U.S. FOOD & DRUG ADMINISTRATION

Closing Remarks

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Key Takeaways

At GDF 2025 we hope you were able to:

- Gain practical regulatory knowledge
- Understand the important role of our shared public health mission
- Become more familiar with OGD's Strategic Priorities

New Resource for Industry

Helpful Webinars and Other Resources for Generic Drug Manufacturers

Abbreviated New Drug Application (ANDA)

- Generic Drug Development
- Helpful Webinars and Other Resources for Generic Drug Manufacturers
- Abbreviated New Drug Application (ANDA) Forms and Submission Requirements
- Patent Certifications and Suitability Petitions

FDA develops resources – workshops, webinars, and seminars – to help generic drug manufacturers improve the quality of their abbreviated new drug application (ANDA) submissions and decrease the number of assessment cycles needed for approval. The following topics highlight FDA's current thinking and recommendations to avoid common deficiencies found in ANDA submissions and is not meant to be a comprehensive list. FDA has published guidance on many of these topics. Guidances referenced in the following sections are supportive and not a complete list. To find a guidance related to drugs, visit Guidances for Drugs.

Content current as of:
03/21/2025

Regulated Product(s)
Drugs
Generic Drugs

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
- **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)**


Our transparency and published resources assist applicants in their pursuit of approval, which improves patient access to generic medicines.
WE ARE THE GENERIC DRUG PROGRAM

Closing Thoughts


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