

FDA Human Drug User Fee Five-Year Financial Plan and Annual Financial Report Template Development

FOCUS GROUP

BACKGROUND

FDA is working towards developing templates for a five-year financial plan and annual financial report for the Human Drugs Program user fees, in order to enhance the program's financial management practices to internal and external stakeholders. The annual financial plan, required by law to be submitted to Congress within 120 days after the fiscal year end to which it applies, is the primary mechanism for reporting on actual user fee program financial expenditures. FDA is considering adding a forward-looking, 5-year financial plan, that would be available externally, to provide more context to the annual reports and to enhance the understanding of FDA's user fee operations by people less familiar with government-run programs but who, nonetheless, hold significant interest in the program.

SCOPE OF FOCUS GROUP

The scope of this focus group is to review the new template designs of the annual plan and the 5-year strategic plan to provide qualitative and quantifiable feedback on the reports' quality and content.

FEEDBACK QUESTIONS

Annual Financial Plan

1. What was your interaction with previous user fee program annual reports submitted by FDA?
2. Did you find previous versions of the report to be informative?
3. Did previous versions of the report leave you with outstanding unanswered questions?
4. What is your first impression of the updated report?
5. Overall, do you feel this report may leave you better informed of the financial state of the user fee program?
6. Are there specific sections or enhancements you believe will address clarity gaps or provide additional value, in comparison with the previous report?
7. Are the added visuals useful?
8. Did the visuals facilitate the delivery of the content or were they a distraction/cause more clarity issues?
9. Are there certain sections where the information does not provide any value?
10. Did you find any section to be too detailed?
11. Did you find any section to not be detailed enough, too high-level?
12. Did the report also provide enough explanation or justification for the data reported?
13. Did the addition of select descriptive tie-ins to performance data provide value?
14. What is still missing from the report?

5-Year Financial Plan

1. On a scale of 1 to 10, for you, how important is having access to a forward-looking multi-year financial plan? (10=high)
2. What are your expectations for a multi-year plan?
3. Do you use a multi-year plan in your organization?
4. Did your first impression of this report meet your expectations?
5. Overall, do you feel this report may leave you better informed of the direction the user fee program is heading?
6. Are there specific sections or enhancements you believe will address clarity gaps or provide additional value?
7. Are the added visuals useful?
8. Did the visuals facilitate the delivery of the content?
9. Are there certain sections where the information does not provide any value?

10. Did you find any section to be too detailed?
11. Did you find any section to not be detailed enough, too high-level?
12. Do you expect the report to provide explanation or justification for the methodologies used, when appropriate?
13. Did the report meet your expectations for infrastructure and/or technology planning?
14. Did you come away with the impression that you know how user fees may be used in the near-future?
15. What is still missing from the report?
16. How much do you agree the FDA user fee 5-year plan should be directly correlated to the execution information provided in the annual reports, and can you elaborate on your selection?
 - Strongly Agree
 - Agree
 - No Comment
 - Disagree
 - Strongly Disagree
17. On a scale of 1 to 10, how disappointed would you be if future financial reports did not reference and report updates to performance data or other information in the 5-year plan (e.g. planned IT investment initiatives)? (10= very disappointed)
18. Do you believe that, in practice, it is reasonable to expect that a 5-year financial plan could change?