Office of Generic Drugs Keynote

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Generic Drug Forum

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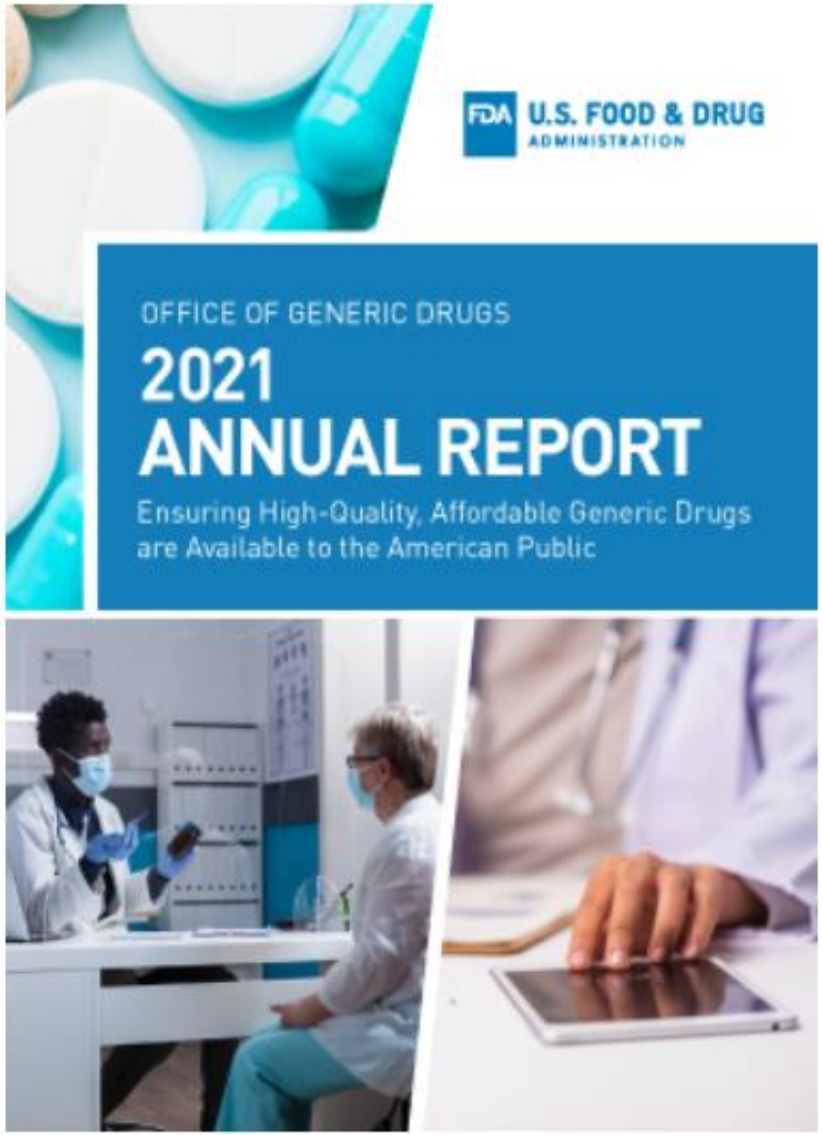
Generic Drug Program 2021 At a Glance

- Approvals/tentative approvals, controlled correspondence, complete response letters, pre-ANDA meetings, and more
- Advancing bioequivalence and generic drug assessments
- Policies that support the efficient development of generic drugs
- Evaluating generic drugs and monitoring generic drug safety

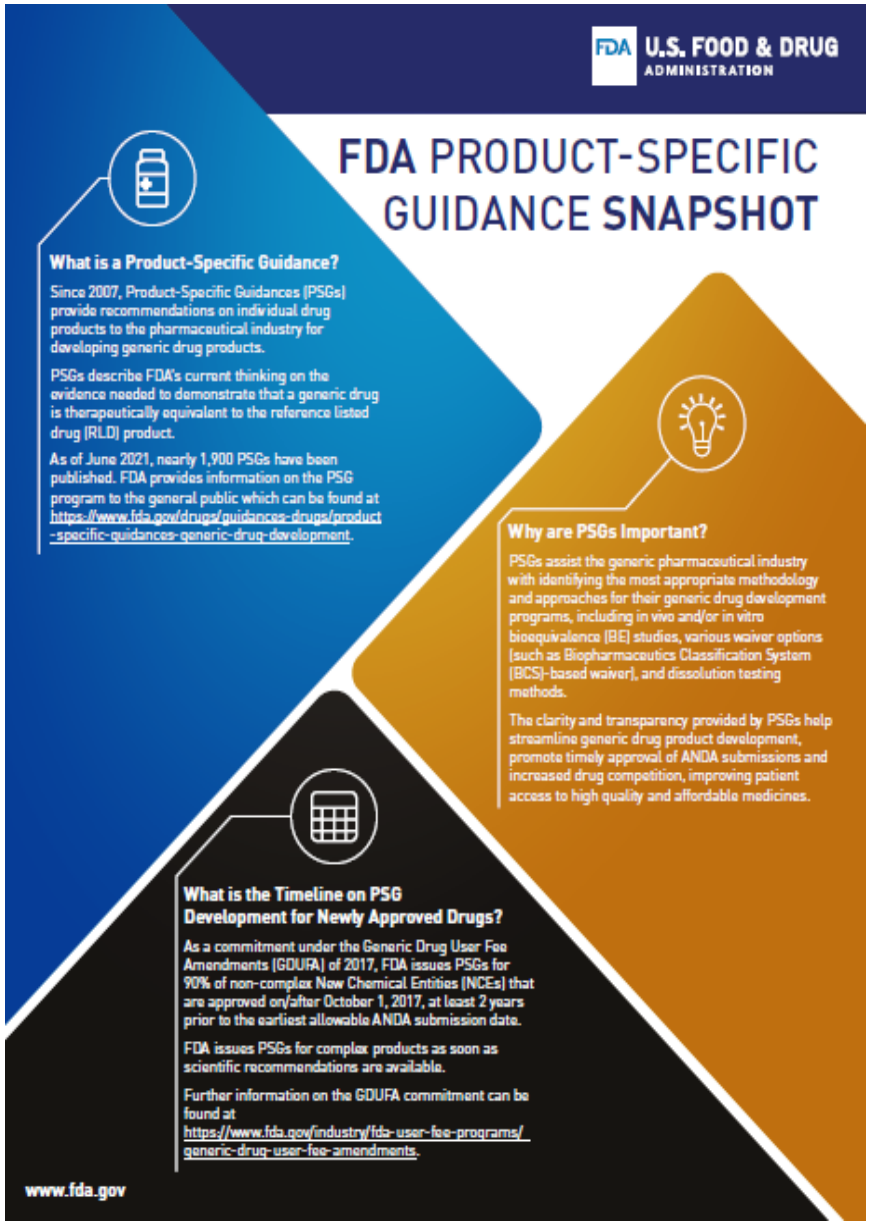
Office of Generic Drugs 2021 Annual Report



Generic Drug Program
Product-Specific Guidances (PSGs)

- Scientific advice to assist generic drug product development
- **149** in 2021
  - **54** PSGs for complex products
- Almost **2000** total

[Product-Specific Guidances for Generic Drug Development]

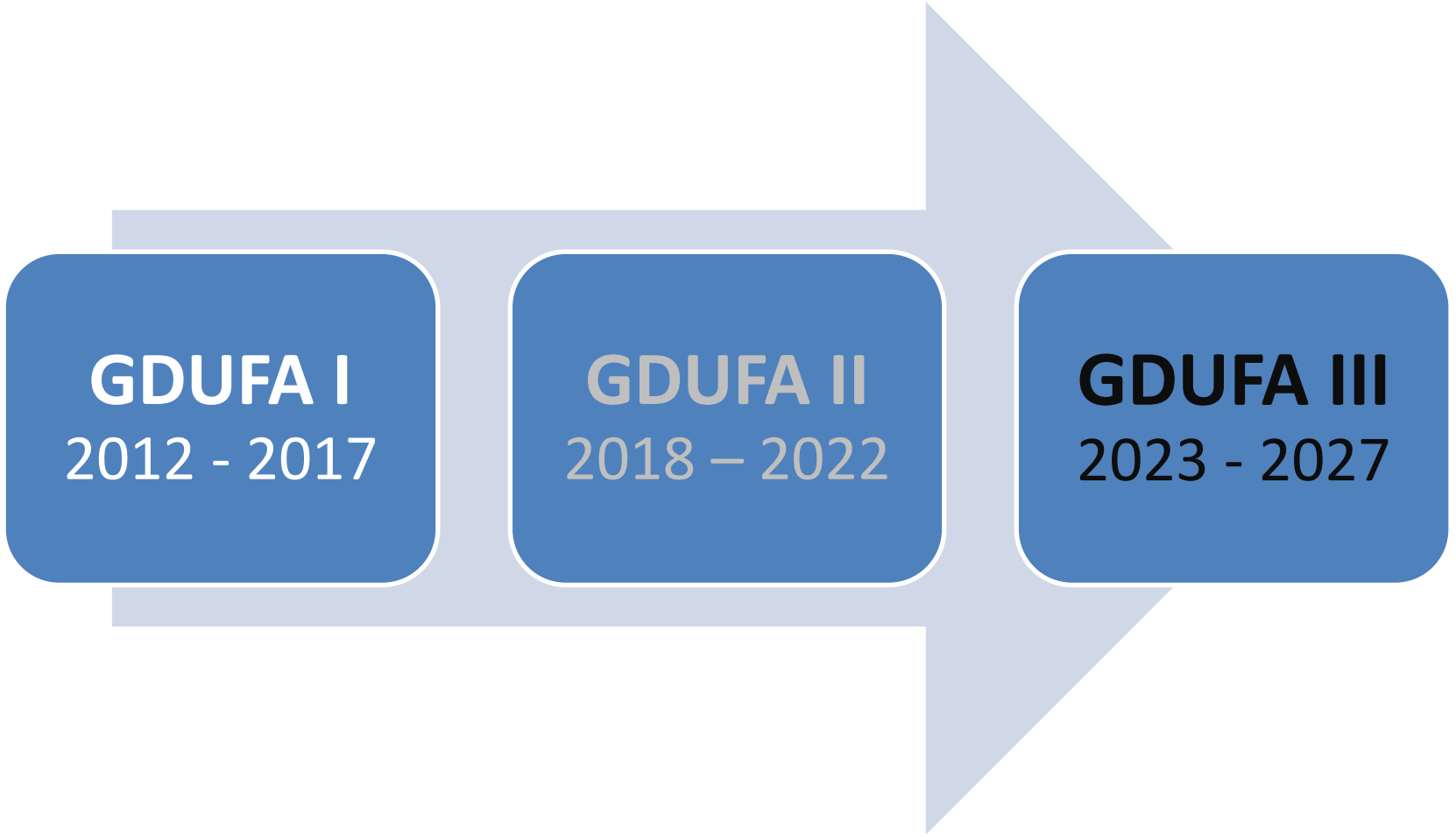


Generic Drug Program
2021 Science & Research

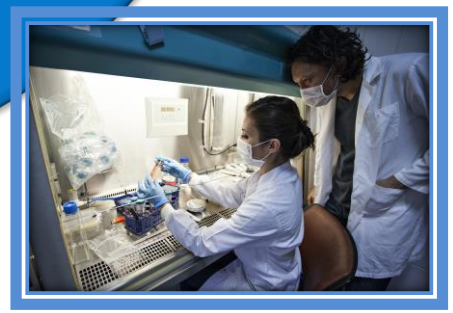
~$20 million in generic drug science and research programs awarded

- **6 new contracts and 10 new grants**
- continued to fund **10 ongoing grants and 20 ongoing contracts**

Generic Drug User Fee Amendments (GDUFA)



Generic Drug Program



Thank You!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