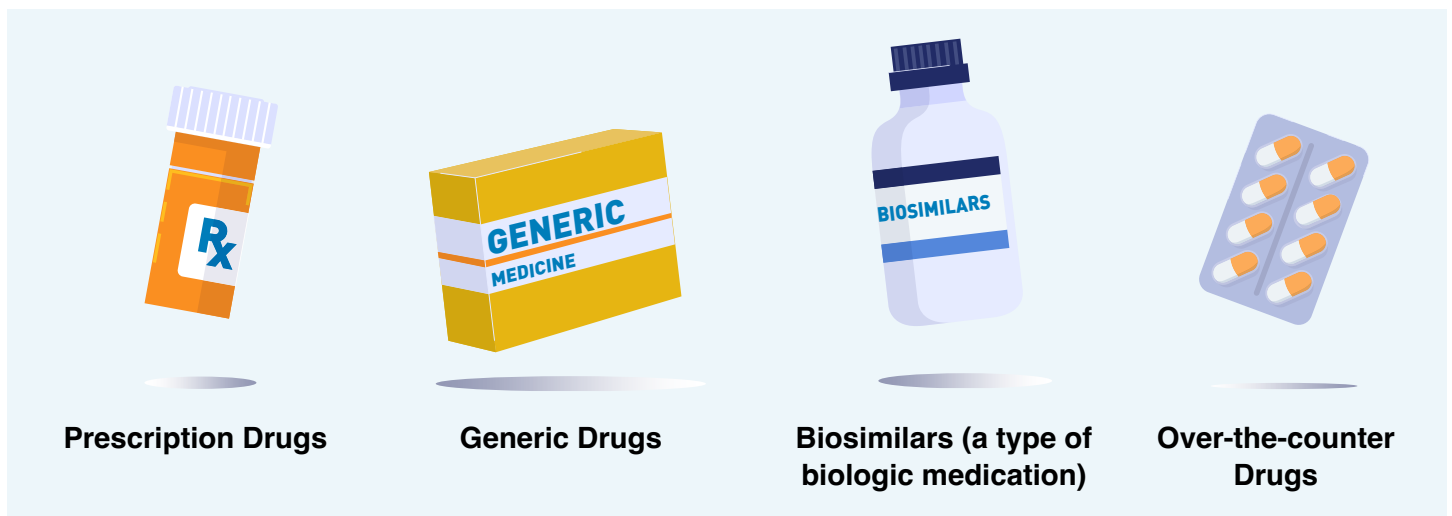


# How the FDA Regulates and Approves Drugs

## How Does the FDA Determine if Drugs are Safe and Effective?

The FDA is responsible for approving new drugs and ensuring they are safe, high quality, and work the way they're supposed to. Scientists and staff at the FDA's Center for Drug Evaluation and Research use science and data to make decisions about:



As part of its public health mission, the FDA protects the American public by ensuring that health care providers and patients have accurate and science-based information to choose medicines and use them correctly.

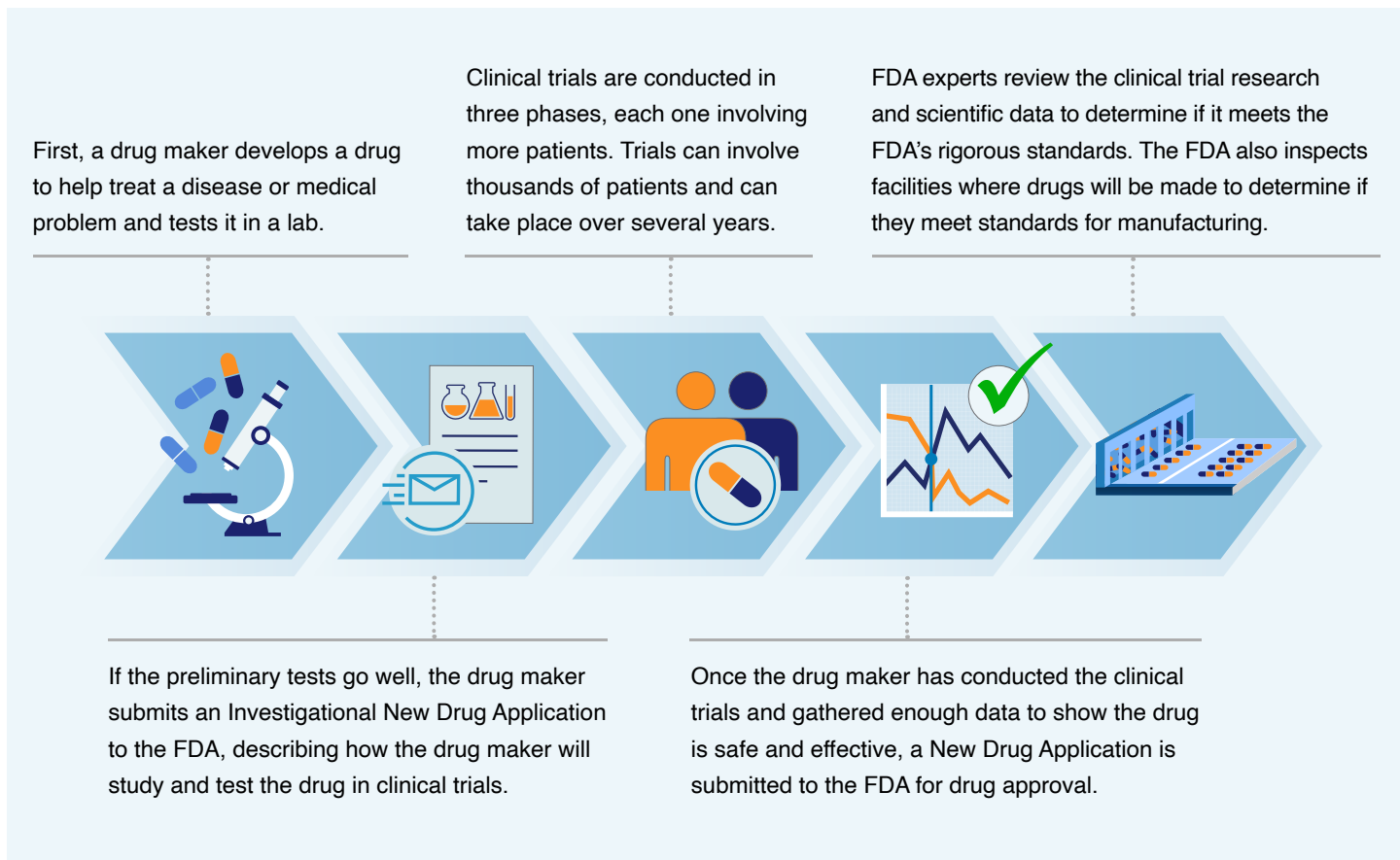
The highly trained scientists and staff at the FDA review data and research to answer questions about drugs, such as:

- Is the new drug safe?
- Does it work the way it's supposed to?
- Is the drug high quality?
- Do the benefits of this drug outweigh the risks?

## How Does the FDA Approve New Drugs?

The FDA makes careful, informed decisions about which new drugs to approve based on evaluation of whether treatments are safe and effective. It follows a comprehensive, multistep process that can take several years to complete. The process is governed by laws and regulations to protect the rights, safety, and welfare of volunteers.

Once these steps are taken, and based on the science, data, and evidence, the FDA makes a decision to approve or not approve the drug.



## What is the FDA's Role After Drugs are Approved?

After the FDA approves drugs and patients start using them, the FDA continues to monitor their safety and effectiveness. The FDA keeps track of new data from patients, health care professionals, or drug makers, including negative or adverse reactions. The FDA can recommend a drug maker update the drug labeling by adding warnings or updating dosage information. The FDA can also issue drug recalls. The FDA conducts ongoing inspections of facilities where drugs are made to ensure manufacturers are following safety and quality standards.

The FDA ensures the public stays informed about drug recalls and safety information. Patients, health care professionals, and consumers can find and report information about medical product safety on the FDA's [MedWatch page](#) and subscribe to MedWatch safety alerts via email or social media.

## What Doesn't the FDA Do?

The FDA's decisions are guided by science and data and are not influenced by industry or politics. The FDA does not control the cost of drugs or get involved in interactions between patients and their health care providers. It is important to remember — the FDA oversees clinical trials for safety and reviews the results of those studies, but it does not develop new therapies or conduct the clinical trials.