Generic Drugs Undergo Rigorous FDA Scrutiny

An FDA scientist in the agency's Division of Product Quality Research evaluates beads used for coating a controlled-release product. For this and other photos of FDA's generic drug research, go to Flickr. (https://www.flickr.com/photos/fdaphotos/sets/72157632813235987) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Español (/consumers/articulos-en-espanol/los-medicamentos-genericos-son-sometidos-al-riguroso-escrutinio-de-la-fda)

Perhaps you've had this experience: You go to your local pharmacy to fill a prescription from your doctor, and the pharmacist confirms there is a generic available.

"If it's a copy, it must not be as good," you think.

You would be wrong.

What are generic drugs, and how does the Food and Drug Administration ensure that they are as safe and effective as brand-name drugs?

Rigorous Standards

A brand-name drug is often patented to protect it from competition and thus to help the drug manufacturer recover the development costs. Several years later when the patent expires, other drug companies can copy the brand-name drug and seek FDA's approval for its generic version.

Today, more than 8 in 10 prescriptions filled in the United States are for generic drugs. The use of generic drugs is expected to grow over the next few years as a number of popular drugs come off patent.

Because generic drug makers are not required to repeat the clinical trials of new drugs and generally do not pay for advertising, marketing and promotion, generics are usually substantially less expensive than brand-name drugs. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 billion to $10 billion a year at retail pharmacies. Billions more are saved when hospitals use generics.

To obtain FDA approval, generic drug makers must prove that their product performs in the same way and is as safe and effective as the brand-name drug. Therefore, health care professionals and consumers can be assured that FDA-approved generic drugs have met the same strict standards as their brand-name counterparts.

The generic drug approval process (https://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/genericdrugs/default.htm) includes a review of scientific data on manufacturing, ingredients and performance. A generic drug approved by FDA that would be substituted by a pharmacist for a brand name drug will:

- Contain the same active ingredients as the brand-name drug. Active ingredients make the drug effective against the disease or condition it is treating. Inactive ingredients may vary.
- Be identical in strength, dosage form and route of administration. If the brand-name drug is a capsule and is taken orally, so is the generic.
- Treat the same medical condition.
- Be absorbed into the bloodstream at a similar rate and over the same period of time.
- Meet the same requirements for identity, strength, purity and quality.
- Be manufactured under the same strict standards that FDA demands of brand-name drugs.

Testing Generic Drugs

The FDA approval process assures that medicines sold in the United States are safe and effective. But FDA also confirms safety and effectiveness by testing selected drugs—both brand and generic—in its laboratories or through research contracts and grants (/industry/generic-drug-user-fee-amendments/gdufa-regulatory-science). This includes the raw ingredients used to make the product, as well as the finished drug.

"If questions are raised about whether a generic drug performs the same as a brand-name product, we perform experiments in FDA laboratories, evaluate data and take a comprehensive scientific look at any possible differences between the products," says Mansoor Khan, R.Ph., Ph.D., director of FDA's Division of Product Quality Research.

In rare cases, new evidence emerges indicating that a generic drug may not have the safety or effectiveness as was previously believed. That's what happened in 2012 with one of the generic forms of Wellbutrin XL 300 mg, a drug to treat depression. FDA sponsored a study comparing Budeprion XL 300 mg, the generic drug, with Wellbutrin XL 300 mg, and concluded that Budeprion XL 300 mg may not be as effective.

FDA encourages consumers and health care professionals to notify FDA of any adverse side effects when using drugs and devices the agency regulates, by reporting them online to MedWatch (https://www.accessdata.fda.gov/scripts/medwatch/), FDA's safety information and adverse event reporting program, or by telephone at 1-800-FDA-1088. Visit FDA's Drug Quality Sampling and Testing Programs (/drugs/science-research-drugs/drug-quality-sampling-and-testing-programs) website to learn more.

How Do I Know if a Generic Is Available?

Not every drug has an approved generic. To find out if there is a generic equivalent for your brand-name drug, use Drugs@FDA (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm). You can search for generic equivalents using FDA's Electronic Orange Book (http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm). You can also consult the most recent monthly approvals for First Generics (http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/drugandbiologicapprovalreports/andagenericdrugapprova

This article appears on the FDA's Consumer Updates page (http://www.fda.gov/ForConsumers/ConsumerUpdates/default.htm), which features the latest on all FDA-regulated products.

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