Enforcement Report - Week of January 2, 2019

Class III Drugs Event

Event ID:
81858

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/20/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
12/26/2018

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Amerigen Pharmaceuticals Inc.
9 Polito Ave Ste 900
Lyndhurst NJ United States

Distribution Pattern:
Product was distributed to 4 wholesalers and 2 retail accounts who may have further distributed the products.

Associated Products

Product Description:
Temozolomide Capsules, 20 mg, packaged in a a) 5-count (NDC 43975-253-05) and b) 14 count (NDC 43975-253-14) bottles, Rx only, Mfd, by: Stason Pharmaceuticals, Inc., Irvine, CA, Dist. By: Amerigen Pharmaceuticals, Lyndhurst, NJ

Product Quantity:
3552 bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0344-2019

Code Information:
a) Lot # 18B005 A and b) Lot # 18B005 B, exp 02/2020

Product Description:
Temozolomide Capsules, 180 mg, packaged in a 14 count bottles, Rx only, Mfd, by: Stason Pharmaceuticals, Inc., Irvine, CA, Dist. By: Amerigen Pharmaceuticals, Lyndhurst, NJ ---- NDC 43975-256-14

Product Quantity:
771 bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0345-2019

Code Information:
Lot # 18E031, exp 05/2020

Not Yet Classified Drugs Event

Event ID:
81685

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/29/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Advanced Pharma Inc.
9265 Kirby Dr
Houston TX United States

Distribution Pattern:
NM, TX, OH

Associated Products

Product Description:
Phenylephrine HCl, 1 mg in Sterile Water for injection, QS 10 mL Injectable Solution, 1 mg/10 mL incorrectly labeled as (10 mcg per mL), 10 mL syringe, Rx only, Avella of Houston, 9265 Kirby Dr., Houston, TX 77054, (877) 794-0404; NDC: 42852-802-61.

Product Quantity:
225 syringes

Reason for Recall:
Labeling: Label Error on Declared Strength: Label incorrectly lists concentration as "10 mcg per mL" rather than the correct concentration of "100 mcg per mL".

Recall Number:

Code Information:
Lot: 11/01/18 8847 80261S, BUD: 03/31/19