

PROTECTING OUR HEALTH

Generic Drugs: What Everyone Should Know

(NAPS)—An estimated half of all prescriptions in the United States are filled with generic drugs. These products carry all the medicinal qualities (and side effects) of their brand-name counterparts, but generics tend to have one additional benefit: lower cost.

According to the U.S. Food and Drug Administration (FDA), a generic drug is a copy that is identical to a brand-name drug in dosage, safety, strength, how it is taken, quality, performance and intended use.

New drugs, like other new products, 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 the patent is in effect.

When patents or other periods of exclusivity on brand-name drugs are near expiration, manufacturers can apply to the FDA to sell generic versions. As those manufacturers don't have the same development costs, they can sell their product at substantial discounts. Also, there is greater competition and less advertising, which keeps the price down.

For example, in the 1950s, when the analgesic acetaminophen was developed, it was only available under its brand name—Tylenol. Today, acetaminophen can be found in many other pain-relief products, including generic and store-brand versions.

“FDA-approved generic drugs are bioequivalent and therapeuti-



Generic drugs provide all the medicinal benefits of their brand-name counterparts.

cally equivalent to their brand-name counterparts,” says Gary Buehler, director of FDA's Office of Generic Drugs. “People can use them with total confidence.”

Both brand-name and generic drug facilities must meet standards of good manufacturing processes. The FDA conducts about 3,500 inspections each year to ensure standards are met. Generic firms have facilities comparable to those of brand-name firms. In fact, 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.

To learn more about generic drugs, contact your physician, pharmacist or insurance company. Or visit the FDA Web site at www.fda.gov/cder/ogd/index.htm.