

APPENDIX C: WAIVERS AND REDUCTIONS GRANTED

ADUFA II directs FDA to waive or reduce fees in five different circumstances when:

- 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.

Tables 8 and 9 summarize the waivers and the reductions granted by FDA for fees payable, as well as the value of each waiver or reduction granted.

TABLE 8: WAIVERS AND REDUCTIONS GRANTED AND USED BY FEE CATEGORY IN FY 2013 AND FY 2012 AS OF SEPTEMBER 30, 2013 AND 2012

REASON	APPLICATION & SUPPLEMENT	PRODUCT	ESTABLISHMENT	SPONSOR	TOTAL
Significant Barrier to Innovation	0	0	0	38	38
Free Choice Feeds	0	0	0	5	5
Minor Use or Minor Species	2	14	2	55	73
Small Business	1	0	0	0	1
FY 2013 TOTAL	3	14	2	98	117
Significant Barrier to Innovation	0	0	0	35	35
Free Choice Feeds	0	0	0	5	5
Minor Use or Minor Species	3	9	2	57	71
Small Business	6	0	0	0	6
FY 2012 TOTAL	9	9	2	97	117

TABLE 9: VALUE OF WAIVERS AND REDUCTIONS GRANTED AND USED IN FY 2013 AS OF SEPTEMBER 30, 2013

FEE CATEGORY	FEE RATE	NUMBER	VALUE
Full Application Fee	\$435,200	3	\$1,305,600
Half Application Fee	\$217,600	0	\$0
Products	\$8,640	14	\$120,960
Establishments	\$104,600	2	\$209,200
Sponsors	\$87,700	98	\$8,594,600
TOTAL		117	\$10,230,360

The value of waivers and reductions presented in Table 9 reflects fees that were due and payable in FY 2013, and revenue that would otherwise have been collected by FDA.

In addition to the waivers and reductions shown in Table 9 there were 9 sponsor waivers issued for the FY 2012 Clean-up billing cycle (these waivers are for FY 2012 invoices but granted in FY 2013). For FY 2012 Fees Exceed Cost Waivers and Reductions there were 9 Sponsors, 17 Products, and 5 Establishment waivers issued.

In FY 2013, FDA denied 15 requests for sponsor fee waiver and reduction.