

Wendy Gould
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URGENT: DRUG RECALL
Testosterone Cypionate Injection, USP

March 15, 2017

Dear Trading Partner,

This notice is to inform you of a drug product recall involving Testosterone Cypionate Injection, USP, 200mg/mL, 1mL vial manufactured by Sun Pharmaceutical Industries, Ltd. Refer to Table 1 for details.

Table 1: Testosterone Cypionate Injection 200mg/mL, 1mL to be recalled

Lot Number	NDC Code	Manufacturing Date	Distribution Date	Expiration Date
JKR0744A	62756-015-40	Oct.2016	12-27-16 to 12-27-16	Sep.2018
JKR0745A	62756-015-40	Oct.2016	12-27-16 to 01-16-17	Sep.2018
JKR0750A	62756-015-40	Oct.2016	01-12-17 to 01-18-17	Sep.2018
JKR0795A	62756-015-40	Oct.2016	01-18-17 to 01-26-17	Sep.2018

Reason for Recall

Sun Pharma has identified black particulate (specks) adhered to the inside of some vials of Testosterone Cypionate Injection 200mg/mL, 1mL vial, manufactured during October 2016. The black particulate speck is approximately 20-30um in size and is stuck or baked onto the interior of the vial. Sun Pharma is voluntarily recalling four batches of Testosterone Cypionate Injection, 1mL vials produced during October 2016.

Immediately examine your inventory and quarantine product lots subject to recall. This recall has been initiated at the retailer level (Class II). Therefore, Sun Pharma is requesting the return of these product lots. In addition, if you have further distributed this product, please notify your customers at once about this recall. Your notification may be enhanced by including a copy of this recall letter.

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

For return of affected product, please email rxrecalls@inmar.com or call **800-967-5952**, during Monday to Friday, from 9:00 am to 5:00 pm (EST). Please complete and return the enclosed response form as soon as possible.

Affected product should be sent to:

Inmar
4332 Empire Road
South Dock
Fort Worth, TX 76155

Sincerely,

A handwritten signature in black ink, appearing to read "W. Gould", with a long horizontal flourish extending to the right.

Wendy Gould
VP, Regional Head of Quality, North America

URGENT: DRUG RECALL – RESPONSE FORM

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

or Email to: rxrecalls@inmar.com

We do not have any stock: ☐

or,

Please enter the quantity you shall be returning.

Product Name	Lot Numbe	Pack size	NDC Number	Exp. Date	Quantity to be Returned
Testosterone Cypionate, Injection, USP, 200mg/mL, 1mL Vial	JKR0744A	1 mL vial	62756-015-40	09/2018	
	JKR0745A	1 mL vial	62756-015-40	09/2018	
	JKR0750A	1 mL vial	62756-015-40	09/2018	
	JKR0795A	1 mL vial	62756-015-40	09/2018	

Name _____ DEA # _____

Company _____

Address _____

City _____ State _____ Zip Code _____

Phone # _____

Wholesaler _____ City/State _____

Wholesaler DEA# _____

For return of affected product, please email rxrecalls@inmar.com or call 800-967-5952#