

Advancing Generic and Biosimilar Development

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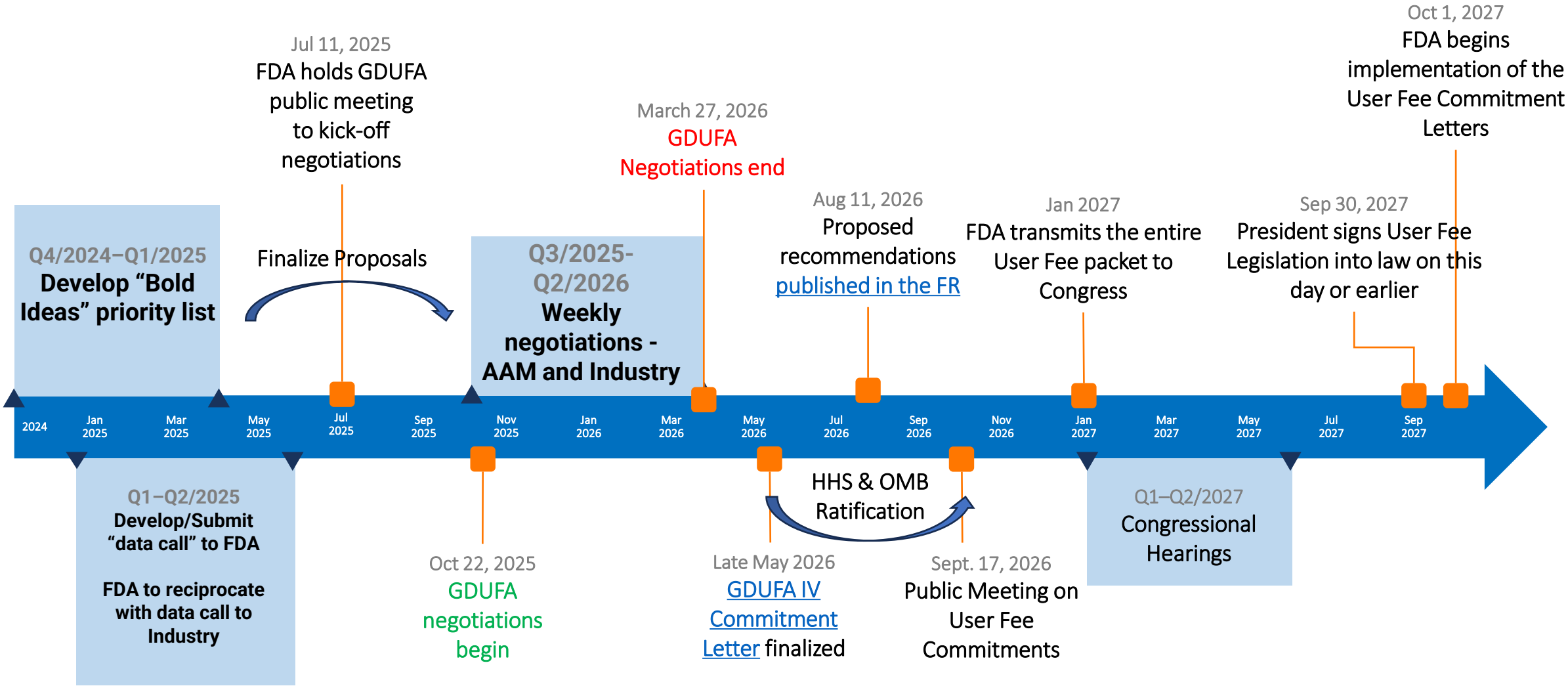
Key Changes in GDUFA IV

- Every five years, FDA and Industry renegotiate the user fee programs, touching on both the fees paid and the programmatic enhancements
- Industry is represented by the Association for Accessible Medicines ("AAM"), the Pharma & Biopharma Outsourcing Association ("PBOA"), and the Bulk Pharmaceuticals Task Force ("BPTF")
  - Six industry representatives participated on behalf of AAM (4 primary and 2 alternate):
    - Primary: Sandoz, Teva, Amneal, & Apotex
    - Alternate: Fresenius Kabi & Lupin
- FDA and Industry come to the table with proposed program enhancements and updates
  - Negotiations are closed to the public, though FDA holds monthly stakeholder meetings and publishes negotiation meeting minutes
  - Historically, FDA seeks additional FTEs to accommodate new programs. GDUFA IV negotiations were unique:
    - FDA had just lost nearly 20% of its staff, with attrition continuing to outpace hiring
    - FDA leadership changes during the negotiations
    - Concern over generic industry sustainability

GDUFA IV Timeline



What GDUFA IV Targets: Four Objectives

1. Improve predictability, transparency and efficiency of ANDA Assessment

- Result – Fewer unnecessary review cycles and avoidable CRLs

2. Modernize regulatory pathways and communications to support Complex Generics

- Result: Earlier resolution of complex scientific questions and greater regulatory certainty, particularly for complex generic products

3. Better Integrate Inspections, Facilities, and Manufacturing into the Application Lifecycle.

- Result: A more integrated review and manufacturing process with fewer late-cycle delays

4. Strengthen the Generic Drug Ecosystem and Supply Chain While Maintaining Sustainable GDUFA Program

- Result – A stronger , more resilient generic drug industry and a sustainable GDUFA program for continued access to quality , affordable medicines.

Key Changes in GDUFA IV

- **GDUFA IV Financials**
  - **Fee changes**: Allocation % and Fee obligation determination date
    - **Allocation %:** ANDA application fee percentage will decrease by 7% (from 33% to 26%) and program fees percentage increases by 7% (from 36% to 43%), a modest shift that is about half FDA's original proposal for a 13% shift
    - **Fee obligation determination date:** The date FDA determines an applicant's annual fee amount will be moved from October 1st to May 1st
  - **Program Enhancements** (*see subsequent slides*): As previously noted, all program enhancements were determined to be resource-neutral, such that Industry will not be paying for additional FDA FTEs under GDUFA IV
  - **"America First" Incentives**:
    - A one-time waiver of the original ANDA submission fee for a domestic applicant whose application identifies only U.S.-located facilities as both the final dosage form (FDF) manufacturer(s) and the active pharmaceutical ingredient (API) supplier(s)
    - The Foreign Fee Differential for non-US facilities will increase by $10,000 ($15,000 to $25,000)

GDUFA IV: Program Enhancements

Executive summary of proposed changes for FY 2028-2032

- **GDUFA IV Program Enhancements**
  - **Structured Review and Review Management**:
    - Consults initiated at receipt with responses requested before midcycle;
    - labeling DRLs by the assessment midpoint;
    - a 90-day goal date extension after a late-cycle IR or DRL response, which an applicant may elect to limit to one per cycle
    - Overall objective is to support approvals in fewer review cycles.
  - **Improved Meeting Framework**:
    - Four meeting types (TYPE 30, 60, 90, and 120) replace the GDUFA III meeting types;
    - grant or deny within 14 days and minutes within 30 days, under a 90% performance goal across all four types
  - **Inspection and Facility Oversight**:
    - Post-PAI meetings requested by the facility, with applicant participation by written authorization;
    - surveillance inspections on request for eligible U.S. facilities;
    - 90-day extension following post-PAI information and 120-day extension for a late pOAI alert
  - **Complex Regulatory Issues, Missed Goal Dates, and Data Integrity**:
    - A new 6-month goal date when the original goal date will be missed by more than 60 days;
    - RPM notification no later than the goal date;
    - prompt notice of a potential complex data issue without identifying the site or facility
  - **Controlled Correspondence**:
    - Three levels (60, 90, and 120 days) replace Levels 1 and 2;
    - an ANDA or pre-assigned ANDA number is required;
    - in-cycle submissions broadened; 10-day window for missing information;
    - clarification requests move to a TYPE 30 meeting

GDUFA IV: Program Enhancements

Executive summary of proposed changes for FY 2028-2032

- **GDUFA IV Program Enhancements**
  - **Data Standardization and Structured Submissions**:
    - Quarterly IID updates capturing inactive ingredients from labeling approved on or after Oct. 1, 2027;
    - a public Maximum Daily Dose database with at least 500 values by end of FY2028;
    - standard tables and formats for BE, impurity, and PK data
  - **DMF Prior Assessment Program**:
    - Eligibility extended to a 24-month patent and exclusivity window, complex API DMFs (4 per FY),
    - and PASs adding an all-U.S.
    - API source (12 per FY);
    - new request contents; first-cycle IRs generally will not result in a refuse-to-receive action
  - **Performance Reporting**:
    - Monthly metrics expand to eight, including first-cycle approvals split by complex and non-complex;
    - quarterly reporting of Level 60/90/120 controlled correspondence and facility-based reclassification requests;
    - new annual metrics on missed and second goal dates