FDA User Fees—FY2017

	FY 2017	FY 2016	% Change
Animal drug user fee rates			
Animal drug application	$350,700	$351,100	-0.1
Supplemental animal drug application for which safety or effectiveness data are required	$175,350	$175,550	-0.1
Annual product fee	$8,195	$7,790	5.2
Annual establishment fee	$111,900	$105,950	5.6
Annual sponsor fee	$103,100	$101,000	2.1
Animal generic drug user fee rates			
Abbreviated generic animal drug application	$232,400	$233,330	-0.4
Abbreviated generic animal drug application (50% of application fee)	$116,200	$116,650	-0.4
Generic new animal drug product	$10,200	$8,705	17.2
Generic new animal drug sponsor paying 100% of the sponsor fee	$96,350	$83,800	15.0
Generic new animal drug sponsor paying 75% of the sponsor fee	$72,263	$62,850	15.0
Generic new animal drug sponsor paying 50% of the sponsor fee	$48,175	$41,900	15.0
Biosimilar user fee rates			
Initial biosimilar biological product development fee	$203,810	$237,420	-14.2
Annual biosimilar biological product development fee	$203,810	$237,420	-14.2
Reactivation fee	$407,620	$474,840	-14.2
Biosimilar biological product application requiring clinical data	$2,038,100	$2,374,200	-14.2
Biosimilar biological product application not requiring clinical data	$1,019,050	$1,187,100	-14.2
Biosimilar biological product supplement with clinical data	$1,019,050	$1,187,100	-14.2
Biosimilar biological product establishment fee	$512,200	$585,200	-12.5
Biosimilar biological product fee	$97,750	$114,450	-14.6
Generic drug user fee rates			
Abbreviated new drug application fee	$70,480	$76,030	-7.3
Prior approval supplement fee	$35,240	$38,020	-7.3
Drug master file fee	$51,140	$42,170	21.3
Domestic active pharmaceutical ingredient facility fee	$44,234	$40,867	8.2
Foreign active pharmaceutical ingredient facility fee	$59,234	$55,867	6.0
Domestic finished dosage form facility fee	$258,646	$243,905	6.0
Foreign finished dosage form facility fee	$273,646	$258,905	5.7
Medical device user fee rates (standard)			
Premarket application, premarket report, efficacy supplement	$234,495	$261,388	-10.3
Panel-track supplement	$175,871	$190,041	-7.5
180-day supplement	$35,174	$39,208	-10.3
Real-time supplement	$16,415	$18,297	-10.3
510(k) premarket notification submission	$4,690	$5,228	-10.3
30-day notice	$3,752	$4,182	-10.3
513(g) request for classification	$3,166	$3,529	-10.3
Annual fee for periodic reporting on a class III device	$8,207	$9,149	-10.3
Annual establishment registration	$3,382	$3,845	-12.0
Outsourcing facility fee rates			
Small business establishment fee	$5,279	$5,203	1.5
Non-small business establishment fee	$16,852	$16,465	2.3
Reinspection fee	$15,837	$15,610	1.5
Prescription drug user fee rates			
Application requiring clinical data	$2,038,100	$2,374,200	-14.2
Application not requiring clinical data	$1,019,050	$1,187,100	-14.2
Supplements requiring clinical data	$1,019,050	$1,187,100	-14.2
Establishments	$512,200	$585,200	-12.5
Products	$97,750	$114,450	-14.6