

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.

This recall has been initiated by Sun Pharma in response to product quality complaint received stating "glass particle observed in prefilled syringe of Fyremadel (ganirelix acetate) Injection 250 mcg/0.5 mL, lot # HAD1190A" . Based on investigation, the assignable cause is identified as breakage of prefilled syringe (PFS) might have occurred due to bent syringe misalignment in centering frame before filling operation leading to syringe not in nest alarm.

Product Name: Fyremadel (ganirelix acetate) Injection, 250 mcg / 0.5 mL

Lot Number: HAD1190A

NDC Number: 55566-1010-1

Expiration Date: 02/2024