SUN PHARMA

URGENT: DRUG RECALL (REVISED TO ADD NDC 62756-090-45)

Medroxyprogesterone Acetate Injectable Suspension, 150 mg/ml

May 27, 2022

Dear Customer,

This notice is to inform you of a voluntary product recall involving the following twenty-seven (27) lots of Medroxyprogesterone Acetate Injectable Suspension, USP, 150 mg/ml:

Product Name	Package Description	Lot Number	NDC Number	Expiration Date
Medroxyprogesterone Acetate Injectable Suspension USP, 150 mg/ml	1 ml Pre-Filled Syringe	JKX4312A	50102-591-40	09/2022
		JKX4313A	50102-591-40	09/2022
		JKX4827A	50102-591-40	09/2023
		HAC1290A	50102-591-40	06/2023
		HAC2082B	50102-591-40	06/2023
		HAC1289A	16714-999-01	06/2023
		JKX2679A	16714-999-01	06/2022
		JKX3762A	16714-999-01	08/2022
		HAC0164A	16714-999-01	06/2023
		HAC1951A	62756-091-40	06/2023
	1 ml Vial	HAC2075A	16714-981-01	06/2023
		HAC2076A	16714-981-01	07/2023
		HAC2077A	16714-981-01	08/2023
		HAC2078A	16714-981-01	08/2023
		HAC3803A	16714-981-01	09/2023
		HAC0551A	16714-981-01	02/2023
		HAC0562A	16714-981-01	03/2023
		HAC1183A	16714-981-01	03/2023
		HAC1807A	16714-981-01	06/2023
		JKX6017A	16714-981-01	12/2022
		JKX6018A	16714-981-01	12/2022
		HAC0163A	16714-981-01	01/2023
		HAC1184A	16714-981-01	04/2023
		HAC0162A	16714-981-01	12/2022
		HAC2074A	62756-090-40	06/2023
		HAC0163B	62756-090-40	01/2023
		HAC1741A	62756-090-40	04/2023
	Carton of twenty-five (25) 1 ml Vial	HAC1741A	62756-090-45	04/2023

For return of affected product, please email rxrecalls@inmar.com or call 1-855-884-7515.

Sun Pharma is sending this letter as a revision to an earlier recall letter dated May 17, 2022 in regards to the same twenty-seven (27) lot numbers of Medroxyprogesterone Acetate Injectable Suspension USP, 150 mg/ml in the table above. In the previous letter, NDC 62756-090-45 for twenty-five (25) count cartons containing 1 ml vial monocartons was not included. Of all the affected lots, only HAC1741A belongs to this NDC. The depth of this recall remains to the retail level.

See enclosed product labeling.

This product recall has been initiated due to a lack of assurance of sterility for Medroxyprogesterone Acetate Injectable Suspension USP, 150 mg/ml 1 ml Pre-Filled Syringe and 1 ml Vial. An investigation was conducted and found that no sterility failure has been observed for any batches distributed for the market. However, out of an abundance of caution, Sun Pharma has voluntarily decided to recall all currently distributed batches of Medroxyprogesterone Acetate Injectable Suspension USP, 150 mg/ml 1 ml Pre-Filled Syringe and 1 ml Vial.

Based on the Health Hazard Evaluation conducted by Sun Pharma, use of this product is unlikely to pose any risk to patient safety.

Sun Pharmaceutical Industries, Inc. initiated shipment of this product on November 4th, 2020.

Immediately examine your inventory and quarantine the lot numbers subject to recall. In addition, if you have further distributed this product, please identify your retail customers and notify them at once of this product recall. Your notification to your retail customers may be enhanced by including a copy of this recall notification letter.

Please complete and return the enclosed response form as soon as possible. After receipt of the response form, a return kit will be provided so the affected product can be sent to:

Inmar, Inc.
3845 Grand Lakes Way
Suite 125
Grand Prairie, TX 75050

If you have any questions, contact Inmar, Inc. at rxrecalls@inmar.com or call 1-855-884-7515 Monday to Friday from 8:30 am to 5:00 pm (EST).

This recall should be carried out to the retail level.

Your assistance is appreciated and necessary to prevent patient harm.
This recall is being made with the knowledge of the Food and Drug Administration.

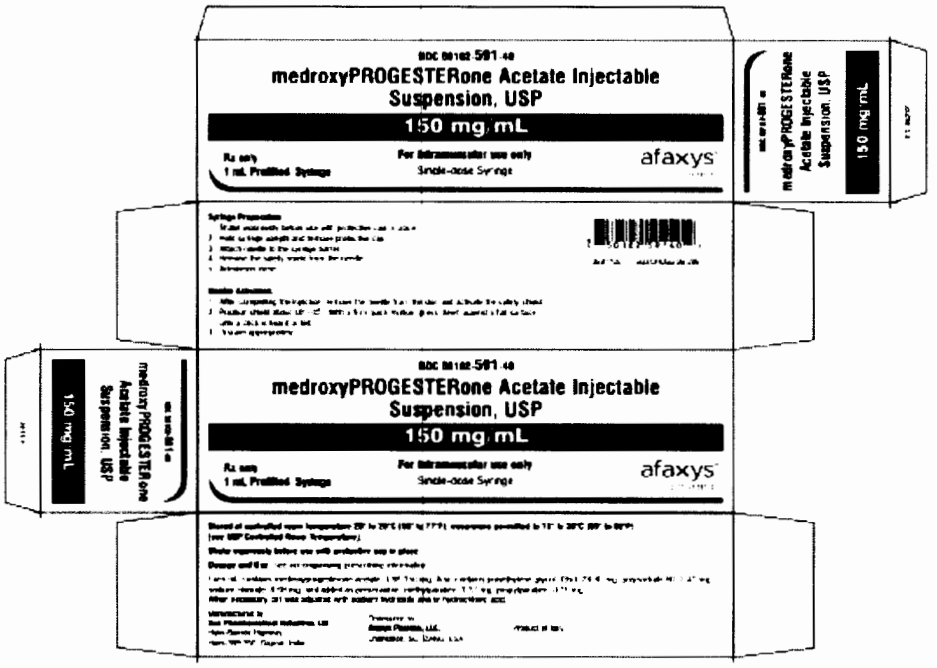
May 27, 2022

James Mullen
Sun Pharmaceutical Industries, Inc.
Manager, North America Cluster Quality Support

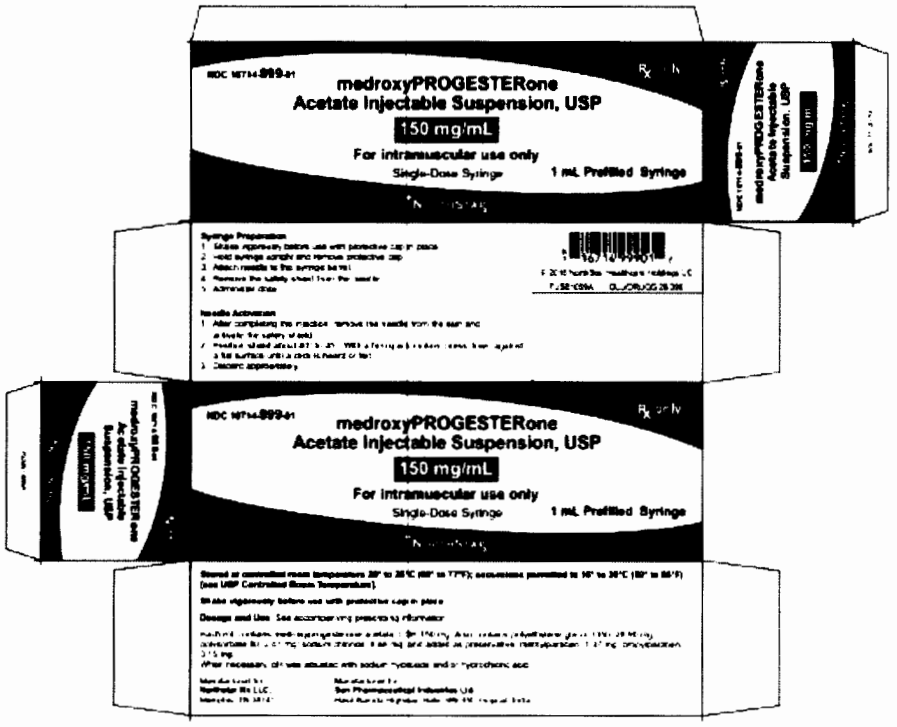
For return of affected product, please email rxrecalls@inmar.com or call 1-855-884-7515.

Enclosure:

NDC 50102-591-40: Afaxys 1 ml Pre-Filled Syringe (PFS)

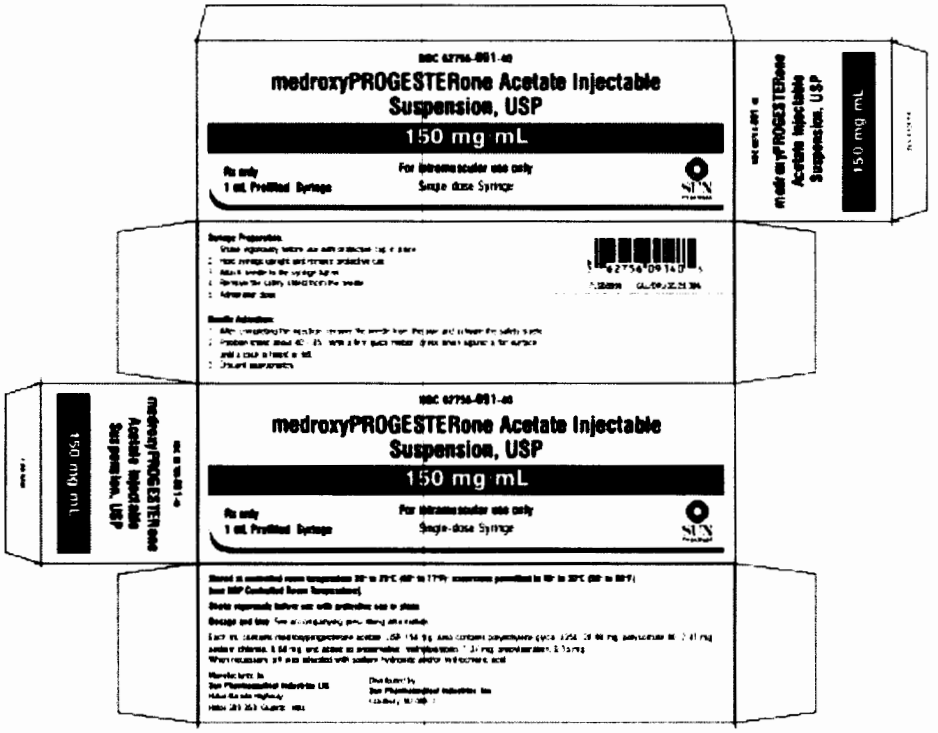


NDC 16714-999-01: NorthStar 1 ml Pre-Filled Syringe (PFS)

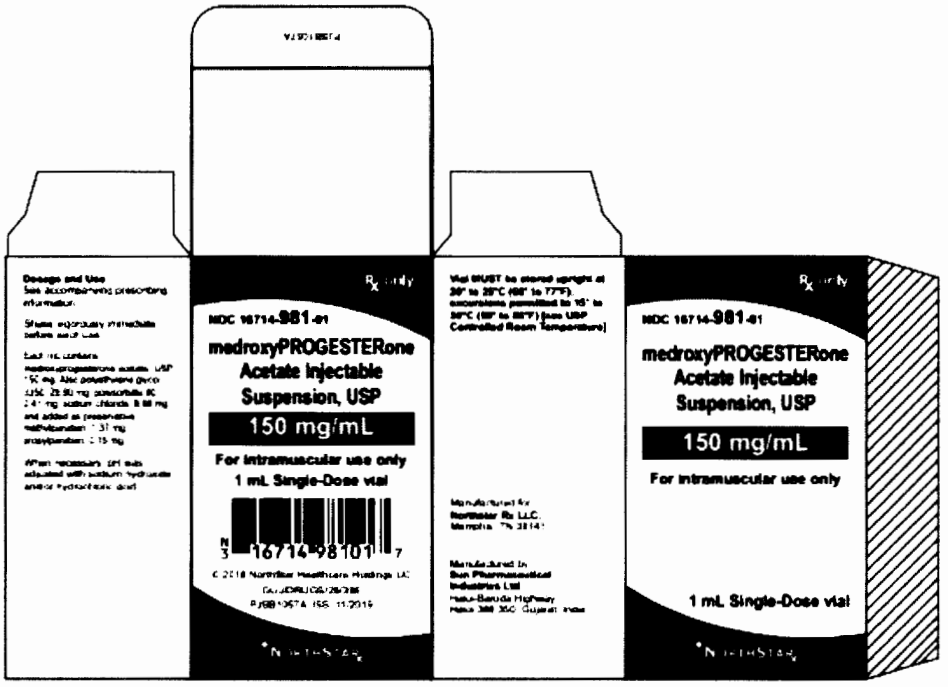


For return of affected product, please email rxrecalls@inmar.com or call 1-855-884-7515.

NDC 62756-091-40: Sun Pharma 1 ml Pre-Filled Syringe (PFS)

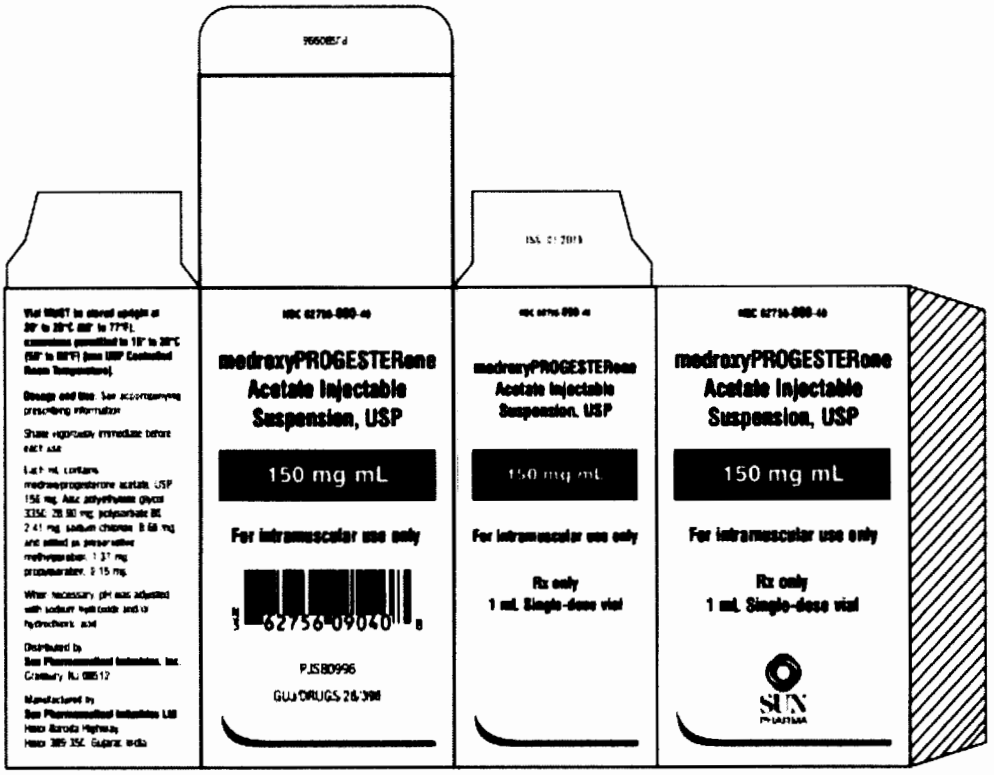


NDC 16714-981-01: NorthStar 1 ml Vial

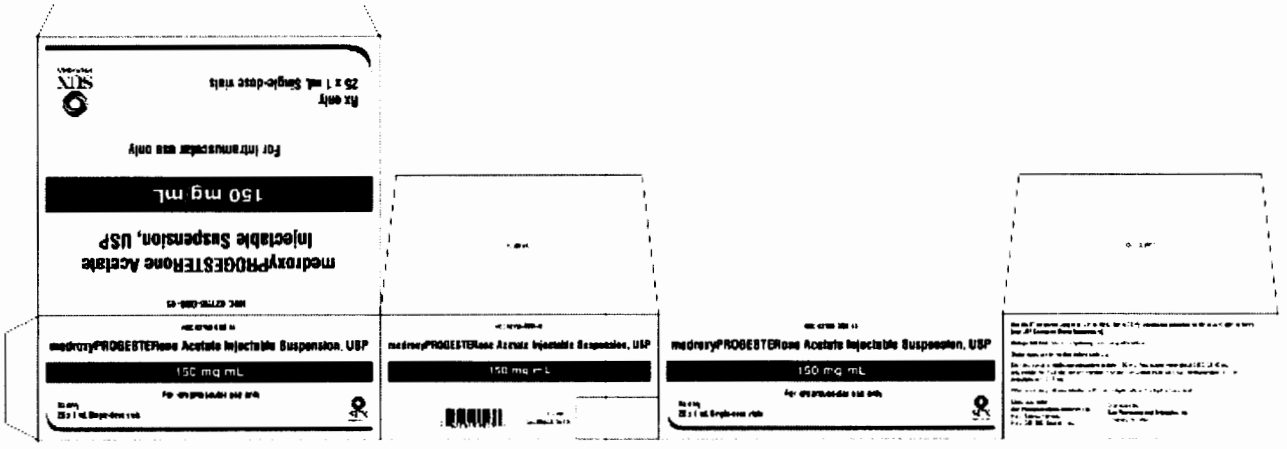


For return of affected product, please email rxrecalls@inmar.com or call 1-855-884-7515.

NDC 62756-090-40: Sun Pharma 1 ml Vial



NDC 62756-090-45: Sun Pharma 1 ml Vial, 25 count carton



For return of affected product, please email rxrecalls@inmar.com or call 1-855-884-7515.

SUN PHARMA

URGENT: DRUG RECALL – RESPONSE FORM (REVISED TO INCLUDE NDC 62756-090-45)

Please Complete This Form and Fax to: 817-868-5362

or Email to: rxrecalls@inmar.com

Product Name	Package Description	Lot Number	NDC Number	Expiration Date
Medroxyprogesterone Acetate Injectable Suspension USP, 150 mg/ml	1 ml Pre-Filled Syringe	JKX4312A	50102-591-40	09/2022
		JKX4313A	50102-591-40	09/2022
		JKX4827A	50102-591-40	09/2023
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		JKX2679A	16714-999-01	06/2022
		JKX3762A	16714-999-01	08/2022
		HAC0164A	16714-999-01	06/2023
		HAC1951A	62756-091-40	06/2023
	1 ml Vial	HAC2075A	16714-981-01	06/2023
		HAC2076A	16714-981-01	07/2023
		HAC2077A	16714-981-01	08/2023
		HAC2078A	16714-981-01	08/2023
		HAC3803A	16714-981-01	09/2023
		HAC0551A	16714-981-01	02/2023
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		HAC1807A	16714-981-01	06/2023
		JKX6017A	16714-981-01	12/2022
		JKX6018A	16714-981-01	12/2022
		HAC0163A	16714-981-01	01/2023
		HAC1184A	16714-981-01	04/2023
		HAC0162A	16714-981-01	12/2022
		HAC2074A	62756-090-40	06/2023
		HAC0163B	62756-090-40	01/2023
		HAC1741A	62756-090-40	04/2023
	Carton of twenty-five (25) 1 ml Vial	HAC1741A	62756-090-45	04/2023

For return of affected product, please email rxrecalls@inmar.com or call 1- 855-884-7515.

SUN PHARMA

URGENT: DRUG RECALL – RESPONSE FORM (REVISED)

Please Complete This Form and Fax to: 817-868-5362 or Email to: rxrecalls@inmar.com

Please check ALL appropriate boxes.

□ I have read and understand the recall instructions provided in the May 27, 2022 letter.

□ I have checked our stock and have quarantined inventory consisting of _____ units.

□ Indicate disposition of recalled product:

□ returned (**specify quantity, date and method**)/held for return;

Number of Labels Required for Return to Inmar: _____

□ previously destroyed (**specify quantity, date and method**);

□ I have identified and notified my retail customers that were shipped or may have been shipped this product by (**specify date and method of notification**); or

□ Attached is a list of retail customers who received/may have received this product. Please notify my customers.

Any adverse events associated with recalled product? □ Yes □ No
If yes, please explain: _____

For return of affected product, please email rxrecalls@inmar.com or call 1-855-884-7515.

SUN PHARMA

URGENT: DRUG RECALL – RESPONSE FORM (REVISED)

Please Complete This Form and Fax to: 817-868-5362
or Email to: rxrecalls@inmar.com

Please check the appropriate box(es) to describe your business

- □ wholesaler/distributor
- □ grocery corporate headquarters
- □ repacker
- □ pharmacy
- □ retailer
- □ hospital pharmacies
- □ hospital/medical facility
- □ Other:

Customer Name: _____ Title: _____

Company: _____ DEA Number: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Phone Number: _____

Customer Debit Memo Number: _____

Wholesaler: _____ City\State: _____

Wholesaler DEA Number: _____

For return of affected product, please email rxrecalls@inmar.com or call 1-855-884-7515.