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

General Methodology

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

Cost Category	FDA Organization
Costs for the Review of ANADAs, Supplemental Abbreviated applications and Investigational Submissions for Generic New Animal Drugs	CVM
Costs for Field Pre-approval Inspection and Investigation	ORA
Costs for Agency General and Administrative Activities	HQ

The costs for each component are shown in Table 6. They were derived using time-reporting systems in CVM 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 AGDUFA program, as explained in the discussion in Appendix C, the cost categories within each organization listed above were identified as parts of the generic new animal drug application review process.

Center Costs

Costs of the AGDUFA program are tracked for each organizational component in CVM, usually at the division level. Most CVM divisions involved in the generic new animal drug review process perform a mixture of activities – some within the scope of AGDUFA program, and some not. CVM groups its organizational components into three categories:

- Direct process activities, such as submission-specific work;
- Indirect process and support activities, such as standard operating procedures and application review support; and
- Center-wide support activities.

CVM's Activity Time Reporting (ATR) System supports the allocations for all three areas.

CVM's ATR

Using the Activity Dictionary in conjunction with the definition of the "process for the review of abbreviated applications for generic new animal drugs" in AGDUFA, CVM was able to attribute activity time reported by its employees to direct and indirect process and support activities as distinguished from non-process activities. These activity definitions are consistent with the allowable costs for the AGDUFA program as detailed in Appendix C.

Center-Wide Costs and Agency-Wide Expenses

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-wide and FDA-wide costs are chargeable to the AGDUFA 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 AGDUFA program are reported as if they were incurred in CVM, 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 which 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 AGDUFA program.

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 the ORA administrative and management personnel. The Agency then multiplies the total number of FTEs used in the AGDUFA program by the average salary cost in ORA to arrive at the ORA salary costs for work that is within the scope of the AGDUFA program. The final step is to allocate ORA obligations for operations and rent to the AGDUFA program based upon the ratio of user fee-related FTEs to total ORA FTEs.

Table 12 summarizes the calculation of ORA costs for the AGDUFA program for FY 2015 and FY 2016.

ORA costs for the AGDUFA program include 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.

FDA multiplies the total number of FTEs used in the AGDUFA 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 AGDUFA program. FDA then allocates ORA obligations for operations and other costs to the generic new animal drug review activities based upon the ratio of user fee-related FTEs to total ORA FTEs.

TABLE 12: OFFICE OF REGULATORY AFFAIRS COSTS OF THE AGDUFA PROGRAM AS OF SEPTEMBER 30, 2015 AND 2016

Cost Component	FY 2015	FY 2016
FTE Utilized	2.0	1.2
ORA Average Salary and Benefits	$124,714	$124,404
Total Salary and Benefits	$249,428	$149,285
Operating and Other Costs[2]	$204,991	$312,073
Total	**$454,419**	**$461,358**

Numbers have been rounded to the nearest dollar

[2] Other costs are central, GSA, rent, rent-related, and Shared Services costs that are applicable to the AGDUFA 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, the Center for Biologics Evaluation and Research, 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 AGDUFA 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 AGDUFA program in CVM and ORA to derive the applicable Agency general and administrative costs. Using this methodology, FDA dedicated $1,323,043 in general and administrative costs to the AGDUFA program in FY 2016. The costs are total costs obligated from non-user fee appropriations and user fees. FDA strives to maintain a low overhead cost for the AGDUFA program. General and administrative costs are approximately 9 percent of the FY 2016 AGDUFA program costs.