

Generic Drug Roundup: March 2008



Each 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

FDA's Office of Generic Drugs

www.fda.gov/cder/ogd/

Generic Drug Approvals (by month)

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