# Generic Drug Roundup: February 2009


Each year, the Food and Drug Administration (FDA) approves scores of generic drugs that treat a wide variety of conditions and help consumers save money.

Significant approvals for prescription products granted by FDA's Office of Generic Drugs since March 2008 include:

---

### Risperidone Tablets

Used for: Treating schizophrenia, bipolar disorder, and other psychiatric conditions

Originally marketed as: Risperdal, by Ortho McNeil Janssen

Date approved: June 30, 2008

Notes: The labeling of the generic risperidone may differ from that of Risperdal because some uses of the drug are protected by patents and exclusivity.

Approval press release: *www.fda.gov/bbs/topics/NEWS/2008/NEW01855.html*

---

### Divalproex Sodium Delayed-Release Tablets

Used for: Treating seizures, bipolar disorder, and migraine headaches

Originally marketed as: Depakote, by Abbott Pharmaceuticals PR

Date approved: July 29, 2008

Notes: Generic divalproex sodium has the same safety warnings as Depakote, including a boxed warning that cautions about the risk of liver damage, pancreatitis, and birth defects.

Approval press release: *www.fda.gov/bbs/topics/NEWS/2008/NEW01867.html*

## Generic Drugs: Vital Facts

Generic drugs cost about 20 percent to 70 percent 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 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.

FDA's Generic Initiative for Value and Efficiency (GIVE) helps increase the number of approvals of generic products. Read about it at *www.fda.gov/oc/initiatives/advance/generics.html*

# *Generic drugs are identical to their brand-name equivalents in dosage, safety, strength, quality, and performance.*

### Ropinirole Hydrochloride Tablets

Used for: Treating moderate to severe Restless Legs Syndrome

Originally marketed as: Requip, by GlaxoSmithKline

Date approved: May 2008

Notes: Ropinirole tablets have been approved in the following dosages: 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, and 4 mg.

Approval press release: *www.fda.gov/bbs/topics/NEWS/2008/NEW01832.html*

### Dorzolamide and Timolol Maleate Ophthalmic Solution

Used for: Treating ocular hypertension (higher-than-normal pressure in the eye) and certain glaucomas

Originally marketed as: CoSopt, by Merck

Date approved: Oct. 28, 2008

### Galantamine Oral Tablets

Used for: Treating mild to moderate dementia of the Alzheimer's type

Originally marketed as: Razadyne (formerly Reminyl), by Ortho McNeil Janssen

Date approved: Aug. 28, 2008

Notes: In 2005, FDA and other international health authorities said they were reviewing the safety of Razadyne due to data from two clinical studies. FDA has asked the manufacturer to revise the labeling and advises patients to ask their health care professional if Razadyne is right for them.

Patient Information: Galantamine hydrobromide (marketed as Razadyne, formerly Reminyl)*www.fda.gov/cder/drug/InfoSheets/patient/galantaminelPIS.pdf*

This article appears on FDA's Consumer Health Information Web page (*www.fda.gov/consumer*), which features the latest updates on FDA-regulated products. Sign up for free e-mail subscriptions at *www.fda.gov/consumer/consumerenews.html*.

### For More Information

Generic Drug Roundup: March 2008
*www.fda.gov/consumer/updates/genericdrugs030308.html*

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*

Drug Information Search Tool: Drugs@FDA
*www.accessdata.fda.gov/scripts/cder/drugsatfda/*