

# Recent Generic Drug Approvals



**E**ach year, FDA approves scores of generic drugs that treat a variety of conditions and help consumers save money.

Generic drugs cost about 20% to 70% less than their brand name counterparts. The Congressional Budget Office has reported that generic drugs save consumers an estimated \$8 billion to \$10 billion a year.

Generic drugs are identical to their brand-name equivalents in dosage, safety, strength, quality, performance characteristics, intended use, and the way they're administered to patients.

Drug manufacturers develop their new drugs under patents that protect their firms' investments in the products. When patents or other periods of exclusivity on the drugs expire, manufacturers can apply to FDA to sell generic versions.

In October 2007, FDA launched the Generic Initiative for Value and Efficiency (GIVE) to help increase the number of approvals of generic products.

GIVE will use existing resources to help FDA modernize and streamline the generic drug approval process. GIVE will also increase the variety of generic drug products available. [FDA](#)

#### For More Information

FDA's GIVE Initiative  
[www.fda.gov/oc/initiatives/advance/generics.html](http://www.fda.gov/oc/initiatives/advance/generics.html)

FDA's Office of Generic Drugs  
[www.fda.gov/cder/ogd/](http://www.fda.gov/cder/ogd/)

Generic Drug Approvals (by month)  
[www.fda.gov/cder/ogd/approvals/default.htm](http://www.fda.gov/cder/ogd/approvals/default.htm)

Significant approvals granted by FDA's Office of Generic Drugs during the past year include

- **Alendronate Sodium Tablets**  
 Used for: Treating and preventing types of osteoporosis  
 Originally marketed as: Fosamax, by Merck & Co.  
 Date approved: Feb. 6, 2008
- **Carvedilol Tablets**  
 Used for: Treating hypertension and heart failure  
 Originally marketed as: Coreg, by SmithKline Beecham, now GlaxoSmithKline  
 Date approved: Sept. 5, 2007
- **Cetirizine HCl Tablets**  
 Used for: Treating symptoms of allergies  
 Originally marketed as: Zyrtec, by Pfizer  
 Date approved: Dec. 12, 2007
- **Granisetron Tablets**  
 Used for: Preventing nausea and vomiting related to chemotherapy and radiation  
 Originally marketed as: Kytril, by Roche  
 Date approved: Dec. 31, 2007
- **Oxcarbazepine Tablets**  
 Used for: Treating certain kinds of seizures and epilepsy  
 Originally marketed as: Trileptal, by Novartis  
 Date approved: Oct. 9, 2007
- **Pravastatin Sodium Tablets**  
 Used for: Treating elevated cholesterol and preventing coronary events  
 Originally marketed as: Pravachol, by Bristol-Myers Squibb  
 Date approved: Apr. 23, 2007
- **Zolpidem Tartrate Tablets**  
 Used for: Treating insomnia  
 Originally marketed as: Ambien, by Sanofi Aventis  
 Date approved: Apr. 23, 2007