Generic drugs.

Safe. Effective. FDA approved.

According to the U.S. Food and Drug Administration

"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.

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

- contain the same active ingredients as the innovator (brand-name) 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 (brand-name) products.

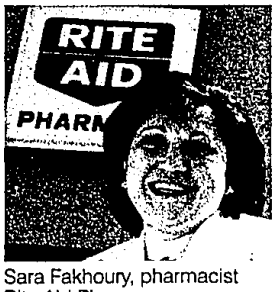
New drugs, like other new products, are developed under patent protection. The patent protects the investment in the drug's development by giving the company the sole right to sell the drug while the patent is in effect. When patents or other periods of exclusivity expire, manufacturers can apply to the FDA to sell generic versions. Brand-name firms account for an estimated 50 percent of generic drug production. They frequently make copies of their own or other brand-name drugs but sell them without the brand name."

In a letter sent to health practitioners by the U.S. Food and Drug Administration about the therapeutic equivalence of generic drugs they write, "For both brand-name and generic drugs, the FDA works with pharmaceutical companies to assure that all drugs marketed in the U.S. meet specifications for identity, strength, quality, purity and potency. In approving a generic drug product, the FDA requires many rigorous tests and procedures to assure that the generic drug is interchangeable with the brand-name drug under all approved indications and conditions of use. For these reasons, the FDA-approved product labeling does not recommend that any additional tests need to be performed by the health care provider when a switch occurs from a brand-name drug product to a generic equivalent drug product."

www.fda.gov

Kevin White, pharmacist
Grand Value pharmacy

Michigan pharmacists trust FDA-approved generics.



Sara Fakhoury, pharmacist
Rite Aid Pharmacy

Demand Generics!

Michigan Pharmacists Association

generic drugs • the unadvertised brand™

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