

Good Health:

Blooming

With Generics!



**Information About Proven,
*More Affordable Generic Drugs***

Compliments of Mylan Pharmaceuticals Inc.

Quick Facts About Generic Pharmaceuticals

- Last year, more than half of all prescriptions in the United States were filled with generic pharmaceuticals.^{1,2}
- Consumers generally pay 30% to 80% less when a generic drug is dispensed instead of the brand-name drug.³
- Generic drugs must contain the same active ingredient(s) as their brand-name counterpart.
- The manufacturing facilities of brand-name and generic pharmaceutical companies are routinely inspected by the Food and Drug Administration (FDA).
- Generic drugs have been used effectively and safely, billions of times by millions of patients.



Generic Pharmaceuticals: Healthcare for the Future



Last year, more than half of all prescriptions in the United States were filled with generic pharmaceuticals.^{1,2} Because of the excellent quality and significant savings these products offer, legislation encouraging the use of generics has been enacted all across America. Generic pharmaceuticals are expected to continue to play a major role in helping to reduce the high cost of healthcare.

What Makes a Drug Generic?



Most prescription drugs have two names: a “generic” name that identifies the active ingredient, and a “brand” name that is used for marketing purposes. For example, acetaminophen is a generic name and Tylenol®* is a brand name *for* acetaminophen. Generally, new drugs are patent-protected for up to 20 years from the date the patent is filed. During the period of patent-protection, only the brand product can be sold. These products are promoted to physicians, pharmacists and other healthcare professionals using a brand name.

*Registered trademark of McNeil-PPC, Inc.



What Happens When the Patent Expires?



When the patent no longer protects a brand-name drug, the FDA — the primary government agency responsible for regulating pharmaceutical products — is allowed to approve products that are equivalent versions of the original. These products, which must receive FDA approval prior to marketing, are generally sold using the “generic” name that identifies the active ingredient.

A Formula for Savings



Consumers generally pay 30% to 80% less when a generic drug is dispensed instead of the brand-name drug.³ These savings are a result of good, old-fashioned American “competition.” As you can well appreciate, when there is more than one company manufacturing and/or selling the same product, there is competition that generally results in cost savings for the consumer. Until the patent expires on a brand-name drug, however, there is generally no competition, and therefore, little incentive for lower prices.



How Generic Drugs Measure Up



Generic drugs must contain the same active ingredient(s) as their brand-name counterpart, and be identical in strength, dosage form (tablet, liquid, etc.), and route of administration (taken by mouth, injection, etc.). Manufacturers must prove that the generic product will supply the same amount of the active ingredient in the body, at a rate comparable to the brand-name drug.



Since generic drugs are equivalent to brand-name drugs that are FDA-approved as safe and effective, generic manufacturers are not required to again prove that the active chemical ingredient is safe and effective. This would be like requiring a new acetaminophen manufacturer to “reprove” that acetaminophen can alleviate pain.



Careful FDA Monitoring



The manufacturing facilities of all pharmaceutical companies—those making brand-name drugs and generic drugs—are routinely inspected by the FDA. To ensure that standards are being met, FDA officials analyze countless samples of products and make thousands of inspections each year. All companies must demonstrate that their manufacturing processes will produce the same consistent quality each time a product is made.

Consumers can be assured that all pharmaceuticals available in the United States—brand name and generic—have undergone, and continue to undergo, the strictest review.

The Tests of Time

Generic pharmaceuticals have a long history of effective and safe use. In fact, there are approximately 8,400 generic drug products available today.⁴ More importantly, they have been used billions of times by millions of patients.

As we move forward, generic pharmaceuticals will play an increasingly important role in our healthcare system by making safe and effective drugs more affordable for all Americans.

References: 1. IMS National Prescription Audit. December 2006. 2. Generic Pharmaceutical Association. About generics. Frequently asked questions. For analysts/researchers. Available at: <http://www.gphaonline.org/Content/NavigationMenu/AboutGenerics/FAQs/default.htm>. Accessed September 28, 2006. 3. Food and Drug Administration. Saving Money on Prescription Drugs. Available at: http://www.fda.gov/ftdac/features/2005/505_save.html. Accessed June 12, 2006. 4. Food and Drug Administration. *Electronic Orange Book*. Available at: <http://www.fda.gov/cder/ob/default.htm>. Accessed June 12, 2006. 5. *U.S. Pharmacist* Generic Company Image Survey. November 2006.

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For more than 45 years, Mylan has been committed to generics, and today our products are ranked first in quality by pharmacists.⁵ For information about proven, *more* affordable medicine from Mylan, and to see if we make a generic alternative for any brand-name prescription product that you may be taking, please visit our website at www.mylan.com or call us at 888-MYLAN RX between 8 AM and 5 PM EST.



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