Feel Safe with Effective Generic Medications

FDA Approved

It's easy to become concerned about generic drugs. Many consumers worry and wonder about the quality and effectiveness of generics compared to their brand name counterparts. But the fact is, the Food and Drug Administration (FDA) requires all generic drugs to have the same quality and performance as the brand name equivalents. When a new generic drug product is approved, it has already met all of the standards established by the FDA.

Similar to any new product being developed, brand name drugs are created under patent protection. This patent protects the drug manufacturer's investment in the drug's development by giving the company the sole right to sell the drug while the patent is in effect. When these patents expire, other manufacturers then have the opportunity to apply to the FDA to sell generic versions.

To enable a generic drug to be created, manufacturers must submit an abbreviated new drug application (ANDA) for approval to market the generic product. Before the FDA approves new generic drugs, the drugs are put through a rigorous, multi-step approval process that covers everything from quality and performance to manufacturing and labeling. According to the FDA, to gain approval a generic drug must:

- *Contain the same active ingredients as the brand name drug*
- *Be identical in strength, dosage form, and route of administration*
- *Have the same use of indications*
- *Be bioequivalent*
- *Meet the same batch requirements for identity, strength, purity, and quality*
- *Be manufactured under the same strict standards of the FDA's good manufacturing practice regulations required for brand name products*

The only differences in the generic compared to the original brand is that the drug may be a different color or shape, may have different dye or fillers, and may also be made by a generic manufacturer.

Currently, over 60 percent of all prescriptions filled in the United States are for generic medications.[1] These medications treat conditions from high blood pressure, high cholesterol, heartburn and stomach ulcers, to insomnia, allergies, arthritis, and more. According to the FDA, more than 70 percent of brand name drugs have generic counterparts, and are readily available to treat many common health conditions. Although most states allow pharmacists to automatically substitute generics for brand name drugs, unless the prescription is written as a DAW (dispense as written), it is up to the consumer to ask their doctor if a generic medication would work for them.

The price variations between brand name and generic drugs can sometimes be astonishing. On average, generic drugs can often save the consumer up to 80 percent on the cost of a prescription when compared with the brand name drug, with the median cost savings being anywhere from 30 percent to 50 percent. According to the National Association of Chain Drug Stores, in 2008, the average retail price of a generic prescription drug was $35.22, compared to the retail price of the comparable brand name prescription drug, which was $137.90. Generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies, and billions more are saved when hospitals consistently use generic drugs.

Most prescription drug plans, including the Christian Brothers Employee Benefit Trust plan, have a lower co-payment for generic medications because the cost of generic medications are considerably less expensive than brand name medications. Staying informed about generic medications will allow consumers to make confident decisions, along with their medical providers, in helping to control prescription medication costs.

Below is a list of some well-known brand name medications that are due to have generic equivalents within the next year.

Generic Drug Release Dates 2011-2012

Cholesterol Lowering Agents
Lipitor®/Caduet®: Loses patent protection in November 2011.

Antidepressant
Lexapro®: An SSRI loses patent protection in March 2012.

Anti-Platelet Drugs
Plavix®: Loses patent protection in May 2012.

Miscellaneous Pulmonary Agents
Singulair®: Loses patent protection in August 2012.

Anti-Hypertensive Therapy
Diovan®/Diovan HCT®: Loses patent protection in September 2012.

[1] "Helped by Generics, Inflation of Drug Costs Slows." New York Times, September 21, 2007.

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Myths *Surrounding Generic Drugs*

One myth is that some consumers believe they are more likely to cause side effects, which is not the case. The FDA conducts almost 3,500 inspections each year of manufacturing facilities to ensure that all quality standards are met.

Another myth is that many consumers feel lower cost equals lower effectiveness. Generic drugs are less expensive because the original manufacturer has already made the investment in the drug's development. Hence, the generic manufacturer does not have to incur the costs associated with creation, testing, sales and advertising, thereby leading to lower costs.