

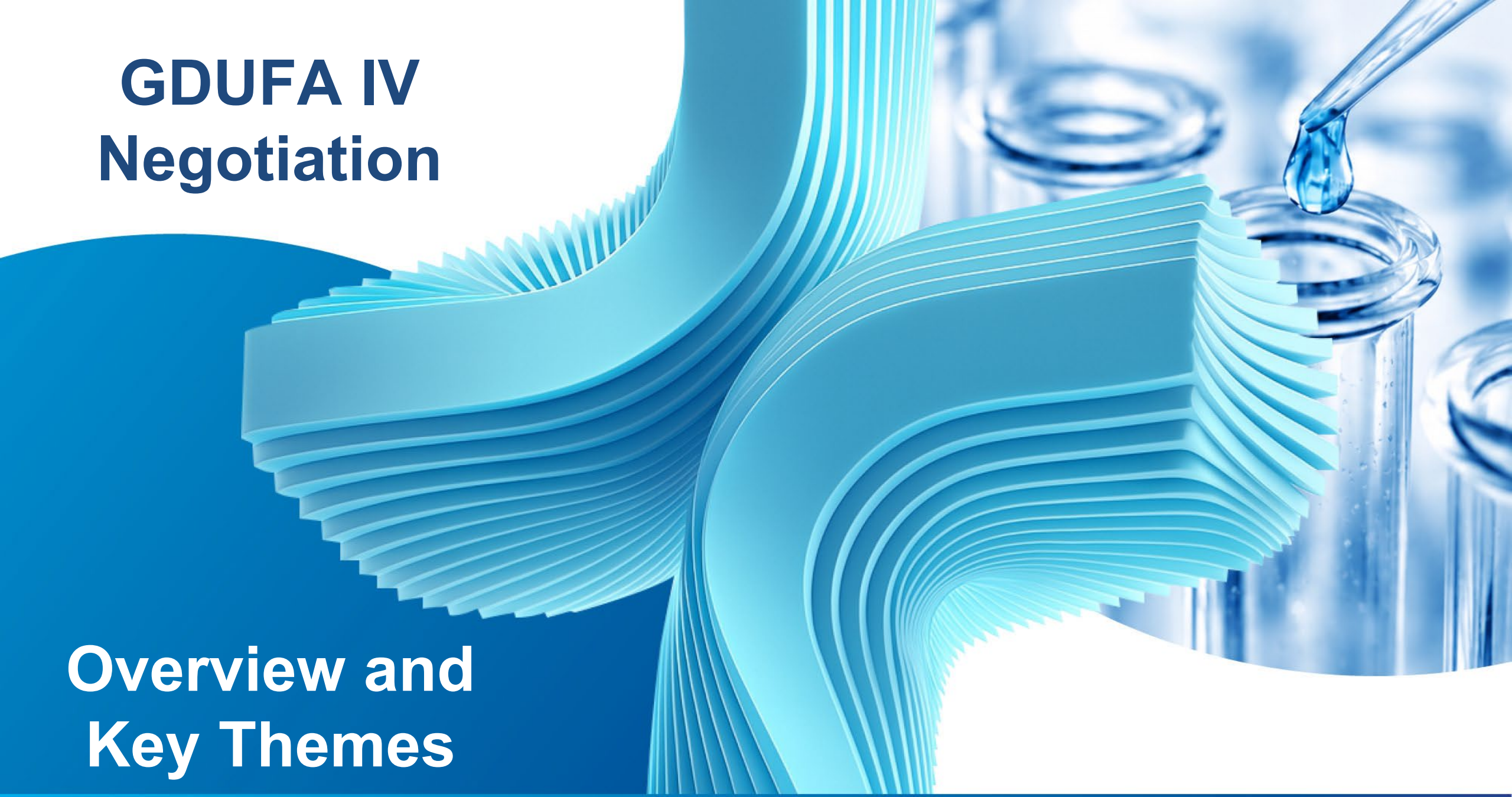
GDUFA IV Panel

GDUFA IV Industry Negotiations Team

NOVEMBER 2-4, 2026

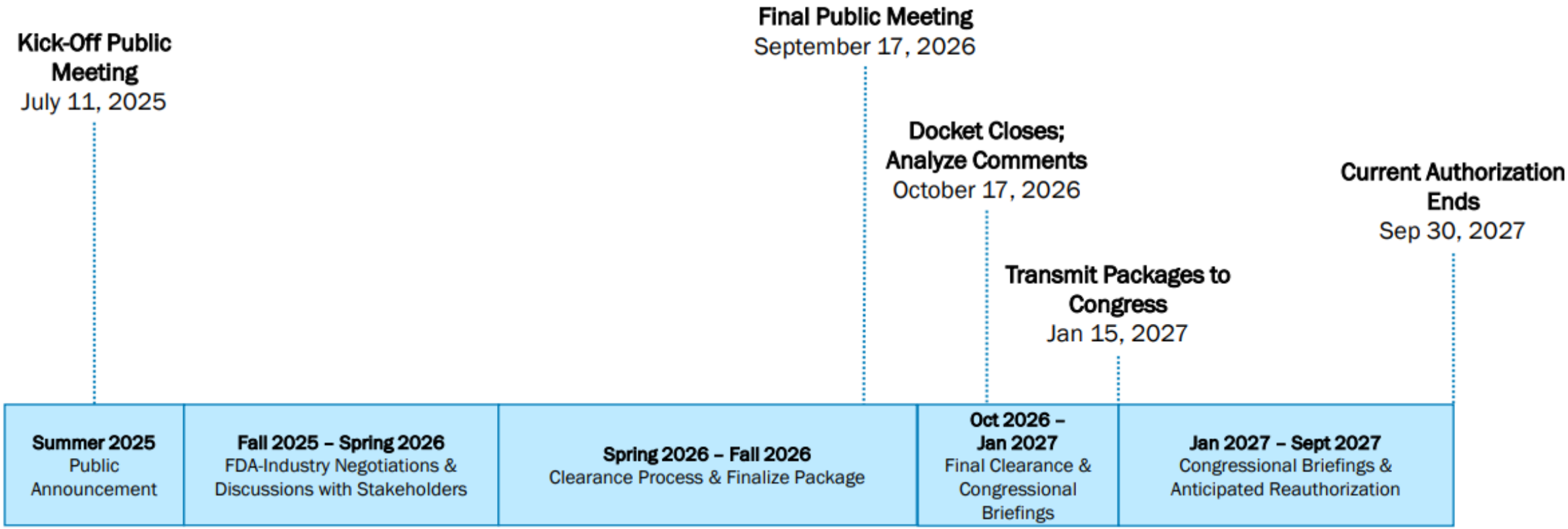
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GDUFA IV Negotiation



Overview and Key Themes

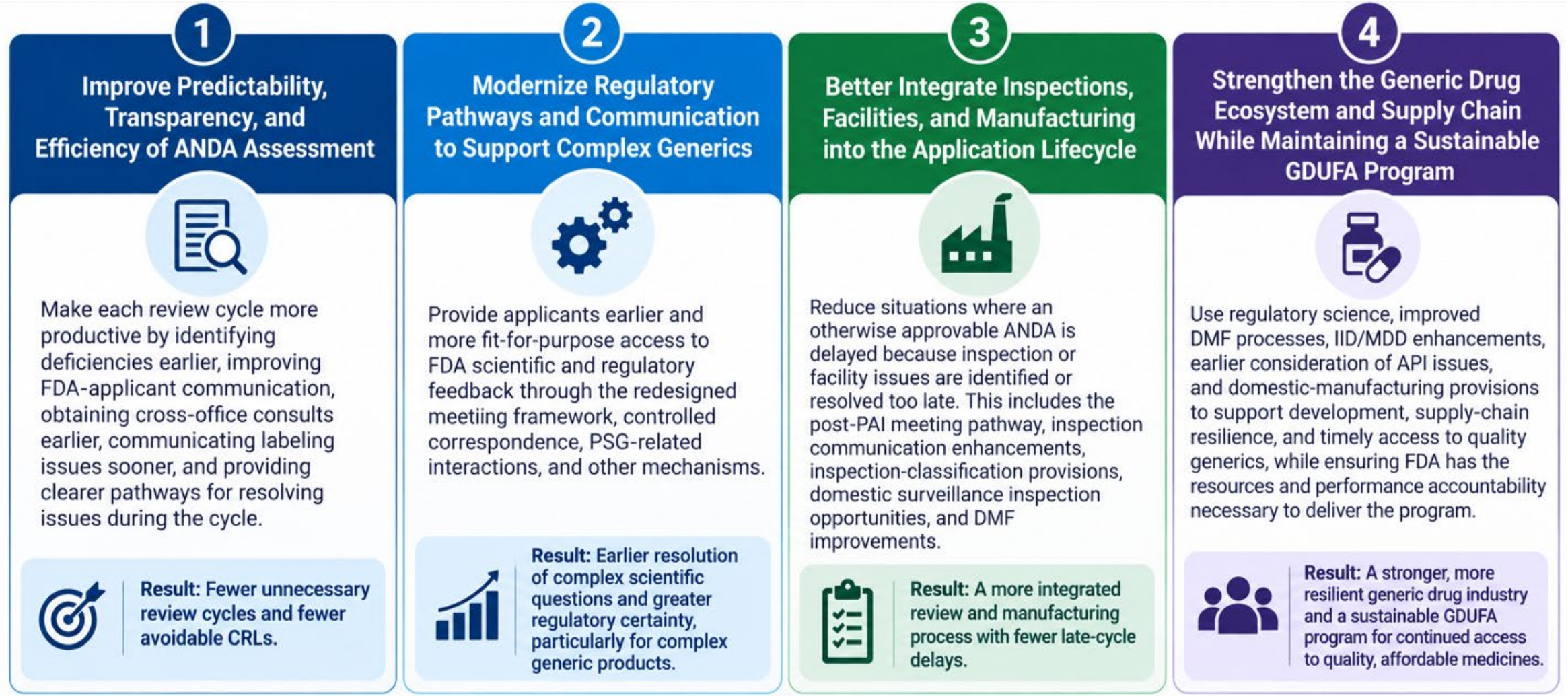
Overview of the Reauthorization Process



Timeline slide taken from GDUFA IV Public meeting held at the FDA on September 17, 2026

What GDUFA IV Targets: Four Objectives

The first-cycle problem: GAO found FDA approved 12% of ANDAs in the first review cycle in FY2015–2017 (GAO-19-565). FDA reports roughly 38–40% of ANDAs submitted in FY2018 and FY2022 were approved by the second cycle, and about 25% of complex product ANDAs (FDA OGD, 2025 Generic Drug Forum).



Program Enhancements

- Improved Meeting Framework: Four Meeting Types
- Controlled Correspondence Enhancements
- Data Standardization and Structured Submissions
- DMF Prior Assessment Program Improvements
- Structured Review and Review Management
- Missed Goal Dates, Complex Data Issues, and Transparency
- Facility Assessments, Inspections, and Post-Inspection Interactions
- Domestic Manufacturing and Supply Chain-Related Provisions
- GDUFA IV Financials

Appendix Contents ›

GDUFA IV: FOUR MEETING TYPES REPLACE THE GIII STRUCTURE

Meetings are tiered by scope, complexity and timing

TYPE 30 Clarification of a Prior FDA Interaction	**TYPE 60** Substantive Follow-Up or Feasibility	**TYPE 90** New, Single-Topic Issue	**TYPE 120** Multiple Topics or High-Coordination Issues
Post-CRL Teleconference	Substantive Follow Up	**Product Development Meeting** (single topic, complex product)	**Product Development Meeting** (multiple topics, complex product)
PSG Teleconference (in vitro and in vivo)	Protocol to Implement Existing PSG (complex product)	Bridging Strategy (non-complex product)	Cross-Cutting Issues Impacting Multiple ANDAs (complex products)
Mid-Cycle Review Meeting (complex product)	**Pre-Submission Meeting** (complex product)	Alternative Approach to a PSG (non-complex product)	Questions and Approaches with which FDA has Limited Experience (complex product)
Clarification of Prior Controlled Correspondence, Written Response Only (WRO), or Meeting Minutes	**Enhanced Mid-Cycle Review Meeting** (complex product)	**Post-CRL Scientific Meeting** (complex product)	Comparative Use Human Factors Study Protocol Discussions (complex product)
	Complex Generic Initial Advisory (CGIA) Meeting (complex product)		

Bold = similar to a GDUFA III meeting type, but with important differences under GDUFA IV

- ✓ **Simpler:** Four meeting types replace a patchwork of GDUFA III meeting categories.
- ✓ **More Strategic:** Sponsors can engage FDA on novel scientific questions and development challenges earlier in the process.
- ✓ **More Predictable:** Standardized timelines and meeting classifications provide greater transparency regarding FDA interactions.

GDUFA IV - Controlled Correspondence program changes

Summary: To expand, clarify criteria, streamline the process, reduce the redundancy and address prior administrative changes

GDUFA III :

- A Controlled Correspondence may be submitted by or on behalf of a generic drug manufacturer or related industry prior to ANDA submission to obtain FDA feedback on specific regulatory or scientific questions.

- however, during an active ANDA assessment cycle, such correspondence is generally limited to requests for additional FDA feedback related to a Product-Specific Guidance (PSG).

GDUFA IV:

- A Controlled Correspondence (CC) can be submitted at various stages with pre-assigned or assigned ANDA number—before an ANDA submission, after a Complete Response Letter (CRL), after tentative approval, or after final approval.

- During an ANDA assessment, the requester must provide an ANDA number or a pre-assigned ANDA number for the product in question. If an ANDA number is included, the applicant does not need to resubmit copies of that CC or the Agency's response when submitting subsequent related Controlled Correspondence.

- If the FDA determines that a Controlled Correspondence request is missing information needed to provide a response, FDA will contact the requester and ask for the missing information. The review clock is effectively paused during the period that FDA is waiting for the requester to respond. Once the missing information is provided, the goal date is extended by the same number of days that the request was outstanding with the requester.

- Requestors may ask for clarification of ambiguities in the Controlled Correspondence response by submitting a TYPE 30 meeting request.

SUBMISSION TYPE	GOAL
Level 60 Controlled Correspondence 90%	within 60 days of submission date.
Level 90 Controlled Correspondence 90%	within 90 days of submission date.
Level 120 Controlled Correspondence 90%	within 120 days of submission date.

GDUFA IV: Data and Submission Standardization

Summary: Facilitate product development and establish more structured submission expectations to enhance review efficiency

Public reference source for MDD values

Maximum Daily Dose Database

- FDA to create public MDD database for reference listed drugs, by end of FY 2028
- Initial pilot of 500 values, considering industry input to help prioritize initial entries
- Throughout GDUFA IV, verified MDDs will continue to be added
- Public input to be requested on the utility of and improvements to the database

More predictable IID maintenance

Inactive Ingredient Database

- Systematic quarterly updates with newly identified inactive ingredients in labeling approved on or after Oct 1, 2027
- Any inactive ingredients approved prior to this may be added upon request
- FDA will continue to transition from maximum potency to MDE

Structured, consistent review inputs

Standardized ANDA Information

- FDA will provide or update standard tables and format information to submit data for:
  - BE summary tables and site information, drug substance and impurity structures, and Individual-subject PK data
- Intended to enhance ANDA review efficiency
- Industry to aspire to submit using the provided table and format recommendations

GDUFA IV - DMF Prior Assessment

Summary – Increase usability of Drug Master File (DMF) prior assessment (PA) Program

- **Expands DMF Prior Assessment (PA) eligibility** to DMFs supporting:
  - **Qualifying ANDAs** where all reference listed drug (RLD) patents and exclusivities will expire within **24 months** of ANDA submission (increased from **12 months** under GDUFA III).
  - **ANDAs containing a complex active pharmaceutical ingredient (API)**.
  - **ANDA supplements** that add a new API source when the associated manufacturing facilities are located in the **United States**.

- **Introduces two new requirements** for DMF prior assessment requests -
  - Striving to issue **information requests (IRs)** for eligible DMFs **30 days before ANDA submission**.
  - For DMFs referenced in a **Prior Approval Supplement (PAS)** involving U.S. facilities, striving to issue a **second-cycle IR (if needed)** within **70 days** of:
    - Receipt of the DMF holder's response to the first-cycle IR, or
    - Submission of the referencing ANDA, whichever occurs later, provided the DMF holder responds to the first-cycle IR within **30 days**.

Structured Review and Review Management

Summary – Improve review efficiency with number of review cycles minimized

- **Enhancements include:**
  - Earlier FDA consultation expectations
    - FDA staff will initiate consults to other review disciplines earlier with request for response before midcycle, and communicate any identified concerns at midcycle
  - Goal date extension limitations
    - Introduces the option for a one-time (90 day) extension and clarifies review extension expectations after response to FDA information request/review comments
  - Improved labeling review process
    - Establishes FDA review timeframe expectations for revised labeling and expectation to avoid goal date extensions due solely to labeling
    - Requires FDA to provide labeling comments in track changes format for prescribing information

Details in Appendix ›

Missed Goal Dates, Complex Data Issues, and Transparency

Summary: Industry sought additional process for so-called "black box ANDAs."

When FDA believes it will miss the goal date of an ANDA by more than 60 days:

- FDA will assign a new, 6-month goal date
- FDA will strive to issue any IRs/DRLs (unrelated to the issue precluding action) by the original goal date
- If the new 6-month goal date is not met, FDA will inform the applicant and offer an opportunity for a meeting

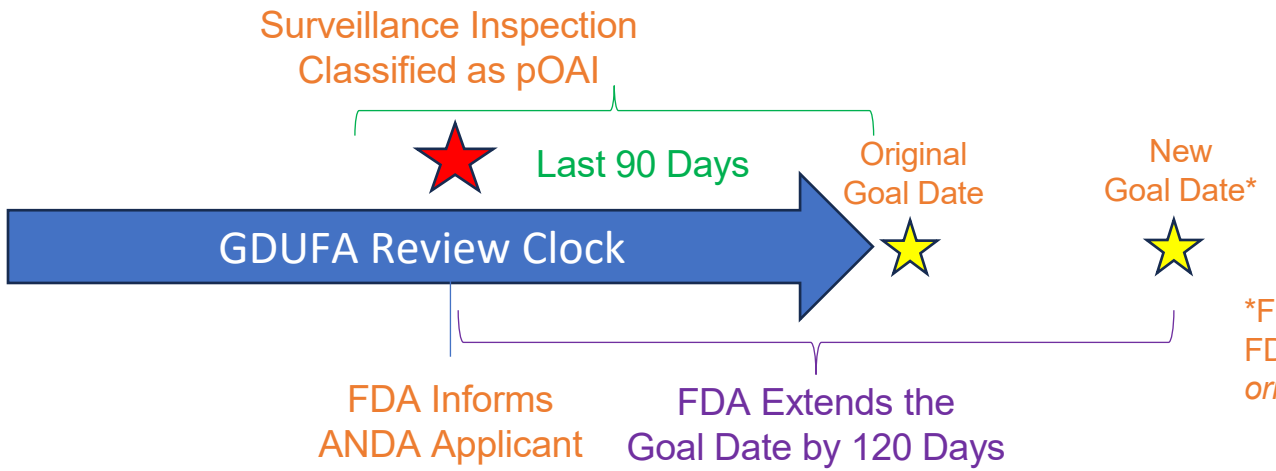
Special Case for "complex data issues." Complex data issues are application agnostic, impacting BLAs, NDAs, and ANDAs

- FDA will inform the applicant as soon as it identifies a potential complex data issue
- If the 6-month goal date is not met, the meeting will be offered to the facility (though the ANDA applicant may participate if a letter of authorization is provided)
- Missed goal dates for "complex data issues" are excluded from FDA's 90% performance metric



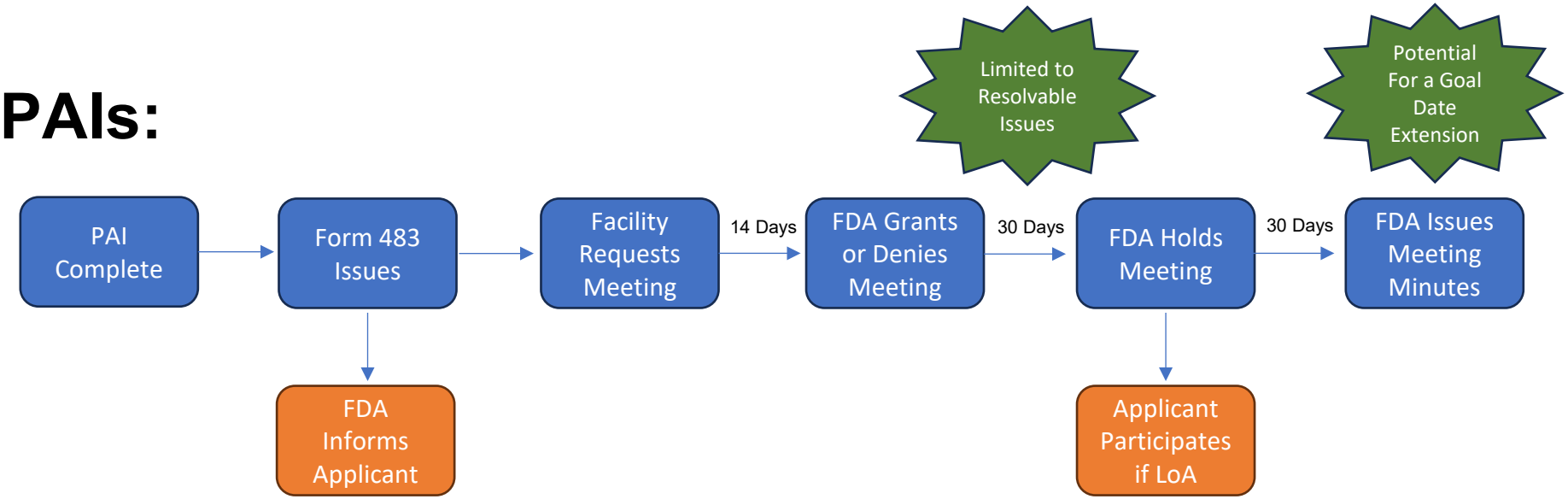
Facility Assessments, Inspections, and Post-Inspection Interactions

Surveillance Inspections:



*For disciplines other than facilities, FDA will continue to work towards the *original* goal date

PAIs:



Domestic Manufacturing and Supply Chain-Related Provisions



Foreign Fee Differential: FDA increased the foreign fee differential from $15,000 to $25,000



ANDA Fee Waiver: Domestic applicants with ANDAs identifying only U.S. finished dosage form and active pharmaceutical ingredient facilities are eligible for a one-time ANDA fee waiver



Early Inspections of U.S. Facilities: Existing U.S. facilities without a recent inspection history may request a surveillance inspection in advance of planned DMF or ANDA submission

GDUFA IV FINANCIALS: USER FEES AT A GLANCE

Four fee streams fund the program

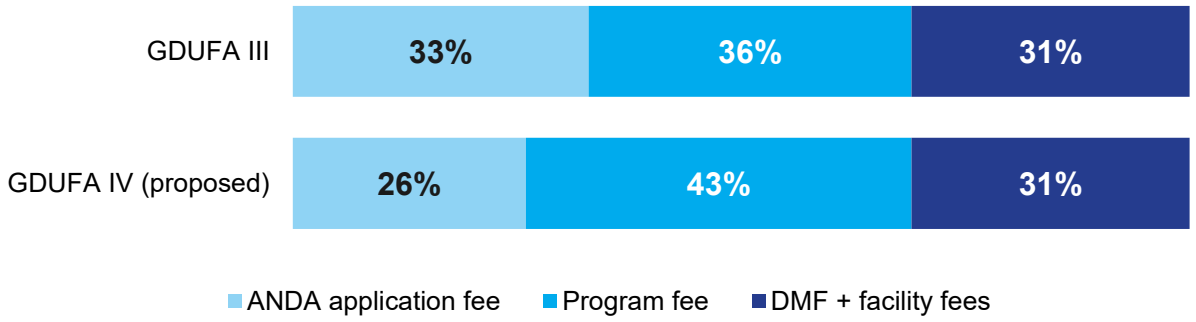
ANDA application fee
one-time, at submission

Annual program fee
small / medium / large tiers retained

DMF fee
one-time, for Type II API DMFs

Annual facility fee
FDF and API sites; foreign differential applies

Allocation shifts 7 points to program fees



May 1
Fee liability date, moved from Oct. 1*

$25,000
Foreign facility fee differential, up from $15,000*

1-time waiver
Original ANDA fee for all-U.S. supply chains*

Resource-neutral
No industry funding for added FDA FTEs

* Requires legislation. Proposed, not final; annual fee rates are set by separate Federal Register notice. No GDUFA IV target revenue amount published. Sources: Proposed GDUFA IV commitment letter § VII; FR notice, Docket FDA-2025-N-0873, § III.F–G