

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 9 and 10 summarize the waivers and the reductions granted by FDA for fees payable in FY 2012, as well as the value of each waiver or reduction granted. Please note that the waivers and the reductions granted in the tables below are for cohort year 2012 only.

**TABLE 9
WAIVERS AND REDUCTIONS GRANTED AND USED BY FEE CATEGORY IN FY 2012
AS OF SEPTEMBER 30, 2012**

REASON	APPLICATION & SUPPLEMENT	PRODUCT	ESTABLISHMENT	SPONSOR	TOTAL
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
TOTAL	9	9	2	97	117

TABLE 10
VALUE OF WAIVERS AND REDUCTIONS GRANTED AND USED IN FY 2012
AS OF SEPTEMBER 30, 2012

FEE CATEGORY	FEE RATE	NUMBER	VALUE
Full Application Fee	\$372,100	9	\$3,348,900
Half Application Fee	\$186,050	0	\$0
Products	\$7,935	9	\$71,415
Establishments	\$93,050	2	\$186,100
Sponsors	\$67,200	97	\$6,518,400
TOTAL		117	\$10,124,815

The value of waivers and reductions presented in Table 10 were fees that were due and payable in FY 2012, and reflect revenue that would otherwise have been collected by FDA.

In addition to the waivers and reductions shown in Table 10 there were 14 sponsor waivers issued for the FY 2011 Clean-up billing cycle. For FY 2011 Fees Exceed Cost Waivers and Reductions there were nine Sponsors, 18 Products and six Establishment waivers issued.

In FY 2012, FDA denied three requests for sponsor fee waiver and reduction.