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Hikma Injectables USA Inc.

URGENT DRUG RECALL – HOSPITAL/MEDICAL CENTER LEVEL - INITIATED 04/30/2024

FENTANYL 1000MCG/100ML (10MCG/ML) IN 0.9% SODIUM CHLORIDE INJECTION PRESERVATIVE FREE, 100ML BAG (503B) CII

Dear Customer:

Hikma Injectables USA Inc. is voluntarily initiating a drug recall of one (1) lot of Fentanyl 1000mcg/100mL (10mcg/mL) in 0.9% Sodium Chloride Injection Preservative Free at the **Hospital/Medical center level.** This recall is being conducted with the knowledge of the Food and Drug Administration.

Item Description	Potency	Unit of sale	NDC	Lot	Use By Date	Ship Dates
Fentanyl in 0.9% Sodium Chloride Injection	10mcg/mL	5 bags/ Shipper	63037-100-05	CH0324001	03/04/2025	04/11/2024 - 04/22/2024

Reason for Recall:
Fentanyl 1000mcg/100mL (10mcg/mL), Lot CH0324001 is being recalled due to a portion of the lot has the incorrect barcode printed on the label. However, all the remainder content of the label such as product name description, lot number, strength, compounding date and use by date are correct.

Important Basic Information:
This recall is limited to the lot number listed above. **No other Hikma 503B products or lots are impacted by this recall.** We have received no Adverse Events complaints for the subject lot to date. The services of **Inmar Rx Solutions, Inc.** have been enlisted to facilitate the product recall.

Labeling:
Please see attachment for Product Labels that will assist in identifying the recalled product.

Action Required:
☐ Stop using this lot immediately and segregate any product remaining in your inventory for return.

☐ Promptly complete a physical count and record this data on the enclosed Return Response Form included with this letter. Complete the Return Response Form and return to Inmar Rx Solutions, Inc. An immediate response to complete the Return Response Form is required **even if there is no affected product/lot in your inventory.**

If you have Product to Return:
☐ Once the Return Response Form is sent to Inmar Rx Solutions, Inc., Inmar will send a return kit and prepaid shipping label for your recall product return.

☐ Once you receive a shipping label and a return kit, immediately ship recalled product to **Inmar Rx Solutions, Inc.** Do not include any other products/lots in this return shipment. Return of the recalled product must be separate from all other returns and returned only to Inmar RX Solutions, **Attention Recall Coordinator, 3845 Grand Lakes Way, Grand Prairie, TX 75050**. All recalled product returned without a return kit may delay the issuance of your credit. Hikma will issue a credit for the quantity of returned product to direct customers of Hikma.

Completed Return Response Form can be submitted by mail, email, or FAX to Inmar Rx Solutions, Inc.
By mail: Inmar RX Solutions Attn: Retail Coordinator, One West Fourth Street, Suite 500, Winston Salem, NC 27101
By email address: HikmaEvent@Inmar.com or by FAX: 1-817-868-5362

For information regarding this recall, please reference the following contact information:

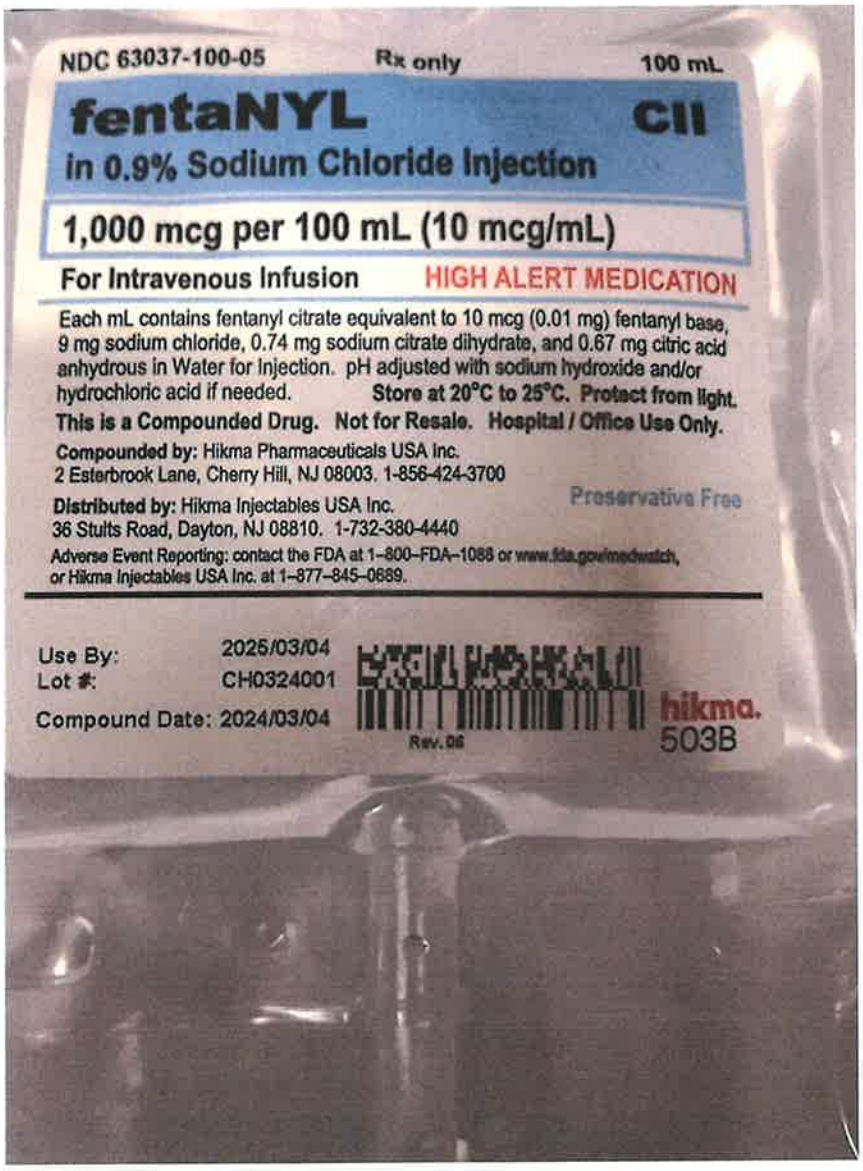
- For information regarding the recall process, call Hikma at 1-800-631-2174 between 8:00am – 6:00pm EST, Monday through Friday, or email at usrecall@hikma.com.
- For medical or technical product information or to report an Adverse Event call Hikma at 1-877-233-2001 between 9:00am – 7:00pm EST, Monday through Friday or email us.hikma@primevigilance.com.
- For additional information regarding the return of the product, call Inmar Rx Solutions, Inc. at 877-861-8973
- Further note that within the upcoming weeks you will receive an Effectiveness Check follow-up notification to verify the efficacy of this recall. The purpose of the audit is to determine that all customers have received the initial notification of the recall and the appropriate actions have been taken to remove the affected product from the market.

We are committed to supplying our customers with quality products. We apologize for this inconvenience and thank you for your time and continued support. Your cooperation and compliance with the requests in this letter are appreciated.

Sincerely,

Junan Guo
Associate VP, Quality Operations for R&D, 3rd Party and 503B

Correct Barcode:



Incorrect Barcode:

Shipper label:

NDC 63037–100–05 Rx only **QTY. 5 units**

fentaNYL Citrate 1,000 mcg per 100 mL (10 mcg/mL)
in 0.9% Sodium Chloride Injection Preservative Free

CII

Container Volume: 100 mL

Store at room temperature (20°C to 25°C).
Protect from light.
Single Use Container

For Intravenous Infusion

Use By:	2025/03/04
Lot:	CH0324001
Compound Date:	2024/03/04

HIGH ALERT MEDICATION

Compounded by:
Hikma Pharmaceuticals USA Inc.
2 Esterbrook Lane, Cherry Hill, NJ 08003
1–856–424–3700

Distributed by:
Hikma Injectables USA Inc.
36 Stults Road, Dayton, NJ 08810
1–732–380–4440

Hikma Pharmaceuticals USA Inc. and Hikma Injectables USA Inc. are FDA Registered as 503B Outsourcing Facilities.
This is a Compounded Drug. Not for Resale. Hospital/Office Use Only.
To report SUSPECTED ADVERSE EVENTS, contact the FDA at 1–800–FDA–1088 or www.fda.gov/medwatch, or Hikma Injectables USA Inc. at 1–877–845–0689.

Each mL contains:

fentanyl citrate equivalent to 10 mcg (0.01 mg) fentanyl base, 9 mg sodium chloride, 0.74 mg sodium citrate dihydrate, and 0.67 mg citric acid anhydrous in Water for Injection. pH adjusted with sodium hydroxide and/or hydrochloric acid, if needed.

Carton ID: CH0324001.1

Rev. 05 NDC: 63037–100–05

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Hikma Injectables USA Inc.

Recall Return Response Form - Hospital/Medical Center Level – 04/30/2024

FENTANYL 1000MCG/100ML (10MCG/ML) IN 0.9% SODIUM CHLORIDE INJECTION PRESERVATIVE FREE, 100ML BAG (503B) CII

Please complete and return this form immediately by FAX 1-817-868-5362 or email to HikmaEvent@inmar.com.

Please check ALL appropriate boxes:

☐ I have read and understand the instructions provided in the enclosed one (1) lot of Fentanyl 1000mcg/100mL (10mcg/mL) in 0.9% Sodium Chloride Injection Preservative Free at the **Hospital/Medical center level** recall packet.

☐ I **have** checked my stock of the recalled product listed below and have quarantined inventory and will be returning the number of units shown below. Upon receipt of this Return Response Form, Inmar Rx Solutions, Inc., will issue return authorization shipping label(s) and a return kit.

Please indicate the number of needed box labels _____.

☐ I **do not have** any stock of the below recalled product and will not be making a return.

Recalled Products:
Fentanyl 1000mcg/100mL (10mcg/mL) in 0.9% Sodium Chloride Injection

Lot No.	Product Name	Use By Date	Product Packaging	NDC No.	Ship Dates	Total Full unit cartons (sealed)	Total Partial Units (opened cartons)
CH0324001	Fentanyl	03/04/2025	1000mcg/100mL (10mcg/mL), 5 bags/Shipper)	63037-100-05	04/11/2024-04/22/2024		

Company Name:_____ DEA# _____

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

Address:_____ City:_____

State_____ Zip_____Phone Number: _____

Fax Number:_____ Email Address:_____

Contact Name: ***(please print)*** _____

Contact Name Signature: _____ Date: _____

- If you have any questions regarding this form or product return please contact **Inmar Rx Solutions, Inc.** at 877-861-8973 during office hours from 9:00am to 5:00pm EST, Monday through Friday.
- Please send this form to **Inmar Rx Solutions, Inc.** by FAX: 1-817-868-5362 or E-mail: HikmaEvent@inmar.com.
- Please include a copy in the box with your returns to ensure proper credit.