

**DEVELOPMENT OF COSTS FOR THE PROCESS FOR  
THE REVIEW OF ANIMAL DRUG APPLICATIONS**

**GENERAL METHODOLOGY**

The costs associated with the process for the review of animal drug applications are based on obligations recorded within FDA’s CVM, ORA, and FDA’s Headquarters (HQ), formerly known as the Office of the Commissioner. These organizations correspond to the cost categories presented as follows:

<u>Cost Category</u>	<u>FDA Organization</u>
Costs for the Review of NADAs, Supplemental Animal Drug Applications and INADs	CVM
Costs for Field Pre-approval Inspection and Investigation	ORA
Costs for Agency General and Administrative	HQ

The costs for each component are shown in Table 6 on page 10. These costs were derived mostly from 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 process for the review of animal drug applications in ADUFA, as explained in the discussion in Appendix D, the cost categories within each organization listed above were identified as parts of the animal drug review process.

**CENTER COSTS**

Costs of the animal drug application review program are tracked for each organizational component in CVM, usually at the division level. Most CVM divisions involved in the new animal drug review process perform a mixture of activities – some within the definition of the process for the review of new animal drug applications, 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 animal drug applications in ADUFA, 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 process of the review of animal drug applications as detailed in Appendix D.

## **CENTER-WIDE 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 for facilities that house CVM staff, telecommunications and utility costs, some computer equipment and support costs, and costs of the Office of Shared Services (OSS), which supports all FDA programs and activities. For these center- and Agency-wide costs, a percentage of them are chargeable to the process for the review of animal drug applications. That percentage is either a specific amount that 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.

In support of the President's Management Agenda and the Secretary's Goal of "One-HHS," FDA was requested to consolidate its administrative functions (including facilities, procurement, finance, equal employment opportunity, and information technology services) to carry out more efficient realignment of the resources, which would provide high quality administrative services from a single organization. FDA created an OSS in FY 2004. It combined the support responsibilities and resources previously located both in the centers and in HQ, and ensured effective and efficient services in a competitive market environment. In this report, resources expended by the OSS in supporting the new animal drug review process are reported as if they were incurred in CVM, ORA, or HQ, for comparability to the FY 2003 base year.

## **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 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 review process for animal drug applications.

Total direct hours reported in FACTS are used to calculate the total number of staff-years 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 staff-years used in the process for the review of animal drug applications by the average salary cost in ORA to arrive at ORA salary costs for work that is a part of the process for the review of animal drug applications as defined in ADUFA. The final step is to allocate ORA obligations for operations and rent to the animal drug review process based upon the ratio of user fee related staff-years to total ORA staff-years.

Table 11 summarizes the calculation of ORA costs for the review of animal drug applications for FY 2011 and FY 2012.

**TABLE 11**  
**OFFICE OF REGULATORY AFFAIRS**  
**COSTS OF THE REVIEW PROCESS FOR ANIMAL DRUG APPLICATIONS**  
**AS OF SEPTEMBER 30, 2012**

COST COMPONENT	FY 2011	FY 2012
Staff Years Utilized	11	12
ORA Average Salary and Benefits per Staff Year	\$110,499	\$114,268
Total Salary and Benefits	\$1,215,489	\$1,371,216
Operating and Other Costs <sup>1</sup>	\$1,126,564	\$1,376,082
<b>GRAND TOTAL (salary/benefits and operating/other costs)</b>	<b>\$2,342,053</b>	<b>\$2,747,298</b>

<sup>1</sup> Other costs are central, GSA rent, rent-related, and Shared Services costs that are applicable to the process for the review of animal drug applications.

ORA costs for the process for the review of animal drug applications described above include total process costs, including costs paid from appropriations and costs paid from fee revenues.

**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 the ORA. For the purpose of these calculations, HQ is considered to be comprised of the following offices:

- Immediate Office of the Commissioner
- Office of the Counselor to the Commissioner
- Office of Legislation
- Office of Policy and Planning
- 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 (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 the Office of Regulatory Affairs)

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

The HQ costs applicable to the process for the review of animal drugs 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 sum of salaries (excluding benefits) applicable to the process for the review of animal drug applications in CVM and ORA to derive the applicable agency general and administrative costs.

Using this methodology, FDA dedicated \$5,614,951 in general and administrative costs to the animal drug review process in FY 2012. The costs are total costs obligated from appropriations and user fees. FDA strives to maintain a low overhead cost for the review process of animal drug applications. General and administrative costs are approximately 8.6 percent of FY 2012 total animal drug review process costs.