U.S. Food and Drug Administration (FDA)

Management's Response to the Evaluation of the FDA's FINANCIAL MANAGEMENT CAPABILITY FOR THE HUMAN DRUG USER FEE PROGRAMS FOR FY 2018, conducted by the Centers for Medicare & Medicaid Services (CMS) Alliance to Modernize Healthcare (referred to as The Health FFRDC) Federal Funded Research and Development Center, operated by the MITRE Corporation, and teamed with Grant Thornton LLP.

In response to a negotiated performance commitment to promote financial transparency and efficiency as part of the Food and Drug Administration Reauthorization Act of 2017, FDA obtained the consulting services of the Health FFRDC to conduct an independent assessment of its financial management capabilities of its human drug user fee programs, specifically the Prescription Drug User Fee Amendments (PDUFA), the Biosimilar User Fee Amendments (BsUFA), and the Generic Drug User Fee Amendments GDUFA). The report provides a snapshot of FDA's human drug user fee management as of September 2018. Highlights of FDA's response to the Health FFRDC's assessment report, aligned with the five focus areas of the Health FFRDC's assessment, are summarized below.

Focus Area 1: Resource Planning, Request and Allocation, and User Fee Administration

Finding	FDA's financial management practices fully comply with current financial management best practices and requirements. Its core financial systems and tools meet Agency-level requirements to track and report user fee program funds. FDA continues to develop enhanced system capabilities (e.g., implementation of full time reporting of staff hours and resource capacity planning). The PDUFA, BsUFA, and GDUFA billing and collection functions and processes are well executed; the process teams continually explore ways to innovate and automate processes to gain efficiencies. The Health FFRDC's analysis identified several opportunities to improve the management of user fee funds, including the need for a more uniform approach and consistent tool sets used at the Agency and center and office levels. It also sites that FDA lacks a fully integrated user fee management policy and procedures framework, leading to localized processes and lack of standardization. Additionally, centers and offices reliance on distributed tools and systems, requiring manual reconciliation and validation, can lead to process inefficiency.
OFBA's Response	FDA agrees with The Health FFRDC's assessment on developing better policies and procedures and the need to consistently leverage them throughout the Agency. FDA will take under advisement some of the more nuanced recommendations for this focus area and will consider their cost-benefit for implementation. The Agency notes that its systems and tools are primarily "state of the art" in the federal sphere and can be better leveraged FDA-wide through communication, collaboration, training, and integration. The Agency's systems and tools allow for micro level tracking and reporting and facilitate analytics for payroll forecasting, acquisition planning, and expenditure tracking.

Focus Area 2: Administration of Fee Program Resources

Finding	FDA realized improvements in user fee administration, specifically, the enterprise-level systems that support budget execution, billing, collection and reporting capabilities. Within the Centers, particularly CDER, management encouraged process improvement and adoption of lean practices. FDA made positive staffing changes over the past few years, in both mix and levels, which introduced new perspectives and better alignment with transaction volumes. Additionally, the Health FFRDC recommended FDA centers and offices, better integrate with and utilize the Agency level systems and tools, as well as, enhance collaboration and communication, clarify roles and responsibilities, and provide more analytic support.
OFBA's Response	FDA agrees with this assessment and will continue to increase efforts to enhance and ensure that agency level tools and systems, used by programs and centers, meet customer and stakeholder needs. This includes center-level automation of workflow tools and leveraging of existing technologies to streamline customer service and request processing. The Agency will also broaden training opportunities on use of the Agency level tools and systems and will facilitate greater collaboration between the CFO's office and the programmatic centers. FDA will leverage its newly restructured User Fee Financial Management Committee (UFFMC) as well as the FDA Executive Committee to facilitate clear direction on user fee policy, strategic direction, and financial management.

Focus Area 3: Oversight and Governance

Finding	The Health FFRDC acknowledges that FDA has a robust governance process overall. The Health FFRDC noted that the formal governance structure for the user fee program, that existed for many years, was in the process of being evaluated and was temporarily dissolved during their assessment. In addition, the Health FFRDC indicated that FDA's user fee governance bodies should make more evidence-based decisions, improve documentation, align investments to strategy, and follow up on investment decisions. It also recommended the creation of higher-level strategic objectives that cut across all user fee programs and link to program performance commitments. This would help user fee oversight bodies align their investments to projects that achieve long term outcomes and performance.
OFBA's Response	Although there has never been an oversight gap as FDA senior leadership continued meeting to discuss user fee requirements during the governance restructuring period, FDA formally re-established its governance structure prior to the publication of the Health FFRDC's assessment. The UFFMC will ensure applicable alignment of user fee investments to strategic priorities of the Agency and will also ensure that key investment decisions are well documented, and results are tracked. FDA acknowledges better documentation and tracking of past investment activities could have occurred and intends to focus on improving such under its new UFFMC. The UFFMC will also receive direct feedback on the strategic policy direction for the user fee programs from FDA's Executive Committee that consist of all the Center Directors, Deputy Commissioners, and the Commissioner. FDA appreciates the need for return on investment (ROI) data to inform user fee investment decisions. The Agency also recognizes that ROI information is not always readily quantifiable and is often more qualitative than quantitative in the federal government. In addition, it is worth noting that not all investments are material to track for ROI basis. FDA takes the Health FFRDC's advice on the utility of ROI under advisement but has no plans to mandate that quantifiable ROI data inform all user fee investment decisions.

Focus Area 4: Technical Capabilities

Finding	The assessment results indicate FDA can financially manage and administer human drug user fees, and that the majority of its financial management employees are at or above their supervisor's desired proficiency level for managing user fee resources. Further, the assessment indicates that FDA staff meet expectations for program knowledge and have the skills to meet legal and regulatory requirements. The Agency successfully hired and maintained financial management staff with all but one of the desired technical competencies.
OFBA's Response	FDA agrees with the Health FFRDC's assessment and will continue to make development of its financial management talent a continuous priority. The Agency will invest in additional staff training within its program centers to ensure that FDA's systems, tools, and processes are fully understood and leveraged beyond the Chief Financial Officer's organization. FDA intends to seek additional opportunities for greater collaboration between the CFO's team and the program centers with respect to developing and documenting analyses that support key user fee investment decisions. Finally, the Agency plans to develop more comprehensive policies, procedures, and automated shared data repositories for managing user fee resources to ensure greater integration and consistency throughout the Agency.

Focus Area 5: User Fee Estimating Methodology

Finding	Predictive modeling requires an ongoing multi-pronged approach to achieve improvements in forecasting accuracy as well as estimating confidence. The Health FFRDC recommends near, mid, and long-term opportunities for FDA to improve its fee forecasting accuracy, examining a variety of additional variables more closely. Broadening of the methodologies it applies would help the Agency balance their inherent strengths and weaknesses as well as provide programs with a more comprehensive understanding of fee unit behavior.
OFBA's Response	FDA will continue to monitor its forecasting methodologies to ensure the Agency maintains an acceptable range of variation. The Agency will use additional data points and forecasting methodology to help refine estimates, where applicable. FDA notes that several fees associated with GDUFA and BsUFA are new, which can cause a higher deviation early in the programs and the relatively small size of the BsUFA program inherently contributes to forecasting uncertainty for the BsUFA program. FDA is open to exploring the quantitative approaches mentioned in the Health FFRDC's assessment to strengthen its ability to determine viability in application to FDA's fee programs. FDA is developing advanced predictive analytics to forecast regulatory submissions as part of its Resource Capacity Planning initiative. FDA expects this new capability will improve forecasting the number of fee-paying submissions.

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