

FDA OTC Glossary

Compliance Actions: FDA has at its disposal various tools to achieve compliance with OTC regulations. These include but are not limited to:

- Regulatory meetings
- Warning letters
- Untitled letters
- Recalls
- Public health advisories
- Press releases
- Seizures
- Injunctions
- Criminal prosecution
- Import detention/refusal

Consumer Product Safety Commission (CPSC): The U.S. Consumer Product Safety Commission is charged with protecting the public from unreasonable risks of injury or death from thousands of types of consumer products under the agency's jurisdiction. The CPSC is committed to protecting consumers and families from products that pose a fire, electrical, chemical, or mechanical hazard or can injure children. The CPSC's work to ensure the safety of consumer products - such as toys, cribs, power tools, cigarette lighters, and household chemicals - contributed significantly to the 30 percent decline in the rate of deaths and injuries associated with consumer products over the past 30 years.

Convenience-Size Packaging: FDA is considering how to define "convenience size packaging" and has set forth a definition in a proposed rule ([71FR74474](#)) as "a package containing no more than two doses, as defined in paragraph (b)(6) of this section, of an OTC drug product that, because of its limited available labeling space, both qualifies for the modified labeling set forth in paragraph (d)(10) of this section and would require more than 60 percent of its total surface area available to bear labeling to meet the labeling requirements set forth in paragraph (d)(10). This definition does not include OTC drug packages that contain ipecac syrup or activated charcoal."

Drug: According to the Federal Food, Drug, and Cosmetic Act, §321(g)(1), "The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement."

In other words, among other things, a drug is an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or an article (other than food) intended to affect the structure or any function of the human body. As regulated by FDA, there are only two categories of drugs: OTC and prescription.

Federal Food, Drug, and Cosmetic Act: Congress passed this Act in 1938, repealing and significantly changing the requirements under the Pure Food and Drugs Act of 1906. The 1938 Act required new drugs to be shown safe before marketing. This started a new system of drug regulation.

GRASE: A drug is not considered a new drug only when it is generally recognized as safe and effective (GRASE). In order to conclude a GRASE determination, a drug must satisfy three criteria:

1. The particular drug product must have been subjected to adequate and well-controlled clinical investigations that establish the product as safe and effective.
2. Those investigations must have been published in the scientific literature available to qualified experts.
3. Experts must generally agree, based on those published studies, that the product is safe and effective for its intended uses. At a minimum, the general acceptance of a product as GRASE must be supported by the same quality and quantity of scientific and/or clinical data necessary to support the approval of a New Drug Application.

Inactive Ingredient: An inactive ingredient is any component of a drug product other than the active ingredient.

Current regulations ([21 CFR § 330.1\(e\)](#)) require that OTC drugs marketed under the OTC monograph system contain “only suitable inactive ingredients which are safe in the amounts administered and do not interfere with the effectiveness of the preparation or with suitable tests or assays to determine if the product meets its professed standards of identity, strength, quality, and purity.”

Intended Use: Intended use is the objective intent of the persons legally responsible for the labeling of drugs. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article.

Examples of expressions and circumstances used to determine “intended use” can be found at [21 CFR 201.128](#).

Investigational New Drug Application (IND): According to [21 CFR 312.3\(b\)](#), “*Investigational new drug* means a new drug or biological drug that is used in a clinical investigation.”

An IND must be submitted to FDA prior to use of a drug in clinical trials. For further information and the requirements for an IND, see [21 CFR Part 312](#). Drugs that contain only monographed active ingredients being used in accordance with the monograph conditions may not require an IND.

Labeling: According to [21 CFR 1.3\(a\)](#), “Labeling includes all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce.”

Note that the term “accompanying” has been interpreted broadly by the Agency, and depending on the circumstances may include packaging, product inserts, Web sites, and other promotional materials.

New Drug Application (NDA): The New Drug Application (NDA) is the vehicle through which drug sponsors formally propose that the Food and Drug Administration (FDA) approve a new pharmaceutical for sale and marketing. The goals of the NDA are to provide enough information to permit FDA reviewers to establish the following:

- Is the drug safe and effective in its proposed use(s), and do the benefits of the drug outweigh the risks?
- Is the drug’s proposed labeling (package insert) appropriate, and what should it contain?
- Are the methods used in manufacturing the drug and the controls used to maintain the drug’s quality adequate to preserve the drug’s identity, strength, quality, and purity?

The requirements for the content of an NDA are set forth in [21 CFR Part 314](#). An NDA is not required prior to marketing a drug that is being marketed in compliance with an OTC monograph.

OTC Drug Review: A three-phase public rulemaking process that results in the establishment of standards (monographs or non-monographs) for an OTC therapeutic drug category. Each step of the rulemaking process is required to be

published in the *Federal Register*, a daily publication in which Federal agencies publicly announce regulations and legal notices.

OTC Monograph System: The OTC monographs represent regulatory standards for the marketing of non-prescription drug products not covered by new drug applications. These standards provide the marketing conditions for some OTC drug products including the active ingredients, labeling, and other general requirements.

OTC Monographs are a kind of "rule book" of conditions for each therapeutic category covering acceptable ingredients, uses (indications), doses, formulations, labeling, and testing. A drug marketed that is consistent with the conditions set forth under a final monograph and all other general applicable OTC requirements does not require an approved NDA for marketing.

Over-the-Counter (OTC) Drug: An OTC or nonprescription drug is a drug product marketed for use by the consumer without the intervention of a health care professional in order to obtain the drug. Any drug that is not a prescription drug is an OTC or nonprescription drug. An OTC drug is considered safe and effective for use by the general public without a prescriber's authorization. Necessary characteristics for OTC drugs include:

- The product has an acceptable safety margin.
- The product has low misuse and abuse potential under conditions of widespread availability
- A healthcare practitioner is not needed for the safe and effective use of the product.
- The product has adequate labeling.

In addition, consumers must be able to self-diagnose, self-select the medication, self-treat, and self-manage the condition for which the OTC drug is intended.

Prescription Drug: A drug that is intended for use by man which, because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or it is one that is limited by an FDA-approved application for use only under the professional supervision of a practitioner licensed by law to administer such drug.

Professional labeling is labeling that provides specific information to healthcare professionals for uses not included in OTC drug labeling. Certain OTC monographs explicitly permit professional labeling. When professional labeling is permitted, it can be provided solely to healthcare professionals. In addition, the product itself must be OTC-monograph compliant and should not have the professional labeling or any representations or claims for the professional use directly on the consumer-directed labeling.

Pure Food and Drugs Act: Congress passed the Pure Food and Drugs Act in 1906, also known as the Federal Food and Drugs Act of 1906, which prohibited misbranded and adulterated food and drugs in interstate commerce. This Act arose due to public education and exposés from muckrakers such as Upton Sinclair and Samuel Hopkins Adams, social activist Florence Kelley, researcher Harvey W. Wiley, and President Theodore Roosevelt.

Self-Selection: Self-selection is the decision a consumer makes to use or not to use a drug product based on reading the information on the drug product label and applying knowledge of his or her personal medical history.

Serious Adverse Event: A serious adverse event is an event that results in or, based on reasonable medical judgment, requires a medical or surgical intervention to prevent one of the following outcomes:

- Death
- A life-threatening experience
- Inpatient hospitalization
- Prolongation of hospitalization
- Persistent or significant disability or incapacity
- Congenital anomaly or birth defect