4.2 – APPENDIX B: FEES, WAIVERS, AND EXEMPTIONS

PDUFA Fee History

PDUFA established three fee categories and set fee revenues for each category annually. 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.[2] Table 10 provides a history of fee rates for the past 10 years.

TABLE 10: TRENDS IN APPLICATION, ESTABLISHMENT, AND PRODUCT FEE RATES

Fiscal Year	Establishment Fee	Product Fee	Application Fee
2007	$313,100	$49,750	$896,200
2008	$392,700	$65,030	$1,178,000
2009	$425,600	$71,520	$1,247,200
2010	$457,200	$79,720	$1,405,500
2011	$497,200	$86,520	$1,542,000
2012	$520,100	$98,970	$1,841,500
2013	$526,500	$98,380	$1,958,800
2014	$554,600	$104,060	$2,169,100
2015	$569,200	$110,370	$2,335,200
2016	$585,200	$114,450	$2,374,200

[2] FDA published FY 2016 prescription drug user fee rates in the *Federal Register* on August 3, 2015 (80 FR 46028), https://www.gpo.gov/fdsys/pkg/FR-2015-08-03/pdf/2015-18914.pdf

PDUFA Fees Forecasted Versus Actual Fees Received

Table 11 depicts FDA's estimates of fee-paying units used in the *Federal Register* (FR) notices for setting PDUFA fees prospectively versus the actual number of fee-paying units received each year for the last 10 years. The application totals below represent full-application equivalents (FAEs).

A full application requiring clinical data counts as one FAE. An application not requiring clinical data counts as one-half of an FAE, as does a supplement requiring clinical data. An application that is withdrawn, or refused for filing, counts as one-fourth of an FAE if the applicant initially paid a full application fee, or one-eighth of an FAE if the applicant initially paid one-half of the full application fee amount.

FDA updates prior-year "actual numbers" annually after the clean-up billing process, which is why FY 2015 actual numbers are different in this year's financial report.

Fees collected in FY 2016 do not include clean-up billing in FY 2017. Therefore, these numbers will be updated in next year's financial report.

TABLE 11: TRENDS IN FORECASTED VS. ACTUAL FEE-PAYING APPLICATIONS, ESTABLISHMENTS, AND PRODUCTS

Fiscal Year	Forecasted vs. Actual	Establishment Fees	Product Fees	Application Fees
2007	FR	375	2,360	131
	Actual	416	2,381	134
2008	FR	390	2,355	130
	Actual	429	2,426	140
2009	FR	400	2,380	137
	Actual	418	2,347	140
2010	FR	415	2,380	135
	Actual	439	2,457	118
2011	FR	415	2,385	134
	Actual	457	2,451	101
2012	FR	450	2,365	127
	Actual	461	2,464	122
2013	FR	455	2,435	122
	Actual	476	2,401	120
2014	FR	455	2,425	116
	Actual	465	2,487	133
2015	FR	472	2,434	115
	Actual	477	2,532	128
2016	FR	485	2,480	120
	Actual	468	2,321	134

PDUFA Waiver and Exemption History

Fees may be waived or reduced under the waiver provisions of the statute. PDUFA directs FDA to waive or reduce fees in five different circumstances:

- when a waiver is necessary to protect the public health;
- when a fee is a significant barrier to innovation;
- when the fees paid exceed FDA's costs of reviewing a firm's prescription drug applications;
- when imposition of the fee creates an inequity between certain 505(b)(1) and 505(b)(2) prescription drug applications (this waiver provision was omitted in PDUFA III and subsequent reauthorizations); and
- when a sponsor withdraws a pending prescription drug application after FDA has filed it, but before FDA has performed substantial work on the marketing application.

Beginning in FY 1998, PDUFA II also provided a waiver, for certain small businesses, of the full application fee for the first application submitted. In addition, other exemptions from application fees were added beginning in FY 1998. These specific exemptions are automatic and do not require a waiver request. They include the following:

- prescription drug applications for designated orphan products (designated for rare diseases or conditions affecting fewer than 200,000 patients in the United States); and
- supplemental applications for pediatric use indications (statutorily repealed by section 5 of Public Law 107-109, effective January 4, 2002).

The increased number of exemptions required by PDUFA II reduced the number of fee-paying applications. Many of the application fee waiver requests FDA received through FY 1997 pertained to orphan products; since designated orphan products are now given automatic exemptions, the number of waiver requests for application fees has decreased substantially.

Beginning in FY 2008, PDUFA IV provided exemptions for product and establishment fees for certain approved orphan products (see 21 USC § 379h(k)).

Table 12 summarizes the waivers granted by FDA for PDUFA fees payable in the 10 most recent fiscal years. FDA annually updates these amounts to include fees collected subsequent to the prior PDUFA financial report.

TABLE 12: TOTAL WAIVERS AS OF SEPTEMBER 30, 2016

Waivers	Applications			Products		Establishments		Total Value of Waivers Approved
	Small Business Waivers	Miscellaneous Waivers (Includes PEPFAR[3])	Value of Waivers Approved	Waivers Approved	Value of Waivers Approved	Waivers Approved	Value of Waivers Approved	
FY 2007	14.0	14.0	$25,093,600	25.8	$1,283,844	13.1	$4,095,372	$30,472,816
FY 2008	26.0	21.0	$55,366,000	17.1	$1,112,130	7.8	$3,053,420	$59,531,550
FY 2009	17.0	10.0	$33,674,400	20.9	$1,494,443	2.9	$1,215,818	$36,384,660
FY 2010	21.4	13.1	$48,520,696	15.9	$1,265,807	5.7	$2,621,489	$52,407,992
FY 2011	16.5	8.5	$38,550,000	29.4	$2,541,739	4.7	$2,345,858	$43,437,596
FY 2012	17.0	5.0	$40,513,000	12.0	$1,187,640	7.3	$3,812,333	$45,512,973
FY 2013	11.5	10.5	$43,093,600	20.0	$1,967,600	6.6	$3,480,750	$48,541,950
FY 2014	16.5	5.0	$46,635,650	21.7	$2,262,682	8.8	$4,898,967	$53,797,298
FY 2015	22.0	4.0	$60,715,200	23.0	$2,538,510	8.4	$4,782,610	$68,036,320
FY 2016	10.5	9.0	$46,296,900	1.0	$114,450	0.2	$97,533	$46,508,883

Numbers have been rounded to the nearest dollar

[3] PEPFAR refers to applications excluded from fees under the President's Emergency Plan for AIDS Relief.

Table 13 summarizes orphan exemptions from PDUFA fees payable in the 10 most recent fiscal years. It includes exempt orphan application fees in FY 2016. To ensure the quality of the information provided in this financial report, FDA annually updates numbers from prior years as appropriate.

TABLE 13: TOTAL ORPHAN EXEMPTIONS AS OF SEPTEMBER 30, 2016

Exemptions	Applications		Products		Establishments		Total Value of Exemptions
	Exempt Orphan Application Fees	Value of Exemptions	Exempt	Value of Exemptions	Exempt Orphan Establishment Fees	Value of Exemptions	
FY 2007	21.3	$19,044,250	-	-	-	-	$19,044,250
FY 2008	27.8	$32,689,500	14.0	$910,420	5.2	$2,056,963	$35,656,883
FY 2009	23.8	$29,621,000	16.0	$1,144,320	7.4	$3,169,869	$33,935,189
FY 2010	21.8	$30,569,625	28.0	$2,232,160	11.5	$5,252,314	$38,054,099
FY 2011	33.0	$50,886,000	33.0	$2,855,160	16.0	$7,976,082	$61,717,242
FY 2012	36.6	$67,306,825	30.0	$2,969,100	12.1	$6,311,414	$76,587,339
FY 2013	35.1	$68,802,850	51.0	$5,017,380	18.2	$9,591,953	$83,412,183
FY 2014	38.5	$83,510,350	38.0	$3,954,280	16.3	$9,050,702	$96,515,332
FY 2015	60.0	$140,112,000	30.0	$3,311,100	15.7	$8,918,795	$152,341,895
FY 2016	48.5	$115,148,700	26.0	$2,975,700	12.6	$7,367,083	$125,491,483

Numbers have been rounded to the nearest dollar