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About FDA

Office of Nonprescription Drug Products: What We Do

Over-the-counter (OTC) drug products are those drugs that are available to consumers without a prescription. There are more than 80 classes (therapeutic categories) of OTC drugs, ranging from acne drug products to weight control drug products. As with prescription drugs, CDER oversees OTC drugs to ensure that they are properly labeled and that their benefits outweigh their risks.

OTC drugs play an increasingly vital role in America's health care system by providing easy access to certain drugs that can be used safely without the help of a health care practitioner. This enables consumers to take control of their own health care in many situations. There are more than 100,000 OTC drug products marketed, encompassing about 800 significant active ingredients.

Most OTC drug products have been marketed for many years, prior to the laws that require proof of safety and effectiveness before marketing. For this reason, FDA has been evaluating the ingredients and labeling of these products as part of "The OTC Drug Review Program." The goal of this program is to establish [OTC drug monographs](#)¹ for each class of products.

OTC drug monographs are a kind of "recipe book" covering acceptable ingredients, doses, formulations, labeling, and testing. OTC drug monographs are continually updated to add additional ingredients and labeling as needed. Products conforming to a monograph may be marketed without FDA pre-approval, while those that do not, must undergo separate review and approval through the [New Drug Application](#)² (NDA) process. The NDA process, and not the monograph process, is also used for new ingredients entering the OTC marketplace for the first time. For example, the newer OTC drug products (previously available only by prescription) are first approved through the NDA process and their "switch" to OTC status is approved via the NDA process.

FDA's review of OTC drugs is primarily handled by CDER's Office of Nonprescription Products. However, scientists and regulators throughout CDER, the Office of General Counsel, and other Centers within FDA are routinely asked to assist in this massive effort. There is also an advisory committee, the "[Nonprescription Drug Advisory Committee](#)³," which meets regularly to assist the agency in evaluating issues surrounding these products.

Links on this page:

1. <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-the-CounterOTCDrugs/StatusofOTCRulemakings/default.htm>
2. <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm>
3. <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/NonprescriptionDrugsAdvisoryCommittee/default.htm>