URGENT VOLUNTARY DRUG RECALL

January 31, 2025

Dear Valued Customer,

Alvogen, Inc. is voluntarily recalling one lot of Fentanyl Transdermal System 25 mcg/h transdermal patches to the consumer level. A small number of patches is impacted. The reason for the recall is that there is a potential that patches could potentially 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.

Product Description	Strength	Pack Size (pouches / carton)	NDC#	Lot#	Exp Date	Ship dates
Fentanyl Transdermal System	25mcg/hr	Carton (5 pouches/carton) Pouch (1 patch/pouch)	47781-424-47 47781-424-11	108319	04/2027	06/11/24 – 10/21/24

Our records indicate you received one or more shipments of the affected lot between 06/11/2024 and 10/21/2024. Please examine your inventory immediately to determine if you have any quantities of this lot remaining.

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.

Alvogen has enlisted the services of Inmar Intelligence to facilitate the recall. Inmar is located at 3845 Grand Lakes Way, Grand Prairie, TX 75050. As instructed below, all returns must be sent to Inmar at this address.

This recall is limited to the lot number listed above and extends to the consumer level. No other Alvogen products or lots are impacted by this recall.

Instructions for Wholesalers/Distributors, Retailers/Pharmacies, and Consumers/Patients/Caregivers are provided below.

Action Required - Wholesalers and Distributors:

1. Stop distributing this lot immediately and segregate any affected product remaining in your inventory for return.
2. Notify your retail and distributor consignees. Include a copy of this letter to any of your direct retail or distributor consignees to whom you distributed the affected product. Wholesalers/Distributors are to conduct a sub-recall to retail/pharmacy customers, to which you have shipped the affected product, by informing them of the recall and requesting that they remove the affected product from sale. Request your retail/pharmacy customers to inform their consumers about the recall and return the stock to the wholesaler/distributor from which it was purchased. Note: you must follow up with your retail/pharmacy

customers who do not acknowledge the receipt of the recall notification and take appropriate actions to return the affected product.
3. Complete and fax/email Response Form following the instructions on the Form or call Inmar Intelligence at 877-560-8457 to request a Return Authorization (RA) kit that will include a pre-paid shipping label for return. Even if you do not possess any affected product in your inventory, please prepare and return a Response Form to Inmar Intelligence indicating that you do not possess any of the affected product.
4. Use the provided Return Authorization labels for this recall to return the product to Inmar Intelligence located at 3845 Grand Lakes Way, Grand Prairie, TX 75050. Do not use the Return Authorization labels for any other product or send them to any other location.
5. Please do not include any other product/lot in this return shipment.

Action Required - Retailer or Pharmacy:
1. Stop dispensing this lot immediately and segregate any product remaining in your inventory for return. Retail and hospital pharmacies that track the lot number dispensed to individuals should contact individuals who have received the impacted lot of **Fentanyl Transdermal System, 25mcg/hr**. identified above. Alternatively, you may contact individuals to whom the recalled product was dispensed between June 11, 2024 and receipt of this notification, advise them of the recall, and recover any units of the impacted lot for return.
2. Please complete and return the enclosed response form as soon as possible. Call Inmar Intelligence at 877-560-8457 to request a Return Authorization (RA) kit to use for return shipment and to discuss any reimbursement questions. As the RA kit will indicate, return of the product for this recall must be made only to Inmar Intelligence.
3. Once you receive the shipping label and RA kit, immediately ship any affected product to Inmar Intelligence.
4. Please do not include any other products/lots in this return shipment.

Action Required – Consumer/Patient/Caregiver:
1. Prior to returning the recalled medication, you should consult with your pharmacist, who can advise you about replacement of your medication or reimbursement for your medication. Since there is a potential for adverse health consequences associated with stopping the medication, you should also consult with your healthcare provider or physician. Once your pharmacist has provided you with a replacement of your medication, or a healthcare provider or physician has provided you a new prescription to treat your condition, we request that you return any remaining product that is the subject of this recall to the pharmacy it was purchased from.
2. Please complete and return the enclosed response form as soon as possible. If the pharmacy refuses to take the product back, replace or reimburse it, please call Inmar Intelligence at 877-560-8457 to request a Return Authorization (RA) kit to use for return shipment and to discuss any reimbursement questions. As the RA kit will indicate, return of the product for this recall must be made only to Inmar Intelligence.
3. Once you receive the shipping label and RA kit, immediately ship any affected product to Inmar Intelligence.
4. Please do not include any other products/lots in this return shipment.

Alvogen will issue a credit for all returned goods associated with this recall notice, as well as the costs of the recall as described in the Healthcare Distribution Alliance (HDA) guidance.

For reimbursement purposes, the identified lot and associated paperwork must be submitted by **August 30, 2025.**

Patient safety and product quality are critical to Alvogen. We appreciate your immediate attention and cooperation and sincerely apologize for any inconvenience caused by this recall. Thank you for your prompt attention to this matter.

For adverse reactions or quality problems experienced with the use of this product, contact firm's website or to the FDA's Med Watch 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 www.fda.gov/MedWatch/getforms.htm 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

This recall is being made with the knowledge of the Food and Drug Administration.

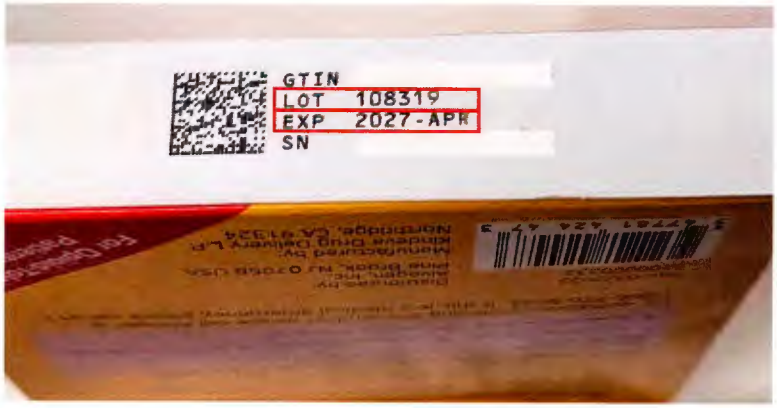
Travis Roberts

VP, Sales & Marketing

Alvogen Inc.

cc: Lisa D. Graver, CEO – Alvogen, Inc.

Product Label:



ALVOGEN

URGENT: DRUG RECALL

RESPONSE FORM for Wholesalers/Retailers to Complete

Fentanyl Transdermal System, 25mcg/hr, 5 Pouches/Carton

Consumer Level - CII

01/31/2025

1. **Please fill out this form completely.** By doing so, this will acknowledge that you have read and understand the recall instructions and have taken the appropriate action.

Customer Name: | DEA #:

DEA # is required; if it is not provided, the processing of your form will be delayed.

Address:

City: | State: | Zip:

Contact Name (Please Print):

Telephone #: | Email:

Contact Signature: | Date:

DEBIT MEMO # (If unsure, leave blank):

Wholesaler Information if not directly purchased from Alvogen Inc.:

Wholesaler Name: | DEA#:

City: | State: | Zip:

I have checked my stock and:

☐ I confirm that all locations that received the impacted product have been notified to the consumer level _____(Initial and date)

☐ I do not have any stock of the recalled items. **OR**

☐ I have quarantined and listed in the box below the quantity of recalled units and I will be returning to these units to Inmar, as soon as possible. Upon receipt of this Response Form, Inmar will issue return authorization label(s). Please indicate the # of needed box labels_____.

Product Name	Package Description	NDC#	Lot#	Expiration Date	Input Total Number of Cartons to Return	Input Total Number of Pouches to Return
Fentanyl Transdermal System, 25mcg/hr	Carton (5 pouches/ Carton) Pouch (1 patch/pouch)	47781-424-47 47781-424-11	108319	04/2027		

If you have any questions regarding this form or product return please contact Inmar at 877-560-8457 (office hours 9am to 5pm EST Monday through Friday).

Please fax this form to: 1-817- 868-5362 or E-mail rxrecalls@inmar.com

Event ID RCL023-25 / N131265

ALVOGEN

URGENT: DRUG RECALL

RESPONSE FORM for Consumer to Complete

Fentanyl Transdermal System, 25mcg/hr, 5 Pouches/Carton

Consumer Level - CII

01/31/2025

INSTRUCTIONS to Consumers / Patients / Caregivers FOR RETURNING RECALLED PRODUCT:

1) Complete the form below and return to Inmar for processing
2) Inmar will provide a pre-paid shipping label within fourteen (14) business days to return the product
3) For reimbursement, please send a copy of your "Proof of Purchase" such as a pharmacy receipt or a claim from your medical/prescription benefit provider along with the completed response form to Inmar.
4) Return the completed form and proof of purchase via **FAX**: 1-817-868-5362 -or- **E-MAIL**: rxrecalls@inmar.com -or- regular **MAIL:** Inmar Pharmaceutical Services, Attn: Recall Coordinator - One West Fourth Street, Suite 500, Winston Salem, NC 27101

Customer/Patient Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Contact Name (Please Print): _____

Telephone #: _____ Email: _____

Contact Signature: _____ Date: _____

Alvogen is accepting the below NDC/Lot for Fentanyl Transdermal System.

Please fill out the table below indicating how much product you will be returning, and its NDC & Lot Number. Please attach a picture or scan of the receipt(s) for **ALL** product(s) you will be returning.

IMPORTANT- Send all receipts with this form. A return kit will be sent to you to send back your product. DO NOT SEND RECEIPTS WITH YOUR RETURN KIT. They will not be processed and your refund will not be sent.

Product Name	Package Description	NDC#	Lot#	Expiration Date	Input Total Number of Cartons to Return	Input Total Number of Pouches to Return
Fentanyl Transdermal System, 25mcg/hr	Carton (5 pouches/ Carton) Pouch (1 patch/pouch)	47781-424-47 47781-424-11	108319	04/2027		

Any adverse events associated with the recalled product? □ Yes □ No

If yes, please explain: _____

If you have any questions regarding this form or product return please contact Inmar at 877-560-8457 (office hours 9am to 5pm EST Monday through Friday).

Please fax this form to: 1-817-868-5362 or E-mail rxrecalls@inmar.com

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