

## TYPE: Drug Safety Communication

*FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death*

Date: **03/22/2016**

### ISSUE

In a continuing effort to educate prescribers and patients about the potential risks related to opioid use, the U.S. Food and Drug Administration today announced required class-wide safety labeling changes for immediate-release (IR) opioid pain medications. Among the changes, the FDA is requiring a new boxed warning about the serious risks of misuse, abuse, addiction, overdose and death. Today's actions are among a number of steps the agency recently outlined in a plan to reassess its approach to opioid medications. The plan is focused on policies aimed at reversing the epidemic, while still providing patients in pain access to effective relief.

The FDA is also requiring several additional safety labeling changes across all prescription opioid products to include additional information on the risk of these medications. This is part of the agency's overall effort to help inform prescribers about the importance of balancing the serious risks of opioids with their role in managing pain.

"Opioid addiction and overdose have reached epidemic levels over the past decade, and the FDA remains steadfast in our commitment to do our part to help reverse the devastating impact of the misuse and abuse of prescription opioids," said Robert Califf, M.D., FDA commissioner. "Today's actions are one of the largest undertakings for informing prescribers of risks across opioid products, and one of many steps the FDA intends to take this year as part of our comprehensive action plan to reverse this epidemic."

"The broad set of actions announced today is reflective of the FDA's efforts to improve informed prescribing of opioids across the board," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research. "We have been and will continue to evaluate all new data to ensure that labels of opioid drugs contain appropriate prescribing information about the benefits and risks of prescription opioids."

The FDA is also aware of, and carefully reviewing, available scientific information about potentially serious outcomes related to interactions between benzodiazepines and opioids. Once a review of all available scientific information is completed, the FDA will take necessary actions to ensure prescribers and the public are informed of the risks involved with the use of these medications.

For additional information please visit <http://www.drugs.com/news/fda-announces-enhanced-warnings-immediate-release-opioid-pain-related-risks-misuse-abuse-overdose-60600.html>

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