Drug Application Process for Nonprescription Drugs

New Drug Application (NDA) and Abbreviated New Drug Application (ANDA)

There are two regulatory pathways to bring a nonprescription drug to market in the U.S. -- the drug application process and Over-the-Counter (OTC) Drug Review (OTC monograph) process.

Drug Application Process

Under the drug application process, a sponsor of a nonprescription drug submits a New Drug Application (NDA) (/drugs/types-applications/new-drug-application-nda) or an Abbreviated New Drug Application (ANDA) (/drugs/types-applications/abbreviated-new-drug-application-anda) to FDA for approval. The sponsor cannot market the nonprescription drug until FDA approves the NDA or ANDA.

Marketing Pathways

Under the drug application process, a nonprescription drug may be marketed either: 1) direct-to-nonprescription (commonly referred to as direct-to-OTC) or 2) prescription-to-nonprescription switch (commonly referred to as Rx-to-OTC switch).

Direct-to-Nonprescription

An NDA may be submitted to market a new drug as nonprescription (direct-to-OTC) without first receiving approval as a prescription drug.

Prescription-to-Nonprescription Switch

However, many nonprescription drugs that have an approved NDA or ANDA were first approved as prescription drugs, before eventually receiving FDA approval to be marketed as nonprescription (an Rx-to-OTC switch).

For more information on the Rx-to-OTC Switches, see the Prescription-to-Nonprescription (Rx-to-OTC) Switches (/drugs/drug-application-process-nonprescription-drugs/prescription-nonprescription-rx-otc-switches) webpage.

Proposed Marketing Pathway

Nonprescription Drug Product with an Additional Condition for Nonprescription Use (ACNU)

FDA is proposing a rule intended to increase options for applicants to develop and market safe and effective nonprescription drug products, which could improve public health by

broadening the types of nonprescription drug products available to consumers. Under the proposed rule, when labeling alone is not sufficient to ensure that the consumer can appropriately self-select or appropriately actually use, or both, a drug product correctly in a nonprescription setting, an applicant may submit a drug application proposing an ACNU that a consumer must successfully fulfill to obtain the nonprescription drug product with an ACNU

We encourage sponsors to meet with FDA staff to discuss any questions that arise during the development of a nonprescription drug product for which an ACNU will be proposed.

For more information about the proposed rule, see the webpage FDA Announces Proposed Rule: Nonprescription Drug Product with an Additional Condition for Nonprescription Use (/drugs/over-counter-otc-nonprescription-drugs/fda-announces-proposed-rule-nonprescription-drug-product-additional-condition-nonprescription-use).

Consumer Studies

One important difference between a drug application for a prescription drug and a nonprescription drug is that consumer behavior studies are often needed to demonstrate that consumers can use the nonprescription drug product safely and effectively without the supervision of a healthcare provider.

Consumer behavior studies are used to evaluate how consumers will use the drug in a nonprescription setting (without the supervision of a health care provider). The consumer behavior studies conducted by a sponsor of nonprescription drug typically include: label comprehension, self-selection, actual use, and human factors studies.

- Label comprehension studies assess the extent to which consumers understand the information on nonprescription drug labeling and then apply this information when making drug product use decisions in a hypothetical situation. For more information, see the Label Comprehension Studies for Nonprescription Drug Products (/regulatory-information/search-fda-guidance-documents/label-comprehension-studies-nonprescription-drug-products) guidance document.
- Self-selection studies assess the ability of consumers to apply drug labeling information to their personal health situation to make correct decisions about whether or not it is appropriate for the consumer to use a drug product. After the label comprehension studies are performed and the most effective Drug Facts Label is developed, self-selection studies are conducted. For more information, see the Self-Selection Studies for Nonprescription Drug Products (/regulatory-information/search-fda-guidance-documents/self-selection-studies-nonprescription-drug-products) guidance document.
- Actual use studies evaluate the use of the product under “real world” conditions to identify any issues with use that have not previously been recognized and to confirm that

consumers can self-diagnose and treat themselves appropriately without the intervention of a healthcare provider.

- Human factors studies assess the adequacy of the product user interface design to eliminate or mitigate potential use-related hazards.

Meet with FDA

FDA encourages all potential drug sponsors or investigators of nonprescription drugs to examine the information available from FDA's Web site related to the NDA or ANDA processes. FDA also encourages all potential drug sponsors or investigators of nonprescription drugs to initiate contact with the Office of Nonprescription Drugs (NDA products) or the Office of Generic Drugs (ANDA products) as early as possible, so that drug sponsors or investigators have the opportunity to consider FDA's recommendations in planning preclinical and clinical development programs.

Additional Information

- New Drug Application (NDA) (/drugs/types-applications/new-drug-application-nda)
- Investigational New Drug (IND) Application (/drugs/types-applications/investigational-new-drug-ind-application)
- Abbreviated New Drug Application (ANDA) (/drugs/types-applications/abbreviated-new-drug-application-anda)
- Label Comprehension Studies for Nonprescription Drug Products (/media/75626/download) guidance document
- Self-Selection Studies for Nonprescription Drug Products (https://www.fda.gov/media/81141/download) guidance document
- Small Business Assistance: Frequently Asked Questions on the Regulatory Process of Over-the-Counter (OTC) Drugs (/drugs/cder-small-business-industry-assistance-sbia/small-business-assistance-frequently-asked-questions-regulatory-process-over-counter-otc-drugs)
- Innovative Approaches for Nonprescription Drug Products (/media/114328/download) draft guidance document
- FDA Announces Proposed Rule: Nonprescription Drug Product with an Additional Condition for Nonprescription Use (/drugs/over-counter-otc-nonprescription-drugs/fda-announces-proposed-rule-nonprescription-drug-product-additional-condition-nonprescription-use)