What's New in PDUFA VIII?

Stability · Transparency · Maturity

Stability

- **Retains review activity performance metrics**
- **Strengthens predictable and timely review**
- **Limits program growth and adjust finances**

- NDA/BLA and supplement performance goals remain anchored in established standard and priority timelines.
- FDA maintains resources for breakthrough therapies, safety surveillance, regulatory science, cell and gene therapy, and bioinformatics.
- Revenue and fee growth are capped, are rightsized to the post-2025 staffing environment, and are sized to enable and encourage restaffing.

Transparency

- **Enhances existing meetings and adds new CMC-focused meetings**
- **Leverages 3rd-party assessments**
- **Enhanced reporting and public meetings**

- New multi-division meetings (MDM) and enhancements to WRO conversions
- New pre-submission and post-inspection meetings focused on CMC
- 3rd party assessments to look at first cycle review outcomes, meeting enhancements, CMC enhancements, and overall PDUFA efficiency
- 10 RISE workshops, 3 RDEA workshops, case studies and public meetings on PFDD, and a public meeting on regulatory science tools such as CID, MIDD, RWE

Maturity

- **Transitions pilots to practice**
- **Provides for predictable pivotal protocol reviews, IR transmissions, and labeling feedback**
- **Supports Sentinel 3.0's development with aim to support RWE's value**

- MIDD and RDEA move from limited pilots to being available to all; unsuccessful pilots terminated
- FDA will prioritize review of protocols flagged as pivotal
- IRs sent after the LCM will need to include a rationale for their tardiness
- Support for Sentinel is explicitly designed to increase ARIA sufficiency

AMERICAN COMPETITIVENESS

Indication Expansion

50% reduction in the application fee if the application includes clinical data from at least one phase 1 trial anchored in the United States initiated after October 1, 2027.

Small Business

Updates the eligibility for the small business waiver to only companies based in the United States (i.e., applicants created or organized under the laws of any State).

Phase 1 Trials

Adds a supplement fee for expansion from orphan to the first non-orphan indication.