Enforcement Report - Week of November 18, 2020

Class II Drugs Event

Event ID:
86529

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/07/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/12/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Baxter Healthcare Corporation
1 Baxter Pkwy
Deerfield IL United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Bupivacaine Hydrochloride in 8.25% Dextrose Injection, USP Spinal 0.75% (15 mg/2 mL) 10 x 2 mL single-dose ampules, Rx only, Manufactured for: Baxter Healthcare Corporation Deerfield, IL 60015 USA, Manufactured by: Baxter Pharmaceuticals India Private Ltd Ahmedabad 382213 India, NDC 36000-092-10

Product Quantity:

Reason for Recall:
Presence of particulate matter in solution - black and transparent particles

Recall Number:
D-0076-2021

Code Information:
Lot #: A0B1241, Exp 10/2020; A0C0091, Exp 12/2020; A0D0268, Exp 02/2022

Class II Drugs Event

Event ID:
86667

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/28/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/06/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA
400 Interpace Pkwy
Parsippany NJ United States

Distribution Pattern:
Nationwide in the U.S. and PR

Associated Products

Product Description:
Mesalamine Delayed-Release Tablets, USP 1.2 gram, 120 tablets per bottle, Rx Only, Manufactured by: Actavis Laboratories, FL, Inc., Fort Lauderdale, FL 33314, Distributed by: Actavis Pharma Inc., Parsippany, NJ 07054, NDC 0591-2245-22.

Product Quantity:
133,829 bottles

Reason for Recall:
Failed Dissolution Specifications: Out-of-specification dissolution results were obtained during stability testing.

Recall Number:
D-0069-2021

Code Information:
Lot #s: 1342498A, Exp. 12/2020; 1342499A, Exp. 01/2021; 1354638A, Exp. 03/2021; 1354639A, 1358274A, 1358448A, 1364618A, 1369884A, Exp. 05/2021; 1366195A, 1369885A, 1373570A, Exp. 06/2021; 1373571A, Exp. 07/2021; 1388571A, Exp. 01/2022; 1395725A, 1396585A, 1397550A, 1399389A, Exp. 04/2022; 1403885A, 1403886A, Exp. 06/2022.

Class II Drugs Event

Event ID:
86695

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/30/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/06/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AVKARE Inc.
615 N 1st St
Pulaski TN United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Mesalamine Delayed-Release Tablets, USP 1.2 gram (Once-Daily), 120 Tablets bottle, Rx Only Manufactured for: AvKARE, Inc. Pulaski, TN 38478 NDC 42291-564-12

Product Quantity:
15,678 bottles

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0070-2021

Code Information:
Lots: 26085 Exp. 07/2021, 26426 Exp. 01/2022, 26983 Exp. 04/2022, 28647 Exp. 06/2022

Class II Drugs Event

Event ID:
86712

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/21/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/09/2020

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
H & H Remedies, LLC
1219 S Broadway St
New Philadelphia OH United States

Distribution Pattern:
Nationwide in the United States

Associated Products

Product Description:
Union (black) salve packaged in a) 1/8 oz; b) 2 oz.; c) 4 oz.; d) 8 oz.; e) 16 oz.; and f) 32 oz. jars. Mfg & Sold by: H & H Remedies, LLC c/o David A. Cox, 1219 South Broadway, New Philadelphia, OH 44663

Product Quantity:
939 jars

Reason for Recall:
CGMP Deviations

Recall Number:
D-0071-2021

Code Information:
Lot #: H20-01S thru H20-12S

Product Description:
White Liniment packaged in a) 1 oz; b) 4 oz.; and c) 6 oz bottles. Mfg & Sold by: H & H Remedies, LLC c/o David A. Cox, 1219 South Broadway, New Philadelphia, OH 44663

Product Quantity:
365 bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-0072-2021

Code Information:
Lot #: H20-01W thru H20-84W

Product Description:
Vapor Ointment packaged in a) 1/8 oz; b) 2 oz.; c) 4 oz.; and d) 8 oz jars. Mfg & Sold by: H & H Remedies, LLC c/o David A. Cox, 1219 South Broadway, New Philadelphia, OH 44663

Product Quantity:
252 jars

Reason for Recall:
CGMP Deviations

Recall Number:
D-0073-2021

Code Information:
Lot #: H20-01V thru H20-10V