

*The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.*

Sun Pharma is recalling the following lots of Testosterone Cypionate Injection, USP:

| <b>Product Name</b>                             | <b>Package Description</b>         | <b>Lot Number</b> | <b>NDC Number</b> | <b>Expiration Date</b> |
|-------------------------------------------------|------------------------------------|-------------------|-------------------|------------------------|
| Testosterone Cypionate Injection, USP, 200mg/ml | Carton containing single 1 ml Vial | JKX3267A          | 62756-015-40      | 8/2022                 |
|                                                 |                                    | JKX3686A          | 62756-015-40      | 8/2022                 |
|                                                 |                                    | JKX4700A          | 62756-015-40      | 10/2022                |
|                                                 |                                    | JKX5727A          | 62756-015-40      | 11/2022                |

This product recall has been initiated due to manufacturing deviations which were reported due to an abnormal appearance on the external surface of the piston/syringe used during the filling operation. In response to these deviations, Sun Pharma initiated internal investigations and did not identify any particulate contamination of vials. However, considering the abnormal appearance on the external surfaces of the piston during filling, Sun Pharma has decided to initiate a voluntary recall out of an abundance of caution.

Sun Pharma conducted a Health Hazard Evaluation (HHE), and found that while there has not been any particulate contamination identified during inspection for the affected lots, there may be a risk to patient safety if particulate contamination is present.

Sun Pharmaceutical Industries Inc. initiated shipment of this product on November 11, 2020.