

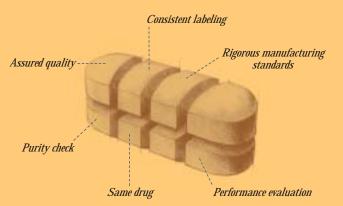


U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

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## What is a generic drug?



When a brand-name drug's patent protection expires, generic versions of the drug can be approved for sale. The generic version works like the brand-name drug in dosage, strength, performance and use, and must meet the same quality and safety standards. All generic drugs must be reviewed and approved by FDA.

# How does FDA ensure that my generic drug is as safe and effective as the brand-name drug?

All generic drugs are put through a rigorous, multi-step review process that includes a review of scientific data on the generic drug's ingredients and performance. FDA also conducts periodic inspections of the manufacturing plant, and monitors drug quality—even after the generic drug has been approved.

### If generic drugs and brand-name drugs have the same active ingredients, why do they look different?

Generic drugs look different because certain inactive ingredients, such as colors and flavorings, may be different. These ingredients do not affect the performance, safety or effectiveness of the generic drug. They look different because trademark laws in the U.S. do not allow a generic drug to look exactly like other drugs already on the market.

### Is my generic drug made by the same company that makes the brand-name drug?

It is possible. Brand-name firms are responsible for manufacturing approximately 50 percent of generic drugs.

#### Are generic drugs always made in the same kind of facilities as brand-name drugs?

Yes. All generic drug manufacturing facilities must meet FDA's standards of good manufacturing practices. FDA will not permit drugs to be made in substandard facilities. FDA conducts about 3,500 inspections a year to ensure standards are met.



FDA makes it tough to become a generic drug in America so you can feel confident about taking your generic drugs. If you still want to learn more, talk with your doctor, pharmacist or other health care professional. Or call **1-888-INFO-FDA** or visit **www.fda.gov/cder** today.



Generic Drugs: Safe. Effective. FDA Approved.