Actavis Inc. Issues a Voluntary Recall of 18 Lots of Fentanyl Transdermal System 25 mcg/h

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MORRISTOWN, N.J., Oct. 21 /PRNewswire/ -- Actavis Inc. today announced a voluntary recall to the wholesale and retail levels only of 18 lots of Fentanyl Transdermal System 25 mcg/hour C-II patches manufactured for Actavis by Corium International in the United States.

Actavis identified one lot of 25 mcg/hour Fentanyl patch (Control/Lot # 30349) shipped to market that contained one patch that released its active ingredient faster than the approved specification in laboratory testing. An accelerated release of Fentanyl from a 25 mcg/hour patch can lead to adverse events for at-risk patients, including excessive sedation, respiratory depression, hypoventilation (slow breathing), and apnea (temporary suspension of breathing). The patches are packaged individually and boxed in quantities of five patches per box.

Fentanyl Transdermal System is indicated for the management of persistent, moderate to severe chronic pain that requires continuous, around-the-clock opioid administration for an extended period of time and cannot be managed by other means such as non-steroidal analgesics, opioid combination products, or immediate release opioids.

As a precautionary measure, although unaware of any injuries associated with this issue, in addition to the aforementioned lot, Actavis is recalling the additional Control/Lot numbers noted below due to the possibility that additional patches may release active ingredient faster than the approved specification. The Control/Lot number appears on the bottom of the product box and on the black and white side of each individual patch packaging, in the lower left corner.Recalled Control/Lot #s30041, Exp 12/201130049, Exp 12/201130066, Exp 12/201130096, Exp 01/201230097, Exp 02/201230123, Exp 01/201230241, Exp 02/201230256, Exp 02/201230257, Exp 03/201230258, Exp 03/201230349, Exp 03/201230350, Exp 03/201230391, Exp 03/201230392, Exp 04/201230429, Exp 04/201230430, Exp 04/201230431, Exp 04/201230517, Exp 04/2012
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