This bill would simply require agencies to create a short, plain language summary and a website link to make it easily accessible so that all Americans can easily find and understand the rules being proposed by the administration.

Giving Americans—and especially small businesses—a one-hundred-word, plain language summary for an otherwise convoluted government rulemaking provides much needed streamlining and transparency.

I hope my colleagues on both sides of the aisle will vote for this bill to help the small business owners who create jobs and economic growth nationwide focus on running their businesses, not sifting through long-winded government documents.

I thank Senator LANKFORD for getting this bill across the finish line in the Senate. I encourage my colleagues to vote in favor of the Providing Accountability Through Transparency Act.

Ms. JACKSON LEE. Mr. Speaker, I rise today in support of S. 111, the Providing Accountability Through Transparency Act.

S. 111 would require each agency, in providing notice of a rulemaking, to include a link to a 100-word plain language summary of the proposed rule, to be made available on the website regulations.gov.

Our job here is public service—not for our benefit, but the enrichment of our communities, state, and Nation.

The bills we pass here directly affect the lives of everyday Americans.

Therefore, the public must be able to access and provide their input regarding rules.

For those who may not be experts in the subject matter of the rule, S. 111 provides that a plain-language summary of 100 words or less be made available by agencies at regulations.gov.

Having this clear and simplistic summary will give members of the public the opportunity to provide specific and useful comments to those of us who serve them.

Plain language makes it easier for the public to read, understand, and use government communications.

As a result, Americans understand documents more quickly, call less often for explanations, and make fewer errors filling out forms.

All in all, Americans comply more accurately and quickly with requirements when written in plain language.

Ultimately, this helps improve government transparency and empower greater participation in the democratic process.

Through plain language, Americans are broadly better able to understand their options and the policies their government is pursuing.

Simply put, Americans are better able to participate in the debate once they understand their choices.

In addition, the Congressional Budget Office expects that preparing this short summary of proposed rules would not significantly increase agencies' administrative costs.

Further, this remains true when the costs of implementation are assessed over a five year period, with the Congressional Budget Office estimating no significant costs accruing through implementation of this policy from 2023 through 2028.

In fact, such a measure is likely to save federal government dollars in the long run.

Because Americans understand more immediately, file documents with greater accuracy, and have less need to seek explanations from bureaucrats, plain language saves government employees time and allows them to work more effectively and efficiently.

Multiple studies have shown that plain language improves bottom lines by saving time, personnel resources, and money, all while providing better service to Americans.

I urge my colleagues to support this common-sense measure that improves transparency, accessibility of information, and the ability of Americans to thoughtfully participate in the democratic process.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New Jersey (Mr. VAN DREW) that the House suspend the rules and pass the bill, S. 111.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes have it.

Mr. VAN DREW. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, further proceedings on this motion will be postponed.

ANIMAL DRUG AND ANIMAL GENERIC DRUG USER FEE AMENDMENTS OF 2023

Mr. BILIRAKIS. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 1418) to amend the Federal Food, Drug, and Cosmetic Act to reauthorize user fee programs relating to new animal drugs and generic new animal drugs, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 1418

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 determined 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 rationale 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 establish 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 activities 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 division 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, including 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.

The SPEAKER pro tempore (Mr. VAN DREW). Pursuant to the rule, the gentleman from Florida (Mr. BILIRAKIS) and the gentlewoman from Washington (Ms. SCHRIER) each will control 20 minutes.

The Chair recognizes the gentleman from Florida.

GENERAL LEAVE

Mr. BILIRAKIS. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and include extraneous material in the RECORD on the bill.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Florida?

There was no objection.

Mr. BILIRAKIS. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise today in support of H.R. 1418, the Animal Drug and Animal Generic Drug User Fee Amendments of 2023, sponsored by my good friend, Mr. PENCE, and, of course, Ms. SCHRIER on the Democrat side and their members on the Energy and Commerce Committee.

Our committee has worked hard on this legislation for many months, holding a legislative hearing in March and two markups this spring before advancing it out of full committee last month by a vote of 49–0.

At each step, our members worked in a bipartisan fashion to consider ways to make improvements to this legislation and keep any controversial policies from getting in the way of passing this bill before its September deadline. Great work.

Overall, the ADUFA amendments of 2023 will reauthorize the two user fee programs established to support the development and review of animal drugs and generics.

These drugs keep our animals healthy, from our household pets to our farm animals, and they ensure that our food supply is safe for humans too. That is how important this bill is.

The bill before us also includes provisions to support the review process in getting new drugs to the market faster and adds new reporting requirements to improve transparency and accountability within the FDA's Center for Veterinary Medicine.

It also takes steps to support utilizing the conditional approval pathway for animal drugs, which will bring more drugs to the market for small animal populations with unmet clinical needs.

There are even more program enhancements contained in these agreements, addressing foreign inspections, fiscal responsibility, and the need for more innovation.

If this legislation is not signed into law before September 30, Mr. Speaker, the review and approval of the medicines that farmers and pet owners rely on will dramatically slow down. We can't let that happen.

Drugmakers will also face regulatory uncertainty in getting their therapies to the market, impacting access to new cures and treatments. They are relying on Congress to do its job, and we will, which is why I strongly urge support of this legislation and encourage my colleagues to vote ''yes.''

I reserve the balance of my time, Mr. Speaker.

Ms. SCHRIER. Mr. Speaker, I yield myself such time as I may consume.

I first thank Chair ROGERS, Ranking Member PALLONE, Representative BILIRAKIS, and, of course, Representative PENCE, who sponsored this bill together with me, for their leadership and hard work on this bipartisan bill. I am a proud sponsor.

The Animal Drug User Fee Agreement is important for the safety of both animal and human health. This bill will accelerate the development of new medications for animals with a predictable and streamlined review process.

It will hold the FDA accountable for performance goals that will improve wait times for inspections and provide regulatory certainty for innovators and pet and animal owners alike.

It will ensure that our Nation's food supply is safe by making sure the medicines that are administered to food-producing animals are safe.

□ 1645

I want to underscore that this bill is a win for everyone, but it is especially good for farmers.

In my district, farmers, ranchers, and dairymen rely on these FDA-approved medications to keep their livestock healthy. For them, keeping animals healthy is not just about their affection and responsibility for these animals. It is critical for food production, food safety, and their very economic survival.

Having timely access to affordable, effective medications is a key part of our domestic food chain, and that is really the heart of our rural economies.

I am happy to go to bat for our rural areas and our agricultural communities with this legislation. I encourage my colleagues to vote ''yes'' on this important bill, Mr. Speaker, and I reserve the balance of my time.

Mr. BILIRAKIS. Mr. Speaker, I yield such time as he may consume to the gentleman from Indiana (Mr. PENCE), the sponsor of the bill along with Ms. SCHRIER.

Mr. PENCE. Mr. Speaker, I am proud to champion the fifth reauthorization of the Animal Drug User Fee Act with Congresswoman SCHRIER.

This important legislation is critical to ensuring safe and effective drugs for our Nation's livestock industry and farm animals for the next 5 years. It provides resources for the review of new and generic animal drugs, accelerates the development of animal therapeutics, and promotes a more predictable and streamlined review process.

It is important we hold the FDA accountable to performance goals that will enhance inspection times and provide regulatory certainty for both innovators and pet owners alike.

Farmers, ranchers, and rural communities across southern Indiana rely on veterinary medicines and therapeutics produced by animal drug manufacturers. Innovators in the Hoosier State, like Elanco Animal Health, are leading the charge to keep American farm animals safe and healthy. We need innovation in veterinary medicine to secure the best care for our Nation's veterinary patients.

This legislation would preserve the security of America's food supply by making certain the medications administered to food-producing animals are safe for animal and human health.

Mr. Speaker, I urge support for final passage of this legislation.

Ms. SCHRIER. Mr. Speaker, I yield myself the balance of my time to close.

I thank Mr. BILIRAKIS and Members on the other side of the aisle for working together on this bipartisan bill. I encourage my colleagues to vote ''yes'' on this bill to make sure we can speed novel medications to animals in this country.

Mr. Speaker, I yield back the balance of my time.

Mr. BILIRAKIS. Mr. Speaker, this is a great bill. It is a necessary bill for our farmers but also our animal owners. I used to be the chair of the Humane Bond Caucus, and we absolutely love our animals. Mr. PENCE and Ms. SCHRIER are doing an excellent job on this particular bill, and I urge unanimous passage.

Mr. Speaker, I yield back the balance of my time.

Ms. JACKSON LEE. Mr. Speaker, I rise in support of H.R. 1418, the ''Animal Drug and Animal Generic Drug User Fee Amendments of 2023'', or ADUFA and AGDUFA, which will enable the U.S. to lead the world in innovation and drug development for animal pharmaceuticals.

The Animal Drug and Animal Generic Drug User Fee Amendment or AGDUFA was designed to enhance the performance of the generic new animal drug review process and enable the FDA to more efficiently ensure that generic new animal drug products are safe and effective.

AGDUFA was originally signed into law in 2008 and reauthorized in 2013 and 2018.

This bill reauthorizes the FDA to collect user fees for certain abbreviated applications for generic new animal drugs, generic new animal drug products and from certain sponsors of abbreviated applications for generic new animal drugs and investigational submissions for generic new animal drugs.

Specifically, this bill ensures that the Center for Veterinary Medicine can continue to meet the needs of the animal drug industry as it evolves.

This bipartisan bill will lead to increased transparency, additional pathways for animal drug approvals, and reduced review times for pioneer and generic drug applications while maintaining high standards for safety and efficacy.

Veterinarians have far fewer FDA-approved animal drugs compared to the number of FDA-approved human drugs.

My district in Houston is home to hundreds of veterinarians working hard to improve the health of animals.

In fact, Houston ranks fourth among metro areas for dog ownership and was named the ''Dog Capital of the World'' in a 2022 study conducted by Protect Our Paws.

Protect Our Paws found that Houston had the highest dog-toperson ratio in the world with 52.1 dogs per 100 humans.

More broadly, with Texas being No. 4 in pet ownership and over 58 percent of households owning at least one pet, we have thousands ot pets and animals to protect.

I have a vested interest in moving these reauthorizations forward because they are critical to animal and human health and well-being.

FDA continues to make progress to mitigate the growth of antimicrobial resistance in food-producing animals, including ending over-the-counter access to medically important antibiotics which are used in both humans and animals, but more needs to be done.

I remain fully committed to moving the Animal Drug and Animal Generic Drug User Fee Amendments of 2023 through a swift reauthorization before the programs expire on September 30th.

I urge all my colleagues to join me in voting in favor of H.R. 1418, the Animal Drug and Animal Generic Drug User Fee Amendments of 2023.''

Ms. JACKSON LEE. Mr. Speaker, I rise today in support of H.R. 813, the Global Investment in American Jobs Act of 2023.

This bill will direct the Secretary of Commerce to conduct an interagency review of and report to Congress on ways to increase the global competitiveness of the United States in attracting foreign direct investment.

The report will look at the economic impact of foreign direct investments in the United States, focusing on manufacturing, services, trade, and jobs in the United States.

This will allow Congress to better understand trends and challenges in global cross-border investments, as well as collaborate with other trusted partner countries.

Specifically, this bill will attract foreign direct investment from responsible private-sector entities, which is directly linked to the long-term economic prosperity, global competitiveness, and security of the United States.

It will promote polices to ensure that United States remains the global leader in developing and deploying cutting-edge technologies, such as self-driving vehicle technology and artificial intelligence.

As digital information becomes increasingly important to the United States economy and the development of new technologies and services that will be crucial to the country's competitiveness in the 21st century global economy, barriers including data localization and infringement of intellectual property rights must be further addressed.

This study will focus on the economic impact of foreign direct investment, challenges associated with foreign direct investment by state-owned enterprises, and the influence of protectionist policies enacted by other countries on the advanced technology economy.

Further, this bill will allow us to reduce our supply-chain dependence on China.

For the success of our larger economy, national security, and global relationships, it is vital that we pass H.R. 813.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Florida (Mr. BILIRAKIS) that the House suspend the rules and pass the bill, H.R. 1418, as amended.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill, as amended, was passed.

A motion to reconsider was laid on the table.

GLOBAL INVESTMENT IN AMERICAN JOBS ACT OF 2023

Mr. BILIRAKIS. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 813) to direct the Secretary of Commerce, in coordination with the heads of other relevant Federal departments and agencies, to conduct an interagency review of and report to Congress on ways to increase the global competitiveness of the United States in attracting foreign direct investment, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 813

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 ''Global Investment in American Jobs Act of 2023''.

SEC. 2. SENSE OF CONGRESS.

It is the sense of Congress that—

(1) the ability of the United States to attract foreign direct investment from responsible private-sector entities based in trusted countries is directly linked to the long-term economic prosperity, global competitiveness, and security of the United States;

(2) it is a top national priority to enhance the global competitiveness, economic prosperity, and security of the United States by—

(A) removing unnecessary barriers to foreign direct investment from responsible private-sector entities based in trusted countries and the jobs that such investment creates throughout the United States;

(B) promoting policies to ensure the United States remains the premier global destination to invest, hire, innovate, provide services, and manufacture products;

(C) promoting policies to ensure the United States remains the global leader in developing and deploying cutting-edge technologies, such as self-driving vehicle technology, artificial intelligence, Internet of Things, quantum computing, blockchain; and

(D) promoting policies that maintain and expand resilient supply chains and reduce the dependence of the United States on supply chains from China and other foreign adversaries;

(3) maintaining the United States commitment to an open investment policy with private-sector entities based in trusted countries encourages other countries to reciprocate and enable the United States to open new markets abroad for United States companies and their products;

(4) while foreign direct investment by responsible private-sector entities based in trusted countries can enhance the United States economic strength, policies regarding foreign direct investment should reflect security interests and should not disadvantage domestic investors, companies, or the workforce;

(5) United States efforts to attract foreign direct investment from responsible private-sector entities based in trusted countries should be consistent with efforts to maintain and improve the domestic standard-of-living, including for the workforce;

(6) as digital information becomes increasingly important to the United States economy and the development of new technologies and services that will be crucial to the country's competitiveness in the 21st century global economy, barriers including data localization and infringement of intellectual property rights must be further addressed;

(7) foreign direct investment by companies or other entities owned, directed, supported, or influenced by the Chinese Communist Party is a threat to United States security and merits an aggressive policy framework to protect United States interests, jobs, intellectual property, and security;