

## **FDA NEWS RELEASE**

**For Immediate Release:** Jan. 26, 2010

### **FDA Approves Morphine Sulfate Oral Solution for Relief of Acute and Chronic Pain**

*Approval is part of Agency's unapproved drugs initiative*

The U.S. Food and Drug Administration today approved Morphine Sulfate Oral Solution for the relief of moderate to severe, acute and chronic pain in opioid-tolerant patients. This medicine will be available in 100 milligrams per 5 mL or 20 milligrams per 1 mL.

This is the only FDA approved morphine sulfate oral solution available at this concentration. Although the use of this medicine to manage pain has been common practice for many years, this form and concentration of morphine was not FDA approved until now.

Today's action is part of the FDA's unapproved drugs initiative. As part of this program, the FDA has worked with the manufacturer of the now-approved product, Roxane Laboratories, to ensure that there is enough drug available for patients. The FDA will also be working with patient organizations and prescribers so that they are aware that an approved product is available, and can notify the FDA if there are any problems with availability.

"An important goal of the unapproved drugs initiative is to make sure that marketed drugs meet current FDA standards," said Douglas Throckmorton, M.D., deputy director for the FDA's Center for Drug Evaluation and Research. "Our action today reflects a careful balance between ensuring patient access to necessary medicines, while making sure companies comply with the law."

One benefit of the FDA approval process is a requirement for manufacturers to provide sufficient information on how to safely prescribe and use a drug. Manufacturers may also have to establish additional safety measures to manage unique risks of a medicine. For this formulation of morphine, the manufacturer had to develop a safety program prior to approval to address the known risks of morphine misuse, abuse and overdose.

#### **For more information:**

March 31, 2009 Warning Letters, companies, and affected products

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm118712.htm>

List of FDA-approved drug products

<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>