FDA Reauthorization Act of 2017	
TITLE I: FEES RELATING TO DRUGS	
Sec. 101. Short title; finding.	• Establishes a short title – "Prescription Drug User Fee Amendments of 2017" – and provides that the fees authorized in the title will go toward human prescription drug activities as set forth in the commitment letter submitted to the Congressional Record.
Sec. 102. Authority to assess and use drug fees.	• Reauthorizes the authority to collect fees at a higher level, and restructures the fees to reduce administrative burden and make funding more predictable. • Modernizes the fee structure. Historically, fees were derived one-third from facility fees, one-third from various application fees, and one-third from product fees. The new structure is derived from 20 percent application fees and 80 percent program fees for approved products. Supplemental application fees and facility fees are eliminated. • Updates the base fee amount. In fiscal year (FY) 2017, the base fee amount was $718,669,000, in FY2018, the base fee amount is $878,590,000. • Replaces the workload adjustment with a capacity planning adjuster so that fees more accurately reflect the workload and existing staff capacity at FDA. • Reauthorizes the authority to collect, and the availability and crediting, of fees.
Sec. 103. Reauthorization; reporting requirements.	• Maintains the existing reauthorization process and reporting requirements. The Secretary of Health and Human Services (HHS) is required to provide recommendations to Congress by January 15, 2022, after an extensive process of public meetings. • Performance and financial reports continue to be due to Congress every year.
Sec. 104. Sunset dates.	• Sunsets the authority to collect fees on October 1, 2022, and the requirement to submit performance and financial reports on January 31, 2023.
Sec. 105. Effective Date.	• Clarifies that the effective date is October 1, 2017, or date of enactment, whichever is later, and the fee structure and amount in this Act applies to all human drug applications received on or after October 1, 2017, regardless of the date of the enactment of this Act.
Sec. 106. Savings Clause.	• Clarifies that submissions made prior to October 1, 2017, will continue to be reviewed and assessed fees based on the agreement for FY2012-2017.
TITLE II: FEES RELATING TO DEVICES	
Sec. 201. Short title; findings.	• Establishes a short title – "Medical Device Drug User Fee Amendments of 2017" – and provides that the fees authorized in the title will go toward medical device activities as set forth in the commitment letter submitted to the Congressional Record.
Sec. 202. Definitions.	• Adds the term "de novo classification request" to enable new fees

	specifically for de novo medical device reviews.
Sec. 203. Authority to assess and use device fees.	• Adds authority to collect fees for de novo classification request. • Updates the target base fee amounts for each year. FY2017 base is $130,184,348, the FY2018 base is increased to $183,280,756, ending at $213,687,660 in FY2022. • Updates the adjustment for inflation and allows the Secretary of HHS to, if necessary, increase the fees to meet the base target. • Reauthorizes the authority to collect, and the availability and crediting, of fees.
Sec. 204. Reauthorization; reporting requirements.	• Maintains the existing reauthorization and reporting requirements. The Secretary of HHS is required to provide recommendations to Congress by January 15, 2022, after an extensive process of public meetings. • Performance and financial reports continue to be due to Congress every year.
Sec. 205. Conformity assessment pilot program.	• Establishes a pilot to provide FDA the authority to audit and certify laboratories who conduct device conformance testing to a recognized standard, and also to withdraw the certification if necessary. • Requires FDA to evaluate the use of this scheme in at least five device types, or device parts that are found in multiple devices. • Requires FDA to obtain public input on the development of the pilot. • Sunsets the authority for the pilot in 2022.
Sec. 206. Reauthorization of review.	• Reauthorizes, and provides flexibility for the Secretary of HHS to better target which device types are most appropriate for, third party review. • Requires the Secretary of HHS to conduct a public guidance development process to identify the factors the Secretary of HHS will use to determine which devices are eligible for third party review.
Sec. 207. Electronic format for submissions.	• FDA currently receives both paper and electronic submissions. This provision requires all submissions to be in electronic format by October 1, 2021. The Secretary of HHS has the authority to extend the date as late as April 1, 2023.
Sec. 208. Savings clause.	• Clarifies that submissions made prior to October 1, 2017, will continue to be reviewed and assessed fees based on the agreement for FY2012-2017.
Sec. 209. Effective date.	• Clarifies that the effective date is October 1, 2017, or date of enactment, whichever is later, and the fee structure and amount in this Act applies to all medical device applications received on or after October 1, 2017, regardless of the date of the enactment of this Act.
Sec. 210. Sunset clause.	• Sunsets the authority to collect fees on October 1, 2022, and the requirement to submit performance and financial reports on January 31, 2023.
TITLE III: FEES RELATING TO GENERIC DRUGS	
Sec. 301. Short title; finding.	• Establishes a short title – "Generic Drug User Fee Amendments of 2017" – and provides that the fees authorized in the title will go toward human generic drug activities, as set forth in the commitment letter submitted to the Congressional Record.

Sec. 302. Definitions.	• The definitions are amended to clarify that submissions by a State or Federal Government entity for drugs not intended for sale do not have to pay user fees. • Includes a definition for a contract manufacturing facility.

Sec. 303. Authority to assess and use human generic drug fees.	• Updates the fee structure to provide more predictability for FDA and flexibility for small businesses.
	• Removes the fees for prior approval supplements and establishes a generic drug applicant program fee.
	• Thirty-three percent of the total revenue will come from application fees, 20 percent of the revenue will come from generic drug facility fees, 7 percent will come from active pharmaceutical ingredient facility fees, and 35 percent will come from a new generic drug applicant program fee.
	• The generic drug applicant program fee is determined by how many applications the applicant has approved by the FDA:
	  • a manufacturer with 20 or more approved applications pays the full fee;
	  • a manufacturer with six-19 approved applications pays 40 percent of the full fee; and
	  • a manufacturer with five or fewer approved applications pays 10 percent of the full fee.
	• The base fee amount is updated from the FY2017 amount of $299,000,000 to $493,600,000 in FY2018.

Sec. 304. Reauthorization; reporting requirements.	• Maintains the existing reauthorization and reporting requirements. The Secretary of HHS is required to provide recommendations to Congress by January 15, 2022, after an extensive process of public meetings. • Performance and financial reports continue to be due to Congress every year.
Sec. 305. Sunset dates.	• Sunsets the authority to collect fees on October 1, 2022, and the requirement to submit performance and financial reports on January 31, 2023.
Sec. 306. Effective date.	• Clarifies that the effective date is October 1, 2017, or date of enactment, whichever is later, and the fee structure and amount in this Act applies to all human generic drug applications received on or after October 1, 2017, regardless of the date of the enactment of this Act.
Sec. 307. Savings clause.	• Clarifies that submissions made prior to October 1, 2017, will continue to be reviewed and assessed fees based on the agreement for FY2012-2017.
TITLE IV: FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS	
Sec. 401. Short title; finding.	• Establishes a short title – "Biosimilar User Fee Amendments of 2017" – and that the fees authorized in the title will go toward biosimilar activities as set forth in the commitment letter submitted to the Congressional Record.
Sec. 402. Definitions.	• Technical update to the definition of the adjustment factor and biosimilar biological product to provide clarity.

Sec. 403. Authority to assess and use biosimilar biological product fees.	• Establishes an independent fee structure for biosimilars for the first time based on the following types of fees:
	  • Initial Biosimilar Development Fee for the first year once a sponsor begins clinical trials for a new biosimilar;
	  • Annual Biosimilar Development Fee for subsequent years a sponsor is developing a new biosimilar;
	  • Biosimilar Program Fee for sponsors of approved biosimilars; and
	  • Application Fee for new biosimilar applications.
	• Eliminates supplement and establishment fees.
	• Allows the Secretary of HHS to determine the appropriate percentage that will come from each of the fees, and each fee amount annually.
	• Updates the base fee amount from $20,000,000 to $45,000,000.

Sec. 404. Reauthorization; reporting requirements.	• Maintains the existing reauthorization and reporting requirements. The Secretary of HHS is required to provide recommendations to Congress by January 15, 2022, after an extensive process of public meetings. • Performance and financial reports continue to be due to Congress every year.
Sec. 405. Sunset dates.	• Sunsets the authority to collect fees on October 1, 2022, and the requirement to submit performance and financial reports on January 31, 2023.
Sec. 406. Effective date.	• Clarifies that the effective date is October 1, 2017, or date of enactment, whichever is later, and the fee structure and amount in this Act applies to all biosimilar applications received on or after October 1, 2017, regardless of the date of the enactment of this Act.
Sec. 407. Savings clause.	• Clarifies that submissions made prior to October 1, 2017, will continue to be reviewed and assessed fees based on the agreement for FY2012-2017.
TITLE V: REAUTHORIZATION OF OTHER PROGRAMS	
Sec. 501. Reauthorization of provision relating to exclusivity of certain drugs containing single enantiomers.	• Reauthorizes section 505(u), which provides the Secretary of HHS the authority to grant exclusivity for drugs containing single enantiomers, until 2022.
Sec. 502. Reauthorization of pediatric humanitarian device exceptions.	• Reauthorizes rules regarding the development of devices for rare pediatric conditions until 2022.
Sec. 503. Reauthorization of the Critical Path Public-Private Partnerships.	• Reauthorizes the Critical Path public-private partnership for an additional 5 years at current law authorization levels.
Sec. 504 Reauthorization of Pediatric Device Consortia.	• Reauthorizes the authority of FDA to issue grants to consortia working to develop devices for pediatrics at current law authorization levels until 2022.
Sec. 505. Reauthorization of Orphan Grants Program.	• Reauthorizes the authority of FDA to issue grants for orphan drug development until 2022.