Action Plan in Response to Human Drug User Fee Financial Management Study

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.

FDA Action 1: FDA will develop a comprehensive fiscal manual, inclusive of sections on budget execution and user fee financial planning and administration. This action will be completed in three phases, which are as follows;

a. Phase I – General aspects of user fee financial management and for the PDUFA program by February 2020
b. Phase II – Complete for the BsUFA and GDUFA programs by June 2020
c. Phase III -- Complete for all other programs (ADUFA, AGDUFA, Color Cert, CQA, EREA, MDUFA, MQSA, PRV, TPA, VQIP and Tobacco) by September 2020

Due Date: The fiscal manual will be completed by September 2020.

FDA Action 2: FDA will develop and implement an online and classroom training module that covers user fee financial planning and administration.

Due Date: The training will be developed and implemented to correspond with the completion of the fiscal manual. The first course will be offered in March 2020, the second in July 2020, and the third in October 2020. *Note: The training course will need to be refreshed in FY 2023 after the next medical product user fee reauthorization cycle.*

FDA Action Plan 3: FDA staffs that have a role in financial planning, billing, collection, fee estimation and forecasting, and budget execution relative to FDA's user fee programs will be required to complete the training, and this requirement will be included in their performance plans for 2020. Upon reauthorization of FDA's user fee programs, these same staff will be required to take a refresher course reflecting applicable new financial requirements.

Due Date: Training must be completed by December 2020 for applicable staffs.

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.

FDA Action 1: FDA will better leverage corporate tools and ensure they are appropriately deployed into the FDA centers and offices. Centers and offices will develop and implement center and or office centric sub-applications ("child applications") of the Integrated Budget and Acquisition Planning System (IBAPS) that meet their center or office specific needs – with complete integration functionality to the agency-wide (or "parent") IBAPS solution.

Due Date: Projected implementation by all centers by September 2021. *Note: Some FDA centers have already implemented IBAPS child applications.*

FDA Action 2: As a follow on to action 1 from Focus Area 1, FDA will utilize a specialized financial working group from the User Fee Financial Management Committee to identify data and automated reporting requirements that facilitate better financial analytics for user fee programs (for all centers and offices), and leverage IBAPS and the Financial Business Intelligence System (FBIS) reporting solutions to satisfy those requirements.

Due Date: Projected implementation by all centers and offices by September 30, 2021. *Note rolling implementation with interim reports should begin to be deployed as early as December 31, 2019.*

FDA Action 3: Train applicable FDA center and office staffs (based on center provided list of names) on existing automated tools and reports. Require that completion of training on agency level automated tools and reports be a critical element for identified staffs in their 2020 performance plans.

Due Date: Complete training of targeted center and office staffs by June 2020.

FDA Action 4: Include in the fiscal manual clearer information about roles and responsibilities relative to FDA user fee financial planning and administration. Also leverage the User Fee Financial Management Committee (UFFMC) to enhance collaboration and provide more regular communication relative to user fee financial management processes within the agency, including posting applicable communication materials to an agency-wide site/repository.

Due Date: Establish an agency-wide data site and publish the fiscal manual by June 2020.

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.

FDA Action 1: FDA will receive strategic policy direction from the FDA's Executive Committee and the UFFMC will leverage such direction when making user fee resource allocation decisions.

Due Data: October 30, 2019

FDA Action 2: FDA will document decisions from the UFFMC more formally in meeting minutes and will require a review of results relative to investment decisions at least once within 1 year after funds have been allocated.

FDA Action 3: FDA will utilize a specialized financial working group from the User Fee Financial Management Committee to enhance its business case templates and documentation required to provide more business analytics and robust financial analysis to facilitate decision making relative to user fee investments.

Due Date: February 2020

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.

Note: *Actions under focus areas 1 through 3 completely address this finding. No further actions to address this finding need to be identified.*

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.

FDA Action: The Office of Program and Strategic Analysis and Office of Planning and Evaluation will develop new predictive models to enhance forecasts of fee-paying units in PDUFA, BsUFA, and GDUFA as part of the resource capacity planning capability. The Office of Program and Strategic Analysis and Office of Planning and Evaluation will work with CBER, CDER's Office of Management, and the Office of Financial Management to outline how to incorporate the new fee forecasting methodologies into the annual fee setting process, including making any changes to MAPPs, SOPs, and delegations of authority as needed.

Due Date: May 2020