Enforcement Report - Week of January 23, 2019

Class II Drugs Event

Event ID:
81504

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/01/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/14/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Bound Tree Medical, LLC
1420 Lakeside Parkway
Dallas TX United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
curaplex Epi Safe Administration and Training Kits # 8600-01100. Kit contains 2 Epi Safe Administration Kit (8600-01101) and 1 Epi Safe Training Kit (8600-01102), Rx Only. Distributed by Sarnova HC, LLC's family of companies: Bound Tree Medical, LLC, Cardio Partners, Inc., Emergency Medical Producs, Inc. & Tri-anim Health Services, Inc. 5000 Tuttle Crossing Blvd, Dublin, OH 43016

Product Quantity:
84 kits

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp date: vials of epinephrine within kit 8600-01100 expired on December 2018, but the outer kit label has an expiration date of January 2020. In addition, device component (syringe) may lack 510(k) clearance.

Recall Number:
D-0371-2019

Code Information:
Lot # ASM0018348, EXP 12-31-2018

Class II Drugs Event

Event ID:
81840

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/19/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/16/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA
1090 Horsham Rd
North Wales PA United States

Distribution Pattern:
U.S.A. nationwide

Associated Products

Product Description:
Olmesartan Medoxomil and Hydrochlorothiazide Tablets, 40 mg/25 mg, packaged in a) 30-count bottle (NDC 0093-7617-56), b) 90-count bottle (NDC 0093-7617-98), Rx only, Manufactured In Israel By: Teva Pharmaceutical, IND. LTD., Jerusalem, 9777402, Israel, Manufactured For: Teva Pharmaceutical USA, INC., North Wales, PA 19454

Product Quantity:
181,456 bottles

Reason for Recall:
Failed dissolution specifications

Recall Number:
D-0381-2019

Code Information:
Lot #: a) 49O005, 49O006, 49O007, 49O010, Exp 02/2019; b) 49O005, 49O009, 49O010, Exp 02/2019

Class II Drugs Event

Event ID:
81867

Product Type:
Drugs

Status:
Completed

Date Terminated:

Recall Initiation Date:
04/17/2017

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/16/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Syntho Pharmaceuticals, Inc.
230 Sherwood Ave
Farmingdale NY United States

Distribution Pattern:
Product was sold to the firm's sole distributor who further distributed the product throughout the United States.

Associated Products

Product Description:
EEMT HS (esterified estrogens and methyltestosterone) 0.625 mg/1.25 mg, tablets,100-count bottle, Rx only, Manufactured By: Syntho Pharmaceuticals, Inc., Farmingdale, NY 11735, Distributed By: Creekwood Pharmaceutical, Inc., Birmingham, AL 35242, NDC 15310-020-01

Product Quantity:
5,000 bottles

Reason for Recall:
CGMP deviations: Lots were recalled due to sub-potency and cGMP violations.

Recall Number:
D-0377-2019

Code Information:
Lot #: S16E01, Exp 05/18

Product Description:
EEMT (esterified estrogens and methyltestosterone) 1.25 mg/2.5 mg, tablets,100-count bottle, Rx only, Manufactured By: Syntho Pharmaceuticals, Inc., Farmingdale, NY 11735, Distributed By: Creekwood Pharmaceutical, Inc., Birmingham, AL 35242, NDC 15310-010-01

Product Quantity:
5,000 bottles

Reason for Recall:
CGMP deviations: Lots were recalled due to sub-potency and cGMP violations.

Recall Number:
D-0378-2019

Code Information:
Lot #: S16E02, Exp 05/18

Class II Drugs Event

Event ID:
81887

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/31/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/14/2019

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Aurobindo Pharma USA Inc.
279 Princeton Hightstown Rd
East Windsor NJ United States

Distribution Pattern:
Product was distributed to 25 distributors and Retail Chains who may have further distributed the product throughout the United States.

Associated Products

Product Description:
Amlodipine and Valsartan Tablets USP 5 mg/160 mg, 30-count bottles, Rx Only, Manufactured for: Aurobindo Pharma USA, Inc., Dayton, NJ 08810. NDC 65862-737-30

Product Quantity:
18,408 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.

Recall Number:
D-0361-2019

Code Information:
Lot # VESA17013-A, exp. 10/2019 Lot # VESA17014-A, exp. 10/2019 Lot # VESA18001-A, exp. 12/2019 Lot # VESA18002-A, exp. 12/2019

Product Description:
Amlodipine and Valsartan Tablets USP 10 mg/160 mg, 30-count bottles, Rx Only, Manufactured for: Aurobindo Pharma USA, Inc., Dayton, NJ 08810. NDC 65862-739-30.

Product Quantity:
60,417 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.

Recall Number:
D-0362-2019

Code Information:
Lot # VFSA17008-A, exp. 10/2019 Lot # VFSA17010-A, exp. 10/2019 Lot # VFSA18002-A, exp. 01/2020 Lot# VFSA18003-A, exp. 01/2020 Lot # VFSA18007-A, exp. 03/2020 Lot # VFSA18008-A, exp. 03/2020 Lot # VKSA17008-A, exp. 05/2019 Lot # VFSA17009-A, exp. 10/2019 Lot # VKSA17014-A, exp. 10/2019 Lot # VKSA17015-A, exp. 10/2019 Lot # VKSA17016-A, exp. 10/2019 Lot # VKSA17017-A, exp. 10/2019 Lot # VKSA18002-A, exp. 01/2020 Lot # VKSA18004-A, exp. 01/2020

Product Description:
Amlodipine and Valsartan Tablets USP 5 mg/320 mg, 30-count bottles, Rx Only, Manufactured for: Aurobindo Pharma USA, Inc., Dayton, NJ 08810. NDC 65862-738-30.

Product Quantity:
27,688 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.

Recall Number:
D-0363-2019

Code Information:
Lot # VMSA17012-A, exp. date 11/2019 Lot # VMSA17013-A, exp. date 11/2019 Lot # VMSA17014-A, exp. date 11/2019 Lot # VMSA17015-A, exp. date 11/2019 Lot # VMSA17016-A, exp. date 11/2019 Lot # VMSA17017-A, exp. date 11/2019

Product Description:
Amlodipine and Valsartan Tablets USP 10 mg/320 mg. 30-count bottles, Rx Only, Manufactured for: Aurobindo Pharma USA, Inc., Dayton, NJ 08810. NDC 65862-740-30.

Product Quantity:
55,788 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.

Recall Number:
D-0364-2019

Code Information:
Lot # VKSA18005-A, exp. date 03/2020 Lot # VKSA18001-A, exp. date 01/2020

Product Description:
Valsartan and Hydrochlorothiazide tablets USP 320mg/12.5 mg, 90-count bottle, Rx Only, Manufactured for: Aurobindo Pharma USA, Inc., Dayton, NJ 08810. NDC 65862-550-90.

Product Quantity:
23,016 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.

Recall Number:
D-0365-2019

Code Information:
Lot # HRSA17033-A, exp. date 10/2020 Lot # HRSA17034-A, exp. date 10/2020 Lot # HRSA17035-A, exp. date 10/2020 Lot # HRSA17036-A, exp. date 10/2020 Lot # HRSA17037-A, exp. date 10/2020

Product Description:
Valsartan and Hydrochlorothiazide tablets USP 160mg/12.5 mg, 90-count bottle, Rx Only, Manufactured for: Aurobindo Pharma USA, Inc., Dayton, NJ 08810. NDC 65862-548-90.

Product Quantity:
92,616 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.

Recall Number:
D-0366-2019

Code Information:
Lot # HTSA17033-A, exp. date 10/2020 Lot # HTSA17034-A, exp. date 10/2020 Lot # HTSA17035-A, exp. date 10/2020 Lot # HTSA17036-A, exp. date 10/2020 Lot # HTSA17040-A, exp. date 10/2020 Lot # HTSA17041-A, exp. date 11/2020 Lot # HTSA17042-A, exp. date 11/2020 Lot # HTSA17043-A, exp. date 11/2020 Lot # HTSA17037-A, exp. date 10/2020 Lot # HTSA17039-A, exp. date 10/2020

Product Description:
Valsartan and Hydrochlorothiazide tablets USP 320 mg/25 mg, 90-count bottles, Rx Only, Manufactured for: Aurobindo Pharma USA, Inc., Dayton, NJ 08810. NDC 65862-551-90.

Product Quantity:
111,239 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.

Recall Number:
D-0367-2019

Code Information:
Lot # HTSB17049-A, exp. date 08/2020 Lot # HTSB17054-A, exp. date 10/2020 Lot # HTSB17055-A, exp. date 10/2020 Lot # HTSB17056-A, exp. date 10/2020 Lot # HTSB17057-A, exp. date 10/2020 Lot # HTSB17058-A, exp. date 10/2020 Lot # HTSB17059-A, exp. date 10/2020 Lot # HTSB17060-A, exp. date 10/2020 Lot # HTSB17062-A, exp. date 10/2020 Lot # HTSB17066-A, exp. date 10/2020 Lot # HTSB17067-A, exp. date 11/2020 Lot # HTSB17068-A, exp. date 11/2020 Lot # HTSB17069-A, exp. date 11/2020 Lot # HTSB18001-A, exp. date 12/2020 Lot # HTSB18002-A, exp. date 12/2020 Lot # HTSB18003-A, exp. date 12/2020 Lot # HTSB18004-A, exp. date 12/2020 Lot # HTSB18005-A, exp. date 12/2020 Lot # HTSB18006-A, exp. date 12/2020 Lot # HTSB18007-A, exp. date 12/2020 Lot # HTSB17063-A, exp. date 10/2020 Lot # HTSB17064-A, exp. date 10/2020 Lot # HTSB17065-A, exp. date 10/2020 Lot # HTSB18029-A, exp. date 03/2021

Product Description:
Valsartan and Hydrochlorothiazide tablets USP 80 mg/12.5 mg, 90-count bottle, Rx Only, Manufactured for: Aurobindo Pharma USA, Inc., Dayton, NJ 08810. NDC 65862-547-90.

Product Quantity:
32,160 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.

Recall Number:
D-0368-2019

Code Information:
Lot # HVSA17011-A, exp. date 11/2020 Lot # HVSA17012-A, exp. date 11/2020 Lot # HVSA18001-A, exp. date 12/2020

Product Description:
Valsartan and Hydrochlorothiazide tablets USP 160 mg/25 mg, 90-count bottle, Rx Only, Manufactured for: Aurobindo Pharma USA, Inc., Dayton, NJ 08810. NDC 65862-549-90.

Product Quantity:
53,064 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.

Recall Number:
D-0369-2019

Code Information:
Lot # HVSB17023-A, exp. date 08/2020 Lot # HVSB17036-A, exp. date 11/2020 Lot # HVSB17037-A, exp. date 11/2020 Lot # HVSB17038-A, exp. date 11/2020 Lot # HVSB17039-A, exp. date 11/2020 Lot # HVSB17040-B, exp. date 11/2020 Lot # HVSB18001-A, exp. date 12/2020 Lot # HVSB18002-A, exp. date 12/2020 Lot # HVSB18003-A, exp. date 12/2020 Lot # HVSB18004-A, exp. date 12/2020

Product Description:
Valsartan tablets USP 320 mg, 90-count bottles, Rx Only, Manufactured for: Aurobindo Pharma USA, Inc., Dayton, NJ 08810. NDC 65862-573-90.

Product Quantity:
20,604 bottles

Reason for Recall:
CGMP Deviations: FDA lab confirmed presence an impurity, N-nitrosodimethylamine (NDEA) contained in the API used to manufacture the product above the interim acceptable daily intake level of 0.083 parts per million.

Recall Number:
D-0370-2019

Code Information:
Lot # VUSD17008-A, exp. date 07/2019 Lot # VUSD17009-A, exp. date 09/2019

Class II Drugs Event

Event ID:
81898

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/07/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/16/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lupin Pharmaceuticals Inc.
111 S Calvert St Fl 21ST
Baltimore MD United States

Distribution Pattern:
Product was distributed to 12 major distributors who may have further distributed the product throughout the United States.

Associated Products

Product Description:
Cephalexin for Oral Suspension USP, 250mg/5mL, 200 mL (when mixed), Rx only, Manufactured for: Lupin Pharmaceuticals, Inc., Baltimore, Maryland, Manufactured by: Lupin Limited, Mandideep, India ---- NDC 68180-0124-02

Product Quantity:
7,215 bottles

Reason for Recall:
CGMP Deviation; manufacturing batch record could not be located

Recall Number:
D-0380-2019

Code Information:
lot # F602820, Expiry December 2019

Class III Drugs Event

Event ID:
81487

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/01/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
01/16/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Bound Tree Medical, LLC
1420 Lakeside Parkway
Dallas TX United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Curaplex Epi Safe Kit, Rx Only, contains: 1mL Vial of Epinephrine, 1 Epi-Safe Syringe, 1 Safety needle, 2 Alcohol Prep Pads,1 Adhesive Dressing, 1 Insert. Distributed by Sarnova, HC. LLC's family companies: Bound Tree Medical. LLC, Cardio Partners, Inc., Emergency Medical Products, Inc. & Tri-amin Health Services, Inc. 5000 Tuttle Crossing Blvd, Dublin, OH 43016. Model 8600-01101

Product Quantity:
747 kits

Reason for Recall:
Labeling: Incorrect or missing Lot and/or Exp Date:The Kit is incorrectly labeled as expiring May 2018 however the correct expiration date is May 2019. In addition, device component (syringe) lacks 510(k) clearance.

Recall Number:
D-0379-2019

Code Information:
LOT # ASM0020274 Exp 5/31/2018