

## Center for Drug Evaluation and Research: FAQ

The Center for Drug Evaluation and Research, a branch of the Food and Drug Administration (FDA), is a consumer watchdog in America's healthcare system. CDER's best-known job is to evaluate new drugs before they can be sold.

The Center's review of new drug applications not only prevents quackery, it provides doctors and patients with the information they need to use medicines wisely.

### What drugs are regulated by CDER?

From aspirin to cancer treatments, CDER ensures that the benefits of drug products outweigh any known risks. The Center oversees the research, development, manufacture and marketing of drugs. CDER ensures truth in advertising for prescription drugs and monitors the use of marketed drugs for unexpected health risks.

Specifically, CDER regulates:

- *Prescription Drugs.* Prescription medicines include any drug product that requires a doctor's authorization to purchase.
- *Generic Drugs.* A generic drug is a drug product that is equivalent to brand name products in terms of quality and performance.
- *Over-the-Counter Drugs.* OTC drug products are available to consumers without a doctor's prescription.

### Does the FDA test drugs?

FDA does not develop, manufacture or test drugs. Drug manufacturers submit full reports of a drug's studies so that the Center can evaluate its data. The studies answer the question: "Does this drug work for the proposed use?" By analyzing the data, CDER reviewers assess the benefit-to-risk relationship and determine if the drug will be approved.

### Why are some drugs changed from prescription to over-the-counter (OTC)?

Under certain circumstances, the status of some drugs that start off as prescription drugs is changed to OTC. When considering such a switch, the CDER's key question is whether the drug can benefit consumers without endangering their safety.

The major issue in deciding whether to switch a drug from prescription to OTC is toxicity. This is a drug's potential for poisonous effects. Since almost any drug, if misused, can have serious side effects, FDA considers the drug's overall safety.

Another consideration in deciding whether or not a drug should be available without a prescription is whether the condition being treated can be self-diagnosed and recognized without the help of a health-care practitioner. Not being able to self-diagnose a medical condition does not automatically prevent a product from switching to OTC status; FDA evaluates each drug on an individual basis.

### Once FDA approves a drug, does this mean that the product is perfectly safe?

No drug product is "perfectly" safe. Every single drug that affects the body will have some side effects. Since the FDA considers both the benefits and risks of all medications before approval, side effects are generally not serious. For every drug FDA approves, the benefits are balanced against its risks. In addition, FDA makes sure the labeling (package insert) outlines the benefits and risks reported in the tested population. You and your health-care provider should

decide together if the benefits outweigh the risks for you. Talking about your medicines with your health-care provider is just as important and good for your health as a complete check-up and taking your medicine as directed.

Sometimes, after a drug has been approved, unexpected risks are detected. When this happens, FDA takes action to inform the public, change a drug's label, or--if necessary--remove the product from the market.