What's New in PDUFA VIII

Enacted in 1992, the Prescription Drug User Fee Act (PDUFA) establishes how regulated industry fees support the human drug review program at the Food and Drug Administration (FDA) and associated Agency performance goals, programs and processes. The law must be renewed every five years, including a negotiation between industry and the FDA and reauthorization of the law by the U.S. Congress.

As Congress prepares to reauthorize PDUFA, here's what's new:

FDA Review Performance

- Retains the processes, timelines, metrics, and reporting on application review activities from previous reauthorizations
- Includes new third-party assessments of drivers of first-cycle review outcomes, meeting enhancements, operational efficiencies, and overall program effectiveness

Regulatory Science Adoption

- Transitions from pilots into standard review practice for maturing regulatory science enhancements and continues support for other regulatory science areas

Improved FDA-Sponsor Communication

- Adds two new manufacturing-focused meeting opportunities to identify, discuss, and resolve pre-submission and pre-approval manufacturing issues
- Refines the use of written responses (WROs) to meeting requests and introduces a new multi-division meeting format to allow for efficient discussions for multi-indication products

Improved Financial Predictability and Accountability

- Reduces base funding and year-over-year increases to address the growth of the program
- Protects FDA ability to hire and retain staff
- Includes enhanced reporting to ensure that funds are used as intended

Promoting American Innovation

- Lowers application fees for drug development programs originating in the US
- Limits small business waivers to US companies only
- Ensures that drugs that expand from rare indications to broad indications pay a supplement fee