Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC25-007-CG
February 5, 2025

FDA announced that Alvogen, Inc. is voluntarily recalling one lot of Fentanyl Transdermal System 25 mcg/h transdermal patches to the consumer level. The reason for the recall is that there is a potential that patches could be multi-stacked, adhered one on top of the other, in a single product pouch. This transdermal system is manufactured by Kindeva Drug Delivery L.P., Northridge, CA and is distributed by Alvogen, Inc. as a private label distributor.

RECOMMENDATIONS

1. Alvogen, Inc. 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.

2. 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.

3. Consumers should contact their physician or health care provider if they have experienced any problems that may be related to taking or using this drug product.

4. Questions regarding this recall should be directed to Alvogen Customer Complaints by calling 866-770-3024 or sending an e-mail to alvogensmb@continuumindia.com, Monday to Friday from 9:00 am to 5:00 pm EST.

5. Review your inventory to identify existence of recalled products.

6. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

T. (800) 377-1037
1267 Professional Pkwy, Gainesville, GA 30507
T. (787) 286-6032
Call Box 4908, Caguas, P.R. 00726
MC-Rx.com

FDA U.S. FOOD & DRUG ADMINISTRATION

Alvogen Issues Voluntary Nationwide Recall for One Lot of Fentanyl Transdermal System 25 mcg/h Due to a Defective Delivery System

SUMMARY:

Company Announcement Date:	January 31, 2025
FDA Publish Date:	January 31, 2025
Product Type:	Drugs
Reason for Announcement:	There is potential that patches could be multi-stacked, adhered one on top of the other, in a single product pouch
Company Name:	Alvogen, Inc.
Brand Name:	Alvogen
Product Description:	Fentanyl Transdermal System 25 mcg/h transdermal patches

COMPANY ANNOUNCEMENT:

FOR IMMEDIATE RELEASE – January 31, 2025 – Morristown, NJ

Alvogen, Inc. is voluntarily recalling one lot of Fentanyl Transdermal System 25 mcg/h transdermal patches to the consumer level. The reason for the recall is that there is a potential that patches could be multi-stacked, adhered one on top of the other, in a single product pouch. This transdermal system is manufactured by Kindeva Drug Delivery L.P., Northridge, CA and is distributed by Alvogen, Inc. as a private label distributor.

There is a possibility that the application of a multi-stacked 25 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 received one serious adverse event related to this recall.

The product is indicated for the management of severe and persistent pain in opioid-tolerant patients, that requires an extended treatment period with a daily opioid analgesic in opioid-tolerant patients, and for which alternative treatment options are inadequate, and is packaged in primary

T. (800) 377-1037
1267 Professional Pkwy, Gainesville, GA 30507
T. (787) 286-6032
Call Box 4908, Caguas, P.R. 00726
MC-Rx.com

cartons of five individually wrapped and labeled pouches. The affected Fentanyl Transdermal System lot is:

Lot 108319 of Fentanyl Transdermal System, 25 mcg/h, expiration date 04/2027.
This lot of Fentanyl Transdermal System was distributed nationwide to the pharmacy and patient level. See image examples for lot 108319 and a multi-stacked patch.

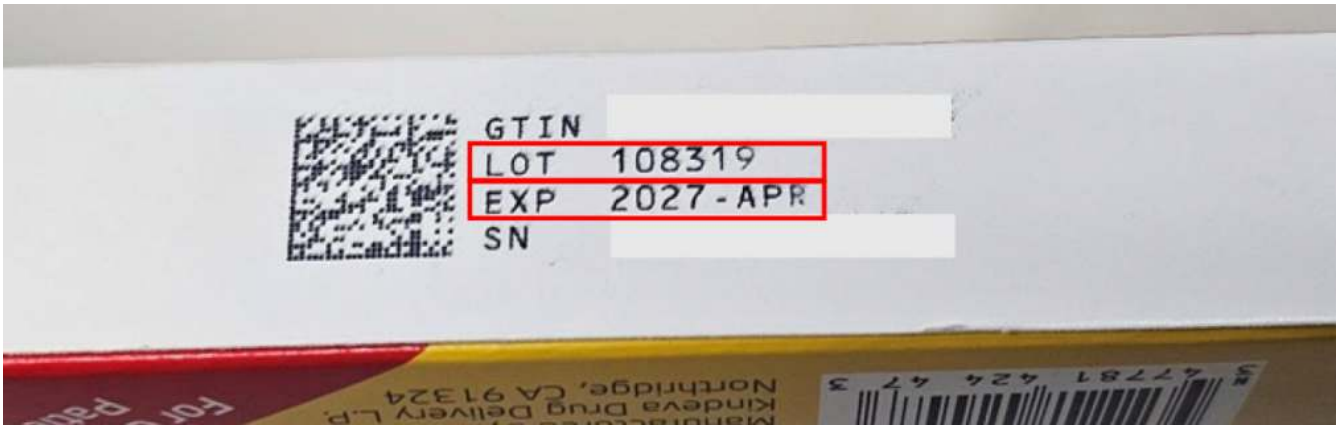
Alvogen, Inc. is notifying its distributors and direct customers by certified letter and is arranging for return and replacement of all recalled products. Pharmacies are requested not to dispense any product subject to this recall.

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. Consumers should contact their physician or health care provider if they have experienced any problems that may be related to taking or using this drug product.

Questions regarding this recall should be directed to Alvogen Customer Complaints by calling 866-770-3024 or sending an e-mail to alvogensmb@continuumindia.com, Monday to Friday from 9:00 am to 5:00 pm EST.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- **Complete and submit the report Online:** www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax: Download form or call 1-800-332-1088** to request a reporting form, then complete and return to the address on the pre-addressed form, or submit **by fax** to **1-800-FDA-0178**



T. (800) 377-1037
1267 Professional Pkwy, Gainesville, GA 30507
T. (787) 286-6032
Call Box 4908, Caguas, P.R. 00726
MC-Rx.com

FDA U.S. FOOD & DRUG ADMINISTRATION

T. (800) 377-1037
1267 Professional Pkwy, Gainesville, GA 30507
T. (787) 286-6032
Call Box 4908, Caguas, P.R. 00726
MC-Rx.com