

4.2 – APPENDIX B: FEES, WAIVERS, AND REDUCTIONS

ADUFA Fee History

ADUFA III established four 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 Table 9 provides a history of fee rates for the past 10 years.

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

| Fiscal Year | Establishment Fee | Sponsor Fee | Product Fee | Application Fee | Supplemental Application Fee |
|-------------|-------------------|-------------|-------------|-----------------|------------------------------|
| 2007 | \$51,350 | \$44,850 | \$4,115 | \$168,600 | \$84,300 |
| 2008 | \$52,700 | \$43,900 | \$4,125 | \$172,500 | \$86,250 |
| 2009 | \$59,450 | \$52,700 | \$4,925 | \$246,300 | \$123,150 |
| 2010 | \$73,850 | \$57,100 | \$6,185 | \$290,400 | \$145,200 |
| 2011 | \$83,100 | \$64,000 | \$7,235 | \$316,200 | \$158,100 |
| 2012 | \$93,050 | \$67,200 | \$7,935 | \$372,100 | \$186,050 |
| 2013 | \$104,600 | \$87,700 | \$8,640 | \$435,200 | \$217,600 |
| 2014 | \$105,800 | \$101,150 | \$9,075 | \$396,600 | \$198,300 |
| 2015 | \$104,150 | \$94,450 | \$8,075 | \$400,600 | \$200,300 |
| 2016 | \$105,950 | \$101,000 | \$7,790 | \$351,100 | \$175,550 |

¹ FDA published FY 2016 animal drug user fee rates in the *Federal Register* on August 3, 2015 (80 FR 45993) <https://www.gpo.gov/fdsys/pkg/FR-2015-08-03/pdf/2015-18913.pdf>

ADUFA 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 ADUFA fees in the *Federal Register* (FR) over the past 10 years. The actual numbers may change over time because of refunds or collection of open receivables. An additional billing will be sent for FY 2016 establishment, 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 APPLICATIONS, ESTABLISHMENTS, AND PRODUCTS

| Fiscal Year | Forecasted vs. Actual | Number of Establishments | Number of Sponsors | Number of Products | Number of Applications |
|-------------|-----------------------|--------------------------|--------------------|--------------------|------------------------|
| 2007 | FR | 55 | 63 | 686 | 17 |
| | Actual | 59 | 64 | 766 | 26 |
| 2008 | FR | 54 | 65 | 690 | 17 |
| | Actual | 60 | 73 | 790 | 12 |
| 2009 | FR | 59 | 66 | 707 | 14 |
| | Actual | 59 | 67 | 785 | 10 |
| 2010 | FR | 59 | 76 | 698 | 15 |
| | Actual | 61 | 63 | 773 | 13 |
| 2011 | FR | 59 | 76 | 672 | 15 |
| | Actual | 57 | 63 | 754 | 11 |
| 2012 | FR | 59 | 81 | 686 | 15 |
| | Actual | 56 | 61 | 749 | 14 |
| 2013 | FR | 57 | 68 | 690 | 14 |
| | Actual | 55 | 62 | 725 | 7 |
| 2014 | FR | 58 | 63 | 702 | 12 |
| | Actual | 53 | 54 | 836 | 22 |
| 2015 | FR | 55 | 63 | 737 | 11 |
| | Actual | 56 | 60 | 885 | 15 |
| 2016 | FR | 56 | 61 | 791 | 13 |
| | Actual | 52 | 59 | 771 | 20 |

Numbers are rounded to the nearest whole number

ADUFA Waiver and Exemption History

ADUFA III directs FDA to waive or reduce fees in five different circumstances, upon request, when the Agency finds that:

- the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances;
- the fees to be paid by such person will exceed the anticipated present and future costs incurred by FDA in conducting the process for the review of animal drug applications for such person;
- the animal drug application or the supplemental animal drug application is intended solely to provide for use of the animal drug in a free-choice medicated feed;
- the animal drug application or the supplemental animal drug application is intended solely to provide for a minor use or minor species indication; or
- the sponsor involved is a small business submitting its first animal drug application to FDA for review.

Table 11 summarizes the waivers and the reductions granted by FDA for fees payable, as well as the value of each waiver or reduction granted by cohort year over the past 10 years. Information for the FY 2016 Fees Exceed Costs waivers was not complete at the end of FY 2016. It will be reported in the FY 2017 ADUFA Financial Report.

**TABLE 11: WAIVERS AND REDUCTIONS GRANTED AND USED BY FEE CATEGORY
AS OF SEPTEMBER 30, 2016**

| Waivers | Types of Waivers | | | | | Total Waivers | Value of Waivers Approved by Fee Category | | | | Total Value of Waivers Approved |
|---------|--|------------------------------------|------------------------------------|---|---------------------------------|---------------|---|-----------|----------------|--------------|---------------------------------|
| | Significant Barrier to Innovation Waivers Approved | Fees Exceed Costs Waivers Approved | Free Choice Feeds Waivers Approved | Minor Use or Minor Species Waivers Approved | Small Business Waivers Approved | | Applications | Products | Establishments | Sponsors | |
| FY 2007 | 25 | 7 | 4 | 67 | 1 | 104 | \$674,400 | \$61,725 | \$308,100 | \$3,543,150 | \$4,587,375 |
| FY 2008 | 25 | 13 | 2 | 57 | 1 | 98 | \$86,250 | \$61,875 | \$158,100 | \$3,073,000 | \$3,379,225 |
| FY 2009 | 36 | 11 | 2 | 66 | 1 | 116 | \$985,200 | \$78,800 | \$356,700 | \$4,743,000 | \$6,163,700 |
| FY 2010 | 43 | 10 | 3 | 72 | 3 | 131 | \$871,200 | \$105,145 | \$516,950 | \$5,938,400 | \$7,431,695 |
| FY 2011 | 43 | 33 | 6 | 72 | 1 | 155 | \$1,264,800 | \$209,815 | \$747,900 | \$7,552,000 | \$9,774,515 |
| FY 2012 | 40 | 31 | 5 | 77 | 6 | 159 | \$3,348,900 | \$206,310 | \$651,350 | \$7,862,400 | \$12,068,960 |
| FY 2013 | 40 | 33 | 5 | 74 | 1 | 153 | \$1,305,600 | \$259,200 | \$836,800 | \$9,822,400 | \$12,224,000 |
| FY 2014 | 52 | 29 | 5 | 73 | 0 | 159 | \$594,900 | \$190,575 | \$740,600 | \$13,048,350 | \$14,574,425 |
| FY 2015 | 49 | 24 | 6 | 71.5 | 0 | 150.5 | \$1,001,500 | \$177,650 | \$520,750 | \$11,428,450 | \$13,128,350 |
| FY 2016 | 62 | - | 5 | 69 | 1 | 137 | \$2,808,800 | \$54,530 | \$0 | \$12,322,000 | \$15,185,330 |

Numbers have been rounded to the nearest dollar