THE OFFICIAL NEWSMAGAZINE OF THE AMERICAN ACADEMY OF PEDIATRICS
AAP News

What criteria must drugs meet to be sold over the counter?

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Drug products can be marketed without a prescription (i.e., nonprescription) or over-the-counter (OTC) if the Food and Drug Administration (FDA) determines they are safe and effective for use by a consumer without supervision by a licensed health care professional.

In general, nonprescription drug products:

- can be used appropriately by consumers for self-diagnosed conditions,
- do not need a health practitioner for safe and effective use, and
- have a low potential for misuse and abuse.

More than 300,000 nonprescription drug products are marketed in the U.S. These include approximately 800 active ingredients in over 80 therapeutic categories such as analgesics and allergy treatment products. The majority of these products are regulated under an OTC monograph and contain active ingredients, such as acetaminophen or hydrocortisone.

Nonprescription drug products may be marketed via two pathways: an OTC monograph or the drug approval process (i.e., new drug application [NDA] or abbreviated new drug application [ANDA]).

OTC monographs are regulations the FDA has been establishing since 1972. They establish specific conditions (i.e., active ingredients, doses, indications and labeling) for 36 different therapeutic categories. Nonprescription drug products conforming to an OTC monograph and other relevant general requirements are generally recognized as safe and effective and are not required to be individually reviewed and approved by the FDA before U.S. marketing.

Nonprescription drug products that do not meet the conditions of the OTC monograph (e.g., drugs containing a new active ingredient or dosing regimen) generally must go through the NDA process. As part of the process, the FDA typically requires studies to assess consumers' abilities to use the product safely and appropriately. Some drugs may be switched from prescription to nonprescription status.

Ninety-five percent of nonprescription drug products marketed under an approved NDA or ANDA previously were marketed for the same indication by prescription, whereas 5% originally were approved for nonprescription use.

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