4.4 – APPENDIX D: DEVELOPMENT OF COSTS FOR THE MDUFA PROGRAM

General Methodology

The costs associated with the MDUFA program are based on obligations attributed to CDRH, CBER, ORA, and HQ. These organizations correspond to the cost categories presented as follows:

Cost Category	FDA Organization
Costs for the Review of PMAs, PDPs, PMRs, Modular PMAs, Supplements, and 510(k)s	CDRH
Costs for the Review of BLAs, PMAs, Modular PMAs, Supplements, and 510(k)s	CBER
Field Inspection and Investigation Costs	ORA
Agency General and Administrative Costs	HQ

The costs for each component are shown in Table 6. They were derived using time-reporting systems in CDRH, CBER, and ORA, and were calculated for HQ as described in more detail in this appendix. Using the definitions of costs and activities included in the MDUFA program, as explained in the discussion in Appendix C, the cost categories within each organization listed above were identified as parts of the medical device review process.

Center Costs

Costs of the MDUFA program are tracked for each organizational component in CDRH and CBER, usually at the division level. Most FDA components involved in the MDUFA program perform a mixture of activities – some within the scope of the MDUFA program, and some not. FDA groups its organizational components into three categories:

- direct review and laboratory
- indirect review and support
- Center-wide costs

The allocation of costs for each category is discussed below.

Direct Review and Laboratory

Employees in all components of CDRH and CBER, other than those noted below as Center indirect review and support components, reported their time in activities that could be used to differentiate between time spent on the MDUFA program and all other time.

Both CDRH and CBER have existing time-reporting systems in place. These time-reporting systems were modified after the enactment of MDUFA, and over the years when necessary, so that time could be reported in categories that could be separated into allowable and excluded

activities with respect to the MDUFA program, as defined in MDUFA and as further defined in Appendix C.

The percent of time reported as having been expended on allowable device review process activities for each cost-center (usually an organization component at the Division level) is then applied to all costs incurred for that cost-center for the entire fiscal year.

In 2013, CDRH updated the majority of its time reporting codes to better align with the new workload outlined in MDUFA III. The new codes reflect areas of interest to the medical device industry and other stakeholders. In addition to these updates, CDRH refined codes to better reflect the included activities for the MDUFA program. After this update, CDRH conducted its time reporting survey for a 2-week period during each quarter of the fiscal year. The costs of the medical device review program presented in this report are based on the updated time reporting codes.

A similar procedure is used in CBER to measure the direct review and laboratory components costs for the device review process. CBER's process for determining allowable and excluded costs for MDUFA direct review and laboratory costs is identical to how CBER determines costs for the process for the review of human drug applications. CBER uses the time-reporting system it has had in place for over 10 years prior to the enactment of MDUFA, and which was validated by studies done prior to, and after, the Prescription Drug User Fee Act (PDUFA) was enacted in 1992. That system collects time reports from all employees other than management and administrative support personnel for a 2-week period during each quarter of the fiscal year. This process was validated by Arthur Andersen, LLP under PDUFA for 1992 and 1993.

CBER's existing time-reporting system was also modified to ensure that activities against which time was reported could be clearly divided into activities that were either allowable or excluded in the MDUFA-defined process for device application review. The results from each 2-week period are extrapolated for the quarter being reported. The extrapolated results for each quarter are averaged to estimate the full year costs.

Indirect Review and Support

Indirect review and support components provide the infrastructure for the review process. In CDRH, these are the Office of the Center Director and the Office of Management and Operations. In CBER, these components include the Office of the Center Director, Office of Management, and the Office of Communications, Outreach, and Development.

In both CDRH and CBER, the allowable costs for these indirect review and support components were determined by multiplying the average percent of allowable costs for all direct review and laboratory components by the total costs of each of these indirect review and support components.

Center-Wide Costs

A number of Center-wide and Agency-wide expenses are paid from the central accounts of the Center or of FDA rather than from funds allocated to a specific Center or division or office within the Center. These costs include rent, telecommunications and utility costs, some computer equipment and support costs, and costs of the Office of Shared Services, which supports all FDA programs and activities. A percentage of these Center and FDA-wide costs are chargeable to the MDUFA program. That percentage is a specific amount that either is

supported by independent documentation or is the amount of time reported for allowable activities (direct and indirect) in the Center, as a percentage of total time reported for all Center direct and indirect activities.

As in prior years, resources expended in FY 2016 by the Office of Shared Services in supporting the MDUFA program are reported as if they were incurred in CDRH, CBER, ORA, or HQ.

Field Inspection and Investigation Costs

ORA incurs all field inspection, investigation, and laboratory analyses costs. ORA costs are incurred in both district offices (the "field") and HQ offices, which are tracked in the Field Accomplishment and Compliance Tracking System (FACTS). FACTS is a time and activity tracking system that captures time spent in a variety of categories, including pre-approval inspections of manufacturing facilities, investigations of clinical studies, and analytical testing of samples, which are all part of the MDUFA program.

Table 14 summarizes the calculation of ORA costs for the MDUFA program for FY 2015 and FY 2016, including costs paid from non-user fee appropriations and costs paid from fee revenues.

Total direct hours reported in FACTS are used to calculate the total number of FTEs required by ORA to perform these activities. In addition to the direct time, an allocation of support time is also included to represent the work done by ORA administrative and management personnel.

The Agency multiplies the total number of FTEs used in the MDUFA program by the average salary and benefits cost in ORA to arrive at ORA salary and benefit costs for work that is within the scope of the MDUFA program. The Agency then allocates ORA obligations for operations and other costs to the medical device review activities based upon the ratio of user-fee-related FTEs to total ORA FTEs.

TABLE 14: OFFICE OF REGULATORY AFFAIRS COSTS OF THE MDUFA PROGRAM AS OF SEPTEMBER 30, 2015 AND 2016

Cost Component	FY 2015	FY 2016
FTE Utilized	56	59
ORA Average Salary and Benefits	$124,714	$124,404
Total Salary and Benefits	$7,023,126	$7,339,836
Operating and Other Costs[4]	$6,289,111	$6,300,252
Total	**$13,312,237**	**$13,640,088**

Numbers have been rounded to the nearest dollar

[4] Other costs are central, GSA, rent, rent-related, and Shared Services costs that are applicable to the MDUFA program.

Agency General and Administrative Costs

The Agency general and administrative costs include all costs incurred in FDA's HQ that are attributable to the Office of the Commissioner and all other FDA headquarters components that are not Centers or ORA. For the purpose of these calculations, HQ is considered to comprise the following offices:

- Immediate Office of the Commissioner
- Office of the Counselor to the Commissioner
- Office of Policy, Planning, Legislation, and Analysis
- Office of External Affairs
- Office of the Executive Secretariat
- Office of the Chief Counsel
- Office of Minority Health
- Office of Women's Health
- Office of the Chief Scientist (excluding the National Center for Toxicological Research)
- Office of Operations
- Office of Foods and Veterinary Medicine (excluding the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine)
- Office of Medical Products and Tobacco (excluding the Center for Drug Evaluation and Research, CBER, CDRH, and the Center for Tobacco Products)
- Office of Global Regulatory Operations and Policy (excluding ORA)

In summary, the HQ costs include all of FDA except for the six product-oriented Centers, ORA, and the National Center for Toxicological Research.

The HQ costs applicable to the MDUFA program were calculated using a method prescribed by the Division of Cost Determination Management, Office of Finance, Office of the Secretary, Department of Health and Human Services. The method uses the percentage derived by dividing total HQ costs by the total FDA salary expenses (excluding benefits) after subtracting the salary expense (excluding benefits) from HQ. That percentage is then multiplied by the total salaries (excluding benefits) applicable to the MDUFA program in CDRH, CBER, and ORA to derive the applicable Agency general and administrative costs.

Using this methodology, FDA dedicated $31,319,784 in general and administrative costs to the MDUFA program in FY 2016. The costs are total costs obligated from non-user fee appropriations and user fees and are approximately 8 percent of the total costs of the MDUFA program in FY 2016.