Animal Drug User Fee Reauthorization Act of 2018	
Title I – Fees Relating to Animal Drugs	
Sec. 101. Short Title; Finding.	• Establishes a title – "Animal Drug User Fee Amendments of 2018" – and provides that the fees authorized by the amendments in the title will go 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 commitment letter submitted to the Congressional Record.
Sec. 102. Definitions.	• Clarifies the definition of an animal drug application to include conditional approval applications submitted under section 571 of the Federal Food, Drug, and Cosmetic Act (FFDCA) in order to assure the goals in the letter apply to these submissions. • Clarifies that fee dollars can be used to implement the Good Manufacturing Practice (GMP) Mutual Inspection Agreement between the US and the EU – with the goal of streamlining inspections of foreign facilities.
Sec 103. Authority to Assess and Use Animal Drug Fees.	• Reauthorizes the authority to collect fees at a higher level beginning in 2019 through 2023. • Total revenue generated from fees in the first year of the agreement is authorized to increase from the fiscal year (FY) 2014 amount of $23.6 million to $30.3 million in FY2019. • Total revenue generated from fees for the duration of the agreements is authorized to increase from the $21.6 million in FY2015-2018 to $29.9 million in FY2020-2023. • Updates the annual fee inflation adjustment for FY2020 and subsequent fiscal years and clarifies adjustments made after FY2020 would be applied on a compounded basis to the most recent adjustment. • Provides the Secretary authority to change the inflation-adjusted fee amount to reflect workload related to the review and approval of new animal drugs. Any increases resulting from the workload adjustment should be reduced by the excess collection amount. Workload adjustments cannot result in fees that are less than those adjusted for inflation. • Provides the Secretary authority to make final year adjustments to fees for an amount up to three months of operating reserves of carryover user fees for the review of animal drug applications for the first three months of FY2024 and list the rationale for such increase in an annual notice. • Exempts from fees supplemental applications submitted solely to add the new animal drug application number to the label, as required by this Act, and applications for genetically engineered animals intended to produce human medical products. • Reauthorizes the authority to collect excess fees and credit such fees to the appropriations account of the agency. • Reduces the statutory fee increase for a fiscal year by the amount of excess collections for the preceding fiscal years. Adjustments cannot result in fee revenues that are less than those established in this Act.

Sec. 104. Reauthorization; Reporting Requirements.	• Maintains the existing reauthorization process and reporting requirements. Requires the Secretary to provide recommendations to Congress by January 15, 2023, after holding public meetings. • Reauthorizes annual deadlines for performance and financial reports to Congress.
Sec. 105. Savings Clause.	• Clarifies that submissions made on or after October 1, 2013, but prior to October 1, 2018, will continue to be reviewed and assessed fees based on the agreement made prior to FY2019.
Sec. 106. Effective Date.	• Clarifies that the effective date to collect fees is October 1, 2018, or the date of enactment, whichever is later.
Sec. 107. Sunset Dates.	• Sunsets the authority to collect fees on October 1, 2023, and the requirement to submit performance and financial reports on January 31, 2024.
Title II – Fees Relating to Generic New Animal Drugs	
Sec. 201. Short Title; Finding.	• Establishes a short title – "Animal Generic Drug User Fee Amendments of 2018" – and provides that the fees authorized by the amendments in the title will go toward expediting the animal generic drug development process and the review of abbreviated, supplemental abbreviated, and investigational generic new drug submissions as set forth in the commitment letter submitted to the Congressional Record.

Sec. 202. Authority to Assess and Use Generic New Animal Drug Fees.	• Reauthorizes user fees to be collected at a total revenue amounts of $18.3 million for each FY2019 through 2023.
	• Restructures collection of fee types as follows:
	  • 25 percent of the total revenue will come from abbreviated generic new animal drug application fees,
	  • 37.5 percent will come from generic new animal drug product fees, and
	  • 37 percent will come from generic new animal drug sponsor fees.
	• Provides the Secretary authority to update the fee adjustment for inflation.
	• Provides the Secretary authority to further change the inflation adjusted fee amounts to reflect workload related to the review and approval of generic new animal drugs and publish such fees in the Federal Register. Any increase resulting from the workload adjustment should be reduced by the excess collection amount. Workload adjustments cannot result in fees that are less than those adjusted for inflation.
	• Establishes exemptions from fees for supplemental abbreviated generic new animal drug applications submitted solely to add the application number to the label of the drug, as required by this Act.
	• Reauthorizes the authority to collect excess fees and credit such fees to the appropriations account of the agency.

Sec. 203. Reauthorization; Reporting Requirements.	• Maintains the existing reauthorization process and reporting requirements. Reauthorizes the requirement that the Secretary provide

	recommendations to Congress by January 15, 2023, after holding public meetings. • Reauthorizes annual deadlines for performance and financial reports to Congress.
Sec. 204. Savings Clause.	• Clarifies that submissions made on or after October 1, 2013, but prior to October 1, 2018, will continue to be reviewed and assessed fees based on the agreement made prior to FY2019.
Sec. 205. Effective Date.	• Clarifies that the effective date to collect fees is October 1, 2018, or date of enactment, whichever is later.
Sec. 206. Sunset Dates.	• Sunsets the authority to collect fees on October 1, 2023, and the requirement to submit performance and financial reports on January 31, 2024.
Title III – Miscellaneous Provisions	
Sec. 301. Electronic Submissions.	• Requires new animal drug applications, abbreviated applications for generic new animal drugs, supplements to an application, or applications for conditional approval of new animal drugs for minor use and minor species to be filed electronically after October 1, 2018.
Sec. 302. Index of Legally Marketed Unapproved New Animal Drugs for Minor Species.	• Requires that legally marketed unapproved new animal drugs intended for minor species include the Index file number on its label beginning October 1, 2018.
Sec. 303. Misbranded Drugs and Devices.	• Clarifies an animal drug will be categorized as misbranded if the drug label does not include an application number in a specified format outlined in this Act beginning September 20, 2023.