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Global Established Pharmaceuticals

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Depo®-Testosterone (testosterone cypionate injection, USP) CIII

Pfizer Kalamazoo site has investigated the product complaints on Depo®-Testosterone regarding crystallization of contents in 100 and 200 mg/mL vials. The investigation has found that although crystals have been observed, the formulation of crystals does not impact patient safety, efficacy, or product quality when the US Product Insert (USPI) instructions are followed prior to administration.

Depo-Testosterone 100 mg/mL is a very highly concentrated and 200 mg/mL is a supersaturated sterile solution for injection, comprised of cottonseed oil, testosterone cypionate and benzyl alcohol. The high concentrations of active ingredient makes the product very susceptible to crystallization when exposed to temperatures lower than the ranges recommended on the label [20°C to 25°C (68°F to 77°F)].

Investigation at the Kalamazoo site has concluded that the product meets all registered product specifications when the USPI and product packaging instructions are followed prior to administration.

Potency testing from these lots confirms two key product quality attributes:

- product can be warmed, shaken, and the crystals re-dissolved, when prepared according to instructions found in the product insert and on the vial label; and,
- potency of the retain and complaint samples confirm product potency at the labeled strength.

This product attribute is addressed with specific instructions within the USPI, on the product vial label, and also on product carton.

The USPI states:

"Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Warming and shaking the vial should redissolve any crystals that may have formed during storage at temperatures lower than recommended."

In addition, the current approved vial label states (see Appendix):

"Warming and shaking the vial should redissolve any crystals that may have formed during storage at temperatures lower than recommended."

Additional evaluation by Pfizer Global Manufacturing and Quality Operations concluded that there was no impact on efficacy, quality or safety of the product based upon confirmation of strict adherence to internal protocols and procedures.

Based on our testing and a medical and safety evaluation of complaint samples submitted to us, distributed lots of Depo-Testosterone continue to be acceptable for use, even with the presence of crystals, when used as directed in the product insert.

This communication and updated product information is available on the Pfizer Injectables Web site www.pfizerinjectables.com.

Please direct any questions related to the content of this letter to Pfizer Medical Information at 1-800-438-1985 or visit www.pfizermedinfo.com.

Sincerely,

Pfizer Injectables

Appendix

Pfizer Item Code	Item Description	NDC
F000020205	Depo-Testosterone ® (testosterone cypionate injection, USP) CIII 200 mg/mL 1mL MDV 1's PREMIERProRX™	0009-0520-01
F000020204	Depo-Testosterone (testosterone cypionate injection, USP) CIII 200 mg/mL 10mL MDV 1's PREMIERProRX™	0009-0520-10

