April 22, 2019
COM-2019-017

Recall: Voluntary Nationwide Recall of Fentanyl Transdermal System Due to Product Mislabeling - Alvogen Inc.

Dear provider of pharmaceutical services,

At PharmPix we are committed to the health and well-being of patients. It is for this reason that we inform you that on April 19, 2019 the US Food and Drug Administration (FDA) issued a statement notifying that Avogen Inc. is voluntarily recalling two lots of Fentanyl Transdermal System, 12 mcg/h. The recall was made because a small number of cartons labeled 12 mcg/h Fentanyl Transdermal System patches contained 50 mcg/h patches. The product affected by the recall is detailed on Table 1.

Table 1: Affected Product of Fentanyl Transdermal System

NDC	Product	Count	Affected Lot	Expiration date
47781-0423-47	Fentanyl Transdermal System, 12 mcg/h	5	180060	05/2020
47781-0423-47	Fentanyl Transdermal System, 12 mcg/h	5	180073	06/2020

The Pharmacy must:

1. Identify if they have the product in inventory and immediately stop using and dispensing the product.
2. Contact all members that in the previous 90 days received the recalled medication and advised them to talk to their doctor. As per manufacturer instructions, 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 pharmacy for replacement.
3. Any question regarding this recall should be directed to Alvogen Customer Complaints by calling 866-770-3024 or sending an e-mail to pharmacovigilance@alvogen.com from Monday to Friday from 9:00 am to 5:00 pm EST.

For additional information visit:
https://www.fda.gov/Safety/Recalls/ucm636384.htm

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