FDA Reauthorization Act of 2017

The Food and Drug Administration Reauthorization Act of 2017 (FDARA) reauthorizes the vital authority for FDA to collect user fees from the makers of prescription brand drugs, medical devices, generic drugs, and biosimilars, and several important programs. The current user fee agreements are set to expire on September 30, 2017.

If the user fee agreements are not reauthorized sixty days in advance of this deadline, the agency will be forced to send layoff notices to more than 5,000 FDA employees. A delay in reauthorizing these agreements would cripple the agency's ability to review applications for drugs and devices, harming patients and families that count on safe and effective medical products and threatening America's global leadership in biomedical innovation.

The four user fee agreements authorized by FDARA will support the goals of the 21st Century Cures Act and advance key bipartisan priorities:

- Prescription Drug User Fee Amendments (PDUFA VI): Enhances patient-focused drug development, supports biomarker development and qualification, dedicates staff to assist in the development and review of rare disease drugs, improves timelines and increases guidance for drug and device combination products, and evaluates ways to modernize the clinical trial process.

- Medical Device User Fee Amendments (MDUFA IV): Enhances the patient voice in the device development process, supports the collection of real world evidence on the safety and effectiveness of devices, and improves the review process for "de novo" devices—low- to moderate-risk devices that are the first of their kind.

- Generic Drug User Fee Amendments (GDUFA II): Improves the fee structure to support small businesses, provides goal dates for all outstanding generic applications, and establishes priority review timelines.

- Biosimilar User Fee Amendments (BsUFA II): Continues to build the biosimilars program, and supports guidance for product developers.