West Virginia Family Health

2019 Drug Recall

Drug Name/Manufacturer	Dose/Package size	Press Release Date	Reason	Recall Classification
January				
Ozurdex implants	Implants	01/02/2019	This recall was issued due to during routine manufacturing inspection, a silicon particulate, approximately 300 microns in diameter, was observed in dispensed Ozurdex implants.	Retail-Level Recall
Amlodipine and Valsartan Tablets, USP, Valsartan and HCTZ Tablets, USP and Valsartan Tablets	5mg/160mg, 5mg/160mg, 5mg/160mg, 5mg/160mg, 10mg/160mg, 10mg/160mg , 10mg/160mg, 10mg/160mg, 10mg/160mg, 10mg/160mg, 10mg /320mg, 10mg /320mg, 10mg /320mg, 10mg /320mg, 10mg /320mg, 10mg /320mg, 10mg /320mg, 5mg /320mg, 5mg /320mg, 5mg /320mg, 5mg /320mg 5mg /320mg, 5mg /320mg, 10mg/160mg, 10mg /320mg, 10mg /320mg, 320mg/12.5mg, 320mg/12.5mg, 320mg/12.5mg, 320mg/12.5mg, 320mg/12.5mg, 160mg/12.5mg, 160mg/12.5mg, 160mg/12.5mg, 160mg/12.5mg 160mg/12.5mg, 160mg/12.5mg, 160mg/12.5mg 320mg/25mg, 320mg/25mg, 320mg/25mg, 320mg/25mg, 320mg/25mg, 320mg/25mg, 320mg/25mg 320mg/25mg, 320mg/25mg, 320mg/25mg 320mg/25mg, 320mg/25mg, 320mg/25mg 320mg/25mg, 320mg/25mg, 320mg/25mg, 320mg/25mg, 80mg/12.5mg	01/01/2019	This recall was issued due to the detection of trace amounts of an unexpected impurity found in the finished drug product. The impurity detected in the finished drug product is N-nitrosodiethylamine (NDEA).	Consumer-Level Recall
Losartan Potassium	Losartan Potassium 25 mg Tablets, 90 count Losartan Potassium 50 mg Tablets, 30 count Losartan Potassium 50 mg Tablets, 90 count Losartan Potassium 50 mg Tablets, 1,000 count Losartan Potassium 100 mg Tablets, 1,000 count losartan potassium 25 mg tablets, 90 count bottle losartan potassium 50 mg tablets, 30 count bottle losartan potassium 50 mg tablets, 90 count bottle losartan potassium 50 mg tablets, 1,000 count bottle losartan potassium 100 mg tablets, 1,000 count bottle	01/03/2019	This recall was issued due to the detection an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited. The impurity detected in the finished drug product is N-nitrosodiethylamine (NDEA). Note: This notice contains an expanded number of impacted batches adding Losartan Potassium 25 mg Tablets and Losartan Potassium 50 mg Tablets to the ongoing recall. It also contains additional lot numbers for Losartan Potassium 100 mg Tablets that were not part of the previous Recall notice received on December 20, 2018.	Consumer-Level Recall
Ceftriaxone Sodium Injection	Ceftriaxone for Injection 250mg Ceftriaxone for Injection 250mg Ceftriaxone for Injection 500mg Ceftriaxone for Injection 500mg Ceftriaxone for Injection 1g Ceftriaxone for Injection 1g Ceftriaxone for Injection 2g	1/7/2019 **1/16/2019	This recall was issued due to repetitive product complaints indicating grey flecks in constituted vials. Note: This recall was originally received as CVS Retail-Level Recall Notice 18-178 on 12/21/18. FDA classified this as a Class I Recall on 01/16/2019.	Class 1 Recall
Cefdinir Oral Suspension	125mg/5 mL 60 mL, 125mg/5 mL 100 mL, 250mg/5 mL 60 mL, 250mg/5 mL 100 mL	01/03/2019	This recall was issued due to the repetitive product complaints indicating reconstituted suspension as observed to be thick.	Retail Level Recall
Estradiol Vaginal	Estradiol Vaginal 10 mcg Inserts 8 each Estradiol Vaginal 10 mcg Inserts 18 each	01/04/2019	This recall was issued due to difficulty in pushing the plunger of the applicator.	Consumer-Level Recall
Vecuronium Bromide for Injection	Vecuronium Bromide for Injection 20mg Vecuronium Bromide for Injection 10mg Vecuronium Bromide for Injection 10mg Vecuronium Bromide for Injection 10mg	01/09/2019	Sun Pharmaceutical Industries announced a voluntary recall of 3 lots of Vecuronium Bromide for Injection 10mg and 1 lot of Vecuronium Bromide for Injection 20mg after the product was found to contain glass.	Voluntary Recall

Rhino 5k capsules	5000mg 30 capsules	01/08/2019	Happy Together, Inc. Boynton Beach, FL is voluntarily recalling all lots within expiry of the Rhino 5k capsules to the consumer level. FDA analysis founds these products to be tainted with sildenafil and Tadalafil. Sildenafil/Tadalafil is an FDA approved drug for the treatment of erectile dysfunction, the presence of sildenafil in the Rhino 5k products renders them unapproved drugs for which safety and efficacy have not been established, therefor subject to recall.	Voluntary Recall
Docusate Sodium	100 mg soft gel caps	01/16/2019	This recall was issued due to a secondary labeling error.	Retail-Level Recall
Nevirapine ER	400 mg Tablets	01/16/2019	This recall was issued due to failure of dissolution test at the 3-month long-term stability interval	Retail-Level Recall