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Hikma Pharmaceuticals USA Inc.

URGENT DRUG RECALL - RETAIL LEVEL - INITIATED 03/12/2024

INFUMORPH 200 10MG/ML, 20ML AMPUL CII
INFUMORPH 500 25MG/ML, 20ML AMPUL CII

Dear Customer:

Hikma Pharmaceuticals USA Inc. is voluntarily initiating a drug recall of four **(4) lots of Infumorph (Preservative-free Morphine Sulfate Sterile Solution), 20mL Ampul** at the **retail level.** This recall is being conducted with the knowledge of the Food and Drug Administration.

Item Description	Potency	Unit of sale	NDC	Lot	Exp. Dates	Ship Dates
Infumorph 200	10mg/mL	1 Ampul/carton	0641-6039-01	052001	11/2024	08/29/2022-02/13/2023
Infumorph 200	10mg/mL	1 Ampul/carton	0641-6039-01	023012	08/2025	04/13/2023-03/04/2024
Infumorph 500	25mg/mL	1 Ampul/carton	0641-6040-01	052003	11/2024	07/18/2022-02/22/2023
Infumorph 500	25mg/mL	1 Ampul/carton	0641-6040-01	023014	08/2025	04/17/2023-10/09/2023

Reason for Recall:
This recall is being conducted due the Monoject 5micron filters (Filter Aspirator) included in the Infumorph carton expired in October 2023, prior to the expiration date of the actual product lots.

Important Basic Information:
This recall is limited to the 4 lot numbers listed above. **No other Hikma products or lots are impacted by this recall.** We have received no adverse events complaints for the subject lots to date. The services of **Inmar Rx Solutions, Inc.** have been enlisted to facilitate the product recall.

Labeling:
Please see attachments for Product Labels and filter aspirator that will assist in identifying the products.

Action Required:
- ☐ Stop distributing these lots immediately and segregate any product remaining in your inventory for return.
- ☐ Immediately copy and forward this letter and the Return Response Form to any of your direct retail or distributor consignees to whom these affected product lots were distributed.
- ☐ Promptly complete a physical count and record this data on the enclosed Return Response Form included with this letter. Complete the Return Response Form indicating that you have contacted your consignees 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 the 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. If you are NOT a Direct Customer of Hikma a credit should be requested from your WHOLESALER.

Completed Return Response Form can be submitted by mail, email, or FAX to Inmar Rx Solutions, Inc.
By mail: Inmar RX Solutions Attn: Recall 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 877-848-0704.
- 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.

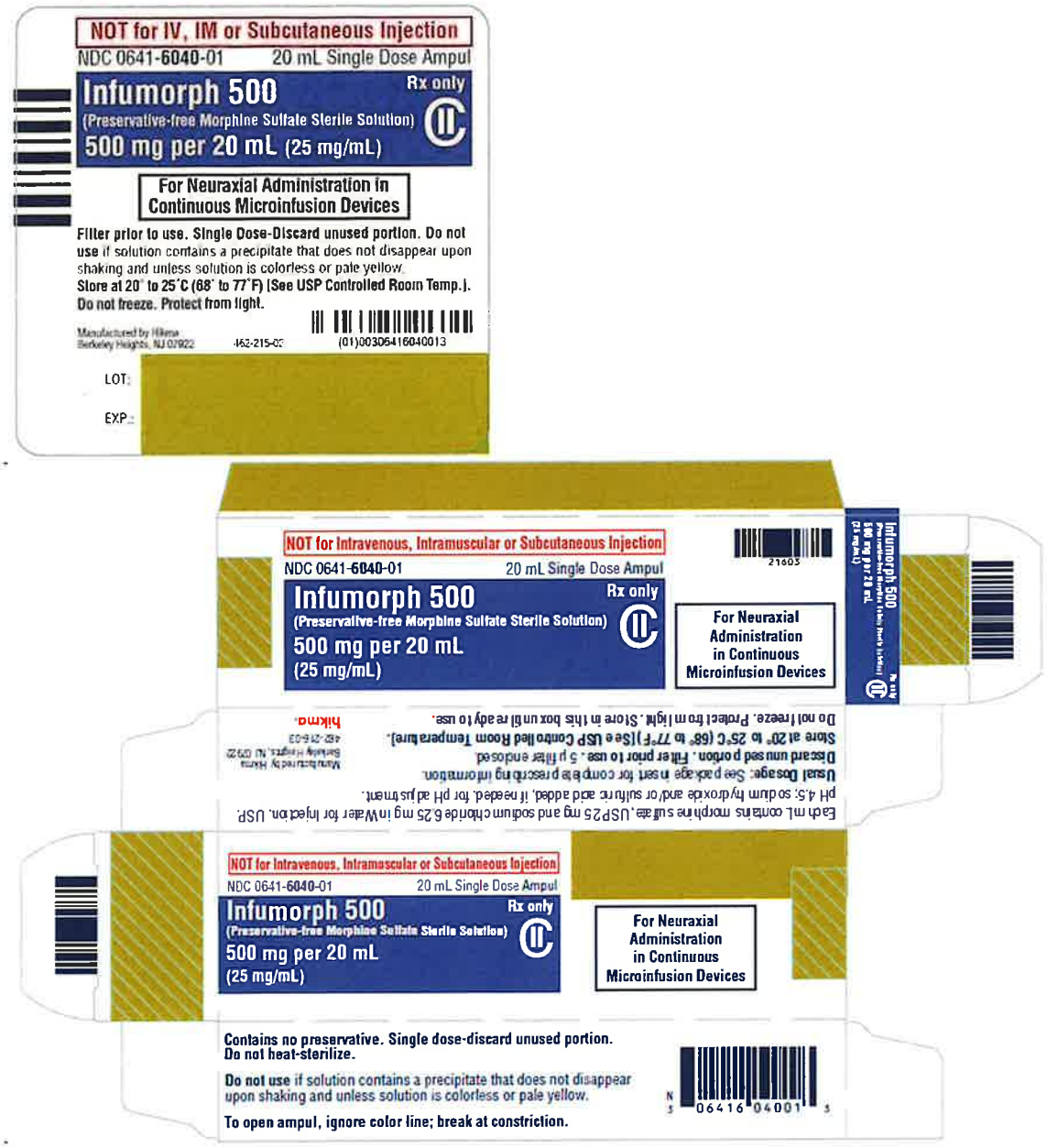
We are committed to supplying our customers with quality products. We apologize for this inconvenience and thank you for your time and continued support. Your cooperation and compliance with the requests in this letter are appreciated.

Sincerely,

Brett Wood
Senior Director of Quality and Technical Operations

Infumorph 10mg/mL Ampul and Shelf-Pack/Carton print Label:

Infumorph 25mg/mL Ampul and Shelf-Pack/Carton print Label



Filter Aspirator

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Recall Return Response Form Retail Level – 03/12/2024

INFUMORPH 200 10MG/ML, 20ML AMPUL CII
INFUMORPH 500 25MG/ML, 20ML AMPUL 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 **Infumorph 200 and 500 (Preservative-free Morphine Sulfate Sterile Solution),** 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.
☐ I **have** informed all my customers of the Retail Level Recall

Recalled Products: Infumorph 200 and 500 (Preservative-free Morphine Sulfate Sterile Solution), 20mL Ampul

Lot No.	Exp. Date	Product Packaging	NDC No.	Ship Dates	Total Full unit cartons (sealed)	Total Partial Units (opened cartons)
052001	11/2024	10mg/mL, 20mL Ampul (1 Ampul/ carton)	0641-6039-01	08/29/2022-02/13/2023		
023012	08/2025	10mg/mL, 20mL Ampul (1 Ampul/ carton)	0641-6039-01	04/13/2023-03/04/2024		
052003	11/2024	25mg/mL, 20mL Ampul (1 Ampul/ carton)	0641-6040-01	07/18/2022-02/22/2023		
023014	08/2025	25mg/mL, 20mL Ampul (1 Ampul/ carton)	0641-6040-01	04/17/2023-10/09/2023		

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 did not purchase the product directly from Hikma Pharmaceuticals, please complete the below section:

Purchased From: Wholesaler Name _____DEA #_____

City_____State_____ Zip_____

- If you have any questions regarding this form or product return, please contact **Inmar Rx Solutions, Inc.** at 877-848-0704 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.