# Fentanyl transdermal patch recall expanded

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The U.S. Food and Drug Administration announced the expansion of a recall of Fentanyl transdermal system CII patches sold in the United States.

The action by Actavis Inc. expands the company's initial recall of 14 lots of Fentanyl transdermal patches announced Feb. 17. That recall was due to a possible fold-over defect in the product. The expanded recall is a precautionary measure because Actavis lacks assurance all patches are free from defects, the FDA said.

All recalled patches were sold nationwide in the United States. Fentanyl patches sold by Actavis in Europe are not affected by the recall.

The patches are used for the management of persistent, moderate to severe chronic pain.

The FDA said exposure to Fentanyl gel may lead to serious adverse events, including respiratory depression and possible overdose, which might be fatal.

Officials said Actavis was formerly known as Abrika Pharmaceuticals Inc. and some pouches containing the patches may be labeled with an Abrika Pharmaceuticals label.

The lots covered by the recall have expiration dates between May 2009 and December 2009. The FDA said anyone who has Fentanyl patches labeled with an Abrika or Actavis logo should check them for those expiration dates.