U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION & RESEARCH

FDA FACT SHEET

WHAT'S INVOLVED IN REVIEWING AND APPROVING GENERIC DRUG APPLICATIONS?

Generic drugs are copies that one company makes of a brand-name drug that was developed by another company. Generally, generic drugs sell at lower prices, and it is in the public's interest to get generic drugs to the market quickly. But, like any other scientific and regulatory process, approval of a generic drug takes time. It takes FDA time to review the complex information needed to demonstrate that a given generic drug can be substituted for the brand-name drug that it copies, and that time also depends on the complexity of the drug product and the completeness of the application. Here is why:

Prescription drugs have significant, sometimes life-saving, positive effects, but they also may present significant risks. FDA approves a drug only after review of extensive testing showing that a drug will provide the benefits described in its labeling, and that those outweigh its risks.

As a copy of the brand-name drug FDA originally reviewed, a generic drug application submitted to FDA for approval must show that:

- **The generic drug is "pharmaceutically equivalent" to the brand.** The generic drug needs to show that it is the same type of product (such as a tablet or an injectable) and uses the same time release technology (such as immediate-release, meaning for immediate effect of the drug, or extended-release, meaning one that is intended to slowly release the active ingredient over time).
- **The manufacturer is capable of making the drug correctly.** Often different companies are involved (such as one company manufacturing the active ingredient and another company manufacturing the finished drug). Generic drug manufacturers must produce batches of the drugs they want to market and provide information about the manufacturing of those batches for FDA to review.
- **The manufacturer is capable of making the drug consistently.** Generic drug manufacturers must explain how they intend to manufacture the drug, and provide evidence that each step of the manufacturing process will produce the same result each time. FDA scientists review those procedures and FDA inspectors go to the generic drug manufacturer's facility to verify that the manufacturer is capable of making the drug consistently and to check that the information the manufacturer has submitted to FDA is accurate.
- **The "active ingredient" is the same as that of the brand.** An active ingredient in a medicine is the component that makes it pharmaceutically active - effective against the illness or condition it is treating. Generic drug companies must provide evidence that shows that their active ingredient is the same as that of the brand-name drug they copy, and FDA must review that evidence.

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- **The right amount of the active ingredient gets to the place in the body where it has effect.** Two drug products with the same amount of active ingredient may be processed differently for different people. Generic drug companies must perform studies that show that the same amount of drug gets to the bloodstream and that it gets there at about the same time. FDA scientists analyze the results to be sure the generic will produce the same result as the brand-name drug.

- **The "inactive" ingredients of the drug are safe.** Some differences, which must be shown to have no effect on how the drug functions, are allowed between the generic drug and the brand. Generic drug companies must submit evidence that all the ingredients used in their products are safe, and FDA must review that evidence.

- **The drug does not break down over time.** Most drugs break down, or deteriorate, over time. Brand-name and generic drug companies must do months-long "stability tests" to show that their versions last for a reasonable time. FDA reviews the results of these studies.

- **The container in which the drug will be shipped and sold is appropriate.** The quality of the drug can deteriorate if its container is not appropriate. Information must be submitted about the containers and FDA must evaluate the information.

- **The label is the same as the brand-name drug's label.** The drug information label for the generic drugs should be the same as the brand. Sometimes, disputes arise related to the patents or exclusivities a brand-name drug has and which ones generic drugs can use. A generic drug can be approved for a use that is not protected by patents or legal exclusivities, and must remove all references to the legally protected use from the drug's label, so long as that removal does not take away information needed for safe use.

- **Relevant patents or legal exclusivities are expired.** As an incentive to develop new drugs, drug companies are awarded patents and legal exclusivities that delay the FDA approval of applications for generic drugs. FDA must comply with the delays in review and approval that the patents and exclusivities impose.

For more information:

- The Generic Drug Approval Process: http://www.fda.gov/Drugs/NewsEvents/ucm508150.htm
- Contact CDER: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ContactCDER/default.htm

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