following:

''(A) Data, analysis and discussion of the changes in the number of individuals hired and funded by fees collected pursuant to section 740, and data, analysis, and discussion of the number of full-time equivalents in the animal

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

''(B) Data, analysis, and discussion of the changes in the fee revenue amounts and costs for the process for the review of animal drug applications, including identifying—

''(i) the drivers of such changes; and

''(ii) changes in the total cost per full-time equivalent in the animal drug review program.

''(C) Data, analysis, and discussion of changes in the average full-time equivalent hours required to complete review of each type of animal drug application.

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

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

(2) in subsection (d)—

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

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

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

''(6) UPDATES TO CONGRESS.—The Secretary, in consultation with regulated industry, shall provide regular updates on negotiations on the reauthorization of this part to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.''; and

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

(i) in subparagraph (A)—

(I) by striking ''Before presenting the recommendations developed under paragraphs (1) through (5) to Congress, the Secretary'' and inserting ''The Secretary''; and

(II) by inserting before the period at the end the following: ", not later than 30 days after each such negotiation meeting"; and

(ii) in subparagraph (B), by inserting ", in sufficient detail," after "shall summarize".

SEC. 302. DEFINITION OF MAJOR SPECIES.

Section 201(nn) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(nn)) is amended by inserting ", or remove species from," after "add species to".

SEC. 303. ANTIMICROBIAL RESISTANCE.

(a) REPORT ON ANTIMICROBIAL STEWARDSHIP.—Not later than December 31, 2023, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report describing—

(1) activities conducted by the Center for Veterinary Medicine of the Food and Drug Administration (referred to in this section as "the Center") during the period of fiscal years 2019 through 2023 to support antimicrobial stewardship in veterinary

settings, including ongoing activities and the targeted completion date of such activities; and

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

(A) the goals of the Center regarding supporting antimicrobial stewardship in veterinary settings;

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

(C) metrics the Center plans to use to evaluate progress toward its goals regarding supporting antimicrobial stewardship in veterinary settings.

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

(1) a description of activities conducted by the Center in the prior fiscal year to support antimicrobial stewardship in veterinary settings, includ-

ing progress made toward goals and activities specified in subsection (a)(2);

(2) in the case of an incomplete activity described in subsection (a)(2)(B) for which the target completion date has passed—

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

(B) if applicable, the updated expected completion date for such activity;

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

(4) a description of activities undertaken to incentivize the development of new drugs for the treatment, prevention, or control of bacterial diseases in animals.

SEC. 304. REGULATION OF ZOOTECHNICAL ANIMAL FOOD SUBSTANCES.

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

"(tt)(1) The term 'zootechnical animal food substance' means a substance that—

"(A) is added to the food or drinking water of animals;

"(B) is intended to—

"(i) affect the byproducts of the digestive process of an animal;

"(ii) reduce the presence of foodborne pathogens of human health significance in an animal intended to be used for food; or

"(iii) affect the structure or function of the body of the animal, other than by providing nutritive value, by altering the animal's gastrointestinal microbiome; and

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

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

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

"(B) is a hormone;

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

"(D) is an ionophore; or

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

"(3) A zootechnical animal food substance shall be deemed to be a food additive within the meaning of paragraph (s) and its introduction into interstate commerce shall be in accordance with a regulation issued under section 409. A zootechnical animal food substance shall not be considered a drug under paragraph (g)(1)(C) solely because the substance has an intended effect described in subparagraph (1).".

(b) FOOD ADDITIVES.—Section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348) is amended—

(1) in subsection (b)—

(A) by redesignating paragraphs (3) through (5) as paragraphs (4) through (6), respectively; and

(B) by inserting after paragraph (2) the following:

"(3) In the case of a zootechnical animal food substance, such petition shall, in addition to any explanatory or supporting data, contain—

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

tended to have and the quantity of such substance required to produce the intended effect; and

"(B) full reports of investigations made with respect to the intended use of such substance, including full information as to the methods and controls used in conducting such investigations.";

(2) in subsection (c)—

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

"(A)(i) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing—

"(I) with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive as the Secretary de-

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

"(II) in the case of a zootechnical animal food substance, the conditions under which such substance may be used to achieve the intended effect; and

"(ii) notify the petitioner of such order and the reasons for such action; or"; and

(B) in paragraph (3)—

(i) in subparagraph (A), by striking "; or" and inserting a semicolon;

(ii) in subparagraph (B), by striking the period and inserting "; or"; and

(iii) by adding at the end the following:

"(C) in the case of a zootechnical animal food substance, fails to establish that the proposed use of the substance, under the conditions of use to be specified in the regulation, will achieve the intended effect."; and

(3) by adding at the end the following:

"(l) ZOOTECHNICAL ANIMAL FOOD SUBSTANCES.—The labeling of a zootechnical animal food substance—

"(1) shall include the statement: 'Not for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in animals.'; and

"(2) may include statements regarding the intended effect of the substance on the structure or function of the body of animals, as set forth in section 201(tt)(1).".

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

"(z) If it is a zootechnical animal food substance and the labeling of the food does not include the statement required by section 409(l)(1).".

(d) RULE OF CONSTRUCTION.—Nothing in this section, or the amendments made by this section, shall be construed to authorize the Secretary of Health and Human Services to require the use of any zootechnical food substance or food additive (as those terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act, as 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