

## Questions About Generic Drugs Answered

According to the Congressional Budget Office, generic drugs save consumers an estimated \$8 billion to \$10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics.

While generic drugs may be cheaper than brand-name drugs, they aren't inferior. In fact, they're "bioequivalent."

Here are some of the most common questions about generic drugs:

WebMD Public Information with the FDA

### **1. What are generic drugs?**

A generic drug is a copy that is the same as a brand-name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use.

### **2. Are generic drugs as safe as brand-name drugs?**

Yes. The FDA requires that all drugs be safe and effective. Since generics use the same active ingredients and are shown to work the same way in the body, they have the same risks and benefits as their brand-name counterparts.

### **3. Are generic drugs as strong as brand-name drugs?**

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

### **4. 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.

### **5. Why are generic drugs less expensive?**

Generic drugs are less expensive because generic manufacturers don't have the investment costs that the developer of a new drug has. New drugs are developed under patent protection. The patent protects the investment -- including research, development, marketing, and promotion -- by giving the company the sole right to sell the drug while it is in effect. As patents near expiration, manufacturers can apply to the FDA to sell generic versions. Because those manufacturers don't have the same development costs, they can sell their product at substantial discounts. Also, once generic drugs are approved, there is greater competition, which keeps the price down. Currently, almost half of all prescriptions are filled with generic drugs.

### **6. Are brand-name drugs made in more modern facilities than generic drugs?**

No. Both brand-name and generic drug facilities must meet the same standards of good manufacturing practices. The FDA won't permit drugs to be made in substandard facilities. It conducts about 3,500 inspections a year to ensure standards are met. Generic firms have facilities comparable to those of brand-name firms. In fact, brand-name firms are linked to an estimated 50% of generic drug production. They frequently make copies of their own or other brand-name drugs but sell them without the brand name.

### **7. 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 a generic drug to look exactly like the brand-name drug. However, a generic drug must duplicate the active ingredient. Colors, flavors, and certain other inactive ingredients may be different.

### **8. Does every brand-name drug have a generic counterpart?**

No. Brand-name drugs are generally given patent protection for 20 years. This provides protection for the drug company that laid out the initial costs (including research, development, and marketing expenses) to develop the new drug. However, when the patent expires, other drug companies can sell

competitive generic versions, but only after they have been thoroughly tested by the manufacturer and approved by the FDA.

### **9. 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.

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