

2.4 – DESCRIPTION OF THE HIRING AND PLACEMENT OF NEW STAFF

In FY 2016, 7 full-time equivalents (FTEs) in the Center for Drug Evaluation and Research (CDER) were supported by outsourcing facility fees. This is a small fraction of the full level of effort required to support oversight of outsourcing facilities during FY 2016 (55 FTEs).

Table 4 presents total fee-paid FTE levels that supported outsourcing facility oversight by FDA organizational components for FY 2015 and 2016. The table displays data for CDER, the Office of Regulatory Affairs (ORA), and FDA Headquarters (HQ).

Due to a system upgrade that was in progress at the end of FY 2015, the typical data for that year's FTE calculations was unavailable. FDA had to estimate the breakdown for FY 2015 using an alternative methodology based on high-level FTEs. In FY 2016, after the system upgrade was complete, FDA was able to return to the normal methodology. In addition, beginning in FY 2015, the calculation to determine the allocation of shared services FTEs among programs was amended to more accurately estimate labor hours expended on CQA activities. This recalculation includes the addition of the Office of Human Resources and a restructuring of the activities related to the Office of Information Management.

TABLE 4: FTEs DEVOTED TO THE OVERSIGHT OF OUTSOURCING FACILITIES PAID FOR BY FEES AS OF SEPTEMBER 30, 2016 OF EACH FISCAL YEAR

| Fiscal Year | CDER | ORA | HQ | Total |
|-------------|------|-----|----|-------|
| 2015 | 2 | 0 | 0 | 2 |
| 2016 | 7 | 0 | 0 | 7 |

Numbers have been rounded to the nearest FTE