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HOUSE OF REPRESENTATIVES
REPORT
118–104

ANIMAL DRUG AND ANIMAL GENERIC DRUG USER FEE AMENDMENTS OF 2023

JUNE 9, 2023.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mrs. RODGERS of Washington, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 1418]

The Committee on Energy and Commerce, to whom was referred 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, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

CONTENTS

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Animal Drug and Animal Generic Drug User Fee Amendments of 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 submis-

sion 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.

PURPOSE AND SUMMARY

H.R. 1418 reauthorizes provisions of the Animal Drug User Fee Act (ADUFA) and the Animal Generic Animal Drug User Fee Act (AGDUFA) through fiscal year (FY) 2028. Specifically, the bill would allow the Food and Drug Administration (FDA) to continue to collect and obligate user fees, paid by regulated industry to supplement Congressional appropriations, for the review of animal drugs and animal generic drugs. It also includes provisions that improve upon the review and development of animal health products and support activities regarding the development and stewardship of animal antimicrobials.

BACKGROUND AND NEED FOR LEGISLATION

The Federal Food, Drug, and Cosmetic Act (FFDCA) provides FDA authorities over the review and regulation of brand-name (pioneer) and generic animal drugs. These authorities are funded through annual discretionary appropriations and further supplemented by user fees paid by regulated industry. The revenue generated by user fees supports FDA in providing greater regulatory certainty to animal application sponsors and in improving upon the animal product development and review process. In determining recommended fee amounts, FDA commits to meet certain performance and application review goals, which are negotiated with the regulated industry and submitted to Congress.

Authorities to collect user fees for pioneer animal drugs were first provided for by Congress in the Animal Drug User Fee Act of 2003 (referred to as ADUFA I, P.L. 108–130) for FY2004 to FY2008. The user fee program established under ADUFA I was modeled after FDA's prescription drug user fee program, which had improved the timeliness and predictability of FDA's review of certain human drugs. Congress later granted FDA authorities over the review of generic animal drugs for FY2009 in the Animal Generic Drug User Fee Act of 2008 (AGDUFA I, P.L. 110–316), which was passed alongside the first reauthorization of ADUFA II. Authorities for AGDUFA have been reauthorized three times since and will sunset September 30, 2023.

Previous reauthorizations of ADUFA and AGDUFA have included additional provisions intended to improve upon FDA's review and regulation of certain animal health products. This legislation proposes several policies to build upon the programs, including new reporting requirements to enhance transparency into the review and reauthorization processes, amendment of the 'major species' definition to support utilization of approval pathways for unmet animal health needs, and codification of reporting dates for FDA on activities relating to stewardship over animal antimicrobials.

ADUFA IV and AGDUFA III will expire at the end of FY2023 and must be reauthorized for FDA to continue collecting and obligating user fee towards the review of animal drug and generic animal drug applications. This legislation will reauthorize both programs through FY2028 and support the implementation of additional provisions considered within this legislation.

COMMITTEE ACTION

On March 30, 2023, the Subcommittee on Health held a hearing on H.R. 1418. The Subcommittee received testimony from:

- Ms. Tracey Forfa, J.D., Director, Center for Veterinary Medicine (CVM), U.S. Food and Drug Administration (FDA);
- Ms. Rachel Cumberbatch, DVM, Director, Regulatory Affairs, Animal Drugs, Animal Health Institute (AHI);
- Ms. Stephanie Batliner, Chair, Generic Animal Drug Alliance (GADA); and
- Ms. Lori Teller, DVM, President, American Veterinary Medical Association (AVMA)

On May 17, 2023, the Subcommittee on Health met in open markup session and forwarded H.R. 1418, as amended, to the full Committee by a record vote of 29 yeas and 0 nays. On May 24, 2023, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 1418, as amended, favorably reported to the House by a record vote of 49 yeas and 0 nays.

COMMITTEE VOTES

Clause 3(b) of rule XIII requires the Committee to list the record votes on the motion to report legislation and amendments thereto. The following reflects the record votes taken during the Committee consideration:

COMMITTEE ON ENERGY AND COMMERCE
118TH CONGRESS
ROLL CALL VOTE # 1

BILL: H.R. 1418, the Animal Drug User Fee Amendments of 2023

AMENDMENT: A motion by Mrs. Rodgers to order H.R. 1418 favorably reported to the House, as amended (Final Passage).

DISPOSITION: AGREED TO, by a roll call vote of 49 yeas and 0 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Rep. Rodgers	X			Rep. Pallone	X		
Rep. Burgess	X			Rep. Eshoo	X		
Rep. Latta	X			Rep. DeGette	X		
Rep. Guthrie	X			Rep. Schakowsky	X		
Rep. Griffith	X			Rep. Matsui	X		
Rep. Bilirakis	X			Rep. Castor	X		
Rep. Johnson	X			Rep. Sarbanes			
Rep. Bucshon	X			Rep. Tonko	X		
Rep. Hudson	X			Rep. Clarke	X		
Rep. Walberg	X			Rep. Cárdenas	X		
Rep. Carter	X			Rep. Ruiz	X		
Rep. Duncan	X			Rep. Peters	X		
Rep. Palmer	X			Rep. Dingell	X		
Rep. Dunn	X			Rep. Veasey			
Rep. Curtis	X			Rep. Kuster	X		
Rep. Lesko	X			Rep. Kelly	X		
Rep. Pence	X			Rep. Barragán	X		
Rep. Crenshaw	X			Rep. Blunt Rochester	X		
Rep. Joyce	X			Rep. Soto	X		
Rep. Armstrong	X			Rep. Craig	X		
Rep. Weber	X			Rep. Schrier	X		
Rep. Allen	X			Rep. Trahan	X		
Rep. Balderson	X			Rep. Fletcher	X		
Rep. Fulcher	X						
Rep. Pfluger	X						
Rep. Harshbarger	X						
Rep. Miller-Meeks	X						
Rep. Cammack	X						
Rep. Obernolte							

05/24/2023

OVERSIGHT FINDINGS AND RECOMMENDATIONS

Pursuant to clause 2(b)(1) of rule X and clause 3(c)(1) of rule XIII, the Committee held a hearing and made findings that are reflected in this report.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to clause 3(c)(2) of rule XIII, the Committee finds that H.R 1418 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII, at the time this report was filed, the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974 was not available.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to reauthorize the FDA animal drug user fee programs and improve the review of products regulated by FDA.

DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 1418 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111–139 or the most recent Catalog of Federal Domestic Assistance.

RELATED COMMITTEE AND SUBCOMMITTEE HEARINGS

Pursuant to clause 3(c)(6) of rule XIII,

(1) the following hearing was used to develop or consider H.R. 1418:

- On March 30, 2023, the Subcommittee on Health held a hearing on H.R. 1418. The Subcommittee received testimony from:
  - Ms. Tracey Forfa, J.D., Director, Center for Veterinary Medicine (CVM), U.S. Food and Drug Administration (FDA);
  - Ms. Rachel Cumberbatch, DVM, Director, Regulatory Affairs, Animal Drugs, Animal Health Institute (AHI);
  - Ms. Stephanie Batliner, Chair, Generic Animal Drug Alliance (GADA); and
  - Ms. Lori Teller, DVM, President, American Veterinary Medical Association (AVMA).

COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974. At the time this report was filed, the estimate was not available.

EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 1418 contains no earmarks, limited tax benefits, or limited tariff benefits.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

TITLE I: FEES RELATING TO ANIMAL DRUGS

Section 1. Short title

Section 1 provides a short title for the legislation, the "Animal Drug and Animal Generic User Fee Amendments of 2023."

Section 2. Table of contents

Section 2 provides a table of contents for the legislation.

TITLE I: FEES RELATING TO ANIMAL DRUGS

Section 101. Short title; finding

Section 101 establishes a short title for Title I, the "Animal Dug User Fee Amendments of 2023." It also dedicates fees authorized by this title toward expediting the animal drug development process and review of animal drug applications as set forth by statute.

Section 102. Definitions

Section 102 adds to the definition of "process for the review of abbreviated applications for new animal drugs" activities necessary to implement US–EU and US–UK mutual recognition agreements, with respect to new animal drug products subject to review.

Section 103. Authority to assess and use animal drug fees

Section 103 reauthorizes FDA's animal drug user fee program through 2028 and updates the base revenue amount for ADUFA V. It also provides for the negotiated resource levels and updated fee-setting process.

Section 104. Reauthorization; reporting requirements

Section 104 reauthorizes FDA reporting requirements to Congress relating to the agency's progress in implementing its user fee authorities and in meeting performance goals, as set forth in the commitment letter submitted to the Congressional Record.

Section 105. Savings clause

Section 105 preserves authorities to assess fees pursuant to part 4 of subchapter C of chapter VII of FFDCA, effective until enactment of this title.

Section 106. Effective date

Section 106 provides that amendments made by this title shall take effect October 1, 2023, or the date of enactment, whichever is later.

Section 107. Sunset dates

Section 107 provides that reporting requirements and authorities to collect and assess user fees for the process of the review of new animal drugs shall cease to be effective October 1, 2028.

TITLE II: FEES RELATING TO GENERIC ANIMAL DRUGS

Section 201. Short title; finding

Section 201 establishes a short title for Title II, "Animal Generic Drug User Fee Amendments of 2023." It also dedicates fees authorized by this title toward expediting the generic new animal drug development process and review of abbreviated applications for generic new animal drug applications as set forth by statute.

Section 202. Authority to assess and use generic new animal drug fees

Section 202 reauthorizes FDA's generic animal drug user fee program through 2028 and updates the base revenue amount for AGDUFA IV. It establishes a new fee type for generic investigational new animal drug files and provides for negotiated resource levels. It also adds to the definition of "process for the review of abbreviated applications for generic new animal drugs" activities necessary to implement US–EU and US–UK mutual recognition agreements with respect to generic new animal drug products subject to review.

Section 203. Reauthorization; reporting requirements

Section 203 reauthorizes FDA reporting requirements to Congress relating to the agency's progress in implementing its user fee authorities and in meeting performance goals, as set forth in the commitment letter submitted to the Congressional Record.

Section 204. Savings clause

Section 204 preserves authorities to assess fees pursuant to part 5 of subchapter C of chapter VII of FFDCA, effective until enactment of this title.

Section 205. Effective date

Section 205 provides that amendments made by this title shall take effect October 1, 2023, or the date of enactment, whichever is later.

Section 206. Sunset dates

Section 206 provides that reporting requirements and authorities to assess user fees for the process of the review of generic new animal drugs shall cease to be effective October 1, 2028.

TITLE III: SUPPORTING ANIMAL AND HUMAN HEALTH

Section 301. Reporting requirements

Section 301 updates requirements for FDA reporting to Congress to include data regarding the review process for animal drug applications and sponsor requests for in-person, face-to-face meetings in FY2024 and FY2025.

Section 302. Major species

Section 302 amends the definition of "major species" in the Federal Food, Drug, and Cosmetic Act to allow for the Secretary, through rulemaking, to add or remove species from the definition.

Section 303. Antimicrobial resistance

Section 303 requires FDA, not later than December 31, 2023, to submit to Congress a report describing activities conducted by FDA's Center for Veterinary Medicine (CVM) during FY2019 through FY2023 to support antimicrobial stewardship in veterinary settings. FDA must also report its goals to support antimicrobial stewardship in veterinary settings, activities it plans to execute in FY2024 through FY2028 to support those goals, and metrics it plans to use to evaluate progress toward those goals. Section 303 also requires FDA to submit, not later than 120 days after the end of each fiscal year in which animal drug user fees are collected, annual progress reports regarding antimicrobial stewardship and activities undertaken to incentivize the development of new animal antimicrobials.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, and existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

* * * * * * *

CHAPTER II—DEFINITIONS

SEC. 201. For the purposes of this Act—

(a)(1) The term "State", except as used in the last sentence of section 702(a), means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(2) The term "Territory" means any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone.

(b) The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term "Department" means the Department of Health and Human Services.

(d) The term "Secretary" means the Secretary of Health and Human Services.

(e) The term "person" includes individual, partnership, corporation, and association.

(f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement.

(2) The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

(h)(1) The term "device" (except when used in paragraph (n) of this section and in sections 301(i), 403(f), 502(c), and 602(c)) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(C) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o).

(2) The term "counterfeit device" means a device which, or the container, packaging, or labeling of which, without authorization, bears a trademark, trade name, or other identifying mark or imprint, or any likeness thereof, or is manufactured using a design, of a device manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such device and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other device manufacturer, processor, packer, or distributor.

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

(j) The term "official compendium" means the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, official National Formulary, or any supplement to any of them.

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(l) The term "immediate container" does not include package liners.

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(n) If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

(o) The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting

powder, or such other use as involves prolonged contact with the body.

(p) The term "new drug" means—

(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(q)(1)(A) Except as provided in clause (B), the term "pesticide chemical" means any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act, including all active and inert ingredients of such pesticide. Notwithstanding any other provision of law, the term "pesticide" within such meaning includes ethylene oxide and propylene oxide when such substances are applied on food.

(B) In the case of the use, with respect to food, of a substance described in clause (A) to prevent, destroy, repel, or mitigate microorganisms (including bacteria, viruses, fungi, protozoa, algae, and slime), the following applies for purposes of clause (A):

(i) The definition in such clause for the term "pesticide chemical" does not include the substance if the substance is applied for such use on food, or the substance is included for such use in water that comes into contact with the food, in the preparing, packing, or holding of the food for commercial purposes. The substance is not excluded under this subclause from such definition if the substance is ethylene oxide or propylene oxide, and is applied for such use on food. The substance is not so excluded if the substance is applied for such use on a raw agricultural commodity, or the substance is included for such use in water that comes into contact with the commodity, as follows:

(I) The substance is applied in the field.

(II) The substance is applied at a treatment facility where raw agricultural commodities are the only food treated, and the treatment is in a manner that does not change the status of the food as a raw agricultural commodity (including treatment through washing, waxing, fumigating, and packing such commodities in such manner).

(III) The substance is applied during the transportation of such commodity between the field and such a treatment facility.

(ii) The definition in such clause for the term "pesticide chemical" does not include the substance if the substance is a food contact substance as defined in section 409(h)(6), and any of the following circumstances exist: The substance is included for such use in an object that has a food contact surface but is not intended to have an ongoing effect on any portion of the object; the substance is included for such use in an object that has a food contact surface and is intended to have an ongoing effect on a portion of the object but not on the food contact surface; or the substance is included for such use in or is applied for such use on food packaging (without regard to whether the substance is intended to have an ongoing effect on any portion of the packaging). The food contact substance is not excluded under this subclause from such definition if any of the following circumstances exist: The substance is applied for such use on a semipermanent or permanent food contact surface (other than being applied on food packaging); or the substance is included for such use in an object that has a semipermanent or permanent food contact surface (other than being included in food packaging) and the substance is intended to have an ongoing effect on the food contact surface.

With respect to the definition of the term "pesticide" that is applicable to the Federal Insecticide, Fungicide, and Rodenticide Act, this clause does not exclude any substance from such definition.

(2) The term "pesticide chemical residue" means a residue in or on raw agricultural commodity or processed food of—

(A) a pesticide chemical; or

(B) any other added substance that is present on or in the commodity or food primarily as a result of the metabolism or other degradation of a pesticide chemical.

(3) Notwithstanding subparagraphs (1) and (2), the Administrator may by regulation except a substance from the definition of "pesticide chemical" or "pesticide chemical residue" if—

(A) its occurrence as a residue on or in a raw agricultural commodity or processed food is attributable primarily to natural causes or to human activities not involving the use of any substances for a pesticidal purpose in the production, storage, processing, or transportation of any raw agricultural commodity or processed food; and

(B) the Administrator, after consultation with the Secretary, determines that the substance more appropriately should be regulated under one or more provisions of this Act other than sections 402(a)(2)(B) and 408.

(r) The term "raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

(s) The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified

by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

(1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or

(2) a pesticide chemical; or

(3) a color additive; or

(4) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act, the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 and the following);

(5) a new animal drug; or

(6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.

(t)(1) The term "color additive" means a material which—

(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

(2) The term "color" includes black, white, and intermediate grays.

(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest.

(u) The term "safe," as used in paragraph (s) of this section and in sections 409, 512, 571, and 721, has reference to the health of man or animal.

(v) The term "new animal drug" means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed—

(1) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a "new animal drug" if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling con-

tained the same representations concerning the conditions of its use; or

(2) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

Provided that any drug intended for minor use or use in a minor species that is not the subject of a final regulation published by the Secretary through notice and comment rulemaking finding that the criteria of paragraphs (1) and (2) have not been met (or that the exception to the criterion in paragraph (1) has been met) is a new animal drug.

(w) The term "animal feed", as used in paragraph (w) of this section, in section 512, and in provisions of this Act referring to such paragraph or section, means an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal.

(x) The term "informal hearing" means a hearing which is not subject to section 554, 556, or 557 of title 5 of the United States Code and which provides for the following:

(1) The presiding officer in the hearing shall be designated by the Secretary from officers and employees of the Department who have not participated in any action of the Secretary which is the subject of the hearing and who are not directly responsible to an officer or employee of the Department who has participated in any such action.

(2) Each party to the hearing shall have the right at all times to be advised and accompanied by an attorney.

(3) Before the hearing, each party to the hearing shall be given reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the action taken or proposed by the Secretary which is the subject of the hearing and a general summary of the information which will be presented by the Secretary at the hearing in support of such action.

(4) At the hearing the parties to the hearing shall have the right to hear a full and complete statement of the action of the Secretary which is the subject of the hearing together with the information and reasons supporting such action, to conduct reasonable questioning, and to present any oral or written information relevant to such action.

(5) The presiding officer in such hearing shall prepare a written report of the hearing to which shall be attached all written material presented at the hearing. The participants in the hearing shall be given the opportunity to review and correct or supplement the presiding officer's report of the hearing.

(6) The Secretary may require the hearing to be transcribed. A party to the hearing shall have the right to have the hearing transcribed at his expense. Any transcription of a hearing shall be included in the presiding officer's report of the hearing.

(y) The term "saccharin" includes calcium saccharin, sodium saccharin, and ammonium saccharin.

(z) The term "infant formula" means a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

(aa) The term "abbreviated drug application" means an application submitted under section 505(j) for the approval of a drug that relies on the approved application of another drug with the same active ingredient to establish safety and efficacy, and—

(1) in the case of section 306, includes a supplement to such an application for a different or additional use of the drug but does not include a supplement to such an application for other than a different or additional use of the drug, and

(2) in the case of sections 307 and 308, includes any supplement to such an application.

(bb) The term "knowingly" or "knew" means that a person, with respect to information—

(1) has actual knowledge of the information, or

(2) acts in deliberate ignorance or reckless disregard of the truth or falsity of the information.

(cc) For purposes of section 306, the term "high managerial agent"—

(1) means—

(A) an officer or director of a corporation or an association,

(B) a partner of a partnership, or

(C) any employee or other agent of a corporation, association, or partnership,

having duties such that the conduct of such officer, director, partner, employee, or agent may fairly be assumed to represent the policy of the corporation, association, or partnership, and

(2) includes persons having management responsibility for—

(A) submissions to the Food and Drug Administration regarding the development or approval of any drug product,

(B) production, quality assurance, or quality control of any drug product, or

(C) research and development of any drug product.

(dd) For purposes of sections 306 and 307, the term "drug product" means a drug subject to regulation under section 505, 512, or 802 of this Act or under section 351 of the Public Health Service Act.

(ee) The term "Commissioner" means the Commissioner of Food and Drugs.

(ff) The term "dietary supplement"—

(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

(A) a vitamin;

(B) a mineral;

(C) an herb or other botanical;

(D) an amino acid;

(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

(2) means a product that—

(A)(i) is intended for ingestion in a form described in section 411(c)(1)(B)(i); or

(ii) complies with section 411(c)(1)(B)(ii);

(B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and

(C) is labeled as a dietary supplement; and

(3) does—

(A) include an article that is approved as a new drug under section 505 or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262) and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 402(f); and

(B) not include—

(i) an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262), or

(ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public,

which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this Act.

Except for purposes of sections 201(g) and 417, a dietary supplement shall be deemed to be a food within the meaning of this Act.

(gg) The term "processed food" means any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.

(hh) The term "Administrator" means the Administrator of the United States Environmental Protection Agency.

(ii) The term "compounded positron emission tomography drug"—

(1) means a drug that—

(A) exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for the purpose of providing dual photon positron emission tomographic diagnostic images; and

(B) has been compounded by or on the order of a practitioner who is licensed by a State to compound or order compounding for a drug described in subparagraph (A), and is compounded in accordance with that State's law, for a patient or for research, teaching, or quality control; and

(2) includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of such a drug.

(jj) The term "antibiotic drug" means any drug (except drugs for use in animals other than humans) composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other drug intended for human use containing any quantity of any chemical substance which is produced by a micro-organism and which has the capacity to inhibit or destroy micro-organisms in dilute solution (including a chemically synthesized equivalent of any such substance) or any derivative thereof.

(kk) PRIORITY SUPPLEMENT.—The term "priority supplement" means a drug application referred to in section 101(4) of the Food and Drug Administration Modernization Act of 1997 (111 Stat. 2298).

(ll)(1) The term "single-use device" means a device that is intended for one use, or on a single patient during a single procedure.

(2)(A) The term "reprocessed", with respect to a single-use device, means an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. The subsequent processing and manufacture of a reprocessed single-use device shall result in a device that is reprocessed within the meaning of this definition.

(B) A single-use device that meets the definition under clause (A) shall be considered a reprocessed device without regard to any description of the device used by the manufacturer of the device or other persons, including a description that uses the term "recycled" rather than the term "reprocessed".

(3) The term "original device" means a new, unused single-use device.

(mm)(1) The term "critical reprocessed single-use device" means a reprocessed single-use device that is intended to contact normally sterile tissue or body spaces during use.

(2) The term "semi-critical reprocessed single-use device" means a reprocessed single-use device that is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.

(nn) The term "major species" means cattle, horses, swine, chickens, turkeys, dogs, and cats, except that the Secretary may add species to*, or remove species from,* this definition by regulation.

(oo) The term "minor species" means animals other than humans that are not major species.

(pp) The term "minor use" means the intended use of a drug in a major species for an indication that occurs infrequently and in only a small number of animals or in limited geographical areas and in only a small number of animals annually.

(qq) The term "major food allergen" means any of the following:

(1) Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, soybeans, and sesame.

(2) A food ingredient that contains protein derived from a food specified in paragraph (1), except the following:

(A) Any highly refined oil derived from a food specified in paragraph (1) and any ingredient derived from such highly refined oil.

(B) A food ingredient that is exempt under paragraph (6) or (7) of section 403(w).

(rr)(1) The term "tobacco product" means any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

(2) The term "tobacco product" does not mean an article that is a drug under subsection (g)(1), a device under subsection (h), or a combination product described in section 503(g).

(3) The products described in paragraph (2) shall be subject to chapter V of this Act.

(4) A tobacco product shall not be marketed in combination with any other article or product regulated under this Act (including a drug, biologic, food, cosmetic, medical device, or a dietary supplement).

(5) The term "tobacco product" does not mean an article that is a food under paragraph (f), if such article contains no nicotine, or no more than trace amounts of naturally occurring nicotine.

(ss) The term "critical food" means a food that is—

(1) an infant formula; or

(2) a medical food, as defined in section 5(b)(3) of the Orphan Drug Act.

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CHAPTER VII—GENERAL AUTHORITY

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SUBCHAPTER C—FEES

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PART 4—FEES RELATING TO ANIMAL DRUGS

SEC. 739. DEFINITIONS.

For purposes of this part:

(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.

(2) The term "supplemental animal drug application" means—

(A) a request to the Secretary to approve a change in an animal drug application which has been approved; or

(B) a request to the Secretary to approve a change to an application approved under section 512(c)(2) for which data with respect to safety or effectiveness are required.

(3) The term "animal drug product" means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the [national drug code] *National Drug Code*, and for which an animal drug application or a supplemental animal drug application has been approved.

(4) The term "animal drug establishment" means a foreign or domestic place of business which is at one general physical location consisting of one or more buildings all of which are within 5 miles of each other, at which one or more animal drug products are manufactured in final dosage form.

(5) The term "investigational animal drug submission" means—

(A) the filing of a claim for an investigational exemption under section 512(j) for a new animal drug intended to be the subject of an animal drug application or a supplemental animal drug application; or

(B) the submission of information for the purpose of enabling the Secretary to evaluate the safety or effectiveness of an animal drug application or supplemental animal drug application in the event of their filing.

(6) The term "animal drug sponsor" means either an applicant named in an animal drug application that has not been withdrawn by the applicant and for which approval has not been withdrawn by the Secretary, or a person who has submitted an investigational animal drug submission that has not been terminated or otherwise rendered inactive by the Secretary.

(7) The term "final dosage form" means, with respect to an animal drug product, a finished dosage form which is approved for administration to an animal without substantial further manufacturing. Such term includes animal drug products intended for mixing in animal feeds.

(8) The term "process for the review of animal drug applications" means the following activities of the Secretary with respect to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions:

(A) The activities necessary for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(B) The issuance of action letters which approve animal drug applications or supplemental animal drug applications or which set forth in detail the specific deficiencies in animal drug applications, supplemental animal drug applications, or investigational animal drug submissions and, where appropriate, the actions necessary to place such applications, supplements or submissions in condition for approval.

(C) The inspection of animal drug establishments and other facilities undertaken as part of the Secretary's re-

view of pending animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(D) Monitoring of research conducted in connection with the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(E) The development of regulations and policy related to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(F) Development of standards for products subject to review.

(G) Meetings between the agency and the animal drug sponsor.

(H) Review of advertising and labeling prior to approval of an animal drug application or supplemental animal drug application, but not after such application has been approved.

[(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.]

(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.

(9) The term "costs of resources allocated for the process for the review of animal drug applications" means the expenses in connection with the process for the review of animal drug applications for—

(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees consulted with respect to the review of specific animal drug applications, supplemental animal drug applications, or investigational animal drug submissions, and costs related to such officers, employees, committees, and contractors, including costs for travel, education, and recruitment and other personnel activities;

(B) management of information and the acquisition, maintenance, and repair of computer resources;

(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

(D) collecting fees under section 740 and accounting for resources allocated for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(10) The term "adjustment factor" applicable to a fiscal year refers to the formula set forth in section 735(8) with the base or comparator month being October 2002.

(11) The term "person" includes an affiliate thereof.

(12) The term "affiliate" refers to the definition set forth in section 735(11).

SEC. 740. AUTHORITY TO ASSESS AND USE ANIMAL DRUG FEES.

(a) TYPES OF FEES.—Beginning in fiscal year 2004, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) ANIMAL DRUG APPLICATION AND SUPPLEMENT FEE.—

(A) IN GENERAL.—Each person that submits, on or after September 1, 2003, an animal drug application or a supplemental animal drug application shall be subject to a fee as follows:

(i) A fee established in subsection (c) for an animal drug application, except an animal drug application subject to the criteria set forth in section 512(d)(4).

(ii) A fee established in subsection (c), in an amount that is equal to 50 percent of the amount of the fee under clause (i), for—

(I) a supplemental animal drug application for which safety or effectiveness data are required; [and]

(II) an animal drug application subject to the criteria set forth in section 512(d)(4)[.]*; and*

(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) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the animal drug application or supplemental animal drug application.

(C) EXCEPTIONS FOR PREVIOUSLY FILED APPLICATION OR SUPPLEMENT.—

(i) If an animal drug application or a supplemental animal drug application was submitted by a person that paid the fee for such application or supplement, was accepted for filing, and was not approved or was withdrawn (without a waiver or refund), the submission of an animal drug application or a supplemental animal drug application for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

(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).

(D) REFUND OF FEE IF APPLICATION REFUSED FOR FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any animal drug application or supplemental animal drug application which is refused for filing.

(E) REFUND OF FEE IF APPLICATION WITHDRAWN.—If an animal drug application or a supplemental animal drug application is withdrawn after the application or supplement was filed, the Secretary may refund the fee or portion of the fee paid under subparagraph (B) if no substantial work was performed on the application or supplement after the application or supplement was filed. The Secretary shall have the sole discretion to refund the fee under this paragraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.

(2) ANIMAL DRUG PRODUCT FEE.—

(A) IN GENERAL.—Each person—

(i) who is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product which has been submitted for listing under section 510; and

(ii) who, after September 1, 2003, had pending before the Secretary an animal drug application or supplemental animal drug application,

shall pay for each such animal drug product the annual fee established in subsection (c).

(B) PAYMENT; FEE DUE DATE.—Such fee shall be payable for the fiscal year in which the animal drug product is first submitted for listing under section 510, or is submitted for relisting under section 510 if the animal drug product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be due each subsequent fiscal year that the product remains listed, upon the later of—

(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section; or

(ii) January 31 of each year.

(C) LIMITATION.—Such fee shall be paid only once for each animal drug product for a fiscal year in which the fee is payable.

(3) ANIMAL DRUG ESTABLISHMENT FEE.—

(A) IN GENERAL.—Each person—

(i) who owns or operates, directly or through an affiliate, an animal drug establishment;

(ii) who is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product which has been submitted for listing under section 510; and

(iii) who, after September 1, 2003, had pending before the Secretary an animal drug application or supplemental animal drug application,

shall be assessed an annual establishment fee as established in subsection (c) for each animal drug establishment listed in its approved animal drug application as an establishment that manufactures the animal drug product named in the application.

(B) PAYMENT; FEE DUE DATE.—The annual establishment fee shall be assessed in each fiscal year in which the animal drug product named in the application is assessed a fee under paragraph (2) unless the animal drug establishment listed in the application does not engage in the manufacture of the animal drug product during the fiscal year. The fee under this paragraph for a fiscal year shall be due upon the later of—

(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section; or

(ii) January 31 of each year.

(C) LIMITATION.—An establishment shall be assessed only one fee per fiscal year under this section.

(4) ANIMAL DRUG SPONSOR FEE.—

(A) IN GENERAL.—Each person—

(i) who meets the definition of an animal drug sponsor within a fiscal year; and

(ii) who, after September 1, 2003, had pending before the Secretary an animal drug application, a supplemental animal drug application, or an investigational animal drug submission,

shall be assessed an annual sponsor fee as established under subsection (c).

(B) PAYMENT; FEE DUE DATE.—The fee under this paragraph for a fiscal year shall be due upon the later of—

(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section; or

(ii) January 31 of each year.

(C) LIMITATION.—Each animal drug sponsor shall pay only one such fee each fiscal year.

(b) FEE REVENUE AMOUNTS.—

[(1) IN GENERAL.—Subject to subsections (c), (d), (f), and (g)—

[(A) for fiscal year 2019, the fees required under subsection (a) shall be established to generate a total revenue amount of $30,331,240; and

[(B) for each of fiscal years 2020 through 2023, the fees required under subsection (a) shall be established to generate a total revenue amount of $29,931,240.]

(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.

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

(A) 20 percent shall be derived from fees under subsection (a)(1) (relating to animal drug applications and supplements);

(B) 27 percent shall be derived from fees under subsection (a)(2) (relating to animal drug products);

(C) 26 percent shall be derived from fees under subsection (a)(3) (relating to animal drug establishments); and

(D) 27 percent shall be derived from fees under subsection (a)(4) (relating to animal drug sponsors).

(c) ANNUAL FEE SETTING; ADJUSTMENTS.—

[(1) ANNUAL FEE SETTING.—The Secretary shall establish, 60 days before the start of each fiscal year beginning after September 30, 2003, 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.]

(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.—(A) For fiscal year [2020] *2025* and subsequent fiscal years, the revenue amounts established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year, by multiplying such revenue amounts by an amount equal to the sum of—

(i) one;

(ii) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 of the preceding 4 fiscal years for which data are available, multiplied by the average proportion of personnel compensation and benefits costs to total Food and Drug Administration costs for the first 3 years 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] *Arlington-Alexandria*, DC–MD–VA–WV; not seasonally adjusted; all items less food and energy; annual index) for the first 3 years 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 Ad-

ministration costs for the first 3 years of the preceding 4 fiscal years for which data are available.

(B) COMPOUNDED BASIS.—The adjustment made each fiscal year after fiscal year [2020] *2025* 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.

(3) WORKLOAD ADJUSTMENTS.—

(A) IN GENERAL.—For fiscal year [2020] *2025* 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)] *subparagraph (B)*. 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.]

(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) 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)] *(B)* 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).

[(4) FINAL YEAR ADJUSTMENT.—For fiscal year 2023, the Secretary may, in addition to other adjustments under this subsection, further increase the fees under this section, if such an

adjustment is necessary, to provide for up to 3 months of operating reserves of carryover user fees for the process for the review of animal drug applications for the first 3 months of fiscal year 2024. If the Food and Drug Administration has carryover balances for the process for the review of animal drug applications in excess of 3 months of such operating reserves, then this adjustment will not be made. If this adjustment is necessary, then the rationale for the amount of the increase shall be contained in the annual notice setting fees for fiscal year 2023.]

(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.

(5) LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of animal drug applications.

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

(1) 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—

(A) the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances;

(B) the fees to be paid by such person will exceed the anticipated present and future costs incurred by the Secretary in conducting the process for the review of animal drug applications for such person;

(C) the animal drug application or supplemental animal drug application is intended solely to provide for use of the animal drug in—

(i) a Type B medicated feed (as defined in section 558.3(b)(3) of title 21, Code of Federal Regulations (or any successor regulation)) intended for use in the manufacture of Type C free-choice medicated feeds; or

(ii) a Type C free-choice medicated feed (as defined in section 558.3(b)(4) of title 21, Code of Federal Regulations (or any successor regulation));

(D) the animal drug application or supplemental animal drug application is intended solely to provide for a minor use or minor species indication; or

(E) the sponsor involved is a small business submitting its first animal drug application to the Secretary for review.

(2) USE OF STANDARD COSTS.—In making the finding in paragraph (1)(B), the Secretary may use standard costs.

(3) RULES FOR SMALL BUSINESSES.—

(A) DEFINITION.—In paragraph (1)(E), the term "small business" means an entity that has fewer than 500 employees, including employees of affiliates.

(B) WAIVER OF APPLICATION FEE.—The Secretary shall waive under paragraph (1)(E) the application fee for the first animal drug application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay application fees for all subsequent animal drug applications and supplemental animal drug applications for which safety or effectiveness data are required in the same manner as an entity that does not qualify as a small business.

(C) CERTIFICATION.—The Secretary shall require any person who applies for a waiver under paragraph (1)(E) to certify their qualification for the waiver. The Secretary shall periodically publish in the Federal Register a list of persons making such certifications.

[(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 sub-

mission 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.]

(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) EFFECT OF FAILURE TO PAY FEES.—An animal drug application or supplemental animal drug application submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid. An investigational animal drug submission under section 739(5)(B) that is submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for review by the Secretary until all fees owed by such person have been paid. The Secretary may discontinue review of any animal drug application, supplemental animal drug application or investigational animal drug submission from a person if such person has not submitted for payment all fees owed under this section by 30 days after the date upon which they are due.

(f) ASSESSMENT OF FEES.—

(1) LIMITATION.—Fees may not be assessed under subsection (a) for a fiscal year beginning after fiscal year 2003 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 2003 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for animal drug applications, supplemental animal drug applications, investigational animal drug submissions, animal drug sponsors, animal drug establishments and animal drug products at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

(g) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—Subject to paragraph (2)(C), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to be appropriated to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account

without fiscal year limitation to such appropriation account for salary and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of animal drug applications.

(2) COLLECTIONS AND APPROPRIATION ACTS.—

(A) IN GENERAL.—The fees authorized by this section—

(i) subject to subparagraph (C), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year, and

(ii) shall be available to defray increases in the costs of the resources allocated for the process for the review of animal drug applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 2003 multiplied by the adjustment factor.

(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of animal drug applications—

(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in subparagraph (A)(ii); and

(II) such costs are not more than 5 percent below the level specified in subparagraph (A)(ii).

(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years [2019 through 2023] *2024 through 2028*, 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) [and paragraph (5)].

(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).]

(h) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.—To qualify for consideration for a waiver or reduction under subsection (d), or for a refund of any fee collected in accordance with subsection (a), a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.

(j) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and

advisory committees not engaged in the process of the review of animal drug applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

(k) ABBREVIATED NEW ANIMAL DRUG APPLICATIONS.—The Secretary shall—

(1) to the extent practicable, segregate the review of abbreviated new animal drug applications from the process for the review of animal drug applications; and

(2) adopt other administrative procedures to ensure that review times of abbreviated new animal drug applications do not increase from their current level due to activities under the user fee program.

SEC. 740A. REAUTHORIZATION; REPORTING REQUIREMENTS.

(a) PERFORMANCE REPORT.—[Beginning with]

(1) IN GENERAL.—Beginning with fiscal year [2019] *2024*, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and 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 concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 101(b) of the Animal Drug User Fee Amendments of [2018] *2023* toward expediting the animal drug development process and the review of the new and supplemental animal drug applications and investigational animal drug submissions during such fiscal year, the future plans of the Food and Drug Administration for meeting the goals, the review times for abbreviated new animal drug applications, and the administrative procedures adopted by the Food and Drug Administration to ensure that review times for abbreviated new animal drug applications are not increased from their current level due to activities under the user fee program.

(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.

(b) FISCAL REPORT.—Beginning with fiscal year [2019] *2024*, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and 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 on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

(c) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

(d) REAUTHORIZATION.—

(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals, and plans for meeting the goals, for the process for the review of animal drug applications for the first 5 fiscal years after fiscal year [2023] *2028*, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

(A) the Committee on Health, Education, Labor, and Pensions of the Senate;

(B) the Committee on Energy and Commerce of the House of Representatives;

(C) scientific and academic experts;

(D) veterinary professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the regulated industry.

(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the reauthorization of this part, the Secretary shall—

(A) publish a notice in the Federal Register requesting public input on the reauthorization;

(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);

(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and

(D) publish the comments on the Food and Drug Administration's Internet Web site.

(3) PERIODIC CONSULTATION.—Not less frequently than once every 4 months during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of veterinary, patient, and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).

(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph;

(B) publish such recommendations in the Federal Register;

(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

(D) hold a meeting at which the public may present its views on such recommendations; and

(E) after consideration of such public views and comments, revise such recommendations as necessary.

(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, [2023] *2028*, the Secretary shall transmit to Congress the revised recommendations under paragraph (4)*,* a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

(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.

[(6)] *(7)* MINUTES OF NEGOTIATION MEETINGS.—

(A) PUBLIC AVAILABILITY.—[Before presenting the recommendations developed under paragraphs (1) through (5) to Congress, the Secretary] *The Secretary* shall make publicly available, on the Internet Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry*, not later than 30 days after each such negotiation meeting*.

(B) CONTENT.—The minutes described under subparagraph (A) shall summarize*, in sufficient detail,* any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.

PART 5—FEES RELATING TO GENERIC NEW ANIMAL DRUGS

SEC. 741. AUTHORITY TO ASSESS AND USE GENERIC NEW ANIMAL DRUG FEES.

(a) TYPES OF FEES.—Beginning with respect to fiscal year 2009, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) ABBREVIATED APPLICATION FEE.—

(A) IN GENERAL.—Each person that submits, on or after July 1, 2008, an abbreviated application for a generic new animal drug shall be subject to a fee as established in subsection (c) for such an application.

(B) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the abbreviated application.

(C) EXCEPTIONS.—

(i) PREVIOUSLY FILED APPLICATION.—If an abbreviated application was submitted by a person that paid the fee for such application, was accepted for filing, and was not approved or was withdrawn (without a waiver or refund), the submission of an abbreviated application for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

(ii) CERTAIN ABBREVIATED APPLICATIONS INVOLVING COMBINATION ANIMAL DRUGS.—An abbreviated application which is subject to the criteria in section 512(d)(4) and submitted on or after October 1, 2013 shall be subject to a fee equal to 50 percent of the amount of the abbreviated application fee established in subsection (c).

(D) REFUND OF FEE IF APPLICATION REFUSED FOR FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any abbreviated application which is refused for filing.

(E) REFUND OF FEE IF APPLICATION WITHDRAWN.—If an abbreviated application is withdrawn after the application was filed, the Secretary may refund the fee or portion of the fee paid under subparagraph (B) if no substantial work was performed on the application after the application was filed. The Secretary shall have the sole discretion to refund the fee under this subparagraph. A determination by the Secretary concerning a refund under this subparagraph shall not be reviewable.

(2) GENERIC NEW ANIMAL DRUG PRODUCT FEE.—

(A) IN GENERAL.—Each person—

(i) who is named as the applicant in an abbreviated application or supplemental abbreviated application for a generic new animal drug product which has been submitted for listing under section 510; and

(ii) who, after September 1, 2008, had pending before the Secretary an abbreviated application or supplemental abbreviated application,

shall pay for each such generic new animal drug product the annual fee established in subsection (c).

(B) PAYMENT; FEE DUE DATE.—Such fee shall be payable for the fiscal year in which the generic new animal drug product is first submitted for listing under section 510, or is submitted for relisting under section 510 if the generic new animal drug product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be due each subsequent fiscal year that the product remains listed, upon the later of—

(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section; or

(ii) January 31 of each year.

(C) LIMITATION.—Such fee shall be paid only once for each generic new animal drug product for a fiscal year in which the fee is payable.

(3) GENERIC NEW ANIMAL DRUG SPONSOR FEE.—

(A) IN GENERAL.—Each person—

(i) who meets the definition of a generic new animal drug sponsor within a fiscal year; and

(ii) who, after September 1, 2008, had pending before the Secretary an abbreviated application, a supplemental abbreviated application, or an investigational submission,

shall be assessed an annual generic new animal drug sponsor fee as established under subsection (c).

(B) PAYMENT; FEE DUE DATE.—Such fee shall be due each fiscal year upon the later of—

(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section; or

(ii) January 31 of each year.

(C) AMOUNT OF FEE.—Each generic new animal drug sponsor shall pay only 1 such fee each fiscal year, as follows:

(i) 100 percent of the amount of the generic new animal drug sponsor fee published for that fiscal year under subsection (c) for an applicant with more than 6 approved abbreviated applications.

(ii) 75 percent of the amount of the generic new animal drug sponsor fee published for that fiscal year under subsection (c) for an applicant with more than 1 and fewer than 7 approved abbreviated applications.

(iii) 50 percent of the amount of the generic new animal drug sponsor fee published for that fiscal year under subsection (c) for an applicant with 1 or fewer approved abbreviated applications.

(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.—

(1) IN GENERAL.—Subject to subsections (c), (d), (f), and (g), for each of fiscal years ⟦2019 through 2023⟧ *2024 through 2028*, the fees required under subsection (a) shall be established to generate a total revenue amount of ⟦$18,336,340⟧ *$25,000,000*.

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

(A) ⟦25 percent⟧ *20 percent* shall be derived from fees under subsection (a)(1) (relating to abbreviated applications for a generic new animal drug) *and fees under subsection (a)(4) (relating to generic investigational new animal drug files)*;

(B) ⟦37.5 percent⟧ *40 percent* shall be derived from fees under subsection (a)(2) (relating to generic new animal drug products); and

(C) ⟦37.5 percent⟧ *40 percent* shall be derived from fees under subsection (a)(3) (relating to generic new animal drug sponsors).

(c) ANNUAL FEE SETTING; ADJUSTMENTS.—

⟦(1) ANNUAL FEE SETTING.—The Secretary shall establish, 60 days before the start of each fiscal year beginning after September 30, 2008, for that fiscal year, abbreviated application fees, 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.⟧

(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.—

(A) IN GENERAL.—For fiscal year [2020] *2025* and subsequent fiscal years, the revenue amounts established under subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year, by multiplying such revenue amounts by an amount equal to the sum of—

(i) one;

(ii) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 of the preceding 4 fiscal years for which data are available, multiplied by the average proportion of personnel compensation and benefits costs to total Food and Drug Administration costs for the first 3 of the preceding 4 fiscal years for which data are available; and

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

(B) COMPOUNDED BASIS.—The adjustment made each fiscal year after fiscal year [2020] *2025* 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.

(3) WORKLOAD ADJUSTMENTS.—

(A) IN GENERAL.—For fiscal year [2020] *2025* 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 submis-

sions, [and investigational generic new animal drug protocol submissions] *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* submitted to the Secretary[; and]*;*

(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

[(ii)] *(iii)* 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] *2026 through 2028*, 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).

(4) FINAL YEAR ADJUSTMENT.—For fiscal year [2023] *2028*, the Secretary may, in addition to other adjustments under this subsection, further increase the fees under this section, if such an adjustment is necessary, to provide for up to 3 months of operating reserves of carryover user fees for the process for the review of abbreviated applications for generic new animal drugs for the first 3 months of fiscal year [2024] *2029*. If the Food and Drug Administration has carryover balances for the process for the review of abbreviated applications for generic new animal drugs in excess of 3 months of such operating reserves, then this adjustment shall not be made. If this adjustment is necessary, then the rationale for the amount of the increase shall be contained in the annual notice setting fees for fiscal year [2023] *2028*.

(5) LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of abbreviated applications for generic new animal drugs.

[(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) 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.—An abbreviated application for a generic new animal drug submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid. An investigational submission for a generic new animal drug that is submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for review by the Secretary until all fees owed by such person have been paid. [The Secretary may discontinue] *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* review of any abbreviated application for a generic new animal drug, supplemental abbreviated application for a generic new animal drug, or investigational submission for a generic new animal drug from a person if such person has not submitted for payment all fees owed under this section by 30 days after the date upon which they are due.

(f) ASSESSMENT OF FEES.—

(1) LIMITATION.—Fees may not be assessed under subsection (a) for a fiscal year beginning after fiscal year 2008 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 2003 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for abbreviated applications, generic new animal drug [sponsors, and generic new animal drug products at any time] *products, generic new animal drug sponsors, and generic investigational new animal drug files at any time* in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

(g) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—Subject to paragraph (2)(C), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to be appropriated to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salary and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of abbreviated applications for generic new animal drugs.

(2) COLLECTIONS AND APPROPRIATION ACTS.—

(A) IN GENERAL.—The fees authorized by this section—

(i) subject to subparagraph (C), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year; and

(ii) shall be available to defray increases in the costs of the resources allocated for the process for the review of abbreviated applications for generic new animal drugs (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 2008 multiplied by the adjustment factor.

(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of abbreviated applications for generic new animal drugs—

(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in subparagraph (A)(ii); and

(II) such costs are not more than 5 percent below the level specified in subparagraph (A)(ii).

(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years [2019 through 2023] *2024 through 2028*, 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).

[(4) OFFSET.—If the sum of the cumulative amount of fees collected under this section for the fiscal years 2014 through 2016 and the amount of fees estimated to be collected under this section for fiscal year 2017 exceeds the cumulative amount appropriated under paragraph (3) for the fiscal years 2014 through 2017, the excess amount shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2018.]

(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) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.—To qualify for consideration for a waiver or reduction under subsection (d), or for a refund of any fee collected in accordance with subsection (a), a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.

(j) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in the process of the review of abbreviated applications for generic new animal drugs, be reduced to offset the number of officers, employees, and advisory committees so engaged.

(k) DEFINITIONS.—In this section and section 742:

(1) ABBREVIATED APPLICATION FOR A GENERIC NEW ANIMAL DRUG.—The terms "abbreviated application for a generic new animal drug" and "abbreviated application" mean an abbreviated application for the approval of any generic new animal drug submitted under section 512(b)(2). Such term does not in-

clude a supplemental abbreviated application for a generic new animal drug.

(2) ADJUSTMENT FACTOR.—The term "adjustment factor" applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by—

(A) for purposes of subsection (f)(1), such Index for October 2002; and

(B) for purposes of subsection (g)(2)(A)(ii), such Index for October 2007.

(3) COSTS OF RESOURCES ALLOCATED FOR THE PROCESS FOR THE REVIEW OF ABBREVIATED APPLICATIONS FOR GENERIC NEW ANIMAL DRUGS.—The term "costs of resources allocated for the process for the review of abbreviated applications for generic new animal drugs" means the expenses in connection with the process for the review of abbreviated applications for generic new animal drugs for—

(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees consulted with respect to the review of specific abbreviated applications, supplemental abbreviated applications, or investigational submissions, and costs related to such officers, employees, committees, and contractors, including costs for travel, education, and recruitment and other personnel activities;

(B) management of information, and the acquisition, maintenance, and repair of computer resources;

(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

(D) collecting fees under this section and accounting for resources allocated for the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

(4) FINAL DOSAGE FORM.—The term "final dosage form" means, with respect to a generic new animal drug product, a finished dosage form which is approved for administration to an animal without substantial further manufacturing. Such term includes generic new animal drug products intended for mixing in animal feeds.

(5) GENERIC NEW ANIMAL DRUG.—The term "generic new animal drug" means a new animal drug that is the subject of an abbreviated application.

(6) GENERIC NEW ANIMAL DRUG PRODUCT.—The term "generic new animal drug product" means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an abbreviated application for a generic new animal drug or a supplemental abbreviated application has been approved.

(7) GENERIC NEW ANIMAL DRUG SPONSOR.—The term "generic new animal drug sponsor" means either an applicant named in an abbreviated application for a generic new animal drug that

has not been withdrawn by the applicant and for which approval has not been withdrawn by the Secretary, or a person who has submitted an investigational submission for a generic new animal drug that has not been terminated or otherwise rendered inactive by the Secretary.

(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.

[(8)**]** *(9)* INVESTIGATIONAL SUBMISSION FOR A GENERIC NEW ANIMAL DRUG.—The terms "investigational submission for a generic new animal drug" and "investigational submission" mean—

(A) the filing of a claim for an investigational exemption under section 512(j) for a generic new animal drug intended to be the subject of an abbreviated application or a supplemental abbreviated application; or

(B) the submission of information for the purpose of enabling the Secretary to evaluate the safety or effectiveness of a generic new animal drug in the event of the filing of an abbreviated application or supplemental abbreviated application for such drug.

[(9)**]** *(10)* PERSON.—The term "person" includes an affiliate thereof (as such term is defined in section 735(11)).

[(10)**]** *(11)* PROCESS FOR THE REVIEW OF ABBREVIATED APPLICATIONS FOR GENERIC NEW ANIMAL DRUGS.—The term "process for the review of abbreviated applications for generic new animal drugs" means the following activities of the Secretary with respect to the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions:

(A) The activities necessary for the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

(B) The issuance of action letters which approve abbreviated applications or supplemental abbreviated applications or which set forth in detail the specific deficiencies in abbreviated applications, supplemental abbreviated applications, or investigational submissions and, where appropriate, the actions necessary to place such applications, supplemental applications, or submissions in condition for approval.

(C) The inspection of generic new animal drug establishments and other facilities undertaken as part of the Secretary's review of pending abbreviated applications, supplemental abbreviated applications, and investigational submissions.

(D) Monitoring of research conducted in connection with the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

(E) The development of regulations and policy related to the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

(F) Development of standards for products subject to review.

(G) Meetings between the agency and the generic new animal drug sponsor.

(H) Review of advertising and labeling prior to approval of an abbreviated application or supplemental abbreviated application, but not after such application has been approved.

(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.

(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.

[(11)**]** *(13)* SUPPLEMENTAL ABBREVIATED APPLICATION FOR GENERIC NEW ANIMAL DRUG.—The terms "supplemental abbreviated application for a generic new animal drug" and "supplemental abbreviated application" mean a request to the Secretary to approve a change in an approved abbreviated application.

SEC. 742. REAUTHORIZATION; REPORTING REQUIREMENTS.

(a) PERFORMANCE REPORTS.—Beginning with fiscal year **[**2019**]** *2024*, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and 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 concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 201(b) of the Animal Generic Drug User Fee Amendments of **[**2018**]** *2023* 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 during such fiscal year.

(b) FISCAL REPORT.—Beginning with fiscal year **[**2019**]** *2024*, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and 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 on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

(c) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

(d) REAUTHORIZATION.—

(1) CONSULTATION.—In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of abbreviated applications for generic new animal drugs for the first 5 fiscal years after fiscal year [2023] *2028*, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

(C) scientific and academic experts;

(D) veterinary professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the regulated industry.

(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the reauthorization of this part, the Secretary shall—

(A) publish a notice in the Federal Register requesting public input on the reauthorization;

(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);

(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and

(D) publish the comments on the Food and Drug Administration's Internet Web site.

(3) PERIODIC CONSULTATION.—Not less frequently than once every 4 months during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of veterinary, patient, and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).

(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the congressional committees specified in such paragraph;

(B) publish such recommendations in the Federal Register;

(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

(D) hold a meeting at which the public may present its views on such recommendations; and

(E) after consideration of such public views and comments, revise such recommendations as necessary.

(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, [2023] *2028*, the Secretary shall transmit to Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such

paragraph, and any changes made to the recommendations in response to such views and comments.

(6) MINUTES OF NEGOTIATION MEETINGS.—

(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to Congress, the Secretary shall make publicly available, on the Internet Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

(B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.

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ANIMAL DRUG USER FEE AMENDMENTS OF 2018

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TITLE I—FEES RELATING TO ANIMAL DRUGS

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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.

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ANIMAL GENERIC DRUG USER FEE AMENDMENTS OF 2018

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TITLE II—FEES RELATING TO GENERIC ANIMAL DRUGS

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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.

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