Enforcement Report - Week of May 29, 2019

Class II Drugs Event

Event ID:
82760

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/02/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/28/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Septodont Inc.
416 S Taylor Ave
Louisville CO United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Articaine DENTAL, Articane hydrochloride 4% and epinephrine 1:100,000, 50 cartridges. 1.7 mL each, Rx only, Manufactured for: DENTSPLY Pharmaceutical, by Novocol Pharmaceutical of Canada, Inc. York, PA 17404, NDC 66312-601-16 Reorder #: 51116

Product Quantity:
240 cartons of 50 glass cartridges each

Reason for Recall:
Labeling: Not Elsewhere Classified. This recall has been initiated due to mislabeling. The printed carton used in manufacturing both batches contained text for both 2% Xylocaine DENTAL and Articadent DENTAL. Xylocaine DENTAL is a trade name for Lidocaine HCL 2% and Epinephrine 1: 100,000 formulation, while Articadent DENTAL is a trade name for Articaine HCI 4% and Epinephrine 1 :100,000. The cartridges contained within the printed carton are labeled appropriately as Articadent DENTAL.

Recall Number:
D-1307-2019

Code Information:
Lot # D02599A, exp. Sept 2020, D02608B, exp. October 2020

Class II Drugs Event

Event ID:
82782

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/03/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/21/2019

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Heritage Pharmaceuticals, Inc.
1 Tower Center Blvd Ste 1700
East Brunswick NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Losartan Potassium Tablets, USP 50 mg 1000 film coated tablets Rx Only Manufactured by: Vivimed Life Sciences Private Limited, Plot No. 101, 102, 107 & 108 SIDCO Pharmaceutical Complex, Alathur, Kanchipuram - 603 110, Tamilnadu, India. Manufactured for: Heritage Pharmaceuticals Inc., East Brunswick, NJ 08816. 1-866-901-DRUG (3784) NDC 23155-645-10

Product Quantity:
3012 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence of an impurity, N-Methylnitrosobutyric acid (NMBA) in the finished product above the interim acceptable daily intake level at the manufacturer

Recall Number:
D-1287-2019

Code Information:
Lot CLO17007A Lot CLO17008A Lot CLO17009A ; Exp 11/2019

Product Description:
Losartan Potassium Tablets USP 100 mg 90 film coated tablets Manufactured by: Vivimed Life Sciences Private Limited, Plot No. 101, 102, 107 & 108 SIDCO Pharmaceutical Complex, Alathur, Kanchipuram - 603 110, Tamilnadu, India. Manufactured for: Heritage Pharmaceuticals Inc., East Brunswick, NJ 08816. 1-866-901-DRUG (3784) NDC 23155-646-09

Product Quantity:
25220 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence of an impurity, N-Methylnitrosobutyric acid (NMBA) in the finished product above the interim acceptable daily intake level at the manufacturer

Recall Number:
D-1288-2019

Code Information:
Lot CLO17012A exp 11/2019 Lot CLO17013A exp 11/2019 Lot CLO18002A exp 01/2020 Lot CLO18020A exp 04/2020 Lot CLO18021A exp 04/2020 Lot CLO18022A exp 04/2020

Product Description:
Losartan Potassium Tablets USP 50 mg 90 film coated tablets Manufactured by: Vivimed Life Sciences Private Limited, Plot No. 101, 102, 107 & 108 SIDCO Pharmaceutical Complex, Alathur, Kanchipuram - 603 110, Tamilnadu, India. Manufactured for: Heritage Pharmaceuticals Inc., East Brunswick, NJ 08816. 1-866-901-DRUG (3784) NDC 23155-645-09

Product Quantity:
34403 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence of an impurity, N-Methylnitrosobutyric acid (NMBA) in the finished product above the interim acceptable daily intake level at the manufacturer

Recall Number:
D-1289-2019

Code Information:
Lot CLO17009B exp 11/2019 Lot CLO17010A exp 11/2019 Lot CLO18023A exp 04/2020

Product Description:
Losartan Potassium Tablets USP 100 mg 1000 film coated tablets Rx only Manufactured by: Vivimed Life Sciences Private Limited, Plot No. 101, 102, 107 & 108 SIDCO Pharmaceutical Complex, Alathur, Kanchipuram - 603 110, Tamilnadu, India. Manufactured for: Heritage Pharmaceuticals Inc., East Brunswick, NJ 08816. 1-866-901-DRUG (3784) NDC 23155-646-10

Product Quantity:
3697 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence of an impurity, N-Methylnitrosobutyric acid (NMBA) in the finished product above the interim acceptable daily intake level at the manufacturer

Recall Number:
D-1290-2019

Code Information:
CLO17014A exp 12/2019 CLO17015A exp 01/2020 CLO17016A exp 01/2020 CLO17017A exp 01/2020 CLO18001A exp 01/2020 CLO18002B exp 01/2020

Product Description:
Losartan Potassium Tablets USP 25 mg 90 film coated tablets Rx Only Manufactured by: Vivimed Life Sciences Private Limited, Plot No. 101, 102, 107 & 108 SIDCO Pharmaceutical Complex, Alathur, Kanchipuram - 603 110, Tamilnadu, India. Manufactured for: Heritage Pharmaceuticals Inc., East Brunswick, NJ 08816. 1-866-901-DRUG (3784) NDC 23155-644-09

Product Quantity:
15541 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence of an impurity, N-Methylnitrosobutyric acid (NMBA) in the finished product above the interim acceptable daily intake level at the manufacturer

Recall Number:
D-1291-2019

Code Information:
Lot CLO17006A exp 11/2019

Class II Drugs Event

Event ID:
82832

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/01/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/19/2019

Initial Firm Notification of Consignee or Public:
Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

Recalling Firm:
Golden State Medical Supply Inc.
5187 Camino Ruiz
Camarillo CA United States

Distribution Pattern:
IL, MI, MN, PA, TN, TX. Two (2) US government and one (1) Veterans Affairs accounts. No foreign accounts.

Associated Products

Product Description:
Losartan Potassium Tablets USP 25 mg 30 count bottle NDC 60429-316-30 Rx only GSMS Incorporated

Product Quantity:
11,668 HDPE bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence of an impurity, N-Methylnitrosobutyric acid (NMBA) in the finished product above the interim acceptable daily intake level at the manufacturer

Recall Number:
D-1282-2019

Code Information:
GS017981 exp 02/2020, GS016958 exp 02/2020, GS017341 exp 02/2020

Product Description:
Losartan Potassium Tablets USP 25 mg 90 count bottle NDC 60429-316-90 Rx only GSMS Incorporated

Product Quantity:
64,362 HDPE bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence of an impurity, N-Methylnitrosobutyric acid (NMBA) in the finished product above the interim acceptable daily intake level at the manufacturer

Recall Number:
D-1283-2019

Code Information:
GS015172 exp 06/2019 GS017634 02/2020, GS017653 exp 02/2020, GS017980 exp 02/2020, GS017276 exp 02/2020, GS017045 exp 02/2020,GS016726 exp 02/2020,

Product Description:
Losartan Potassium Tablets USP 25 mg 1000 count bottle NDC 60429-316-10 Rx only GSMS Incorporated

Product Quantity:
11,286 HDPE Bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence of an impurity, N-Methylnitrosobutyric acid (NMBA) in the finished product above the interim acceptable daily intake level at the manufacturer

Recall Number:
D-1284-2019

Code Information:
GS015204 exp 06/ 2019, GS018318 exp 02/2020, GS014817 exp 06/2019, GS017342 exp 02/2020, GS017808 exp 02/2020

Product Description:
Losartan Potassium Tablets USP 100 mg 90 count bottle NDC 60429-318-90 Rx only GSMS Incorporated

Product Quantity:
138,213 HDPE Bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence of an impurity, N-Methylnitrosobutyric acid (NMBA) in the finished product above the interim acceptable daily intake level at the manufacturer

Recall Number:
D-1285-2019

Code Information:
GS014045,exp 06/2019, GS014305 exp 06/2019, GS014044 exp 0/2019, GS016535 exp 01/2020, GS016524 exp 01/2020, GS017384 exp 02/2020, GS017385 exp 01/2020, GS017539 exp 01/2020, GS017540 exp 01/2020, GS017543 exp 01/2020, GS017542 exp 01/2020 GS017984 exp 02/2020, GS017985 exp 02/2020, GS017986 exp 02/2020, GS018263 exp 02/2020, GS018264 exp 02/2020, GS018265 exp 02/2020

Product Description:
Losartan Potassium Tablets USP 100 mg 1000 count bottle NDC 60429-318-10 Rx only GSMS Incorporated

Product Quantity:
8,767 HDPE Bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence of an impurity, N-Methylnitrosobutyric acid (NMBA) in the finished product above the interim acceptable daily intake level at the manufacturer

Recall Number:
D-1286-2019

Code Information:
GS014054 exp 06/2019, GS016338 exp 12/2019, GS016341 exp 01/2020, GS016342 exp 01/2020, GS016343 exp 01/2020, GS016344 exp 01/2020, GS016345 exp 01/2020, GS016539 exp 01/2020, GS016969 exp 01/2020, GS016973 exp 01/2020, GS017337 exp 01/2020, GS018524 exp 02/2020

Not Yet Classified Drugs Event

Event ID:
82820

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/11/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Novartis Pharmaceuticals Corp.
1 Health Plz
East Hanover NJ United States

Distribution Pattern:
Nationwide with in the United States

Associated Products

Product Description:
Promacta (eltrombopag) 12.5 mg for Oral Suspension, Rx Only Manufactured by: Halo Pharmaceuticals, Inc. Whippany, New Jersey 07981 Distributed by: Novartis Pharmaceuticals Corporation East Hanover, NJ 07936 Product of Ireland NDC 0078-0972-61 On packet NDC 0078-0972-19

Product Quantity:
792 cartons

Reason for Recall:
Cross Contamination with Other Products: product is being recalled due to possible cross-contamination with peanut flour.

Recall Number:

Code Information:
Lot #: 8H57901589, Exp. 09/2020; 9H57900189 and 9H57900289, Exp. 12/2020.