

4.2 – APPENDIX B: FEES, WAIVERS, AND REDUCTIONS

AGDUFA Fee History

AGDUFA established three fee categories and set fee revenues for each category. Based on the statutory revenues and estimated numbers of fees that would be paid in each category, FDA published the FY 2016 fee rates for all categories in August 2015.¹

The sponsor fee rate that a company qualifies for is based on the number of approved Abbreviated New Animal Drug Applications (ANADAs) that company held at the beginning of the fiscal year. Sponsors with one approved ANADA, or without any approved ANADAs, but with active generic investigational new animal drug submissions, qualify for the 50 percent sponsor fee rate. Sponsors with two to six approved ANADAs qualify for the 75 percent sponsor fee rate. Sponsors with more than six approved ANADAs qualify for the 100 percent sponsor fee rate.

Table 9 provides a history of fee rates for the past eight years.

TABLE 9: TRENDS IN SPONSOR FEES, PRODUCT FEES, AND APPLICATION FEE RATES

Fiscal Year	100% Sponsor Fee	75% Sponsor Fee	50% Sponsor Fee	Product Fee	Abbreviated Application Fee - Not Subject to Section 512(d)(4)	Abbreviated Application Fee - Subject to Section 512(d)(4)
2009	\$56,350	\$42,265	\$28,175	\$3,005	\$41,400	N/A
2010	\$54,050	\$40,537	\$27,025	\$3,255	\$75,000	N/A
2011	\$55,950	\$41,963	\$27,975	\$5,440	\$92,600	N/A
2012	\$54,350	\$40,763	\$27,175	\$6,200	\$124,900	N/A
2013	\$63,000	\$47,250	\$31,500	\$6,515	\$148,300	N/A
2014	\$72,800	\$54,600	\$36,400	\$8,035	\$177,900	\$88,950
2015	\$80,900	\$60,675	\$40,450	\$8,500	\$189,200	\$94,600
2016	\$83,800	\$62,850	\$41,900	\$8,705	\$233,300	\$116,650

¹ FDA published FY 2016 generic new animal drug user fee rates in the *Federal Register* on August 3, 2015 (80 FR 46012). <https://www.gpo.gov/fdsys/pkg/FR-2015-08-03/pdf/2015-18909.pdf>

AGDUFA Fees Forecasted Versus Actual Fee Paying Submissions

Table 10 summarizes the number and type of fees received by cohort year in comparison to what FDA estimated it would receive when the Agency established AGDUFA fees in the *Federal Register* (FR) notice for that cohort year. The actual numbers may change over time because of refunds or collection of open receivables. An additional billing will be sent for FY 2016 sponsor and product fees that were not included in the original billing. For that reason, the FY 2016 cohort is considered incomplete at this time.

TABLE 10: TRENDS IN FORECASTED VS. ACTUAL FEE PAYING SPONSORS, PRODUCTS, AND APPLICATIONS

Fiscal Year	Forecasted vs. Actual	Number of Sponsors	Number of Products	Number of Applications
2009	FR	30	563	35
	Actual	37	657	25
2010	FR	33	549	20
	Actual	38	402	14
2011	FR	34	347	18
	Actual	38	367	9
2012	FR	37	322	14
	Actual	44	369	25
2013	FR	34	324	12
	Actual	45	395	16
2014	FR	38	342	10
	Actual	45	426	10
2015	FR	38	364	11
	Actual	44	417	15
2016	FR	43	418	10
	Actual	43	397	6

Numbers are rounded to the nearest whole number

AGDUFA Waiver and Reductions History

AGDUFA directs FDA to waive or reduce one or more fees under AGDUFA upon request when FDA finds that the generic new animal drug is intended solely to provide for a minor use or minor species indication.

Table 11 summarizes the numbers and values of waivers and reductions granted by FDA under AGDUFA for fees payable in each FY since 2009; it also reflects the revenue that would otherwise have been collected by FDA.

**TABLE 11: WAIVERS AND REDUCTIONS GRANTED AND USED BY FEE CATEGORY
AS OF SEPTEMBER 30 FOR EACH FISCAL YEAR**

Minor Use / Species Waivers	Applications		Products		Sponsors				Total Value of Waivers Approved
	Waivers Approved	Value of Waivers Approved	Waivers Approved	Value of Waivers Approved	Sponsors (100%) Waivers Approved	Sponsors (75%) Waivers Approved	Sponsors (50%) Waivers Approved	Value of Waivers Approved	
FY 2009	0	\$0	1	\$3,005	0	0	1	\$28,175	\$31,180
FY 2010	0	\$0	1	\$3,255	0	0	2	\$54,050	\$57,305
FY 2011	0	\$0	2	\$10,880	0	0	2	\$55,950	\$66,830
FY 2012	0	\$0	2	\$12,400	0	0	2	\$54,350	\$66,750
FY 2013	0	\$0	1	\$6,515	0	0	1	\$31,500	\$38,015
FY 2014	0	\$0	1	\$8,035	0	0	1	\$36,400	\$44,435
FY 2015	0	\$0	3	\$25,500	0	0	1	\$40,450	\$65,950
FY 2016	0	\$0	3	\$26,115	0	0	1	\$41,900	\$68,015

Numbers have been rounded to the nearest dollar