this legislation, we finally have an opportunity to open up these channels that will help everyone.

I voted for this legislation through the subcommittee and through full committee and am proud to offer my full support to pass this legislation.

Mr. GENE GREEN of Texas. Mr. Speaker, I yield 3 minutes to the gentlewoman from Colorado (Ms. DEGETTE), my colleague and a member of our committee.

Ms. DEGETTE. Mr. Speaker, today we have an opportunity to make long-overdue reforms to the way that the FDA reviews over-the-counter medicines. These medicines play a critical role in treating Americans' ailments and in helping us stay healthy. In fact, almost 7 in 10 parents report giving their kids OTC medicine to help treat sudden medical symptoms. Similarly, 81 percent of adults use these drugs as a first response to treat a minor ailment.

Think about it. Despite the widespread use of over-the-counter medicines, the FDA is currently forced to use a cumbersome and laborious monograph pathway to approve them. This antiquated, 40-year-old OTC review system has not kept pace with new medical advances and the rapid expansion of this market, which now comprises over 300,000 drugs. As a result, the current monograph review system fails to respond to the OTC safety issues in a timely and effective way, which can pose serious healthcare risks for children and families.

Between 2004 and 2005, for example, the Centers for Disease Control and Prevention reported 1,500 cases of children under the age of 2 visiting emergency rooms due to serious side effects or overdoses associated with over-the-counter cough and cold products.

Since the CDC made this startling finding, the FDA has been trying to revise the cough and cold monograph system to warn parents about the risks that these common drugs can pose to children, but the FDA can't do it because they have been hamstrung due to the burdensome process it must undergo to revise these monographs.

The Over-the-Counter Monograph Safety, Innovation, and Reform Act would streamline the FDA's review of over-the-counter drugs and provide it with new tools to protect children and warn parents about potentially dangerous OTC drugs.

I want to add my thanks to the bipartisan team that passed this bill, Representatives LATTA, BURGESS, GREEN, GUTHRIE, and DINGELL for all working together with me on this important legislation, and, in addition, Ranking Member PALLONE, Chairman WALDEN, the FDA, and the many stakeholders that have worked closely with us throughout the process.

Mr. Speaker, the bill is a rare triple win for regulators, consumers, and industry. I urge my colleagues' support.

Mr. GENE GREEN of Texas. Mr. Speaker, I have no other speakers, and I yield back the balance of my time.

Mr. LATTA. Mr. Speaker, once again, I just want to thank all the members for all their hard work on this. Especially, I want to thank the gentleman from Oregon, the chairman of the full committee, for his work on this piece of legislation. Also, I want to thank the staff.

Mr. Speaker, I urge passage of the bill.

The SPEAKER pro tempore (Mr. SMITH of Nebraska). The question is on the motion offered by the gentleman from Ohio (Mr. LATTA) that the House suspend the rules and pass the bill, H.R. 5333, 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.

ANIMAL DRUG AND ANIMAL GENERIC DRUG USER FEE AMENDMENTS OF 2018

Mr. MULLIN. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 5554) 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. 5554

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 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 three 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 three 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 three 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 three 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 calculated 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 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.

''(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) in subsection (b), by striking ''Committee on Health, Education, Labor, and Pensions'' and inserting ''the Committee on Health, Education, Labor and Pensions'';

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

(4) 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 submitted 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 subparagraph (1), by striking ''; or'' and inserting '';'';

(2) in subparagraph (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. CONDITIONAL APPROVAL OF NEW ANIMAL DRUGS.

(a) IN GENERAL.—Section 571 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ccc) is amended—

(1) in the section heading, by striking ''**SPECIES**'' and inserting ''**SPECIES AND CERTAIN NEW ANIMAL DRUGS**'';

(2) in subsection (a)—

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

''(1)(A) Except as provided in paragraph (3), any person may file with the Secretary an application for conditional approval of—

''(i) a new animal drug intended for a minor use or a minor species; or

''(ii) a new animal drug not intended for a minor use or minor species—

''(I) that is intended to treat a serious or life-threatening disease or condition or addresses an unmet animal or human health need; and

''(II) for which the Secretary determines that a demonstration of effectiveness would require a complex or particularly difficult study or studies.

''(B) The Secretary shall, not later than September 30, 2019, issue guidance or regulations further clarifying the criteria specified in subparagraph (A)(ii).

''(C) An application under this paragraph shall comply in all respects with the provisions of section 512 except for subsections (a)(4), (b)(2), (c)(1), (c)(2), (c)(3), (d)(1), (e), (h), and (n) of such section unless otherwise stated in this section, and any additional provisions of this section.

''(D) New animal drugs for which conditional approval is sought under this section are subject to the same safety standards that would be applied to new animal drugs under section 512(d) (including, for antimicrobial new animal drugs, with respect to antimicrobial resistance).''; and

(B) in paragraph (3)—

(i) in subparagraph (B), by striking '', or'' and inserting ''; or'';

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

(iii) by striking ''A person may not file'' and inserting ''(A) A person may not file''; and

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

''(B) A person may not file an application under paragraph (1)(A)(ii) if the application seeks conditional approval of a new animal drug that contains an antimicrobial active ingredient.'';

(3) in subsection (f)—

(A) in paragraph (1), in the matter preceding subparagraph (A), by inserting ''for the conditionally approved use'' after ''shall''; and

(B) in paragraph (2)—

(i) by striking ''An intended use'' and inserting ''The Secretary shall, through regulation or guidance, determine under what conditions an intended use''; and

(ii) by striking ''shall not'' and inserting ''may''; and

(4) by adding at the end the following new subsection:

''(k) SUNSET.—

''(1) The Secretary's authority to grant conditional approval of new animal drugs not intended for a minor use or minor species pursuant to subsection (a)(1)(A)(ii) terminates on October 1, 2028.

''(2) The Secretary—

''(A) may not accept any new applications for such conditional approval pursuant to subsection (a)(1)(A)(ii) on or after such date; and

''(B) may continue all activities under this section with respect to drugs that were conditionally approved pursuant to (a)(1)(A)(ii) prior to such date.

''(3) The Secretary may, until October 1, 2032, accept applications for approval under 512 of drugs conditionally approved pursuant to (a)(1)(A)(ii).''.

(b) EXCEPTION FROM FEES IN CASE OF CERTAIN PREVIOUSLY SUBMITTED APPLICATIONS FOR CONDITIONAL APPROVAL.—Section 740(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–12(a)(1)(C)) is amended—

(1) in the caption by striking ''EXCEPTION'' and inserting ''EXCEPTIONS'';

(2) by striking ''If an animal drug'' and inserting the following:

''(i) If an animal drug''; and

(3) by inserting after clause (i), as so designated, the following new clause:

''(ii) Beginning with fiscal year 2019, in the case of an animal drug application submitted by a person under section 512(b)(1), where such person (or their licensor, assignor, or predecessor-in-interest) previously submitted an application for conditional approval under section 571 for the same product and paid the applicable fee under subparagraph (A), the application under section 512(b)(1) shall not be subject to a fee under subparagraph (A) if submitted within the timeframe specified in section 571(h).''.

(c) REPORT ON INCORPORATING VETERINARY OVERSIGHT.—Not later than September 30, 2019, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate identifying how the Food and Drug Administration will incorporate veterinary oversight for all approved medically important antimicrobial drugs administered to animals that are not yet subject to veterinary oversight. Such report shall address requirements related to revisions of labeling to reflect that medically important antimicrobial drugs administered to animals shall be subject to veterinary oversight.

(d) GAO STUDY OF CONDITIONAL APPROVAL PROGRAMS.—

(1) STUDY.—The Comptroller General of the United States (referred to in this section as the ''Comptroller General'') shall conduct a study on the effectiveness and overall impact of the conditional approval pathway under section 571 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ccc).

(2) ISSUANCE OF REPORT.—Not later than January 1, 2026, the Comptroller General shall submit to the Committee on Health, Education, Labor and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report containing the results of the study under paragraph (1).

(3) CONTENTS OF REPORTS.—The report submitted under paragraph (2) shall address—

(A) for each drug for which a conditional approval has been awarded since October 1, 2018—

(i) whether the drug was granted conditional approval pursuant to clause (i) or (ii) of section 571(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (a);

(ii) whether the drug was dual labeled during its conditional approval;

(iii) the indications for which the drug was granted conditional approval under section 571 of such Act (21 U.S.C. 360ccc) and whether the drug was approved or not approved under section 512 of such Act (21 U.S.C. 360b);

(iv) the number of years the drug was so conditionally approved and a description of the complexity of the investigation to demonstrate the drug's effectiveness;

(v) whether, and to what extent, the conditional approval pathway under such section 571 (21 U.S.C. 360ccc) impacted the sponsor's decision to develop the drug or seek approval of the drug under section 512 of such Act (21 U.S.C. 360b);

(vi) whether, and to what extent, conditional approval pursuant to clause (ii) of section 571(a)(1)(A) of such Act (21 U.S.C. 360b(a)(1)(A)) addressed a serious or life-threatening condition; and

(vii) whether, and to what extent, conditional approval pursuant to clause (ii) of section 571(a)(1)(A) of such Act (21 U.S.C. 360b(a)(1)(A)) addressed an unmet animal or human health need, and whether before such conditional approval there were available therapies for the disease or condition involved;

(B) an analysis of the conditional approval program under section 571 of such Act (21 U.S.C. 360ccc), including—

(i) the resources used by the Food and Drug Administration in reviewing applications for conditional approval of drugs pursuant to such program and renewal of such conditional approval, including the effects of the program on the Food and Drug Administration's review of animal drugs for which conditional approval is not used;

(ii) whether any improvements to the program under section 512 of such Act (21 U.S.C. 360b) are necessary to incentivize the development of animal drugs that would likely not otherwise be developed, or developed in as timely a manner, to address—

(I) serious or life-threatening conditions; and

(II) an unmet animal or human health need; and

(iii) whether the conditional approval pathway has resulted in a greater number of animal drugs approved under section 512 of such Act (21 U.S.C. 360b) for serious or life-threatening conditions or unmet animal or human health needs than would have otherwise come to market under the practices and commitments of the Center for Veterinary Medicine of the Food and Drug Administration as such practices and commitments existed as of the day before the date of enactment of this Act; and

(C) how the Center for Veterinary Medicine of the Food and Drug Administration has utilized complex adaptive or other novel investigation designs, data from foreign countries, real-world evidence (including ongoing surveillance activities, observational studies, and registry data), biomarkers, or surrogate endpoints—

(i) to support the approval of products under section 512 of such Act (21 U.S.C. 360b), including how many such products have been approved since October 1, 2018; and

(ii) to support the approval of products under section 512 of such Act (21 U.S.C. 360b)

that received conditional approval under section 571 of such Act (21 U.S.C. 360ccc), including how many such products have been approved since October 1, 2018.

SEC. 305. GUIDANCE ADDRESSING INVESTIGATION DESIGNS.

(a) IN GENERAL.—For purposes of assisting sponsors in incorporating complex adaptive and other novel investigation designs, data from foreign countries, real world evidence (including ongoing surveillance activities, observational studies, and registry data), biomarkers, and surrogate endpoints (referred to in this section as ''elements of investigations'') into proposed clinical investigation protocols and applications for new animal drugs under sections 512 and 571 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b; 360ccc), the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall issue guidance addressing the use of such elements of investigations in the development and regulatory review of such new animal drugs.

(b) CONTENTS.—The guidance under subsection (a) shall address how the Secretary will evaluate the elements of investigations proposed or submitted pursuant to section 512(b)(1)(A) of the Federal Food, Drug, and Cosmetic Act or to meet the commitment under section 571(a)(2)(F) of such Act, and how sponsors of such applications may obtain feedback from the Secretary on technical issues related to such investigations prior to the submission of an application to the Secretary.

(c) MEETING.—Prior to issuing the guidance under subsection (a), the Secretary shall consult with stakeholders, including representatives of regulated industry, consumer groups, academia, veterinarians, and food producers, through a public meeting to be held not later than 1 year after the date of enactment of this Act.

(d) TIMING.—The Secretary shall issue a draft guidance under subsection (a) not later than 1 year after the date of the public meeting under subsection (c), and shall finalize such guidance not later than 1 year after the date on which the public comment period on such draft guidance ends.

SEC. 306. FOOD ADDITIVES INTENDED FOR USE IN ANIMAL FOOD.

(a) FOOD ADDITIVE PETITIONS FOR ANIMAL FOOD.—Section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348) is amended by adding at the end the following:

''(k) FOOD ADDITIVES INTENDED FOR USE IN ANIMAL FOOD.—(1) In taking action on a petition under subsection (c) for, or for recognition of, a food additive intended for use in animal food, the Secretary shall review reports of investigations conducted in foreign countries, provided by the petitioner.

''(2) Not later than 12 months after the date of enactment of the Animal Drug and Animal Generic Drug User Fee Amendments of 2018, the Secretary shall post on the internet website of the Food and Drug Administration—

''(A) the number of petitions for food additives intended for use in animal food filed under subsection (b) that are pending;

''(B) how long each such petition submitted under subsection (b) has been pending, including such petitions the Secretary has extended under subsection (c)(2); and

''(C) the number of study protocols that have been pending review for over 50 days, and the number that have received an extension.

''(3) In the case of a food additive petition intended for use in animal food, the Secretary shall provide information to the petitioner on the required contents of such petition. If the Secretary requires additional studies beyond what the petitioner proposed, the Secretary shall provide the scientific rationale for such requirement.''.

(b) ENSURING THE SAFETY OF PET FOOD.—Section 1002(a) of the Food and Drug Administration Amendments Act of 2007 (21 U.S.C. 2102(a)) is amended—

(1) by striking paragraph (1); and

(2) by redesignating paragraphs (2) and (3) as paragraphs (1) and (2), respectively.

(c) GUIDANCE ON PRE-PETITION CONSULTATION PROCESS FOR ANIMAL FOOD ADDITIVES.—(1) IN GENERAL.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall publish draft guidance relating to the voluntary pre-petition consultation process for food additives intended for use in animal food.

(2) CONTENTS.—The guidance under paragraph (1) shall include—

(A) the recommended format to submit to the Food and Drug Administration existing data, including any applicable foreign data, for assessment prior to submission of a food additive petition for animal food under section 409(b) of the Federal Food, Drug, and Cosmetic Act;

(B) the manner and the number of days by which the Food and Drug Administration intends to review and respond to such existing data, including with respect to providing a scientific rationale for any additional data request;

(C) circumstances under which the submission of study protocols is recommended prior to submission of a food additive petition under such section 409(b);

(D) the manner in which the Secretary intends to inform the person submitting a study protocol for a food additive if the review of such study protocol will take longer than 50 days; and

(E) best practices for communication between the Food and Drug Administration and industry on the development of pre-petition submissions of study protocols and existing data for food additives.

(3) FINAL GUIDANCE.—The guidance under paragraph (1) shall be finalized, withdrawn, or reissued not later than 1 year after the close of the comment period on the draft guidance.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Oklahoma (Mr. MULLIN) and the gentleman from Texas (Mr. GENE GREEN) each will control 20 minutes.

The Chair recognizes the gentleman from Oklahoma.

GENERAL LEAVE

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

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

There was no objection.

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

Mr. Speaker, I am proud of this legislation to reauthorize the Animal Drug User Fee Act, ADUFA, which will continue agreements between the FDA and the animal drug industry to pay user fees that will help speed the approval of new drugs.

Farmers, ranchers, families, and veterinarians need ADUFA so they can keep their animals and pets safe and healthy.

In the rural and agricultural communities across the country, including my home State of Oklahoma, ADUFA is critical to farmers, ranchers, and all American consumers. These animals are a major food source for our communities and our families, so it is vitally important that we move quickly today and reauthorize ADUFA.

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

Mr. GENE GREEN of Texas. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise in support of H.R. 5554, the Animal Drug and Animal Generic Drug User Fee Amendments of 2018.

This bill reauthorizes the Food and Drug Administration's animal drug and animal generic drug user fee programs and ensures that the FDA continues to have the tools it needs to approve animal drugs to help our pets and livestock live healthier lives.

Mr. Speaker, I include in the RECORD the remainder of my statement.

Mr. Speaker, I rise in support of H.R. 5554, the Animal Drug and Animal Generic Drug User Fee Amendments of 2018.

This bill reauthorizes the Food and Drug Administration's Animal Drug and Animal Generic Drug User Fee Programs and ensures the FDA continues to have the tools it needs to approve animal drugs to help our pets and livestock live healthier lives.

This legislation reauthorizes the FDA's authority to collect user fees from the animal drug and generic animal drug industries for additional five years and reflects bipartisan agreement and recommendations negotiated between the FDA and the animal drug industry with input from farmers and ranchers, veterinarians, food and feed producers, and other public health stakeholders.

These critical user fee agreements have helped to accelerate the development of animal drugs, reduce application review times at the FDA, and create a more predictable and streamlined process for getting animal drugs to market.

It is critical that we pass H.R. 5554 today as the current authorization for these programs will expire on September 30th of this year. If ADUFA and AGDUFA are not reauthorized by the deadline, the FDA will lack the resources and subject matter experts it needs to do this important work.

This will be the fourth reauthorization of ADUFA and the third reauthorization of AGDUFA. These user fee programs have proven to be highly successful and allow the Center for Veterinary Medicine at FDA to meet and exceed its performance goals.

The FDA's gold standard for safety and efficacy extends beyond products just for humans, but also for animal drugs. Safe and effective animal medications, as approved by FDA, protect our companion animals and keep our food supply safe. Reauthorizing ADUFA and AGDUFA ensures this continues.

As a result of our bipartisan compromise, this bill also creates a conditional approval pathway for certain new animal drugs that are intended to treat a serious or life-threatening disease or condition or address an unmet health need for which ongoing efficacy studies are complex or particularly difficult. I am

pleased we have reached consensus on this policy and that the provision includes a 10-year sunset.

The Energy and Commerce Committee has worked in a strong bipartisan fashion to move this bill forward. I commend my colleagues, Rep. KURT SCHRADER and Rep. MARKWAYNE MULLIN, for introducing this important legislation and advancing it for floor consideration.

I urge my colleagues to join me and vote in support of the Animal Drug and Animal Generic Drug User Fee Amendments of 2018.

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

Mr. MULLIN. Mr. Speaker, I yield 2 minutes to the gentleman from Texas (Mr. BURGESS), the chairman.

Mr. BURGESS. Mr. Speaker, I thank the gentleman for yielding.

Mr. Speaker, I rise to speak in support of this critical bill to reauthorize the Animal Drug User Fee Act and the Animal Generic Drug User Fee Act for an additional 5 years. Among other things, these user fees provide critical resources to the Food and Drug Administration's Center for Veterinary Medicine to ensure efficient and timely review of animal drug applications, quality assurance measures for animal feed, and surveillance of the safety and efficacy of animal drugs on the market.

In addition to reauthorizing these user fee programs, this legislation also includes new authority to facilitate greater innovation in the animal drug space.

Mr. Speaker, these user fee programs must be reauthorized by September 30 to avoid a major disruption of the operations of the Center for Veterinary Medicine. The clock is ticking. The agency must start sending pink slips to employees 60 calendar days before the end of the fiscal year. That is the end of this month.

We are talking about real consequences for animal health and for the American people. House passage of this bill today is an important step, and I urge the Senate to do its work and promptly take up and pass this bill so that President Trump can sign it into law. I thank the gentleman for the recognition.

Mr. GENE GREEN of Texas. Mr. Speaker, I yield 1½ minutes to the gentleman from Oregon (Mr. SCHRADER), our colleague from the Energy and Commerce Committee.

Mr. SCHRADER. Mr. Speaker, H.R. 5554 is a bipartisan bill to reauthorize the animal drug and animal generic drug user fee programs, and I am proud to lead it with my colleague, Mr. MULLIN.

ADUFA and AGDUFA are crucial to FDA's work to review and approve applications for animal drugs. Over the past several years, animal drug user fee programs have streamlined the approval process for pharmaceuticals and eliminated the FDA's application backlog, reduced review times, and created a more predictable process.

As a veterinarian from Oregon, I am particularly grateful to see this bill come to the floor. I am acutely aware of the great innovations that are occurring in the human health sphere, and I want to ensure our four-footed friends also have access to the latest and greatest medical innovations. That is why I am particularly pleased with this bill and its language to expand conditional approval for animal drugs with major uses in major species.

□ 1830

Conditional approval is a careful, deliberative process based on similar pathways for drugs for minor uses and minor species that was already established in 2004.

Conditional approval is critical for veterinary medicine since it is not cost-effective for drug companies to pursue large, complete clinical trials, given the small population of intended beneficiaries, without some initial interest and success under the conditional approval program.

Before being conditionally approved, drugs must demonstrate a reasonable expectation of effectiveness and meet every other FDA standard for approval, including safety. They still need to get complete FDA approval within 5 years and must apply for annual renewal.

I thank Chairman WALDEN; Ranking Member PALLONE; Mr. GREEN; my colleague from North Carolina (Mr. HUDSON), who worked very hard on the bill; and certainly Mr. MULLIN for his partnership in leading this way.

Mr. Speaker, I urge my colleagues to support this important bill.

Mr. GENE GREEN of Texas. Mr. Speaker, I have no further speakers, and I yield back the balance of my time.

Mr. MULLIN. Mr. Speaker, I thank my colleagues on both sides of the aisle for their bipartisan approach, and I urge a ''yes'' vote from all my colleagues.

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

Mr. BUTTERFIELD. Mr. Speaker, I rise in support of H.R. 5554, the Animal Drug and Animal Generic Drug User Fee Act of 2018. These user fee agreements are important to millions of North Carolinians living with companion animals. They are also important to the agricultural community. Some of you may not be aware that North Carolina is the second largest pork producer, the second largest turkey producer, and the third largest poultry producer in the country. Our agricultural community and family farms are essential to feeding our nation and they depend on medicines to keep animals healthy.

I am pleased that the final legislation includes language that I have worked on with my colleagues including Representatives HUDSON and SCHRADER to enable conditional approval of innovative veterinary drugs that have been demonstrated to be safe to use and have a reasonable expectation of effectiveness. The FDA already has this authority for unmet medical needs in minor uses and minor species, and this expanded authority can help improve protections for animal and human health.

This legislation must be passed before Congress adjourns for August or the FDA will be required to halt the programs. I urge my colleagues to support this important legislation.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Oklahoma (Mr. MULLIN) that the House suspend the rules and pass the bill, H.R. 5554, 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.

REPORT ON H.R. 6385, DEPARTMENT OF STATE, FOREIGN OPERATIONS, AND RELATED PROGRAMS APPROPRIATIONS BILL, 2019

Mr. ROGERS of Kentucky, from the Committee on Appropriations, submitted a privileged report (Rept. No. 115–829) on the bill (H.R. 6385) making appropriations for the Department of State, foreign operations, and related programs for the fiscal year ending September 30, 2019, and for other purposes, which was referred to the Union Calendar and ordered to be printed.

The SPEAKER pro tempore. Pursuant to clause 1, rule XXI, all points of order are reserved on the bill.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, proceedings will resume on motions to suspend the rules previously postponed.

Votes will be taken in the following order:

H.R. 4946, by the yeas and nays;

H.R. 4960, by the yeas and nays.

The first electronic vote will be conducted as a 15-minute vote. The second electronic vote will be conducted as a 5-minute vote.

SPECIALIST TREVOR A. WIN'E POST OFFICE

The SPEAKER pro tempore. The unfinished business is the vote on the motion to suspend the rules and pass the bill (H.R. 4946) to designate the facility of the United States Postal Service located at 1075 North Tustin Street in Orange, California, as the ''Specialist Trevor A. Win'E Post Office'', on which the yeas and nays were ordered.

The Clerk read the title of the bill.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from North Carolina (Mr. WALKER) that the House suspend the rules and pass the bill.

The vote was taken by electronic device, and there were—yeas 368, nays 0, not voting 60, as follows:

[Roll No. 329]

YEAS—368

Abraham	Allen	Arrington
Adams	Amash	Babin
Aguilar	Amodei	Bacon