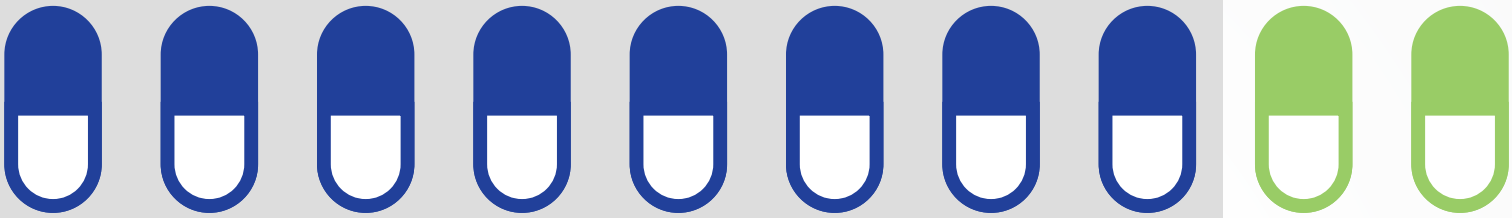
FACTS ABOUT GENERIC DRUGS

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



SAME QUALITY &

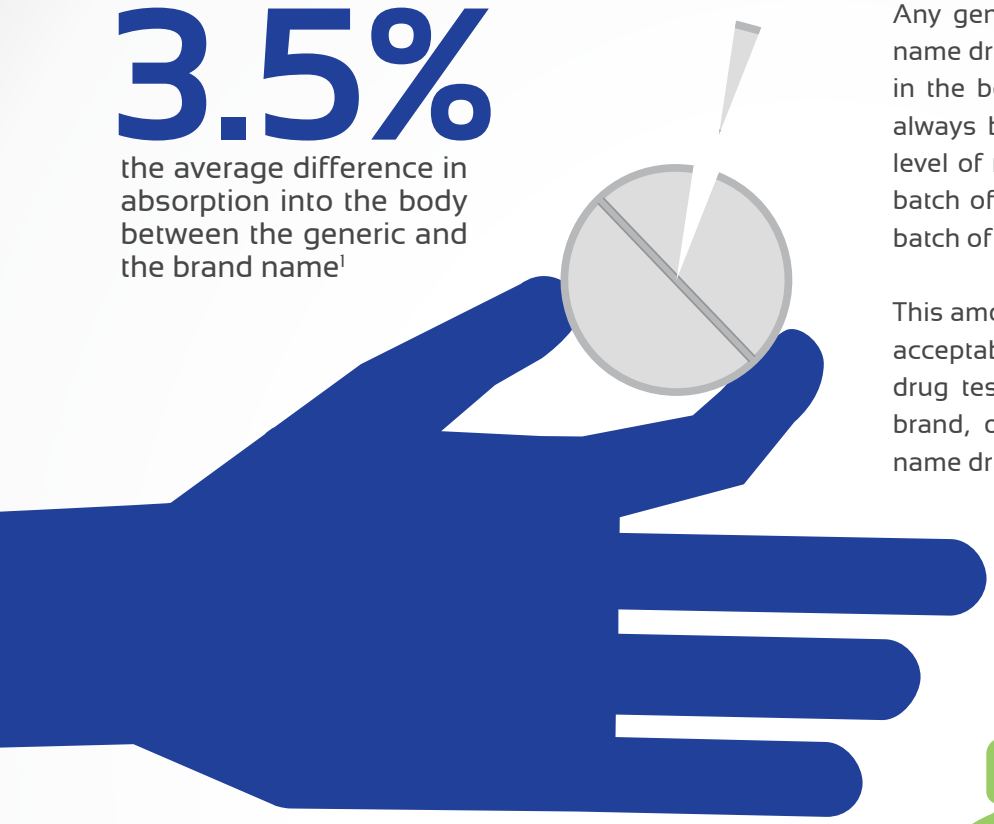
PERFORMANCE

- 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.

3.5%

the average difference in absorption into the body between the generic and the brand name[1]



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.

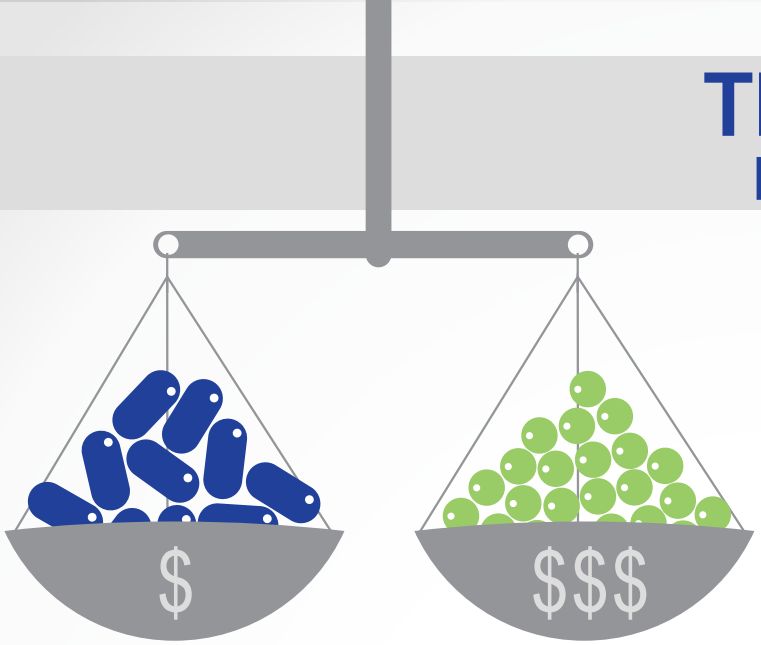
This amount of difference would be expected and acceptable, whether for one batch of brand name drug tested against another batch of the same brand, or for a generic tested against a brand name drug.

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.

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[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.