Alvogen – Recall of fentanyl transdermal system

- On April 22, 2019, the FDA announced a voluntary, consumer-level recall of two lots of Alvogen's fentanyl transdermal system 12 mcg/h transdermal patches because a small number of cartons labeled 12 mcg/h fentanyl transdermal system patches contained 50 mcg/h patches.
    - The 50 mcg/h patches that were included in cartons labeled 12 mcg/h are individually labeled as 50 mcg/h.
- The recalled lots were distributed nationwide to the pharmacy level.

Product Description	NDC#	Lot# (Expiration Date)
Fentanyl transdermal system, 12 mcg/h	47781-423-47	180060 (5/2020); 180073 (6/2020)

- Fentanyl transdermal system is indicated for the management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.
- Per Alvogen, application of a 50 mcg/h patch instead of a prescribed 12 mcg/h patch could result in serious, life threatening, or fatal respiratory depression. Groups at potential increased risk could include first time recipients of such patches, children, and the elderly.
- To date, Alvogen has not received any reports of adverse events related to this issue.
- Alvogen is notifying its distributors and direct customers by certified letter and is arranging for return and replacement of all recalled products. Pharmacies are requested not to dispense any product subject to this recall.
- Patients that have product subject to this recall should immediately remove any patch currently in use and contact their health care provider. Patients with unused product should return it to point of purchase for replacement.
- Questions regarding this recall should be directed to Alvogen Customer Complaints by calling **1-866-770-3024** or sending an e-mail to **pharmacovigilance@alvogen.com**.
- Patients should contact their healthcare provider if they have experienced any problems that may be related to taking or using fentanyl transdermal systems.