

## **FDA NEWS RELEASE**

**For Immediate Release:** Apr. 5, 2010

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### **FDA Approves New Formulation for OxyContin**

The U.S. Food and Drug Administration today approved a new formulation of the controlled-release drug OxyContin that has been designed to help discourage misuse and abuse of the medication.

OxyContin is made to slowly release the potent opioid oxycodone to treat patients who require a continuous, around-the-clock opioid analgesic for management of their moderate to severe pain for an extended period of time. Because of its controlled-release properties, each OxyContin tablet contains a large quantity of oxycodone, which allows patients to take their drug less often. However, people intent on abusing the previous formulation have been able to release high levels of oxycodone all at once, which can result in a fatal overdose and contributes to high rates of OxyContin abuse.

The reformulated OxyContin is intended to prevent the opioid medication from being cut, broken, chewed, crushed or dissolved to release more medication. The new formulation may be an improvement that may result in less risk of overdose due to tampering, and will likely result in less abuse by snorting or injection; but it still can be abused or misused by simply ingesting larger doses than are recommended.

“Although this new formulation of OxyContin may provide only an incremental advantage over the current version of the drug, it is still a step in the right direction,” said Bob Rappaport, M.D., director of the Division of Anesthesia and Analgesia Products in the FDA’s Center for Drug Evaluation and Research.

“As with all opioids, safety is an important consideration,” he said. “Prescribers and patients need to know that its tamper-resistant properties are limited and need to carefully weigh the benefits and risks of using this medication to treat pain.”

According to the U.S. Substance Abuse and Mental Health Services Administration’s National Survey on Drug Use and Health, approximately half a million people used OxyContin non-medically for the first time in 2008.

The manufacturer of OxyContin, Purdue Pharma L.P., will be required to conduct a postmarket study to collect data on the extent to which the new formulation reduces abuse and misuse of this opioid. The FDA is also requiring a REMS (Risk Evaluation and Mitigation Strategy) that will include the issuance of a Medication Guide to patients and a requirement for prescriber education regarding the appropriate use of opioid analgesics in the treatment of pain.

Purdue Pharma is based in Stamford, Conn.