U.S. FOOD & DRUG ADMINISTRATION

Overview of Generic Drug Program

GRX-BioSims Annual Meeting November 2026

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Generic Drug Program: Challenges, Status, Advances

1. **The Stakes & Our Commitment**
   Why generic drug quality and public confidence matter.
2. **Program Performance in Numbers**
   ANDA submission trends, FY2026 metrics, and review goal attainment.
3. **Science, Innovation & Notable Approvals**
   GDUFA research outcomes, alternative BE approaches, revised peptide PSGs, and first generic approvals.
4. **Addressing Challenges**
   Drug shortage prevention, domestic manufacturing incentives, and Q1/Q2 transparency legislation.
5. **The Road Ahead**
   GDUFA IV commitments, informatics modernization, and upcoming events.

Generic Drugs: Public Confidence Matters

THE STAKES

89% of U.S. prescriptions are for a generic but they account for just under 12% of drug costs.

THE CHALLENGE

Concerns about generic drug product quality and data integrity can erode public confidence, with real consequences for patients and the American healthcare system.

THE COMMITMENT

FDA will continue its efforts to maintain public confidence in generics, embrace emerging technologies and scientific innovation, and strengthen its position as the global gold standard for regulatory science.

Ensuring Every Patient Receives a Quality Therapeutically Equivalent Generic Medicine

FDA applies the same rigorous standards to every drug throughout its lifecycle: brand or generic, domestic or foreign.

FDA and Reagan-Udall Foundation will host a 2027 public meeting to better understand perceptions about generic drug quality and identify gaps and solutions.

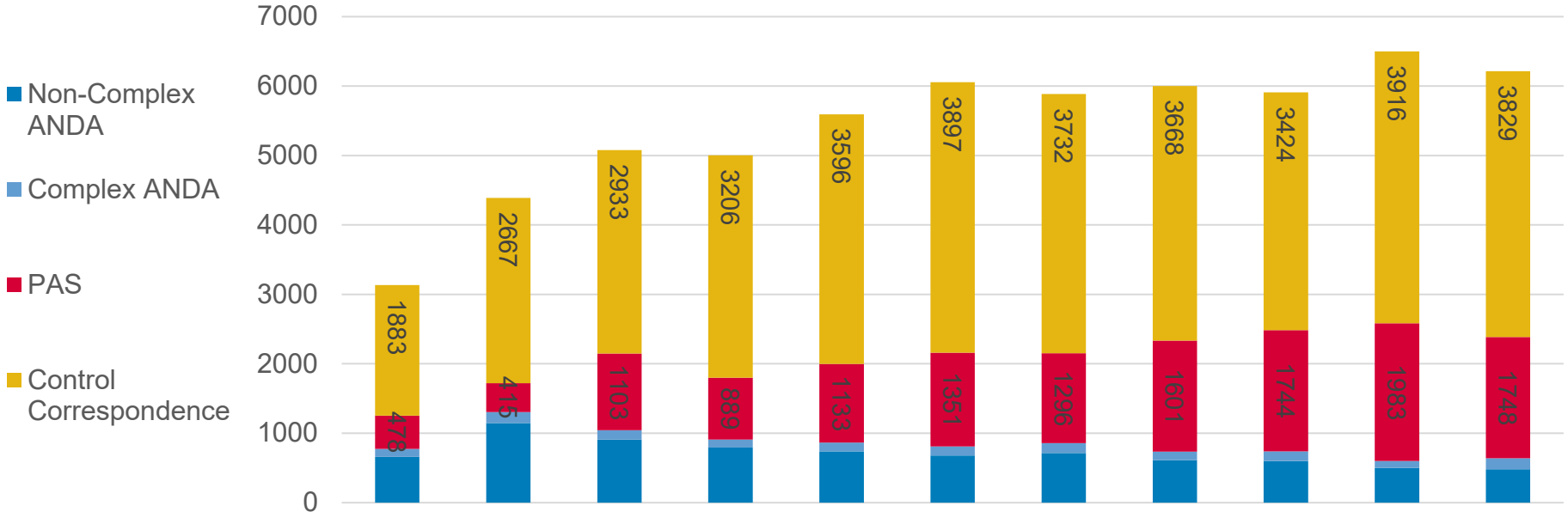
REAGAN-UDALL FOUNDATION for the Food and Drug Administration

Assuring Generic Drug Quality, Safety, and Efficacy

To better understand public perceptions about generic drugs, the Foundation will convene a series of invitation-only roundtables on generic drug quality, safety, and efficacy.

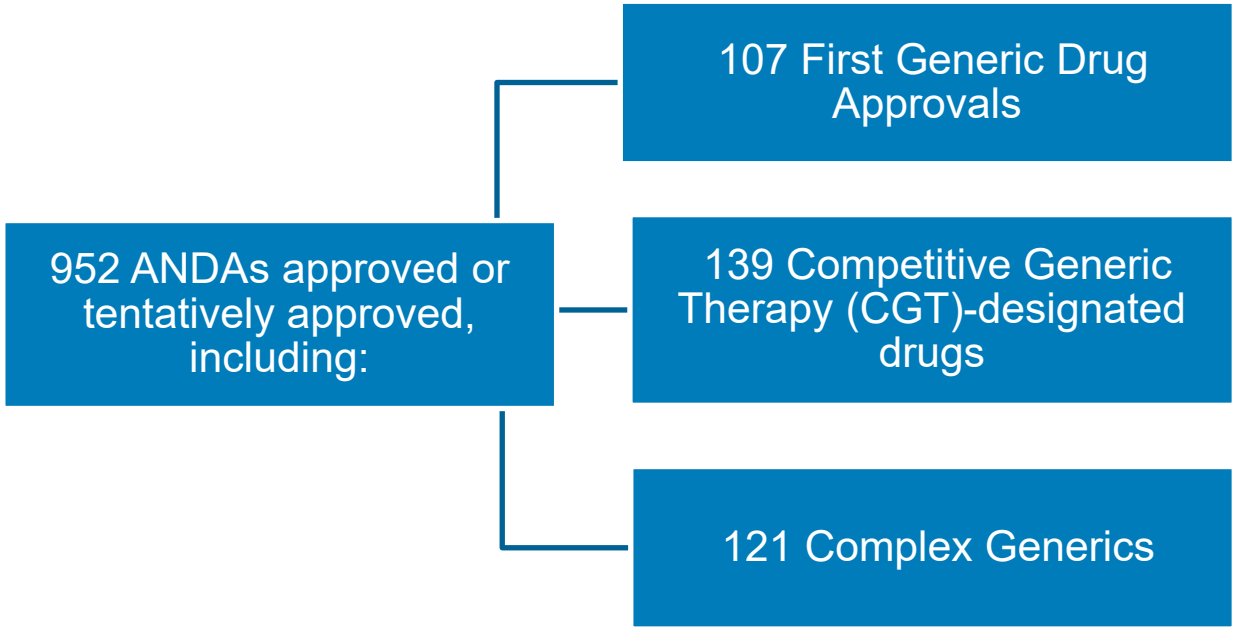
Metrics & Performance at a Glance

Submission Trends: FY2016–FY2026

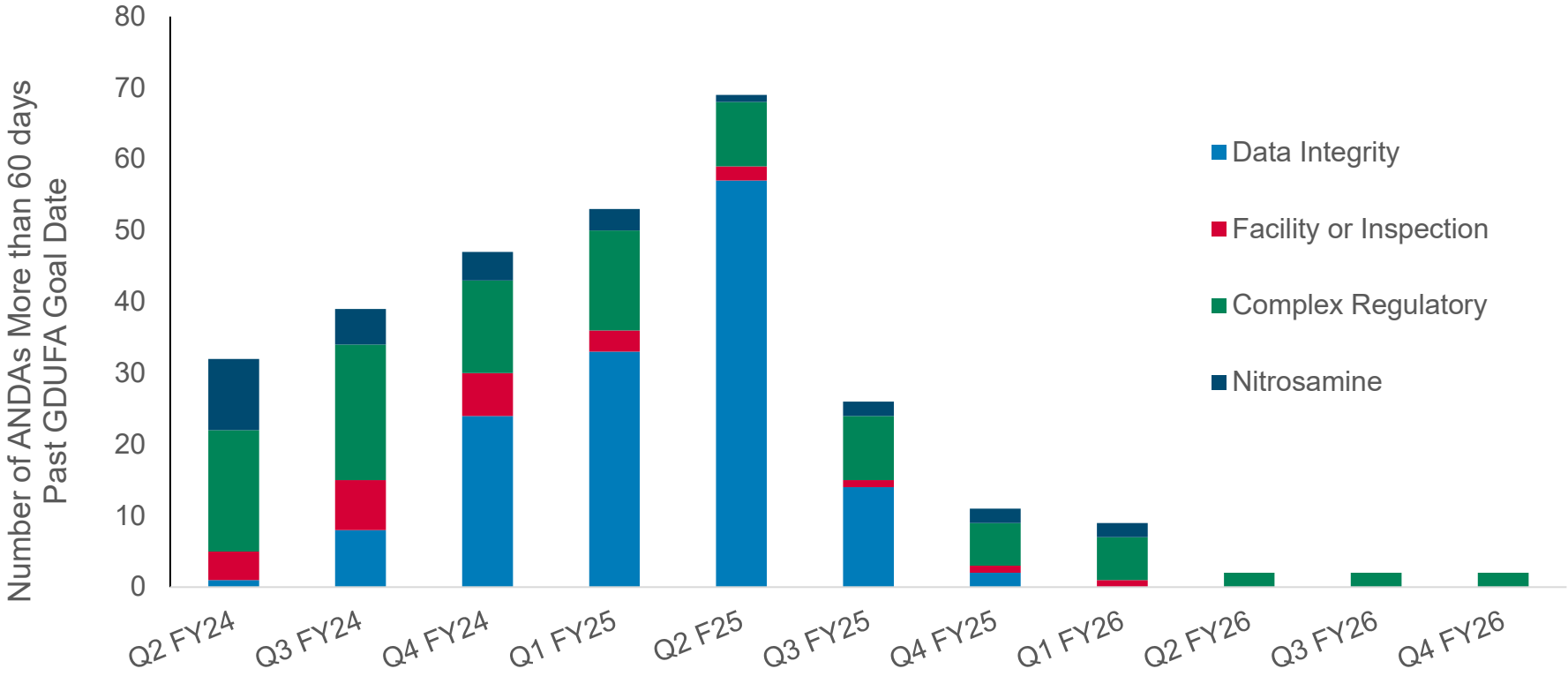


Fiscal Year	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026
Total Original ANDAs	775	1306	1044	909	865	809	857	733	740	600	638
Percent Complex	15%	12%	13%	13%	15%	16%	16%	17%	19%	17%	25%
Percent RTRed	32%	11%	12%	6%	5%	6%	6%	5%	3%	3%	1.5%

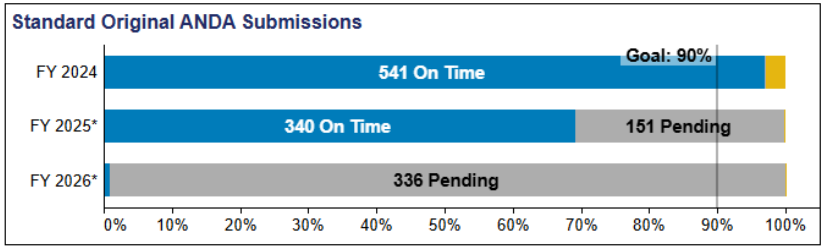
FY2026 Program Performance at a Glance

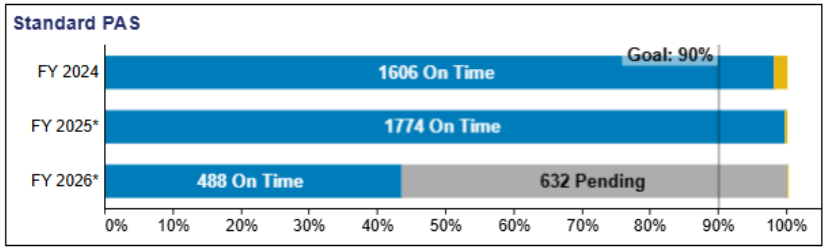


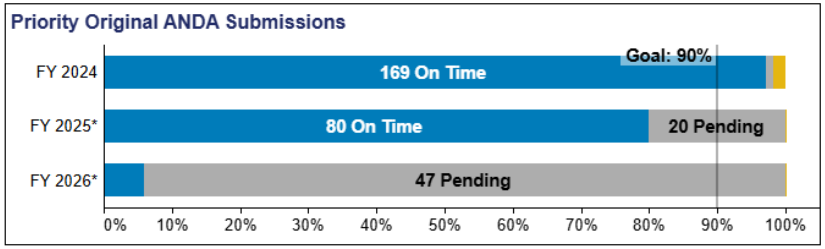
Update ANDAs >60 Days Past Goal Date

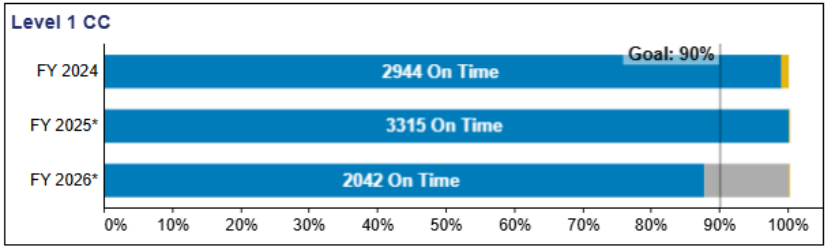


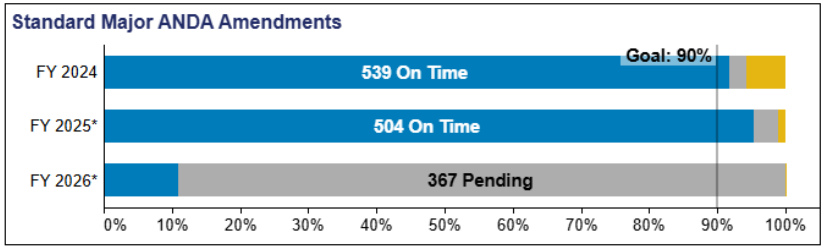
Continued Commitment to Transparency: New GDUFA Dashboard – FDA Track

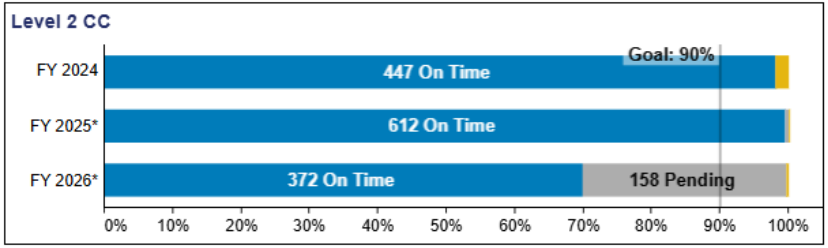








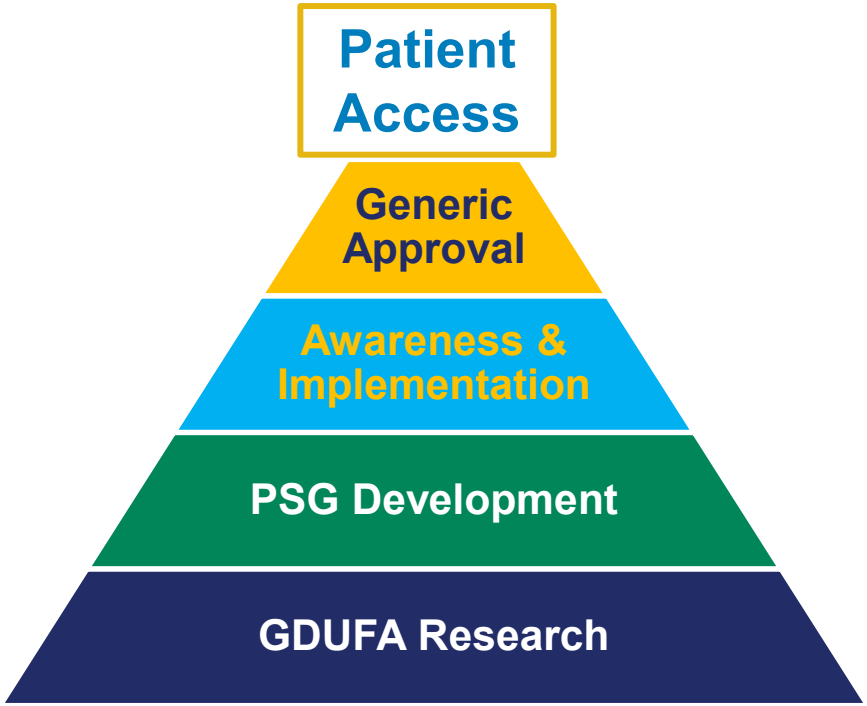




GDUFA Science and Notable Approvals

Driving Patient Access Through Transparent Innovation

GDUFA Science & Research: Driving Access via Transparent Innovation



89% of U.S. prescriptions are for generics

952 Approved and Tentatively Approved ANDAs

10 Public Workshops

Over 17,000 attendees

91 Presentations

44 Posters

54 Scientific Articles

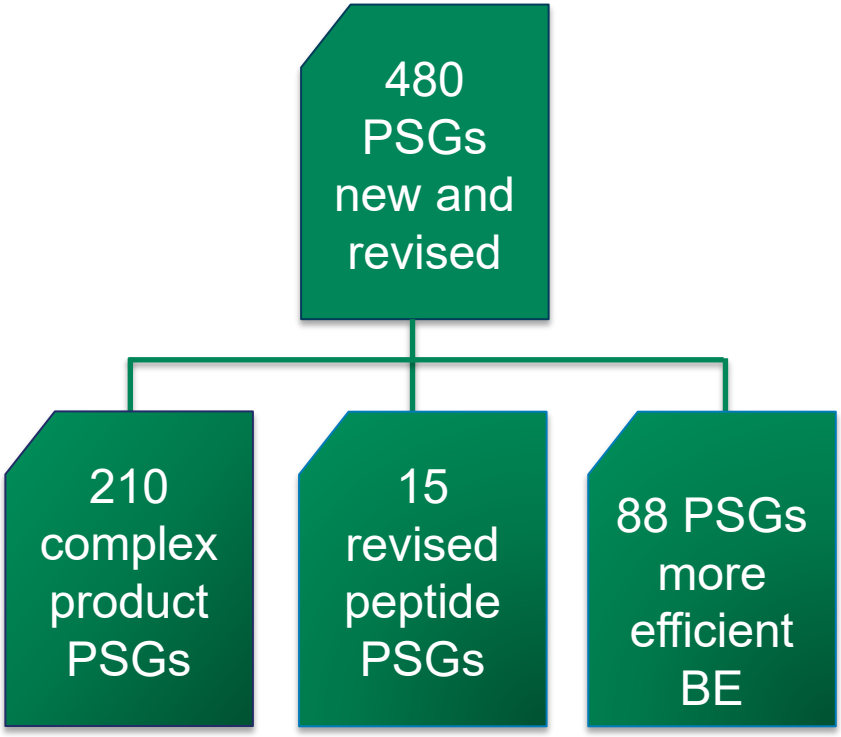
480 new and revised PSGs

32 Research Contracts & Grants awarded

8 Research Priorities[1]

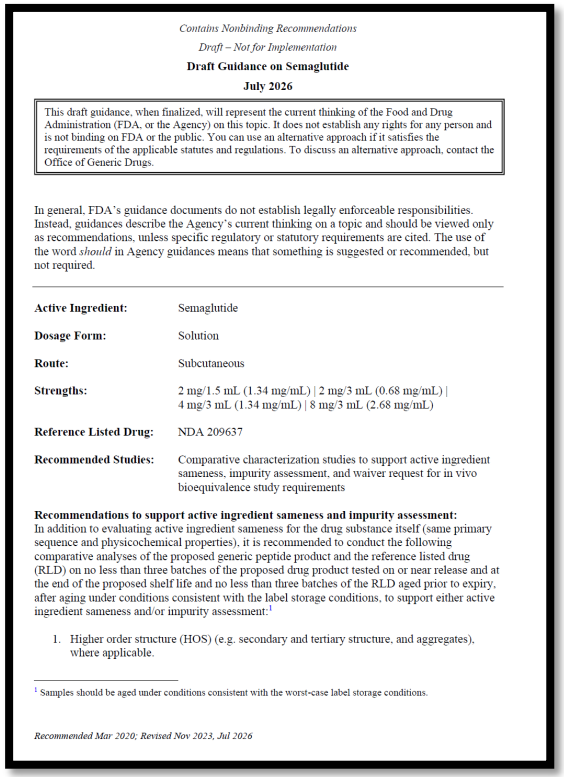
1. FY2027 GDUFA Research Priorities posted Oct 2026

GDUFA Research and PSGs: More Efficient BE Approaches



- In vitro approaches for some ‘simple’ injectable suspension products
- Alternative PK assessments to steady-state PK studies for long-acting injectables
- Option based and streamlined BE approaches for inhalation products
- Alternative comparator approach for when an RLD has been discontinued
- In vitro and dermal PBPK model approaches for topical products

Revised Peptide Product-Specific Guidances



Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Semaglutide

July 2026

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Active Ingredient:	Semaglutide
Dosage Form:	Solution
Route:	Subcutaneous
Strengths:	2 mg/1.5 mL (1.34 mg/mL) | 2 mg/3 mL (0.68 mg/mL) | 4 mg/3 mL (1.34 mg/mL) | 8 mg/3 mL (2.68 mg/mL)
Reference Listed Drug:	NDA 209637
Recommended Studies:	Comparative characterization studies to support active ingredient sameness, impurity assessment, and waiver request for in vivo bioequivalence study requirements

Recommendations to support active ingredient sameness and impurity assessment:
In addition to evaluating active ingredient sameness for the drug substance itself (same primary sequence and physicochemical properties), it is recommended to conduct the following comparative analyses of the proposed generic peptide product and the reference listed drug (RLD) on no less than three batches of the proposed drug product tested on or near release and at the end of the proposed shelf life and no less than three batches of the RLD aged prior to expiry, after aging under conditions consistent with the label storage conditions, to support either active ingredient sameness and/or impurity assessment:[1]

1. Higher order structure (HOS) (e.g. secondary and tertiary structure, and aggregates), where applicable.

[1] Samples should be aged under conditions consistent with the worst-case label storage conditions.

Recommended Mar 2020; Revised Nov 2023, Jul 2026

17 Peptide PSGs Revised July 2026

- Non-clinical methods can support a proposed generic peptide (***recombinantly***, synthetically, or semi-synthetically produced) and its RLD can be expected to have the same clinical effect and safety profile
- Active ingredient-related impurity comparison
  - ***Report*** all active ingredient-related impurities present at a ***level above 0.1%***.
  - ***Identify*** all active ingredient-related impurities present at a ***level above 0.5%***.
  - Active ingredient-related impurity levels ***should not be greater than those found in the RLD or 1.0%*** of the drug substance, ***whichever is greater***.
- A new or elevated common impurity outside of the specified levels above ***does not preclude submission as an ANDA***.
- If non-active ingredient-related impurities meet these criteria and limits, and aggregation profiles are comparable to that of the RLD, ***in vitro innate immune testing may not be scientifically necessary***.

FY2026 First Generic Approvals: Highlights

Conjugated Estrogens (Premarin)

Beclomethasone Dipropionate MDI (Qvar)

Fluticasone propionate Aerosol (Flovent HFA)

Dapagliflozin (Farxiga)

Nintedanib Capsules (Ofev)

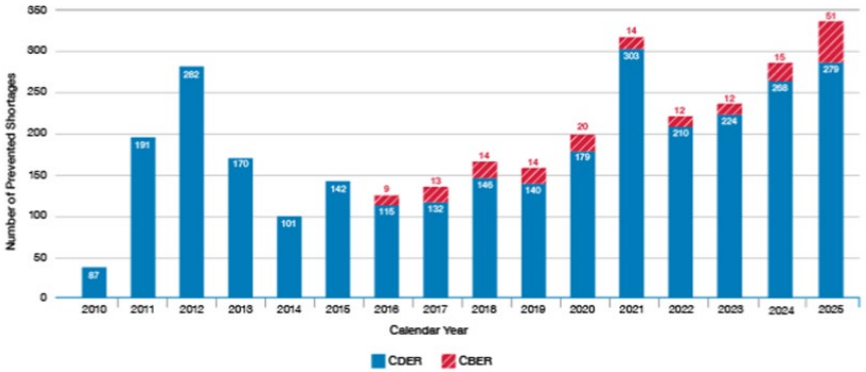
Rifapentine Tablets (Priftin)

Facing Challenges: New Initiatives

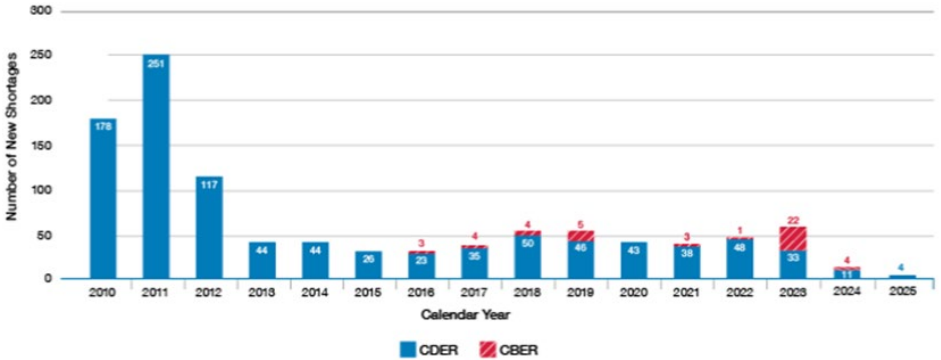
Drug Shortage Successful Efforts

- In 2025, only 4 new drug shortages were reported, the fewest since tracking began, while 279 shortages were prevented through proactive dialogue and collaboration with industry.

Prevented Shortages



New Shortages



2025: CDER New Shortages 4, CDER Prevented Shortages 279

Drug Shortage Prevention and Mitigation

- **Early Notification to the Drug Shortage Staff (DSS) is critical.**
  - Communicate early about potential shortages
  - Provide short and long-term plans for preventing and addressing shortages while maintaining and improving quality
  - Work with FDA to minimize shutdowns or slowdowns that could lead to shortages
- **Contact DSS at Drugshortages@fda.hhs.gov or Report through the CDER Nexgen Portal**

ANDA Prioritization Pilot: Domestic Manufacturing and Testing

Launched October 3, 2025

Goal: Strengthen domestic pharmaceutical supply chain by providing faster reviews for generic companies who test and manufacture their products in the U.S.

Pilot Program Metrics through Sept 2026:

- **10** submissions met the criteria

The following three criteria must be met to be eligible:

- Finished dosage form (FDF) manufacturer(s) is exclusively located in the U.S.
- Active pharmaceutical ingredient (API) supplier(s) is exclusively located in the U.S.
- Either the pivotal bioequivalence (BE) testing conducted in the U.S. or the ANDA qualifies for a waiver of bioequivalence testing

How to Request:

Requests for prioritization should follow the Manual of Policies and Procedures (MAPP) 5240.3, *Prioritization of the Review of Original ANDAs, Amendments, and Supplements*, specifically under the Onshoring Pilot Program

Q1/Q2 Legislation: Implementation Update

- Section 6703 of the Consolidated Appropriations Act, "Increasing Transparency in Generic Drug Applications" enacted February 3, 2026.
  - Grants FDA new authority to share more information with generic drug applicants on how a proposed generic formulation may not be qualitatively (Q1) or quantitatively (Q2) same to the proposed RLD.
    - This act applies to generic products that are required by regulation to be Q1/Q2 to the RLD with respect to one or more inactive ingredients, such as parenteral, ophthalmic, and otic drugs (21 CFR 314.94(a)(9) (iii-iv)), or where FDA determines there is a scientific justification for an in vitro bioequivalence approach if the drug is Q1/Q2 to the RLD for one or more inactive ingredients.
    - OGD implemented this new authority immediately upon enactment and through the end of FY 26 responded to 362 requests in controlled correspondence with 99% meeting the GDUFA goal date.

The Road Ahead

GDUFA IV, Informatics Modernization & Upcoming Events

GDUFA IV: Enhancements for a Stronger Generic Program

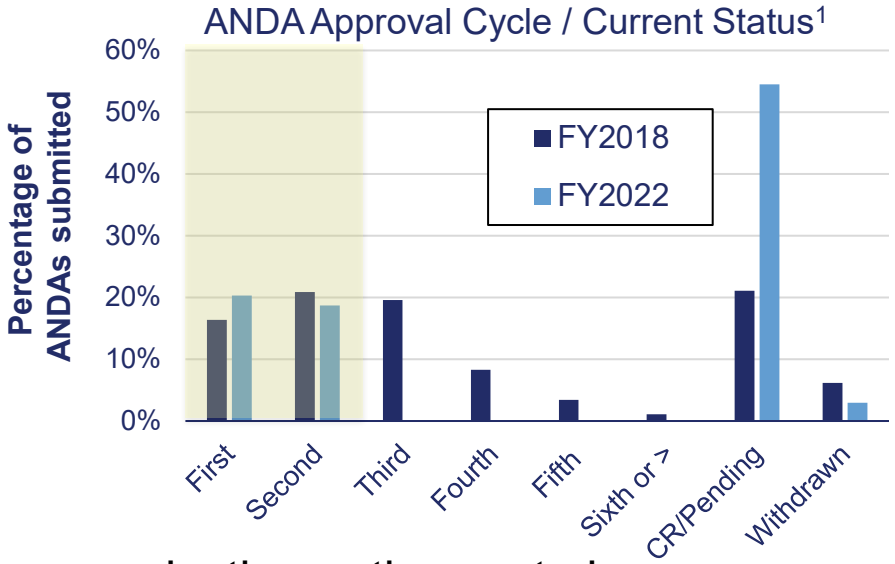
- **Enhanced Assessment Transparency & Predictability**
  - **Improved efficiency:** updated review timelines and increased communications throughout the process.
  - New goal dates for ANDAs for which the goal date is missed by more than 60 days.
- **Pre-ANDA & Product Development Acceleration**
  - **Application-Related Meetings:** Structured TYPE 30, 60, 90, and 120 day meetings for scientific exchange, especially supporting Complex Generic Products.
  - **Early DMF Review:** Expanded eligibility criteria for DMF prior assessments to include complex API and PAS seeking to add new domestic API source.
- **Facility & Inspection Improvements**
  - **Post-PAI Meetings:** New meeting to discuss inspection findings that may impact approval and corrective actions that may address those issues within the current review cycle.
  - **Surveillance Inspections:** Eligible domestic facilities that are expanding capacity may request surveillance inspections prior to ANDA/DMF submission.

Informatics Modernization in Generics

- OGD is exploring AI and machine learning tools to modernize the generic drug review process.
- Modernization efforts aim to enhance review efficiency, improve consistency, and better leverage large datasets generated through GDUFA-funded science.
- Pilot programs to leverage AI tools to support filing review, BE data analyses, formulation sameness assessment, and risk-based surveillance.
- Large informatics effort to consolidate platforms - OneNexus

Increasing Review Efficiency

- Typically, more than 60% of ANDAs take more than 2 cycles to reach approval or be withdrawn
  - Each additional review cycle means delayed patient access and increased resource burden for both FDA and industry.



- **Goal:** Reduce number of ANDAs that have more than 3 review cycles
  - The generic program is leveraging communication pathways to improve transparency and the clarity of regulatory science expectations.
  - FDA will continue to communicate common and avoidable deficiencies to improve the completeness and quality of submissions.

1. as of Oct 2024

Upcoming Events

- FDA and Center for Research on Complex Generics (CRCG) collaborations: www.complexgenerics.org

  Dec 1-2: **FDA-CRCG Long-Acting Injectable Generics:**
  Advancing Innovation in Product Development and Regulatory Assessment

- OGD and CDER Small Business & Industry Assistance (SBIA) collaborations: https://sbiaevents.com

  Apr 13-14: Generic Drug Forum


FDA
We care about enhancing access to generic drugs
WE ARE THE GENERIC DRUG PROGRAM

U.S. FOOD & DRUG ADMINISTRATION

Thank You