APPROPRIATION LANGUAGE ANALYSIS

Language Provision	Explanation
Prescription Drug User Fee	The Administration will propose legislation to allow FDA to collect fees for prescription drugs. The additional resources are estimated at $1,262,182,000. This will strengthen and improve the process for the review of human drugs and improve risk management for drugs approved under PDUFA.
Medical Device User Fee	The Administration will propose legislation to allow FDA to collect fees for medical devices. The additional resources are estimated at $439,001,000. This will strengthen the review processes and meet performance goals for the medical device program.
Generic Drug User Fee	The Administration will propose legislation to allow FDA to collect fees for generic drugs. The additional resources are estimated at $615,746,000. This will help bring timely review for human generic drug applications and reduce backlog of human generic drug applications.
Biosimilar User Fee	The Administration will propose legislation to allow FDA to collect fees for biosimilars. The additional resources are estimated at $86,736,000. This provides a mechanism and structure for the collection of development-phase user fees to support FDA's biosimilar review program activities.
Animal Drug User Fee	The Administration will propose legislation to allow FDA to collect fees for animal drugs. The additional resources are estimated at $46,110,000. This will help ensure a cost-efficient, high quality animal drug review process that is predictable and performance driven.
Animal Generic Drug User Fee	The Administration will propose legislation to allow FDA to collect fees for animal generic drug. The additional resources are estimated at $6,375,000. This will help protect human and animal health and accelerate innovation in the industry.
Export Certification Fee	The Administration will propose legislation to allow FDA to increase the funding cap for the export certification fee from $175 per certification to $600 per certification for an estimated total of $8,976,000. This proposal, and the increased certification fee ceiling it promotes, is necessary to ensure that FDA can efficiently implement the export certification program, while ensuring that other public health programs do not suffer.
Working Capital Fund	A Working Capital Fund (WCF) supports agency-wide business services. The WCF would serve as a revolving fund with extended availability and serves as the funding mechanism for centralized business services support across FDA. Services rendered under the WCF would be performed at pre-established rates to cover the cost of business operations.