

MAJOR ACTIVITIES TABLE

(Dollars in Thousands)	FY 2018 Omnibus						FY 2019 Annualized CR						FY 2020 President's Budget						FY 2020 President's Budget +/- FY 2019 Annualized CR							
	Food Safety		Medical Product Safety and Availability		Total		Food Safety		Medical Product Safety and Availability		Total		Food Safety		Medical Product Safety and Availability		Total		Food Safety		Medical Product Safety and Availability		Total			
	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000		
Programs																										
Budget Authority:																										
Foods.....	3,861	1,059,316	---	---	3,861	1,059,316	3,861	1,059,316	---	---	3,861	1,059,316	3,912	1,084,636	---	---	3,912	1,084,636	51	25,320	---	---	51	25,320		
Center.....	1,147	326,212	---	---	1,147	326,212	1,147	326,212	---	---	1,147	326,212	1,175	334,712	---	---	1,175	334,712	28	8,500	---	---	28	8,500		
Field.....	2,714	733,104	---	---	2,714	733,104	2,714	733,104	---	---	2,714	733,104	2,737	749,924	---	---	2,737	749,924	23	16,820	---	---	23	16,820		
Human Drugs.....	---	---	2,003	495,395	2,003	495,395	---	---	2,003	495,395	2,003	495,395	---	---	2,097	713,895	2,097	713,895	---	---	94	218,500	94	218,500		
Center.....	---	---	1,239	359,226	1,239	359,226	---	---	1,239	359,226	1,239	359,226	---	---	1,301	551,084	1,301	551,084	---	---	62	191,858	62	191,858		
Field.....	---	---	764	136,169	764	136,169	---	---	764	136,169	764	136,169	---	---	796	162,811	796	162,811	---	---	32	26,642	32	26,642		
Biologies.....	---	---	806	217,138	806	217,138	---	---	806	217,138	---	---	---	---	826	262,138	826	262,138	---	---	20	45,000	20	45,000		
Center.....	---	---	583	175,132	583	175,132	---	---	583	175,132	---	---	---	---	603	220,132	603	220,132	---	---	20	45,000	20	45,000		
Field.....	---	---	223	42,006	223	42,006	---	---	223	42,006	---	---	---	---	223	42,006	223	42,006	---	---	---	---	---	---		
Animal Drugs and Feeds.....	584	127,181	190	47,253	774	174,434	584	127,181	190	47,253	774	174,434	607	141,061	194	51,253	801	192,314	23	13,880	4	4,000	27	17,880		
Center.....	281	64,579	176	44,340	457	108,919	281	64,579	176	44,340	457	108,919	304	72,859	180	48,340	484	121,199	23	8,280	4	4,000	27	12,280		
Field.....	303	62,602	14	2,913	317	65,515	303	62,602	14	2,913	317	65,515	303	68,202	14	2,913	317	71,115	---	5,600	---	---	---	5,600		
Devices and Radiological Health.....	---	---	1,539	332,893	1,539	332,893	---	---	1,539	332,893	1,539	332,893	---	---	1,565	423,893	1,565	423,893	---	---	26	91,000	26	91,000		
Center.....	---	---	1,045	247,888	1,045	247,888	---	---	1,045	247,888	1,045	247,888	---	---	1,071	338,888	1,071	338,888	---	---	26	91,000	26	91,000		
Field.....	---	---	494	85,005	494	85,005	---	---	494	85,005	494	85,005	---	---	494	85,005	494	85,005	---	---	---	---	---	---		
National Center for Toxicological Research.....	49	10,317	252	54,195	301	64,512	49	10,317	252	54,195	301	64,512	25	5,087	276	61,425	301	66,512	-24	-5,230	24	7,230	---	2,000		
FDA Headquarters.....	200	54,239	391	97,956	591	171,195	200	54,239	391	97,956	591	171,195	200	54,239	420	108,456	620	180,195	---	---	29	10,500	29	9,000		
FDA White Oak Consolidation.....	---	---	---	---	---	43,044	---	---	---	---	---	43,044	---	---	---	---	---	50,927	---	---	---	---	---	7,883		
Other Rent and Rent Related.....	---	36,300	---	35,643	---	71,943	---	36,300	---	35,643	---	71,943	---	39,215	---	54,229	---	93,444	---	2,915	---	18,586	---	21,501		
GSA Rental Payments.....	---	79,477	---	90,731	---	170,208	---	79,477	---	90,731	---	170,208	---	80,963	---	90,607	---	171,570	---	1,486	---	-124	---	1,362		
SUBTOTAL, BA Salaries and Expenses.....	4,694	1,366,830	5,181	1,371,204	9,875	2,800,078	4,694	1,366,830	5,181	1,371,204	9,875	2,800,078	4,744	1,405,201	5,378	1,765,896	10,122	3,239,524	50	38,371	197	394,692	247	439,446		
Opioids.....	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Opioids -- No Year.....	---	---	8	94,000	8	94,000	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
21st Century Cures.....	---	---	100	60,000	100	60,000	---	---	100	60,000	100	60,000	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Transfer of Sea Food Activities.....	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
MCMI.....	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Building and Facilities.....	---	---	---	---	---	11,788	---	---	---	---	---	11,788	---	---	---	---	---	11,788	---	---	---	---	---	---	---	---
Non-Field Activities.....	1,677	455,347	3,686	978,737	5,363	1,453,084	1,677	455,347	3,686	978,737	5,363	1,453,084	1,704	466,897	3,851	1,328,325	5,555	1,812,722	27	11,550	165	349,588	192	359,638		
Field Activities.....	3,017	795,706	1,495	266,093	4,512	1,061,799	3,017	795,706	1,495	266,093	4,512	1,061,799	3,040	818,126	1,527	292,735	4,567	1,110,861	23	22,420	32	26,642	55	49,062		
White Oak, Rent Activities, and B&F.....	---	115,777	---	126,374	---	296,983	---	115,777	---	126,374	---	296,983	---	120,178	---	144,836	---	327,729	---	4,401	---	18,462	---	30,746		
Opioids.....	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Opioids -- No Year.....	---	---	8	94,000	8	94,000	---	---	8	94,000	8	94,000	---	---	---	---	---	---	---	---	---	---	---	---	---	---
21st Century Cures.....	---	---	100	60,000	100	60,000	---	---	100	60,000	100	60,000	---	---	100	75,000	100	75,000	---	---	---	15,000	---	15,000		
Transfer of Sea Food Activities.....	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
MCMI.....	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Total BA.....	4,694	1,366,830	5,289	1,525,204	9,983	2,965,866	4,694	1,366,830	5,289	1,525,204	9,983	2,965,866	4,744	1,405,201	5,478	1,840,896	10,222	3,326,312	50	38,371	189	315,692	239	360,446		
Total BA, Pre-Transfer.....	4,694	1,366,830	5,289	1,525,204	9,983	2,965,866	4,694	1,366,830	5,289	1,525,204	9,983	2,965,866	4,744	1,405,201	5,478	1,840,896	10,222	3,326,312	50	38,371	189	315,692	239	360,446		

(Dollars in Thousands)	FY 2018 Omnibus						FY 2019 Annualized CR						FY 2020 President's Budget						FY 2020 President's Budget +/- FY 2019 Annualized CR							
	Food Safety		Medical Product Safety and Availability		Total		Food Safety		Medical Product Safety and Availability		Total		Food Safety		Medical Product Safety and Availability		Total		Food Safety		Medical Product Safety and Availability		Total			
	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000		
Programs																										
Total User Fees.....	---	15,863	6,028	1,698,281	7,035	2,396,269	50	15,863	6,472	1,836,708	7,624	2,534,633	102	44,425	6,587	1,948,815	7,840	2,815,774	52	28,562	115	112,107	216	281,141		
Current Law																										
Prescription Drug (PDUFA).....	---	---	3,419	911,346	3,419	911,346	---	---	3,364	1,010,323	3,364	1,010,323	---	---	3,422	1,062,367	3,422	1,062,367	---	---	58	52,044	58	52,044		
Medical Device (MDUFA).....	---	---	667	193,291	667	193,291	---	---	825	204,730	825	204,730	---	---	865	219,527	865	219,527	---	---	40	14,797	40	14,797		
Generic Drug (GDUFA).....	---	---	1,577	493,600	1,577	493,600	---	---	1,817	501,721	1,817	501,721	---	---	1,818	511,682	1,818	511,682	---	---	1	9,961	1	9,961		
Biosimilars (BsUFA).....	---	---	119	40,214	119	40,214	---	---	209	38,847	209	38,847	---	---	225	39,618	225	39,618	---	---	16	771	16	771		
Animal Drug (ADUFA).....	---	---	121	18,093	121	18,093	---	---	121	30,331	121	30,331	---	---	121	30,524	121	30,524	---	---	---	---	---	---		
Animal Generic Drug (AGDUFA).....	---	---	54	9,419	54	9,419	---	---	63	18,335	63	18,335	---	---	63	18,700	63	18,700	---	---	---	---	365	365		
Family Smoking Prevention and Tobacco Control Act.....	---	---	---	---	971	672,000	---	---	---	---	1,065	672,000	---	---	---	---	1,114	712,000	---	---	---	---	---	---	49	40,000
Mammography Quality Standards Act (MQSA).....	---	---	36	20,522	36	20,522	---	---	42	20,522	42	20,522	---	---	42	21,351	42	21,351	---	---	---	---	829	829		
Color Certification.....	---	---	---	---	36	10,125	---	---	---	---	37	10,062	---	---	---	---	37	10,534	---	---	---	---	---	---	472	472
Export Certification.....	---	2,003	22	2,693	22	4,696	---	2,003	26	2,693	26	4,696	---	2,003	26	2,693	26	4,696	---	---	---	---	---	---	---	---
Priority Review Vouchers (PRV) Tropical Disease.....	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Priority Review Vouchers (PRV) Pediatric Disease.....	---	---	1	7,686	1	7,686	---	---	---	7,686	---	7,686	---	---	---	7,997	---	7,997	---	---	---	---	311	311		
Food and Feed Recall.....	---	1,434	---	---	---	1,434	5	1,434	---	---	5	1,434	5	1,492	---	---	5	1,492	---	---	---	---	---	---	58	58
Food Reinspection.....	---	6,414	---	---	---	6,414	24	6,414	---	---	24	6,414	24	6,673	---	---	24	6,673	---	---	259	---	---	---	259	259
Voluntary Qualified Importer Program.....	---	5,300	---	---	---	5,300	20	5,300	---	---	20	5,300	20	5,515	---	---	20	5,515	---	---	215	---	---	---	215	215
Third Party Auditor Program.....	---	712	---	---	---	712	1	712	---	---	1	712	---	742	---	---	1	742	---	30	---	---	---	---	30	30
Outsourcing Facility.....	---	---	12	1,417	12	1,417	---	---	5	1,520	5	1,520	---	---	5	1,676	5	1,676	---	---	---	---	---	---	156	156
Proposed																										
Export Certification (Proposed).....	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	4,280	---	4,280	---	---	---	---	---	---	4,280	4,280
Over the Counter Monograph (Proposed).....	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	28,400	---	28,400	---	---	---	---	---	---	28,400	28,400
Tobacco User fee for e-cigarettes and other (Proposed).....	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	100,000	---	100,000	---	---	---	---	---	---	---	100,000
Food and Feed additive user fee (Proposed).....	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	28,000	---	28,000	---	---	---	---	---	---	---	28,000
Total Program Level, Pre-Transfer	4,694	1,382,693	11,317	3,223,485	17,018	5,362,135	4,744	1,382,693	11,761	3,361,912	17,607	5,500,499	4,846	1,449,626	12,065	3,789,711	18,062	6,142,086	102	66,933	304	427,799	455	641,587		
HHS OIG transfer	---	---	---	---	---	-1,500	---	---	---	---	---	-1,500	---	---	---	---	---	---	---	---	---	---	---	---	---	1,500
Total BA, Post-Transfer	4,694	1,366,830	5,289	1,525,204	9,983	2,964,366	4,694	1,366,830	5,289	1,525,204	9,983	2,964,366	4,744	1,405,201	5,478	1,840,896	10,222	3,326,312	50	38,371	189	315,692	239	361,946		
Total Program Level, Post-Transfer	4,694	1,382,693	11,317	3,223,485	17,018	5,360,635	4,744	1,382,693	11,761	3,361,912	17,607	5,498,999	4,846	1,449,626	12,065	3,789,711	18,062	6,142,086	102	66,933	304	427,799	455	643,087		

* Total Budget Authority includes \$10 million for the China Initiative for FY 2018, and \$7.5 million for FY 2018 for Foreign High Risk Inspections, FDA White Oak Consolidation, Building and Facilities Account, Family Smoking Prevention and Tobacco Control Act, and Color Certification User Fees are not included in Food Safety and Nutrition and Medical Product Safety and Availability activities. Medical
 ** For 2018, the Pre-Transfer levels do not reflect the transfer of \$1.5 million from FDA Headquarters to the HHS Office of Inspector General to support oversight of FDA's expanded authorities.
 ***In addition to the funding displayed in FY 2018 Enacted column, the Further Additional Supplemental Appropriations for Disaster Relief and Requirement Act, 2018 included \$7.6 million in one-time, no-year
 ****Does not reflect priority review voucher user fee for Medical Countermeasures as no companies have announced planned use of the voucher.
 *****Funding and FTE levels for FYs 2018 - 2020 have been comparably adjusted to reflect the realignment of: intergovernmental affairs (IGA) FTE to FDA HQ; operational support FTE from FDA HQ to the centers and offices as part of implementation of FDA's Working Capital Fund (WCF); and FDA HQ organizations as per the December 2018 Congressional Notification.
 *****NCTR Food Safety project ending in FY 2019 and reallocated to Medical Product Safety in FY 2020.