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

General Methodology

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

Cost Category	FDA Organization
Costs for the Review of NDAs, BLAs, and Supplements	CDER
Costs for the Review of NDAs, BLAs, and Supplements	CBER
Field Inspection and Investigation Costs	ORA
Agency General and Administrative Costs	HQ

The costs for each component are shown in Table 7. They were derived using time-reporting systems in CDER, 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 PDUFA program, as explained in the discussion in Appendix C, the cost categories within each organization listed above were identified as parts of the human drug application review process.

Center Costs

Costs of the PDUFA program are tracked for each organizational component in CDER and CBER, usually at the division level. Most FDA components involved in the PDUFA program perform a mixture of activities—some within the scope of the PDUFA 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 CDER and CBER, other than those noted below as Center indirect review and support components, are required to report their time for a total of 8 weeks (2 weeks per quarter) each fiscal year in activity-based time reporting systems. The activities in the systems allow identification of the nature of the activity so that time reported can be separated into allowable and excluded activities as defined by PDUFA.

The average percentage of time reported on the PDUFA program in CDER and CBER is applied to all costs incurred for the entire fiscal year in those Centers. This method provides an estimate of each Center's costs incurred while conducting the PDUFA program in FY 2016.

Indirect Review and Support

Indirect review and support components provide the infrastructure for the review process. In CDER, these components include the Office of the Center Director, the Office of Management, the Office of Communications, portions of the Office of Executive Programs, and the Office of Strategic Programs. In CBER, these components include portions of the Office of the Center Director, Office of Management, and the Office of Communications, Outreach and Development. Most employees of these components do not report their time.

FDA assumes the time of management and administrative personnel supporting the PDUFA program is equivalent to the proportion of time Center employees in direct review and laboratory components spend on human drug review activities. Thus, the average percentage of time expended on human drug review activities for all direct review and laboratory components in FY 2016 was applied to all costs incurred for the entire fiscal year by the 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 PDUFA 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 PDUFA program are reported as if they were incurred in CDER, 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 headquarters 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 PDUFA program.

Table 14 summarizes the calculation of ORA costs for the PDUFA program for FY 2015 and FY 2016.

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 PDUFA 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 PDUFA program.

The Agency then allocates ORA obligations for operations and other costs to the human drug review activities based upon the ratio of user fee related FTEs to total ORA FTEs.

ORA costs for the PDUFA program described below include costs paid from non-user fee appropriations and costs paid from fee revenues.

TABLE 14: ORA COSTS OF THE PDUFA PROGRAM AS OF SEPTEMBER 30, 2015 AND 2016

Cost Component	FY 2015	FY 2016
FTE Utilized	125	157
ORA Average Salary and Benefits	$124,714	$124,404
Total Salary and Benefits	$15,570,436	$19,531,428
Operating and Other Costs[4]	$15,145,890	$20,982,379
Total	**$30,716,326**	**$40,513,807**

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 PDUFA 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 CDER, CBER, the Center for Devices and Radiological Health, 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 PDUFA 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 PDUFA program in CDER, CBER, and ORA to derive the applicable Agency general and administrative costs.

Using this methodology, FDA dedicated $87,636,234 in general and administrative costs to the PDUFA program in FY 2016. The costs are total costs obligated from appropriations and user fees. FDA strives to maintain a low overhead cost for the PDUFA program. General and administrative costs are approximately 8 percent of the FY 2016 PDUFA program costs.