

## FOOD AND DRUG ADMINISTRATION

### User Fee History

(Dollars in Thousands)

#### USER FEES: Appropriations

	FY 2005 Actual		FY 2006 Actual		FY 2007 Actual		FY 2008 Enacted		FY 2009 Estimate	
	FTE	\$	FTE	\$	FTE	\$	FTE	\$	FTE	\$
<b><u>Definite Appropriations:</u></b>										
<b>PDUFA</b>										
- <i>Human Drugs</i>	1,049	\$185,555	1,110	\$205,279	1,103	\$223,476	1,308	\$320,084	1,527	\$358,782
- <i>Biologics</i>	243	\$41,175	213	\$52,014	242	\$48,540	278	\$66,824	296	\$72,509
- <i>Office of Regulatory Affairs</i>	39	\$6,138	44	\$7,389	50	\$6,266	50	\$10,178	50	\$10,178
- <i>Headquarters and Office of the Commissioner</i>	124	\$14,020	114	\$14,829	121	\$16,042	135	\$29,531	137	\$32,203
- <i>GSA Rent</i>		\$11,212		\$14,100		\$9,001		\$23,498		\$18,691
- <i>Other Rent and Rent Related Activities</i>		\$8,334		\$7,000		\$7,000		\$9,297		\$16,000
- <i>FDA Consolidation at White Oak</i>		\$3,000		\$5,033		\$10,105		\$0		\$2,745
<b>Subtotal, PDUFA</b>	<b>1,455</b>	<b>\$269,434</b>	<b>1,481</b>	<b>\$305,644</b>	<b>1,516</b>	<b>\$320,430</b>	<b>1,771</b>	<b>\$459,412</b>	<b>2,010</b>	<b>\$511,108</b>
<b>MDUFMA</b>										
- <i>Medical Devices and Radiological Health</i>	108	\$15,492	130	\$19,838	151	\$22,329	146	\$26,647	146	\$28,911
- <i>Biologics</i>	22	\$5,260	26	\$5,452	28	\$5,731	31	\$10,109	31	\$10,968
- <i>Office of Regulatory Affairs</i>	8	\$966	8	\$1,123	8	\$1,182	9	\$1,434	9	\$1,556
- <i>Headquarters and Office of the Commissioner</i>	15	\$2,644	20	\$2,654	21	\$2,808	22	\$5,450	22	\$5,914
- <i>GSA Rent</i>		\$2,237		\$2,237		\$2,349		\$3,622		\$3,930



- Other Rent and Rent Related Activities									\$72	
Subtotal, Generic Animal Drug								22	\$4,831	
<b>Indefinite Appropriations:</b>										
<b>MQSA</b>										
- Devices and Radiological Health	26	\$4,373	26	\$4,784	21	\$4,141	26	\$5,717	26	\$6,003
- Office of Regulatory Affairs	8	\$8,586	8	\$8,980	8	\$9,457	8	\$12,454	8	\$13,077
- Headquarters and Office of the Commissioner	2	\$226	2	\$234	2	\$240	2	\$227	2	\$238
Subtotal, MQSA	36	\$13,185	36	\$13,998	31	\$13,838	36	\$18,398	36	\$19,318
Export Certification	8	\$1,425	13	\$2,033	18	\$2,732	18	\$2,500	18	\$2,600
Certification Fund	35	\$5,506	33	\$5,694	36	\$6,954	36	\$7,000	36	\$7,700
Total, User Fees	1,729	\$325,200	1,805	\$369,114	1,864	\$391,425	2,131	\$549,437	2,426	\$628,430

**USER FEES: Obligations**

	FY 2003 Actual		FY 2004 Actual		FY 2005 Actual		FY 2006 Actual		FY 2007 Actual	
	FTE	\$	FTE	\$	FTE	\$	FTE	\$	FTE	\$
<b>PDUFA:</b>										
- Human Drugs	742	\$125,103	972	\$162,653	1,049	\$185,555	1,110	\$205,279	1,103	\$223,476
- Biologics	269	\$44,959	217	\$40,170	243	\$41,175	213	\$52,014	242	\$48,540
- Office of Regulatory Affairs	41	\$5,629	41	\$5,808	39	\$6,138	44	\$7,389	50	\$6,266
- Headquarters and Office of the Commissioner	149	\$15,745	122	\$13,535	124	\$14,020	114	\$14,829	121	\$16,042
- GSA Rent		\$8,719		\$6,146		\$11,212		\$14,100		\$9,001
- Other Rent and Rent Related		\$0		\$3,770		\$8,334		\$7,000		\$7,000

<b>Activities</b>											
- White Oak											
		\$0		\$0		\$3,000		\$5,033		\$10,105	
Subtotal, PDUFA	1,201	\$200,155	1,352	\$232,082	1,455	\$269,434	1,481	\$305,644	1,516	\$320,430	
<b>MDUFMA</b>											
- Medical Devices and Radiological Health	14	\$10,661	100	\$17,253	108	\$15,492	130	\$19,838	151	\$22,329	
- Biologics	5	\$2,157	21	\$3,437	22	\$5,260	26	\$5,452	28	\$5,731	
- Office of Regulatory Affairs	4	\$449	6	\$676	8	\$966	8	\$1,123	8	\$1,182	
- Headquarters and Office of the Commissioner	10	\$1,071	10	\$1,142	15	\$2,644	20	\$2,654	21	\$2,808	
- GSA Rent		\$400		\$1,080		\$2,237		\$2,237		\$2,349	
- Other Rent and Rent Related Activities		\$100		\$287		\$562		\$765		\$803	
Subtotal, MDUFMA	33	\$14,838	137	\$23,875	153	\$27,161	184	\$32,069	208	\$35,202	
<b>ADUFA</b>											
- Animal Drugs and Feeds			3	\$983	39	\$7,538	54	\$8,264	51	\$10,969	
- Headquarters and Office of the Commissioner			0	\$0	3	\$384	4	\$493	4	\$522	
- GSA Rent				\$100		\$567		\$628		\$675	
- Other Rent and Rent Related Activities						\$0		\$291		\$103	
Subtotal, ADUFA				\$1,083	42	\$8,489	58	\$9,676	55	\$12,269	
<b>MQSA</b>	38	\$13,074	36	\$12,716	36	\$13,185	36	\$13,998	31	\$13,838	
Export Certification	13	\$1,663	11	\$1,806	8	\$1,425	13	\$2,033	18	\$2,732	
Certification Fund	32	\$7,855	35	\$6,128	35	\$5,506	33	\$5,694	36	\$6,954	
<b>Subtotal</b>	<b>83</b>	<b>\$22,592</b>	<b>82</b>	<b>\$20,650</b>	<b>79</b>	<b>\$20,116</b>	<b>82</b>	<b>\$21,725</b>	<b>85</b>	<b>\$23,524</b>	

<b>Total, FDA</b>	<b>1,317</b>	<b>\$237,585</b>	<b>1,571</b>	<b>\$277,690</b>	<b>1,729</b>	<b>\$325,200</b>	<b>1,805</b>	<b>\$369,114</b>	<b>1,864</b>	<b>\$391,425</b>
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**USER FEES: Collections**

	<b>FY 2005 Actual</b>	<b>FY 2006 Actual</b>	<b>FY 2007 Actual</b>	<b>FY 2008 Enacted</b>	<b>FY 2009 Estimate</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
<b>PDUFA Collections</b>	\$307,959	\$340,093	\$375,597	\$459,412	\$511,108
<b>MDUFMA Collections</b>	\$31,103	\$35,011	\$29,825	\$48,431	\$52,547
<b>ADUFA Collections</b>	\$8,302	\$11,018	\$13,472	\$13,696	\$13,698
<b>Generic Prescription Drug Collections</b>	\$0	\$0	\$0	\$0	\$16,628
<b>Generic Animal Drug Collections</b>	\$0	\$0	\$0	\$0	\$4,831
<b>MQSA Collections</b>	\$13,922	\$13,485	\$13,600	\$18,398	\$19,318
<b>Export Certification</b>	\$2,205	\$2,164	\$2,780	\$2,500	\$2,600
<b>Certification Fund</b>	\$5,926	\$6,633	\$6,640	\$7,000	\$7,700
<b>Total, User Fees Collections</b>	<b>\$369,417</b>	<b>\$408,405</b>	<b>\$441,914</b>	<b>\$549,437</b>	<b>\$628,430</b>