

Generic Drugs: Questions and Answers

What are generic drugs?

A generic drug is identical -- or bioequivalent -- to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. According to the Congressional Budget Office, generic drugs save consumers an estimated \$8 to \$10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics.

Is there a generic equivalent for my brand-name drug?

To find out if there is a generic equivalent for your brand-name drug, use [Drugs@FDA](#), a catalog of FDA-approved drug products, as well as drug labeling.

You can also search for generic equivalents by using the "Electronic Orange Book." Search by proprietary "brand" name," then search again by using the active ingredient name. If other manufacturers are listed besides the "brand name" manufacturer when searching by the "active ingredient," they are the generic product manufacturers.

Since there is a lag time after generic products are approved and they appear in the "Orange Book," you should also consult the most recent monthly approvals for "First Generics".

Are generic drugs as effective as brand-name drugs?

Yes. 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 and the way it should be used.

FDA requires generic drugs have the same high quality, strength, purity and stability as brand-name drugs.

Not every brand-name drug has a generic drug. When new drugs are first made they have drug patents. Most drug patents are protected for 20 years. The patent, which protects the company that made the drug first, doesn't allow anyone else to make and sell the drug. When the patent expires, other drug companies can start selling a generic version of the drug. But, first, they must test the drug and the FDA must approve it.

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; therefore, generic drugs are usually less expensive than brand-name drugs. But, generic drug makers must show that their product performs in the same way as the brand-name drug.

How are generic drugs approved?

Drug companies must submit an abbreviated new drug application (ANDA) for approval to market a generic product. The Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the Hatch-Waxman Act, made ANDAs possible by creating a compromise in the drug industry. Generic drug companies gained greater access to the market for prescription drugs, and innovator companies gained restoration of patent life of their products lost during FDA's approval process.

New drugs, like other new products, are developed under patent protection. The patent protects the investment in the drug's development by giving the company the sole right to sell the drug while the patent is in effect. When patents or other periods of exclusivity expire, manufacturers can apply to the FDA to sell generic versions.

The ANDA process does not require the drug sponsor to repeat costly animal and clinical research on ingredients or dosage forms already approved for safety and effectiveness. This applies to drugs first marketed after 1962.

What standards do generic drugs have to meet?

Health professionals and consumers can be assured that FDA approved generic drugs have met the same rigid standards as the innovator drug. To gain FDA approval, a generic drug must:

- contain the same active ingredients as the innovator drug (inactive ingredients may vary)
- be identical in strength, dosage form, and route of administration
- have the same use indications
- be bioequivalent
- meet the same batch requirements for identity, strength, purity, and quality
- be manufactured under the same strict standards of FDA's good manufacturing practice regulations required for innovator products

FACT: FDA requires generic drugs to have the same quality and performance as brand name drugs.

- When a generic drug product is approved, it has met rigorous standards established by the FDA with respect to identity, strength, quality, purity, and potency. However, some variability can and does occur during manufacturing, for both brand name and generic drugs. When a drug, generic or brand name, is mass-produced, very small variations in purity, size, strength, and other parameters are permitted. FDA limits how much variability is acceptable.
- Generic drugs are required to have the same active ingredient, strength, dosage form, and route of administration as the brand name product. Generic drugs do not need to contain the same inactive ingredients as the brand name product.
- The generic drug manufacturer must prove its drug is the same as (bioequivalent) the brand name drug. For example, after the patient takes the generic drug, the amount of drug in the bloodstream is measured. If the levels of the drug in the bloodstream are the same as the levels found when the brand name product is used, the generic drug will work the same.

- Through review of bioequivalence data, FDA ensures that the generic product performs the same as its respective brand name product. This standard applies to all generic drugs, whether immediate or controlled release.
- All generic manufacturing, packaging, and testing sites must pass the same quality standards as those of brand name drugs, and the generic products must meet the same exacting specifications as any brand name product. In fact, many generic drugs are made in the same manufacturing plants as brand name drug products.

FACT: Research shows that generics work just as well as brand name drugs.

- A study evaluated the results of 38 published clinical trials that compared cardiovascular generic drugs to their brand name counterparts. There was no evidence that brand name heart drugs worked any better than generic heart drugs.[1]

FACT: FDA does not allow a 45 percent difference in the effectiveness of the generic drug product.

- FDA recently evaluated 2,070 human studies conducted between 1996 and 2007. These studies compared the absorption of brand name and generic drugs into a person's body. These studies were submitted to FDA to support approval of generics. The average difference in absorption into the body between the generic and the brand name was 3.5 percent[2]. Some generics were absorbed slightly more, some slightly less. 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. In fact, there have been studies in which brand name drugs were compared with themselves as well as with a generic. As a rule, the difference for the generic-to-brand comparison was about the same as the brand-to-brand comparison.
- 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.

FACT: When it comes to price, there is a big difference between generic and brand name drugs. On average, the cost of a generic drug is 80 to 85 percent lower than the brand name product.

- In 2010 alone, the use of FDA-approved generics saved \$158 billion, an average of \$3 billion every week.[3]

FACT: Cheaper does not mean lower quality.

- 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 are often approved to market a single product; this creates competition in the market place, often resulting in lower prices.

FACT: 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. The investigations may lead to changes in how a product (brand name and generic counterparts) is used or manufactured.

FACT: FDA is actively engaged in making all regulated products – including generic drugs – safer.

- FDA is aware that there are reports noting that some people may experience an undesired effect when switching from 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.

[1] Kesselheim et al. Clinical equivalence of generic and brand name drugs used in cardiovascular disease: a systematic review and meta-analysis. JAMA. 2008;300(21):2514-2526

[2] 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.

[3] SAVINGS An Economic Analysis of Generic Drug Usage in the U.S., GPhA, September 2011, page 1.

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<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm>