

SUMMARY OF CHANGES

(dollars in thousands)	Budget Authority	User Fees	Program Level	*FTE
FY 2019 Annualized CR.....	2,964,366	2,534,633	5,498,999	17,607
FY 2020 Program Changes				
Budget Authority Changes				
Infrastructure and B&F.....	30,746	---	30,746	---
Seafood Decomposition Study; Biotech Education; Botanical Supplement Research.....	-1,800	---	-1,800	---
Advancing FSMA.....	16,480	---	16,480	2
Strengthening Response Capabilities for Foodborne Outbreaks.....	16,300	---	16,300	50
Promoting Innovation and Emerging Technology While Maintaining Product Safety.....	8,220	---	8,220	22
Promote Domestic Manufacturing.....	38,500	---	38,500	10
New Domestic Drug Industry.....	12,000	---	12,000	27
MedTech Manufacturing.....	12,000	---	12,000	4
New Medical Data Enterprise.....	60,000	---	60,000	15
Transform Medical Device Safety, Cybersecurity, Review, and Innovation.....	55,000	---	55,000	13
New Platform for Drug Development.....	50,000	---	50,000	30
Modernizing Generic Drug Development and Review.....	27,000	---	27,000	5
Investment and Innovation for Rare Diseases.....	20,000	---	20,000	5
Opioids-International Mail Facilities (IMF).....	55,000	---	55,000	14
Medical Countermeasures Initiatives.....	7,000	---	7,000	16
Integrated Pathogen Reduction of the Blood Supply.....	20,000	---	20,000	4
Office of Laboratory Science and Safety.....	1,000	---	1,000	---
Compounding.....	13,500	---	13,500	30
Opioids (No Year).....	-94,000	---	-94,000	-8
21st Century Cures.....	15,000	---	15,000	---
Total Budget Authority Changes.....	361,946	---	361,946	239
User Fee Changes				
Current Law				
Prescription Drug (PDUFA).....	---	52,044	52,044	58
Medical Device (MDUFA).....	---	14,797	14,797	40
Generic Drug (GDUFA).....	---	9,961	9,961	1
Biosimilars (BsUFA).....	---	771	771	16
Animal Drug (ADUFA).....	---	193	193	---
Animal Generic Drug (AGDUFA).....	---	365	365	---
Family Smoking Prevention and Tobacco Control Act.....	---	40,000	40,000	49
Indefinite				
Mammography Quality Standards Act (MQSA).....	---	829	829	---
Color Certification.....	---	472	472	---
Export Certification.....	---	---	---	---
Priority Review Vouchers (PRV) Tropical Disease.....	---	---	---	---
Priority Review Vouchers (PRV) Pediatric Disease.....	---	311	311	---
Food and Feed Recall.....	---	58	58	---
Food Reinspection.....	---	259	259	---
Voluntary Qualified Importer Program.....	---	215	215	---
Third Party Auditor Program.....	---	30	30	---
Outsourcing Facility.....	---	156	156	---
Export Certification (Proposed).....	---	4,280	4,280	---
Over the Counter Monograph (Proposed).....	---	28,400	28,400	---
Innovative Food Products (Proposed).....	---	28,000	28,000	52
Expand Tobacco Product (Proposed).....	---	100,000	100,000	---
Subtotal, Current Law.....	---	281,141	281,141	216
Net Program Changes.....	361,946	281,141	643,087	455
Total FDA Request for FY 2020.....	3,326,312	2,815,774	6,142,086	18,062

* FTE figures do not include an estimated 87 reimbursable, 2 CRADA, 2 FOIA, and 36 PEPFAR.