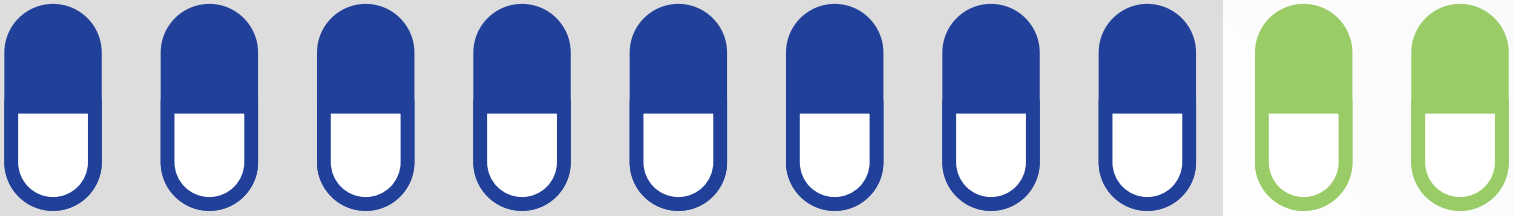
FACTS ABOUT GENERIC DRUGS

Today, nearly **8 in 10** prescriptions filled in the U.S. are for generic drugs.



- FDA requires generic drugs to have the **same active ingredient**, **strength**, **dosage form**, and **route of administration** as the brand-name drug.
- The generic manufacturer **must prove its drug is the same** (bioequivalent) as the brand-name drug.
- All manufacturing, packaging, and testing sites **must pass the same quality standards** as those of brand-name drugs.
- Many generic drugs are made in the same manufacturing plants as the brand-name drugs.

ALL FDA-APPROVED GENERIC DRUGS
MUST BE EQUIVALENT TO THE BRAND-NAME DRUG.

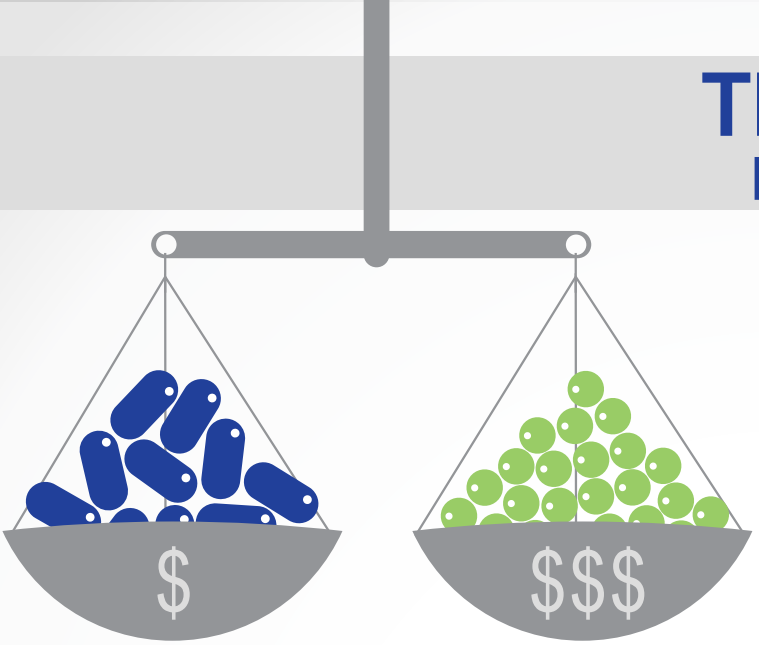
Any generic drug modeled after a single, brand name drug must perform approximately the same in the body as the brand name drug. There will always be a slight, but not medically important, level of natural variability just as there is for one batch of brand name drug compared to the next batch of brand name product.

This amount of difference would be expected and acceptable, whether for one batch of brand name drug tested against another batch of the same brand, or for a generic tested against a brand name drug.

80-85% LESS
Average cost of a generic drug vs. its brand-name counterpart

In 2010 alone, the use of FDA-approved generics saved **$158 billion.**

THE LOWER PRICE DOESN'T MEAN INFERIOR.



Generic manufacturers are able to sell their products for lower prices because they are not required to repeat the costly clinical trials of new drugs and generally do not pay for costly advertising, marketing, and promotion In addition, multiple generic companies apply to FDA to approve a generic for the same brand name drugs. Multiple generic companies are often approved to market a single product. Competition in the market place, often results in lower prices.

FDA MONITORS ADVERSE EVENTS REPORTS FOR GENERIC DRUGS.

The monitoring of adverse events for all drug products, including generic drugs, is one aspect of the overall FDA effort to evaluate the safety of drugs after approval. Many times, reports of adverse events describe a known reaction to the active drug ingredient.

Reports are monitored and investigated, when appropriate. Investigations may lead to changes in how a product is used or manufactured.

FDA IS ACTIVELY ENGAGED IN MAKING GENERIC DRUGS SAFER.

FDA is aware that there are reports that some people may experience an undesired effect when switching from a brand name drug to a generic formulation or from one generic drug to another generic drug. FDA wants to understand what may cause problems with certain formulations if, in fact, they are linked to specific generic products.

FDA is encouraging the generic industry to investigate whether, and under what circumstances, such problems occur. The Agency does not have the resources to perform independent clinical studies and lacks the regulatory authority to require industry to conduct such studies. FDA will continue to investigate these reports to ensure that it has all the facts about these treatment failures and will make recommendations to healthcare professionals and the public if the need arises.

CENTER FOR DRUG EVALUATION AND RESEARCH · FDA ·

[1]Davit et al. Comparing generic and innovator drugs:
a review of 12 years of bioequivalence data from the United States Food and Drug Administration.
Ann Pharmacother. 2009;43(10):1583-97.

FACT

DO GENERIC DRUGS TAKE LONGER TO WORK IN THE BODY?

No. Generic drugs work in the same way and in the same amount of time as brand-name drugs.

FACT

WHY ARE GENERIC DRUGS LESS EXPENSIVE?

Creating a drug costs lots of money. Since generic drug makers do not develop a drug from scratch, the costs to bring the drug to market are less. But they must show that their product performs in the same way as the brand-name drug. All generic drugs are approved by FDA.

Your medication guide should be kept with you and up to date. List your prescription and over-the-counter medicines as well as your dietary supplements.

Name of my medicine	How much do I take?	When do I take it?	What do I use it for?					
xxxx (Example)	1 Tablet 400 mg	Morning	Arthritis					

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

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FACTS ABOUT GENERIC DRUGS

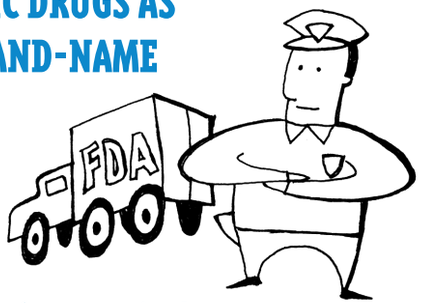
FOOD AND DRUG ADMINISTRATION

FACT WHAT ARE GENERIC DRUGS?

A generic drug is the same as a brand-name drug in:

- dosage
- safety
- strength
- quality
- the way it works
- the way it is taken
- the way it should be used

FACT ARE GENERIC DRUGS AS SAFE AS BRAND-NAME DRUGS?



Yes. The FDA says that all drugs must work well and be safe. Generic drugs use the same active ingredients as brand-name drugs and work the same way. So they have the same risks and benefits as the brand-name drugs.

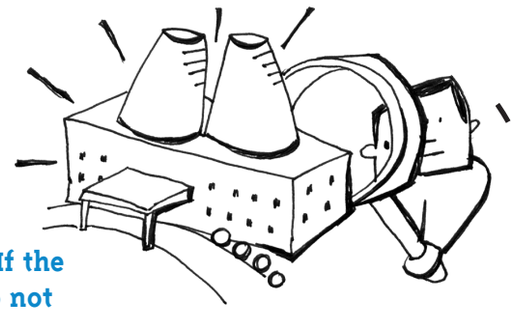
FACT ARE GENERIC DRUGS AS STRONG AS BRAND-NAME DRUGS?

Yes. FDA requires generic drugs must be as:

- high quality
- strong
- pure, and
- stable

as brand-name drugs

FACT ARE BRAND-NAME DRUGS MADE IN BETTER FACTORIES THAN GENERIC DRUGS?



No. All factories must meet the same high standards. If the factories do not meet certain standards, the FDA won't allow them to make drugs.

FACT IF BRAND-NAME DRUGS AND GENERIC DRUGS HAVE THE SAME ACTIVE INGREDIENTS, WHY DO THEY LOOK DIFFERENT?

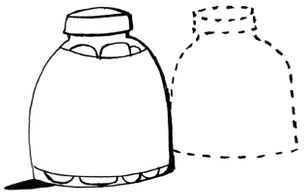
In the United States, trademark laws do not allow generic drugs to look exactly like the brand-name drug. However, the generic drug must have the same active ingredients.

Colors, flavors, and certain other parts may be different. But these things don't affect the way the drug works and they are looked at by FDA.

Generic Drugs:
Safe. Effective. FDA Approved.

FACT DOES EVERY BRAND-NAME DRUG HAVE A GENERIC DRUG?

No. When new drugs are first made they have drug patents. Most drug patents are protected for 17 years. The patent protects the company that made the drug first. The patent doesn't allow anyone else to make and sell the drug. When the patent expires, other drug companies can start selling the generic version of the drug. But, first, they must test the drug and the FDA must approve it.



FACT WHAT IS THE BEST SOURCE OF INFORMATION ABOUT GENERIC DRUGS?

Contact your doctor, pharmacist or other healthcare worker for information on your generic drugs. For more information, you can also visit the FDA website at: http://www.fda.gov/cder and click on Consumer Education.