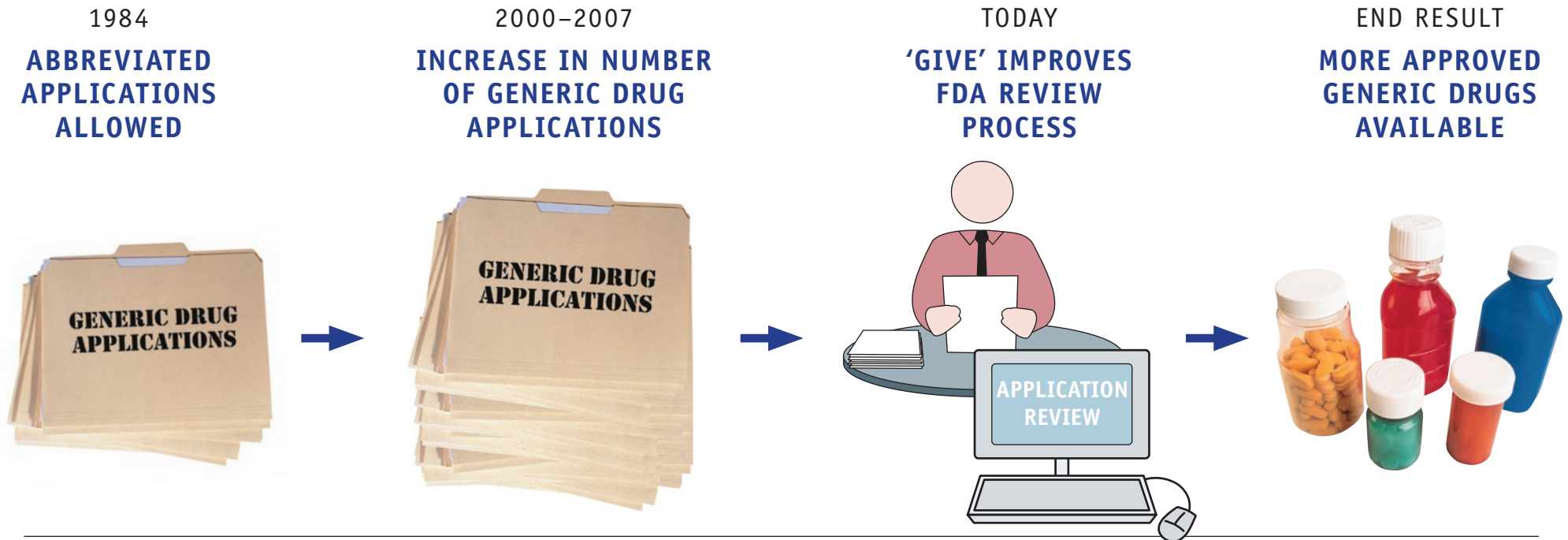


FDA's New GIVE Initiative

www.fda.gov/consumer/updates/GIVE_diagram100407.html

On Oct. 4, FDA announced the Generic Initiative for Value and Efficiency (GIVE), a new program aimed at optimizing the generic drug review process to increase efficiency. It was spurred by recent developments affecting FDA's generic drugs approval process.



The Drug Price Competition and Patent Term Restoration Act of 1984 put in place a process allowing generic-drug producers to submit abbreviated new drug applications to FDA's Office of Generic Drugs (OGD).

Qualifying generic drugs would be approved after a stringent review process.

Factors such as advancements in medical science and a growing need and market for less expensive medications lead to a dramatic increase in the number of generic-drug producers, and in the number of new products they propose.

The number of abbreviated new drug applications submitted to OGD jumps.

OGD responds with various process improvements. These help it approve a record number of applications during fiscal years 2006 and 2007.

Process improvements are combined into GIVE, a harmonized activity that will implement process improvements throughout OGD's entire system.

GIVE is focused on 3 main areas:

- Mobilizing staff efforts to increase review productivity.
- Optimizing the capacity and capability of all assets within OGD and leveraging wherever possible resources from other FDA components.
- Using every avenue possible to recruit, hire and train reviewers for our critical needs areas.

Consumers have timely access to more generic drugs.

