

URGENT: DRUG RECALL

Testosterone Cypionate Injection, USP, 200mg/ml

June 8, 2022

Dear Customer,

This notice is to inform you of a voluntary product recall involving the following lot of Testosterone Cypionate Injection, USP:

Product Name	Package Description	Lot Number	NDC Number	Expiration Date
Testosterone Cypionate Injection, USP, 200mg/ml	Carton containing single 1 ml Vial	HAC3427A	62756-015-40	8/2023

See enclosed product labeling on Page 3.

This product recall has been initiated due to a manufacturing deviation which was reported due to a microbial excursion which occurred in the filling area during environmental monitoring. An internal investigation was conducted and found that the cause of the excursion was due to a laboratory error. All quality parameters, including sterility, were within specifications and no microbial growth was found.

Sun Pharma conducted a health hazard evaluation (HHE), and found that while there are no out of specification results for lot HAC3427A, potential contamination is likely to pose a risk to patient safety if present. Therefore, Sun Pharma has decided to voluntarily recall batch HAC3427A out of an abundance of caution.

Sun Pharmaceutical Industries, Inc. initiated shipment of this product on November 16th, 2021.

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:

For return of affected product, please email rxrecalls@inmar.com or call 1-855-893-5571.

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 1-855-893-5571 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.

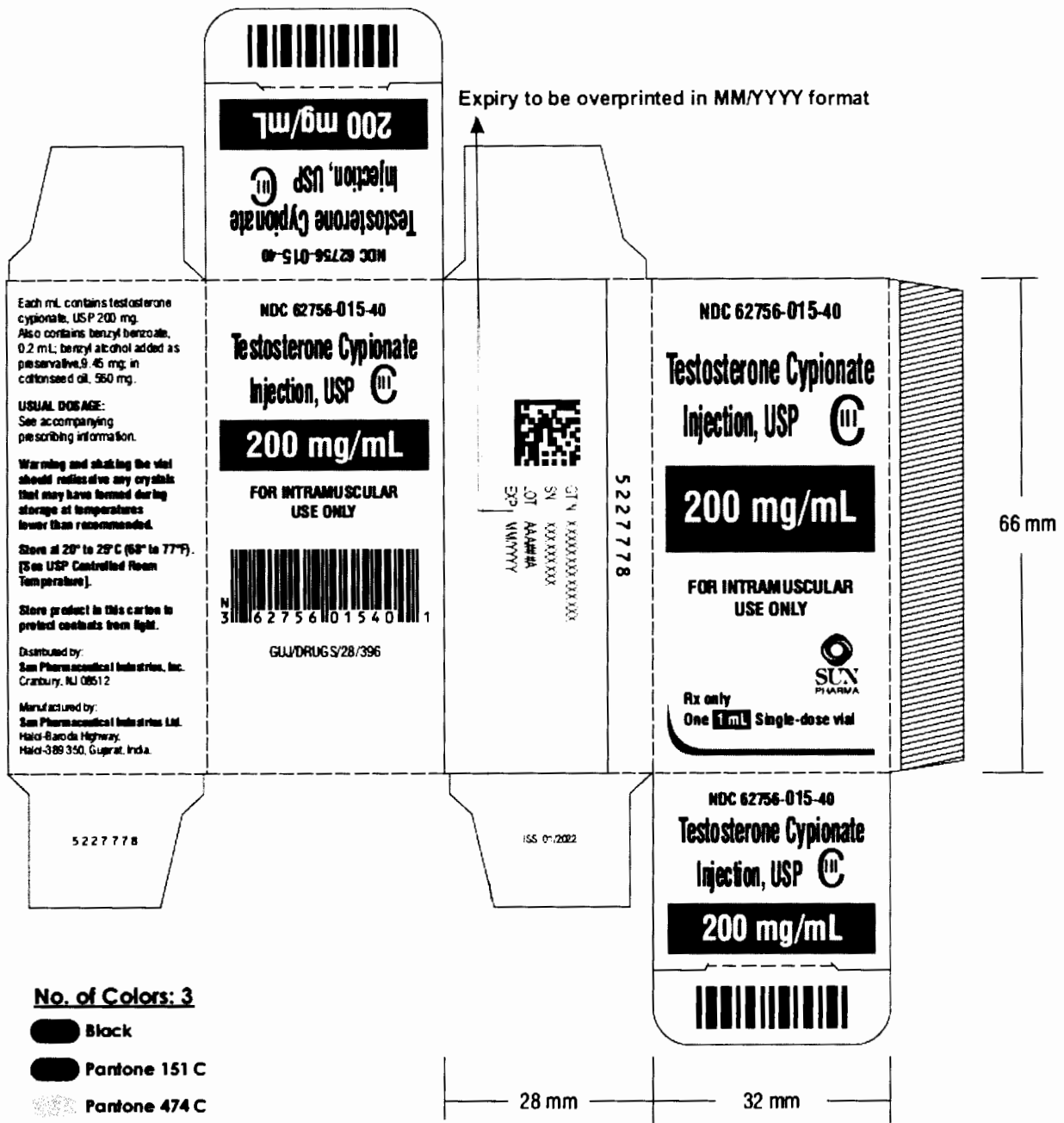


June 8, 2022

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

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Enclosure:



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URGENT: DRUG RECALL – RESPONSE FORM

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
Testosterone Cypionate Injection, USP, 200mg/ml	Carton containing single 1 ml Vial	HAC3427A	62756-015-40	8/2023

Please check ALL appropriate boxes.

- I have read and understand the recall instructions provided in the June 8, 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: _____

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

- | | |
|---|--|
| <input type="checkbox"/> wholesaler/distributor | <input type="checkbox"/> retailer |
| <input type="checkbox"/> grocery corporate headquarters | <input type="checkbox"/> hospital pharmacies |
| <input type="checkbox"/> repacker | <input type="checkbox"/> hospital/medical facility |
| <input type="checkbox"/> pharmacy | <input type="checkbox"/> Other: |

Customer Name: _____ Title: _____

Company: _____ DEA Number: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Phone Number: _____

Customer Debit Memo Number: _____

Wholesaler: _____ City\State: _____

Wholesaler DEA Number: _____

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