Working Together to Increase Access to Generic Drugs

Office of Generic Drugs

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Generic Drugs Forum

April 9, 2026

Driving Access

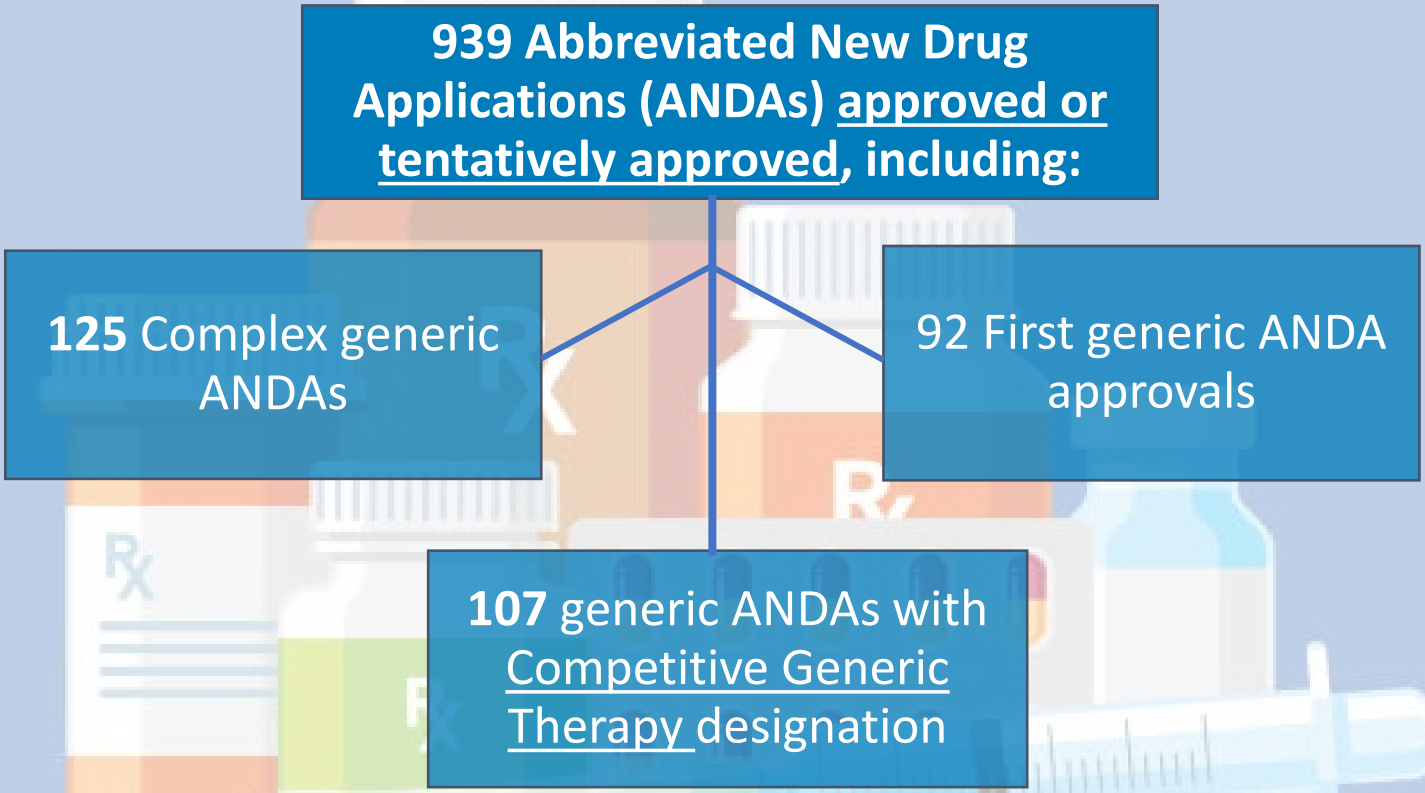
State of the Generic Drug Program: Key Approval & Receipt Metrics

Notable Generic Approvals and Initiatives

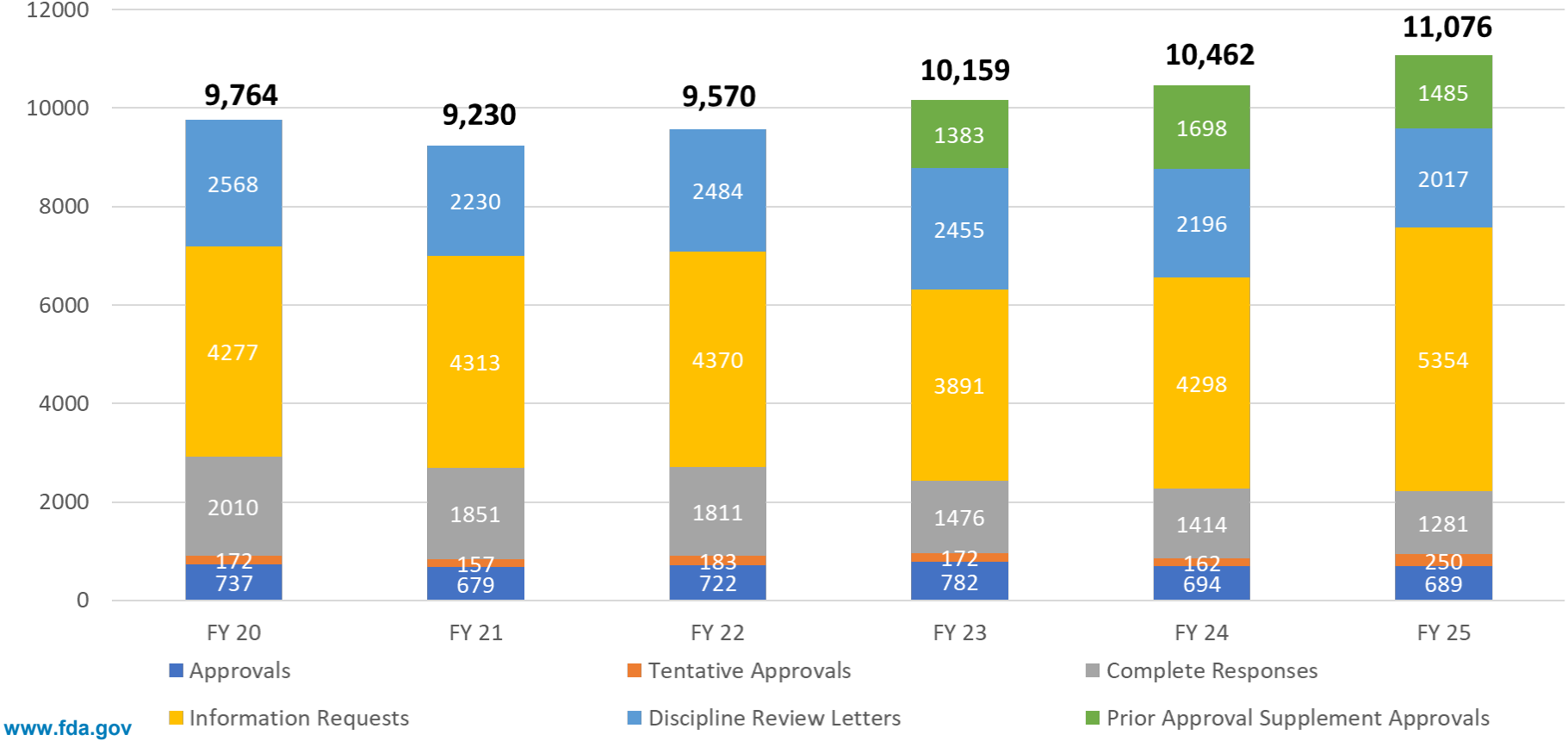
Applicant and Public Resources

Looking to the Future

State of the Generic Drug Program: Generic Approvals Fiscal Year (FY) 2025



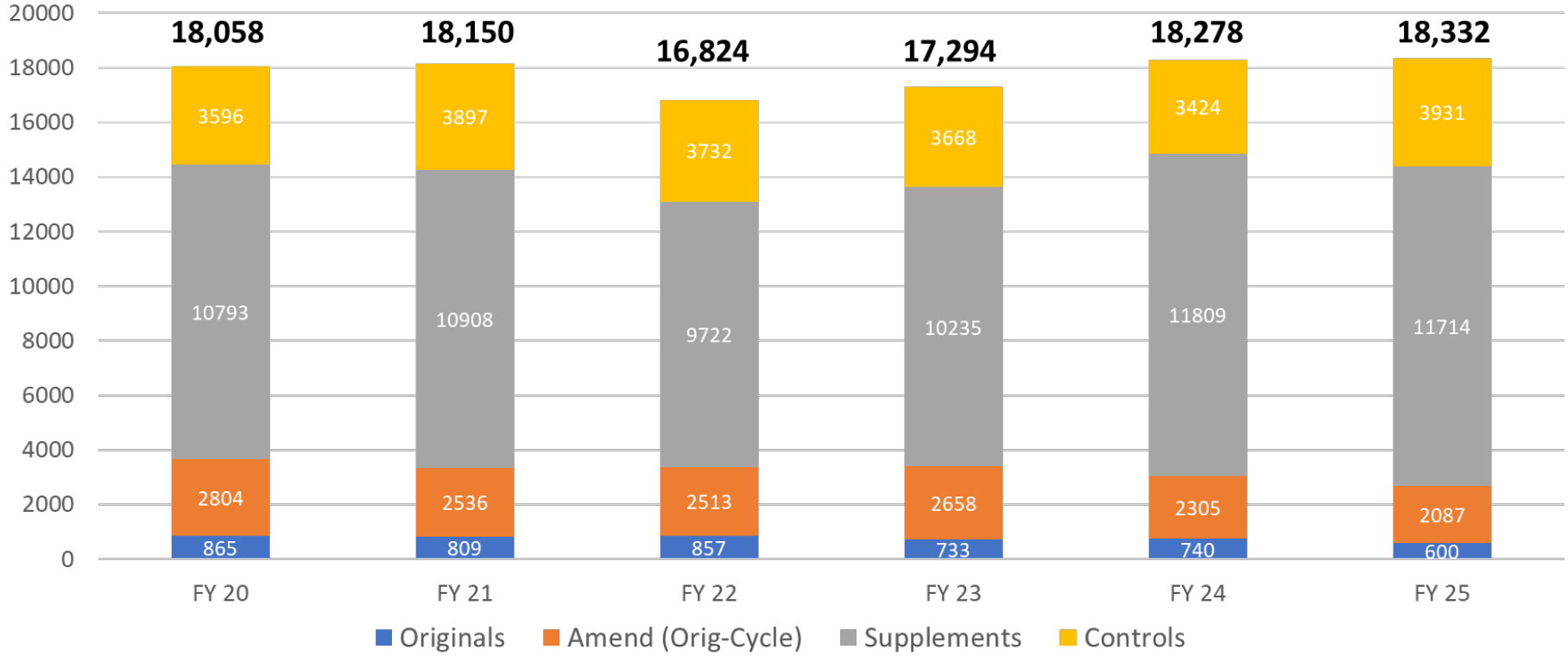
ANDA Program: Key Actions



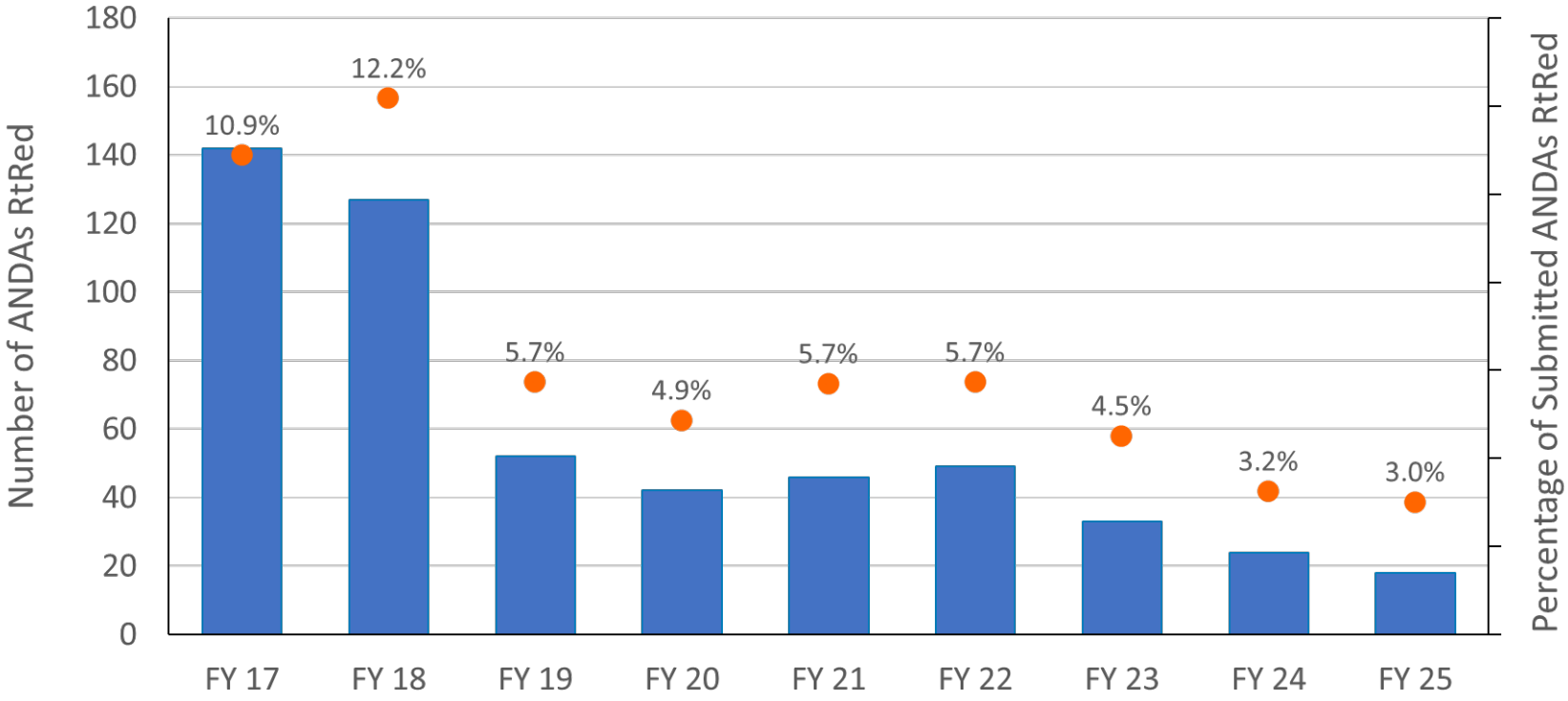
Notable FY 2025 Generic Approvals

Established Name	Brand Name	Indication	Approval Date
Liraglutide Injection	Saxenda	Chronic weight management	August 2025
Iron Sucrose Injection	Venofer	Iron deficiency anemia in CKD/dialysis	August 2025
Sitagliptin + Metformin XR	Janumet XR	Type 2 diabetes	June 2025
Rivaroxaban	Xarelto	Anticoagulation	March 2025
Siponimod	Mayzent	Multiple sclerosis	April 2025

ANDA Program: Key Receipts



Reduction in ANDA Refuse-to-Receive



Improving Quality of ANDA Submissions: Resource Page for ANDA Applicants

https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/helpful-webinars-and-other-resources-generic-drug-manufacturers

Webinars and Other Resources for Industry

(Topics arranged alphabetically)

- Bioequivalence
  - Bioequivalence Studies: Overview and General Considerations
  - Inactive Ingredient Database and Maximum Daily Dose
  - Nasal and Inhalation Products
  - Oral Products
  - Parenteral (Injection), Ophthalmic, and Otic Products
  - Sample Retention
  - Topical and Transdermal Products
- Communication with FDA: Pathways and Best Practices
- Comparative Analysis for Drug-Device Combination Products
- Data Integrity
- Labeling
- Pharmacology/Toxicology
  - Excipients and Impurities
  - Nitrosamines
- Product-Specific Guidance (PSG)
- Quality (Manufacturing, Drug Substance, and Microbiology)
- Risk Evaluation Mitigation Strategy (REMS)
- Additional Resources on Published Webinars, Seminars, and Workshops

Increased Transparency for ANDAs with Missed Goal Dates

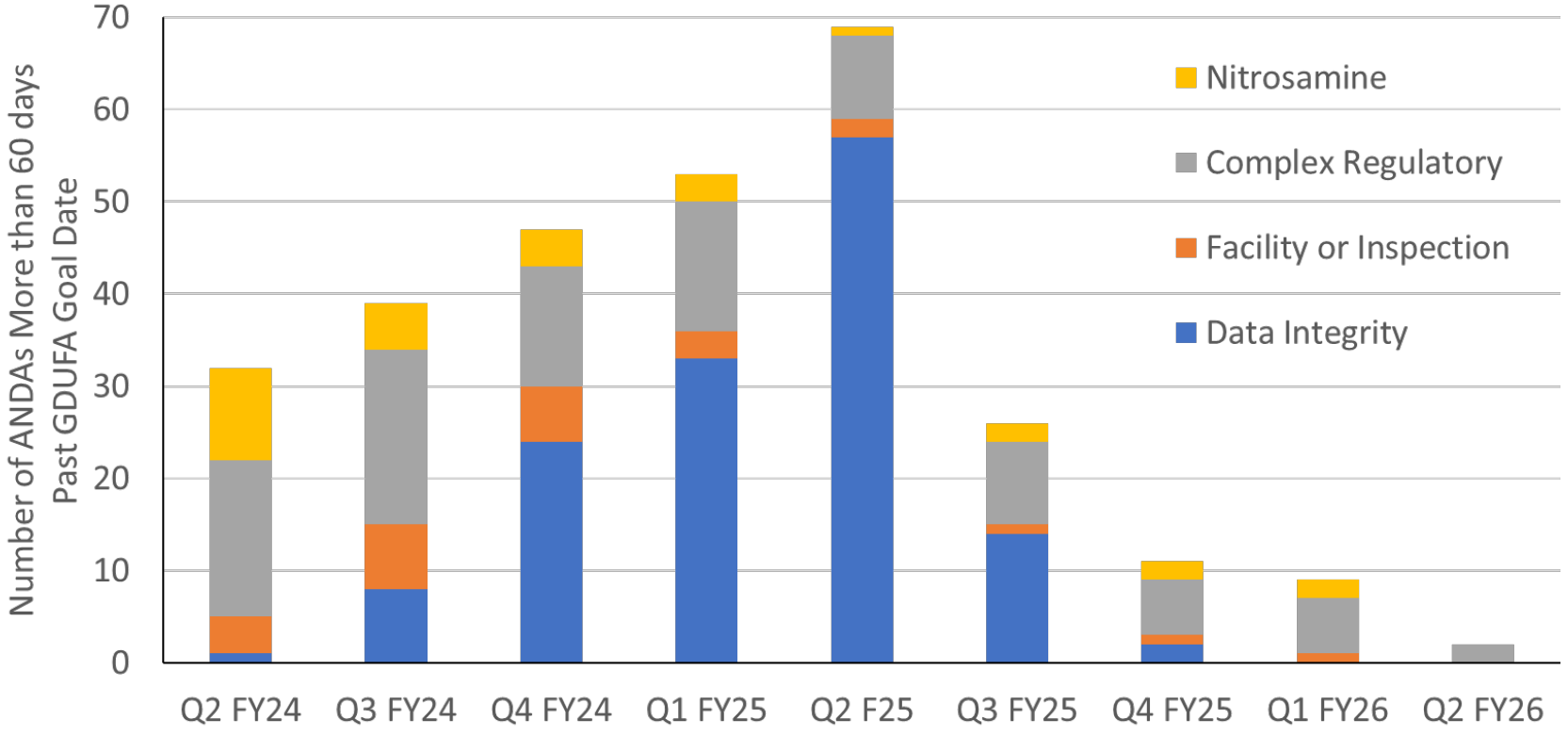
When the Transparency Pilot is Utilized:

- The pilot is broadened from its initial focus on 60-day misses.
- It is specifically utilized when goal dates are likely to be missed due to a complicated issue that requires more in-depth communication.

We aim to provide information on:

- By the goal date, applicants will be notified whether to anticipate an action on that date, such as an imminent action or a missed goal date.
- Which discipline(s) (e.g., Bioequivalence, Quality, etc.) may be affected.
- Status inquiries and updates provided by the Regulatory Project Manager.
- The pilot incorporates frequent touchpoints and clear escalation pathways to ensure consistent communication.

ANDAs > 60 days Past Goal Date



Increasing Transparency in Generic Drug Applications

- The Consolidated Appropriations Act (H.R. 7148), enacted February 3, 2026, requires FDA to identify the specific inactive ingredient causing Q1 (qualitative) and Q2 (quantitative) sameness failures and quantify the deviation when proposed generic formulations don't match the reference listed drug (RLD).
- Applies to:
  - Proposed generic products required[1] to be Q1/Q2 or when formulation sameness is part of a bioequivalence approach.[2]
  - All controlled correspondence, pre-ANDA meetings, ANDAs, and post-approval supplements pending on or submitted after February 3, 2026.

1. 314.94(a)(9)(iii-v): drug products intended for parenteral, ophthalmic, otic, or topical use
2. For example, when recommended in a product-specific guidance

Ensuring Public Confidence in Generic Drugs

- **Public Perception**: Health care professionals and the public continue to express concerns about generic medications and the quality of foreign-manufactured drugs, even though generics account for more than 90% of dispensed medications in the United States.

- **FDA Communications Strategy**: The FDA continues to develop communications (website and social media campaign) to improve public trust through greater transparency and enhanced information sharing about the generic drug program and regulatory processes.
- **Industry Expectations**: The generic drug industry must maintain rigorous quality standards, ensure manufacturing consistency, and provide early and transparent communication about their applications and products

Rewarding Careers in FDA's Generic Drug Program

We're Hiring:

- **Chemists, Health Scientists, Pharmacists, Pharmacologists, Pharmaceutical Scientists, Physicians, Regulatory Counsels, and Toxicologists.**

The Office of Generic Drugs ensures high-quality, affordable generic drugs are available to the American public. ***Join our team*** to provide regulatory oversight of generic drugs, conduct science-based research to advance development of these products, and evaluate generic drug applications to ensure they meet the same high standards as brand-name drugs.

Apply Today

- **U.S. Citizenship or Green Card Required**
- Education: **PhD, MD, PharmD, or JD degree**
- Location: **Silver Spring, MD**
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We care about enhancing access to generic drugs
WE ARE THE GENERIC DRUG PROGRAM