

# Enforcement Report - Week of January 1, 2020

## Class II Drugs Event

**Event ID:**

84509

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:****Recall Initiation Date:**

12/11/2019

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

12/23/2019

**Initial Firm Notification of Consignee or Public:**

Letter

**Recalling Firm:**

Spectrum Laboratory Products  
14422 S San Pedro St  
Gardena CA United States

**Distribution Pattern:**

Nationwide in the USA and Canada

## Associated Products

**Product Description:**

Estriol [(16a, 17B)-Estra-1,3,5(10)-triene-3,16,17-triol; Oestriol] Micronized, USP, CAS 50-27-1, packaged in a) 1 G glass bottles, b) 5 G glass bottles, c) 25 G glass bottles, d) 100 G glass bottles, e) 500 G glass bottles, and f) 1 KG plastic bottles, Rx Only, Spectrum Chemical Mfg Corp., Gardena, CA 90248.

**Product Quantity:**

6.284 kg

**Reason for Recall:**

Subpotent Drug: Supplier indicated assay results did not meet specifications.

**Recall Number:**

D-0628-2020

**Code Information:**

Lot #s: 1HG0308, 1HH0630, 1HI0854, 4HL0005,4HL0036, 4IH0032, Exp. 04/16/2021

## Class III Drugs Event

**Event ID:**

84525

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:****Recall Initiation Date:**

12/16/2019

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

12/23/2019

**Initial Firm Notification of Consignee or Public:**

Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

**Recalling Firm:**

Pharmedium Services, LLC  
150 N Field Dr Ste 350  
Lake Forest IL United States

**Distribution Pattern:**

Nationwide in the U.S.

## Associated Products

**Product Description:**

NORepinephrine Bitartrate 8 mg added to 250 mL 5% Dextrose Injection USP (32 mcg per mL) Total Volume 258.00 mL Viaflex Bag, High Alert, Rx Only, PharMEDium Services LLC., 12620 W Airport Blvd #130 Sugar Land, TX 77478.

**Product Quantity:**

5820 bags

**Reason for Recall:**

Subpotent Drug

**Recall Number:**

D-0625-2020

**Code Information:**

Lot #s: 192930039S Exp. 12/18/19; 192930041S Exp. 12/18/19; 192940048S Exp. 12/19/19; 192940049S Exp. 12/19/19; 192950031S Exp. 12/20/19; 192950032S Exp. 12/20/19; 192960039S Exp. 12/22/19; 192960040S Exp. 12/22/19; 192960041S Exp. 12/22/19; 192960042S Exp. 12/22/19; 192970034S Exp. 12/22/19; 192970036S Exp. 12/22/19; 192970037S Exp. 12/22/19; 192980043S Exp. 12/25/19; 192980044S Exp. 12/25/19; 192980045S Exp. 12/25/19; 193010042S Exp. 12/26/19; 193020042S Exp. 12/27/19; 193030039S Exp. 12/28/19; 193030040S Exp. 12/28/19; 193030049S Exp. 12/28/19; 193040045S Exp. 12/29/19; 193040046S Exp. 12/29/19; 193040047S Exp. 12/29/19; 193080040S Exp. 1/2/20; 193080041S Exp. 1/2/20; 193080042S Exp. 1/2/20; 193080043S Exp. 1/2/20; 193080044S Exp. 1/2/20; 193090034S Exp. 1/3/20; 193090035S Exp. 1/3/20; 193090036S Exp. 1/3/20; 193100041S Exp. 1/4/20; 193100042S Exp. 1/4/20; 193100043S Exp. 1/4/20; 193120036S Exp. 1/8/20; 193150028S Exp. 1/9/20; 193170033S Exp. 1/11/20; 193170034S Exp. 1/11/20; 193170035S Exp. 1/11/20; 193180035S Exp. 1/12/20; 193190035S Exp. 1/15/20; 193190038S Exp. 1/15/20; 193220038S Exp. 1/16/20; 193230037S Exp. 1/17/20; 193240029S Exp. 1/18/20; 193240030S Exp. 1/18/20; 193240031S Exp. 1/18/20; 193250028S Exp. 1/19/20; 193360031S Exp. 1/30/20

**Product Description:**

NORepinephrine Bitartrate 8 mg added to 500 mL 5% Dextrose Injection USP (16 mcg per mL) Total Volume 508.00 mL Viaflex Bag, High Alert, Rx Only, PharMEDium Services LLC., 12620 W Airport Blvd #130 Sugar Land, TX 77478.

**Product Quantity:**

864 bags

**Reason for Recall:**

Subpotent Drug

**Recall Number:**

D-0626-2020

**Code Information:**

Lot #s: 193040035S, Exp. 12/29/2019; 193120031S, Exp. 01/08/2020; 193150024S, Exp. 01/09/20; 193180030S, Exp. 01/12/20; 193240028S, Exp. 01/18/20; 193250022S, Exp. 01/19/20.

**Product Description:**

NORepinephrine Bitartrate 4 mg added to 250 mL 5% Dextrose Injection USP (16 mcg per mL) Total Volume 254.00 mL Viaflex Bag, High Alert, Rx Only, PharMEDium Services LLC., 12620 W Airport Blvd #130 Sugar Land, TX 77478.

**Product Quantity:**

5808 bags

**Reason for Recall:**

Subpotent Drug

**Recall Number:**

D-0627-2020

**Code Information:**

Lots: 192930026S Exp. 12/18/19; 192950020S Exp. 12/20/19; 192960029S Exp. 12/21/19; 192970024S Exp. 12/22/19; 193010034S Exp. 12/26/19; 193030036S Exp. 12/28/19; 193040029S Exp. 12/29/19; 193050030S Exp. 1/1/20; 193080025S Exp. 1/2/20; 193080026S Exp. 1/2/20; 193080027S Exp. 1/2/20; 193090017S Exp. 1/3/20; 193090018S Exp. 1/3/20; 193100032S Exp. 1/4/20; 193120028S Exp. 1/8/20; 193160027S Exp. 1/10/20; 193170024S Exp. 1/11/20; 193170025S Exp. 1/11/20; 193180026S Exp. 1/12/20; 193190031S Exp. 1/15/20; 193230027S Exp. 1/17/20; 193240015S Exp. 1/18/20; 193240016S Exp. 1/18/20; 193240017S Exp. 1/18/20; 193240018S Exp. 1/18/20; 193250017S Exp. 1/19/20