

Abbreviated New Drug Application (ANDA)

An abbreviated new drug application (ANDA) contains data which is submitted to FDA for the review and potential approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, lower cost alternative to the brand-name drug it references.

A generic drug product is one that is comparable to an innovator drug product in dosage form, strength, route of administration, quality, performance characteristics, and intended use. All approved products, both innovator and generic, are listed in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*

(<https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>) (Orange Book).

Generic drug applications are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, generic applicants must scientifically demonstrate that their product performs in the same manner as the innovator drug. One way applicants demonstrate that a generic product performs in the same way as the innovator drug is to measure the time it takes the generic drug to reach the bloodstream in healthy volunteers. This demonstration of "bioequivalence" gives the rate of absorption, or bioavailability, of the generic drug, which can then be compared to that of the innovator drug. To be approved by FDA, the generic version must deliver the same amount of active ingredients into a patient's bloodstream in the same amount of time as the innovator drug.

The "Drug Price Competition and Patent Term Restoration Act of 1984 (<https://www.congress.gov/bill/98th-congress/senate-bill/01538>)," also known as the Hatch-Waxman Amendments, established bioequivalence as the basis for approving generic copies of drug products. These Amendments permit FDA to approve applications to market generic versions of brand-name drugs without repeating costly and duplicative clinical trials to establish safety and efficacy. Under the Hatch-Waxman Amendments, brand-name companies gained patent term extension to account for the time the patented product is under review by FDA and also gained certain periods of marketing exclusivity. In addition to the ANDA approval pathway, generic drug companies gained the ability to challenge patents in court prior to marketing as well as 180-day generic drug exclusivity.

Resources for ANDA Submissions

The following resources provide ANDA applicants with the statutory and regulatory requirements of an ANDA application, assistance from CDER to help you meet those requirements, and internal ANDA review principles, policies, and procedures. Summary tables,

application forms, and other ANDA submission resources are available in [ANDA Forms & Submission Requirements \(/drugs/abbreviated-new-drug-application-anda-generics/abbreviated-new-drug-application-anda-forms-and-submission-requirements\)](#)).

Guidance Documents for ANDAs

Guidance documents represent the Agency's current thinking on a particular topic. These documents provide guidelines for the content, evaluation, and ultimate approval of applications and also to the design, production, manufacturing, and testing of regulated products for FDA review staff, applicants, and ANDA holders.

- [Generic Drugs Guidances \(/drugs/guidance-compliance-regulatory-information/guidances-drugs\)](#)(Search "Generics" under topics)
- [Biopharmaceutics Guidances \(/drugs/guidance-compliance-regulatory-information/guidances-drugs\)](#) (Search "Biopharmaceutics" under topics)
- [Product-Specific Guidances for Generic Drug Development \(https://www.accessdata.fda.gov/scripts/cder/psg/index.cfm\)](#)

Laws, Regulations, Policies, and Procedures

The Federal Food, Drug, and Cosmetic Act (/federal-food-drug-and-cosmetic-act-fdc-act) is the basic food and drug law of the United States. The law is intended to assure consumers that foods are pure and wholesome, safe to eat, and produced under sanitary conditions; that drugs and devices are safe and effective for their intended uses; that cosmetics are safe and made from appropriate ingredients; and that all labeling and packaging is truthful, informative, and not deceptive.

Code of Federal Regulations

The final regulations published in the Federal Register (<https://www.federalregister.gov/>) (a daily published record of proposed rules, final rules, meeting notices, etc.) are collected in the Code of Federal Regulations (<https://www.ecfr.gov/cgi-bin/ECFR?page=browse>) (CFR). Section 21 of the CFR contains most of the regulations pertaining to food and drugs. The regulations document most actions of all drug applicants that are required under Federal law. The following regulations directly apply to the ANDA process:

- [21CFR Part 314: Applications for FDA Approval to Market a New Drug \(https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=314\)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=314)
- [21CFR Part 320: Bioavailability and Bioequivalence Requirements \(https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=320\)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=320)

Manual of Policies and Procedures

CDER's Manual of Policies and Procedures (</about-fda/center-drug-evaluation-and-research-cder/cder-manual-policies-procedures-mapp>) (MAPPs) document internal practices and procedures followed by CDER staff to help standardize the drug review process and other activities, both internal and external. Chapter 5200 covers generic drugs processes and activities.

Additional Resources

- Reference Listed Drug (RLD) Access Inquiries (</drugs/abbreviated-new-drug-application-anda/reference-listed-drug-rld-access-inquiries>): A list identifying all products about which FDA has received an inquiry from a prospective generic applicant indicating that they are unable to purchase the samples of the RLD necessary to support their application because of limitations on the distribution of the drug.
- Investigational New Drug Application (IND) (</drugs/types-applications/investigational-new-drug-ind-application>): Resources to assist drug sponsors with submitting applications for approval to begin new drug experiments on human subjects.
- New Drug Application (NDA): (</drugs/types-applications/new-drug-application-nda>)Resources to assist drug applicants with submitting applications for approval to market a new drug.
- Pharmaceutical Quality Resources (</drugs/development-approval-process-drugs/pharmaceutical-quality-resources>): Resources to help meet compliance with the approval process for new drug applications; includes a review of the manufacturer's compliance with Current Good Manufacturing Practice.
- Clinical Trials and Human Subject Protection (</science-research/science-and-research-special-topics/clinical-trials-and-human-subject-protection>): Regulations and guidelines for scientists who design and run experiments (clinical trials) to test the safety and effectiveness of new drugs on human subjects.
- Surveillance: Post Drug-Approval Activities (</drugs/guidance-compliance-regulatory-information/surveillance>): FDA's post drug-approval activities to monitor the ongoing safety of marketed drugs by reassessing drug risks based on new data learned after the drug is marketed, and recommending ways of trying to most appropriately manage that risk.
- Small Business & Industry Assistance Program (</drugs/development-approval-process-drugs/cder-small-business-industry-assistance-sbia>) (SBIA): CDER's SBIA program offers a variety of multimedia learning resources. The SBIA Learn web page ([<https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda>](/drugs/cder-small-business-and-industry-assistance/cder-sbia-learn-webinars-conferences-trainings-</div><div data-bbox=)

upcoming-events) has many helpful courses and recordings in the “Generic Drugs” section.

- [RLD Holder Letter Template 2018 \(/media/111808/download\)](/media/111808/download)

Resources For You

- [Office of Generic Drugs \(OGD\) Annual Reports \(/drugs/generic-drugs/annual-reports\)](/drugs/generic-drugs/annual-reports)
- [The Generic Drug Approval Process \(/drugs/news-events/generic-drug-approval-process\)](/drugs/news-events/generic-drug-approval-process)
- [Fact Sheet: What's Involved in Reviewing and Approving Generic Drug Applications? \(/drugs/generic-drugs/what-approval-process-generic-drugs\)](/drugs/generic-drugs/what-approval-process-generic-drugs)
- [Investigational New Drug \(IND\) Application \(/investigational-new-drug-ind-application\)](/investigational-new-drug-ind-application)
- [Therapeutic Biologic Applications \(BLA\) \(/therapeutic-biologic-applications-bla\)](/therapeutic-biologic-applications-bla)
- [New Drug Application \(NDA\) \(/new-drug-application-nda\)](/new-drug-application-nda)

Related Information

- [Generic Drugs: Industry Resources \(/drugs/generic-drugs/industry-resources\)](/drugs/generic-drugs/industry-resources)
- [Generic Drug Development \(/drugs/abbreviated-new-drug-application-anda/generic-drug-development\)](/drugs/abbreviated-new-drug-application-anda/generic-drug-development)
- [Generic Drugs Program \(/generic-drugs\)](/generic-drugs)
- [Office of Generic Drugs \(/about-fda/about-center-drug-evaluation-and-research/office-generic-drugs\)](/about-fda/about-center-drug-evaluation-and-research/office-generic-drugs)