

Drugs@FDA Glossary of Terms

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Abbreviated New Drug Application (ANDA)

An Abbreviated New Drug Application (ANDA) contains data that, when submitted to FDA's Center for Drug Evaluation and Research, Office of Generic Drugs, provides for the review and ultimate approval of a generic drug product. Generic drug applications are called "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, a generic applicant must scientifically demonstrate that its product is bioequivalent (i.e., performs in the same manner as the innovator drug). Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, low cost alternative to the American public.

Abbreviated New Drug Application (ANDA) Number

This six-digit number is assigned by FDA staff to each application for approval to market a generic drug in the United States.

Active Ingredient

An active ingredient is any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals.

Approval History

The approval history is a chronological list of all FDA actions involving one drug product having a particular FDA Application number (NDA). There are over 50 kinds of approval actions including changes in the labeling, a new route of administration, and a new patient population for a drug product.

Application

See New Drug Application (NDA), Abbreviated New Drug Application (ANDA), or Biologic License Application (BLA)

Approval Letter

An official communication from FDA to a new drug application (NDA) sponsor that allows the commercial marketing of the product.

Application Number

See FDA Application Number

Biologic License Application (BLA)

Biological products are approved for marketing under the provisions of the Public Health Service (PHS) Act. The Act requires a firm who manufactures a biologic for sale in interstate commerce to hold a license for the product. A biologics license application is a submission that contains specific information on the manufacturing processes, chemistry, pharmacology, clinical pharmacology and the medical affects of the biologic product. If the information provided meets FDA requirements, the application is approved and a license is issued allowing the firm to market the product.

Biological Product

Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources — human, animal, or microorganism — and may be produced by biotechnology methods and other cutting-edge technologies. Gene-based and cellular biologics, for example, often are at the forefront of biomedical research, and may be used to treat a variety of medical conditions for which no other treatments are available.

In general, the term "drugs" includes therapeutic biological products.

Brand Name Drug

A brand name drug is a drug marketed under a proprietary, trademark-protected name.

Chemical Type

The Chemical Type represents the newness of a drug formulation or a new indication for an existing drug formulation. For example, Chemical Type 1 is assigned to an active ingredient that has never before been marketed in the United States in any form. (list of Chemical Types and their meanings (/drugs/drug-approvals-and-databases/drugsfda-frequently-asked-questions#chemtype_reviewclass))

Company

The company (also called applicant or sponsor) submits an application to FDA for approval to market a drug product in the United States.

Discontinued Drug Product

Products listed in Drugs@FDA as "discontinued" are approved products that have never been marketed, have been discontinued from marketing, are for military use, are for export only, or have had their approvals withdrawn for reasons other than safety or efficacy after being discontinued from marketing.

Dosage Form

A dosage form is the physical form in which a drug is produced and dispensed, such as a tablet, a capsule, or an injectable.

Drug

A drug is defined as:

- A substance recognized by an official pharmacopoeia or formulary.
- A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
- A substance (other than food) intended to affect the structure or any function of the body.
- A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device.
- Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process.)

Drug Product

The finished dosage form that contains a drug substance, generally, but not necessarily in association with other active or inactive ingredients.

FDA Action Date

The action date tells when an FDA regulatory action, such as an original or supplemental approval, took place.

FDA Application Number

This number, also known as the NDA (New Drug Application) number, is assigned by FDA staff to each application for approval to market a new drug in the United States. One drug can have more than one application number if it has different dosage forms or routes of administration

Generic Drug

A generic drug is the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use. Before approving a generic drug product, FDA requires many rigorous tests and procedures to assure that the generic drug can be substituted for the brand name drug. The FDA bases evaluations of substitutability, or "therapeutic equivalence," of generic drugs on scientific evaluations. By law, a generic drug product must contain the identical amounts of the same active ingredient(s) as the brand name product. Drug products evaluated as "therapeutically equivalent" can be expected to have equal effect and no difference when substituted for the brand name product.

Label

The FDA approved label is the official description of a drug product which includes indication (what the drug is used for); who should take it; adverse events (side effects); instructions for uses in pregnancy, children, and other populations; and safety information for the patient. Labels are often found inside drug product packaging.

Marketing Status

Marketing status indicates how a drug product is sold in the United States. Drug products in Drugs@FDA are identified as:

- Prescription
- Over-the-counter
- Discontinued
- None - drug products that have been tentatively approved

Medication Guide

A medication guide contains information for patients on how to safely use a drug product.

NDA (see New Drug Application)**New Drug Application (NDA)**

When the sponsor of a new drug believes that enough evidence on the drug's safety and effectiveness has been obtained to meet FDA's requirements for marketing approval, the sponsor submits to FDA a new drug application (NDA). The application must contain data from specific technical viewpoints for review, including chemistry, pharmacology, medical, biopharmaceutics, and statistics. If the NDA is approved, the product may be marketed in the United States. For internal tracking purposes, all NDA's are assigned an NDA number.

New Drug Application (NDA) Number

This six digit number is assigned by FDA staff to each application for approval to market a new drug in the United States. A drug can have more than one application number if it has different dosage forms or routes of administration. In Drugs@FDA, you can find the NDA number under the column named "FDA Application."

NME (see New Molecular Entity)**New Molecular Entity (NME)**

An NME is an active ingredient that contains no active moiety that has been previously approved by the Agency in an application submitted under section 505 of the Federal Food, Drug, and Cosmetic Act, or has been previously marketed as a drug in the United States.

Over-the-Counter Drugs (OTC)

FDA defines OTC drugs as safe and effective for use by the general public without a doctor's prescription.

Patient Package Insert (PPI)

A patient package insert contains information for patients' understanding of how to safely use a drug product.

Pharmaceutical Equivalents

FDA considers drug products to be pharmaceutical equivalents if they meet these three criteria:

- they contain the same active ingredient(s)
- they are of the same dosage form and route of administration
- they are identical in strength or concentration

Pharmaceutically equivalent drug products may differ in characteristics such as

- shape
- release mechanism
- labeling (to some extent)
- scoring
- excipients (including colors, flavors, preservatives)

Prescription Drug Product

A prescription drug product requires a doctor's authorization to purchase.

Product Number

A product number is assigned to each drug product associated with an NDA (New Drug Application). If a drug product is available in multiple strengths, there are multiple product numbers.

Reference Listed Drug (see RLD)

Review

A review is the basis of FDA's decision to approve an application. It is a comprehensive analysis of clinical trial data and other information prepared by FDA drug application reviewers. A review is divided into sections on medical analysis, chemistry, clinical pharmacology, biopharmaceutics, pharmacology, statistics, and microbiology.

Review Classification

The NDA and BLA classification system provides a way of describing drug applications upon initial receipt and throughout the review process and prioritizing their review. (List of Review Classifications and their meanings (/drugs/drug-approvals-and-databases/drugsfda-frequently-asked-questions#chemtype_reviewclass))

RLD (Reference Listed Drug)

A Reference Listed Drug (RLD) is an approved drug product to which new generic versions are compared to show that they are bioequivalent. A drug company seeking approval to market a generic equivalent must refer to the Reference Listed Drug in its Abbreviated New

Drug Application (ANDA). By designating a single reference listed drug as the standard to which all generic versions must be shown to be bioequivalent, FDA hopes to avoid possible significant variations among generic drugs and their brand name counterpart.

Route

A route of administration is a way of administering a drug to a site in a patient. A comprehensive list of specific routes of administration appears in the CDER Data Standards Manual ([/\(!--\\$ssLink\('ucm071666.htm'\)--\)\]](#)).

Strength

The strength of a drug product tells how much of the active ingredient is present in each dosage.

Supplement

A supplement is an application to allow a company to make changes in a product that already has an approved new drug application (NDA). CDER must approve all important NDA changes (in packaging or ingredients, for instance) to ensure the conditions originally set for the product are still met.

Supplement Number

A supplement number is associated with an existing FDA New Drug Application (NDA) number. Companies are allowed to make changes to drugs or their labels after they have been approved. To change a label, market a new dosage or strength of a drug, or change the way it manufactures a drug, a company must submit a supplemental new drug application (sNDA). Each sNDA is assigned a number which is usually, but not always, sequential, starting with 001.

Supplement Type

Companies are allowed to make changes to drugs or their labels after they have been approved. To change a label, market a new dosage or strength of a drug, or change the way it manufactures a drug, a company must submit a supplemental new drug application (sNDA). The supplement type refers to the kind of change that was approved by FDA. This includes changes in manufacturing, patient population, and formulation.

Tentative Approval

If a generic drug product is ready for approval before the expiration of any patents or exclusivities accorded to the reference listed drug product, FDA issues a tentative approval letter to the applicant. The tentative approval letter details the circumstances associated with the tentative approval. FDA delays final approval of the generic drug product until all patent or exclusivity issues have been resolved. A tentative approval does not allow the applicant to market the generic drug product.

Therapeutic Biological Product

A therapeutic biological product is a protein derived from living material (such as cells or tissues) used to treat or cure disease.

Therapeutic Equivalence (TE)

Drug products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product. Drug products are considered to be therapeutically equivalent **only** if they meet these criteria:

- they are pharmaceutical equivalents (contain the same active ingredient(s); dosage form and route of administration; and strength.)
- they are assigned by FDA the same therapeutic equivalence codes starting with the letter "A." To receive a letter "A", FDA
- designates a brand name drug or a generic drug to be the Reference Listed Drug (RLD).
- assigns therapeutic equivalence codes based on data that a drug sponsor submits in an ANDA to scientifically demonstrate that its product is bioequivalent (i.e., performs in the same manner as the Reference Listed Drug).

Therapeutic Equivalence (TE) Codes

The coding system for therapeutic equivalence evaluations allows users to determine whether FDA has evaluated a particular approved product as therapeutically equivalent to other pharmaceutically equivalent products (first letter) and to provide additional information on the basis of FDA's evaluations (second letter). Sample TE codes: AA, AB, BC (More on TE Codes (</drugs/development-approval-process-drugs/orange-book-preface#TEC>))

- FDA assigns therapeutic equivalence codes to pharmaceutically equivalent drug products. A drug product is deemed to be therapeutically equivalent ("A" rated) only if:
- a drug company's approved application contains adequate scientific evidence establishing through *in vivo* and/or *in vitro* studies the bioequivalence of the product to a selected reference listed drug.
- those active ingredients or dosage forms for which no *in vivo* bioequivalence issue is known or suspected.
- Some drug products have more than one TE Code.
- Those products which the FDA does not deem to be therapeutically equivalent are "**B**" rated.

Over-the-counter drugs are not assigned TE codes.