FDA-Approved Bargain Drugs:

Generic Products Must Meet High Standards

Generic drugs are much appreciated for their cost-effectiveness. According to the Congressional Budget Office, they save consumers an estimated $8 billion to $10 billion a year compared with the price of trade-name products. An equally important attribute of generic drugs is that they are reviewed by the Food and Drug Administration to ensure that they provide the same level of benefit to patients as their trade-name counterparts. The FDA has approved approximately 7,000 generic drugs for various treatments, including benign prostatic hyperplasia, various ovarian and breast cancers, and high blood pressure.

The basic requirements for approval of generic and trade-name drugs are the same, although the generic drug manufacturer does not need to repeat the safety and efficacy studies conducted by the developer of the original product. In approving a generic drug, the FDA relies on its previous finding that the original drug is safe and effective. The generic version must have the same dosage form, safety, strength, route of administration, and conditions of use as the trade-name product. The drug's sponsor must show that a generic drug delivers the same amount of its active ingredient in the same amount of time as the trade-name counterpart. This bioequivalence is critical for drawing the conclusion that both the original and generic drugs will produce similar therapeutic results.

With the exception of language protected by patents or exclusivity, the labeling of the generic drug, including directions for use, must be virtually the same as that of the trade-name product. Both generic and trade-name drug companies are required to submit information to ensure that the approved products can be manufactured to the FDA's specifications.

Following approval, both generic and trade name firms must submit data to the FDA showing that their products continue to meet the agency's specifications until the established expiration date. The FDA regularly assesses the quality of generic medications on the market and thoroughly researches and evaluates reports about their performance. A recent FDA review found that the average difference between the bioequivalence of more than 270 generic drugs approved in 1997 and their trade-name counterparts was 3.5 percent. This is about the same as the differences found between batches of trade-name products.

Protection and Encouragement

The Drug Price Competition and Patent Term Restoration Act of 1984 encourages the production of generic medicines while protecting the rights of brand-name manufacturers. The law builds in certain protections for the original drug developer in terms of patents and market exclusivities, but it also allows sponsors of identical products to apply for their approval by the FDA without repeating the original developer's clinical trials. In addition, the law rewards a period of exclusive marketing for a first generic version of a brand-name drug, thereby encouraging generic firms to challenge innovator patents.

For more information, visit the FDA's Web site at *www.fda.gov/cder/ogd.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
Office of Public Affairs
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