

# Financial Report Template

## EXECUTIVE SUMMARY

The [REDACTED], as amended, requires the Food and Drug Administration (FDA) to report annually on the financial aspects of its implementation. This report covers fiscal year (FY) 20XX.

- Summary of legal conditions that must be satisfied for FDA to collect and spend [REDACTED] user fees
- Summary of data presented in report (financial data, performance data, etc.)

## I. MANAGEMENT DISCUSSION

The management discussion provides the contextual background to familiarize the reader with the [REDACTED] program. The management discussion will begin with a high-level summary of the organization (i.e., structure, operating environment, and strategies), followed by a review of the fiscal year's performance and financial highlights. It provides stakeholders with a narrative behind the organizations financial statements.

### A. BACKGROUND

- Organization Chart - Illustration the user fee program offices organization and where it fits into the greater FDA organizational structure
- User Fee Structure - Existing language of types of user fees and how they are collected
- Authorization Act Review - Review of authorization acts for the user fee program

### B. LEGAL CONDITIONS

- Review of specific legal conditions that FDA must satisfy to collect and spend [REDACTED] user fees.

| Legal Condition   | Legal Condition Description | Statutory Requirement |
|-------------------|-----------------------------|-----------------------|
| Legal Condition 1 | FDA's ...                   | FDARA, [REDACTED] X   |
| Legal Condition 2 | ...                         | ...                   |
| Legal Condition 3 | ...                         | ...                   |

### C. STRATEGIC PLAN

Strategic planning is a forward-looking management practice to establish operational priorities and align resources in support of those priorities. Review of the organization strategic goals orients the readers to the financial position in accordance with organizational priorities.

- Strategic Goal 1, 2...X - Definition of the FDA strategic goals for the program, specifically reviewing the goal, strategy to achieving it, and basis for that target
- Forward Looking Strategy - Review of future program plans, such as modernization efforts and process changes to support the achievement of the program goals in the future

### D. PERFORMANCE SUMMARY

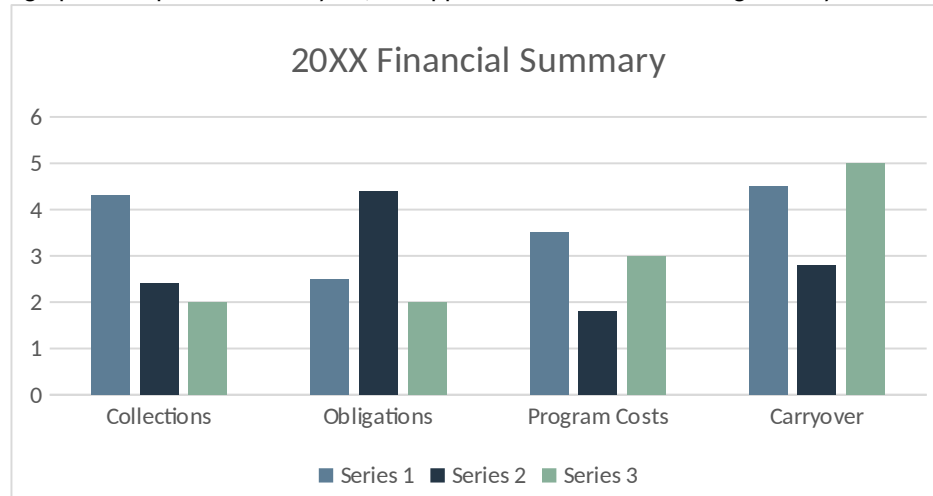
Annual performance summary highlights the organizations operational ability to achieve the strategic goals. The performance summary provides the basis for the need for funding as well as the reviews the impact funding had on the organization's operations. Review of performance identifies success and shortfalls in the organization's operations, and informs stakeholders as to challenges and external variables that impact the organization. Performance indicators help shape resource priorities and strategic plans.

- Reference to Performance Report for further detail on program accomplishments
- Summary table of FY 20XX performance:

| Performance Target   | Performance Description | Achievement (%) |
|----------------------|-------------------------|-----------------|
| Performance Target 1 | FDA's ...               | 100% Met        |
| Performance Target 2 | ...                     | ...             |
| Performance Target 3 | ...                     | ...             |

**E. FINANCIAL SUMMARY**

The financial summary will review the fiscal year highlights, to introduce the program financial position in a concise way. The financial summary will tie the operation and financial performance together by describing the fiscal year highlights in terms of operational activities and external impacts. The financial summary will incorporate graphical depictions of the year, to support a better understanding of the year financially.



**II. FINANCIAL INFORMATION**

**A. FINANCIAL STATEMENTS**

Inclusion of a summarized, unaudited, form of program financial statements. The inclusion of an abbreviated form of financial statement provides the overall financial position of the program in a standard format. The inclusion of financial statements within the UF financial reports will foster assurance that financial management and reporting is being done properly by providing a summary of information in a familiar manner.

- Summary of Balance Sheet
- Summary of Statement of Net Cost
- Summary of Statement of Changes in Net Position
- Summary of Statement of Budgetary Resources

**B. FINANCIAL ANALYSIS**

Financial analysis provides the contextual evaluation of the financial data, explaining the implications of the financial position and setting stakeholders expectations for the past, present, and future performance of the organization. The financial analysis will incorporate financial data presentation, in addition to explanatory narrative, in the forms of graphs and charts provides a greater understanding to the financial data and position in a concise and visual way.

Within the financial analysis each major financial component will be reviewed, leveraging the existing financial report templates for key financial components and content. The major financial components included within that financial analysis are listed below:

- User Fee Collections
- User Fee Obligations
- Carryover Balances
- Collections Realized
- Reserves and Balance Available for Allocation
- Total [REDACTED] Program Costs
- Full-Time Equivalent

### III. MANAGEMENT ASSURANCE

#### A. RISKS AND CHALLENGES

The review of challenges and risks identifies factors that could impact the organization's operational and financial capability and explains to stakeholders the risk level associated with those factors in terms of exposure to loss and ability to accomplish the program directives and goals. The discussion of future programmatic challenges and risks educate the stakeholders on the financial and operational obstacles the program faces, as well as sets stakeholders expectations for what to expect in upcoming year(s). Within this section the risks and challenges will be presented by explicitly identifying operational or programmatic difficulties that may be overlooked within the context of the financial position or performance review.

#### B. GOVERNANCE

This section will review the management assurances and accountability measures to ensure that the FDA and the [REDACTED] program effectively manage risk, maintain internal control, ensure effective delivery of services and affirm responsible stewardship of resources. Publication of the internal controls, systems and processes demonstrates to stakeholders that the program is operationally secure and responsibly handling its resources. Providing accountability reviews within user fee program financial report provides assurance to Congress and the industry that resources are secure and the program is operationally compliant which will enhance operational and building stakeholder confidence.

### IV. APPENDICES

#### A. APPENDIX A: CONDITIONS FOR ASSESSMENT AND USE OF FEES

Further description of legal conditions and adjustment factors

#### B. APPENDIX B: FEES, WAIVERS, AND EXEMPTIONS

Explanation of fee categories and the set fee revenues for each category

#### C. APPENDIX C: FINANCIAL STATEMENT NOTES

Detail on assumptions, concepts and accounts referenced within the financial statements and financial analysis

#### D. APPENDIX D: ALLOWABLE AND EXCLUDED COSTS FOR THE PROGRAM

Discussion of [REDACTED] program costs, and excluded products and activities

#### E. APPENDIX E: DEVELOPMENT OF COSTS FOR THE PROGRAM

Discussion of the costs associated with the [REDACTED] program, in terms of their reliance on how on obligations attributed to CDER, CBER, ORA, and HQ.