Enforcement Report - Week of November 10, 2021

Class I Drugs Event

Event ID:
88861

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/12/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/02/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Bryant Ranch Prepack, Inc. dba BRP Pharmaceuticals
1919 N Victory Pl
Burbank CA United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Methocarbamol 500mg Tablet, packaged in a) #30 count (NDC 7133517952), b) #60 count (NDC 7133517954), and c) #90 count (NDC 7133517957) bottles, Rx only, Prinston Laboratories, Packaged by Bryant Ranch Prepack Burbank, CA 91504

Product Quantity:
a) 124, b) 29, c) 73

Reason for Recall:
Labeling: Label Error on Declared Strength; Bottles labeled as Methocarbamol 500 mg Tablets actually contain Methocarbamol 750 mg Tablets

Recall Number:
D-0092-2022

Code Information:
Lot #: 163935, Exp: 10/31/2022

Class I Drugs Event

Event ID:
88867

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/19/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/03/2021

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
MERCK SHARP & DOHME CORP
1 Merck Dr
Whitehouse Station NJ United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Cubicin (daptomycin for injection), 500 mg per vial, Single-dose vial, Rx only. Manuf. for: Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Whitehouse Station, NJ 08889, USA. Manuf. by: Baxter Pharmaceuticals LLC., Bloomington, IN 47403, USA, NDC: 67919-011-01

Product Quantity:
76,163 vials

Reason for Recall:
Presence of Particulate Matter: Identified as Glass Particles

Recall Number:
D-0093-2022

Code Information:
Lot #: 934778, Exp. Date Jun 2022

Class II Drugs Event

Event ID:
88798

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/05/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/29/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Dr. Reddy's Laboratories, Inc.
107 College Rd E
Princeton NJ United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Dr. Reddy's Ezetimibe and Simvastatin Tablets, 10 mg/10 mg, a) 90 count (NDC 43598-742-90) and b) 1000 count (NDC 43598-742-10) bottles, Rx only, Manufactured by: Dr. Reddy's Laboratories LA LLC, Shreveport, LA 71106, USA, Distributed by: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540 USA, , packaged in bottles.

Product Quantity:
a) 776 bottles, b) 84 bottles

Reason for Recall:
Failed Excipient Specifications; product manufactured using an excipient found to be OOS for conductivity

Recall Number:
D-0081-2022

Code Information:
a) L100256, exp 01/2023; b) L100257, exp 01/2023

Product Description:
Dr. Reddy's Ezetimibe and Simvastatin Tablets, 10 mg/20 mg, a) 30 count (NDC 43598-744-30), b) 90 count (NDC 43598-744-90) bottles, Rx only, Manufactured by: Dr. Reddy's Laboratories LA LLC, Shreveport, LA 71106, USA, Distributed by: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540 USA

Product Quantity:
a) 30,839 bottles, b) 3,830 bottles

Reason for Recall:
Failed Excipient Specifications; product manufactured using an excipient found to be OOS for conductivity

Recall Number:
D-0082-2022

Code Information:
a) L100298 and L100304, exp 01/2023 b) L100235, exp 01/2023

Product Description:
Dr. Reddy's Ezetimibe and Simvastatin Tablets, 10 mg/80 mg, a) 30 count (NDC 43598-745-30), b) 90 count (NDC 43598-745-90), and c) 500 count (NDC 43598-745-05) bottles, Rx Only, Manufactured by: Dr. Reddy's Laboratories LA LLC, Shreveport, LA 71106, USA, Distributed by: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540 USA

Product Quantity:
a) 3,444 bottles b) 469 bottles c) 142 bottles

Reason for Recall:
Failed Excipient Specifications; product manufactured using an excipient found to be OOS for conductivity

Recall Number:
D-0083-2022

Code Information:
a) L100160, exp 01/2023 b) L100249, exp 01/2023 c) L100250, exp 01/2023

Product Description:
Dr. Reddy's Ezetimibe and Simvastatin Tablets, 10 mg/40 mg, a) 30 count (NDC 43598-743-30), b) 90 count (NDC 43598-743-90) bottles, Rx Only, Manufactured by: Dr. Reddy's Laboratories LA LLC, Shreveport, LA 71106, USA, Distributed by: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540 USA

Product Quantity:
a) 11,590 bottles b) 3,585 bottles

Reason for Recall:
Failed Excipient Specifications; product manufactured using an excipient found to be OOS for conductivity

Recall Number:
D-0084-2022

Code Information:
a) L100158, exp 12/2022 b) L100159, exp 12/2022

Product Description:
Dr. Reddy's Ezetimibe and Simvastatin Tablets, 10 mg/40 mg, 500 count bottles, Rx Only, Manufactured by: Dr. Reddy's Laboratories LA LLC, Shreveport, LA 71106, USA, Distributed by: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540 USA NDC 43598-743-05

Product Quantity:
696 bottles

Reason for Recall:
Failed Excipient Specifications and Presence of Foreign Tablets/Capsules; product manufactured using an excipient found to be OOS for conductivity and some Ezetimibe and Simvastatin Tablets, 10 mg/10 mg were found in the bottle

Recall Number:
D-0085-2022

Code Information:
L100208, exp 01/2023

Class II Drugs Event

Event ID:
88856

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/12/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/01/2021

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Product was distributed to major distributors who may have further distributed the product nationwide.

Associated Products

Product Description:
Irbesartan Tablets USP, 75 mg a) 30 count (NDC 68180-410-06) and b) 90 count (NDC 68180-410-09) bottles, Rx only

Product Quantity:
51,144 bottles

Reason for Recall:
CGMP Deviations: impurity N-nitrosoirbesartan detected in API

Recall Number:
D-0086-2022

Code Information:
a) Lot# H000843, exp. date 28/02/2023 H805727, exp. date 30/11/2021 H901579, exp. date 31/03/2022 b) Lot# H000844, exp. date 28/02/2023 H000964, exp. date 31/03/2023 H804311, exp. date 31/08/2021 H805267, exp. date 30/11/2021 H805268, exp. date 30/11/2021 H805269, exp. date 30/11/2021 H805725, exp. date 30/11/2021 H805726, exp. date 30/11/2021 H901497, exp. date 31/01/2022 H901577, exp. date 31/03/2022 H901578, exp. date 31/03/2022 H902258, exp. date 31/05/2022

Product Description:
Irbesartan Tablets USP, 150 mg a) 30 count (NDC 68180-411-06) and b) 90 count (NDC 68180-411-09) bottles, Rx only

Product Quantity:
134,016 bottles

Reason for Recall:
CGMP Deviations: impurity N-nitrosoirbesartan detected in API

Recall Number:
D-0087-2022

Code Information:
a) Lot# H804403, exp. date 31/08/2021 H805251, exp. date 30/11/2021 H805640, exp. date 30/11/2021 H901580; exp. date 30/04/2022 b) Lot# H804492, exp. date 31/08/2021 H805252, exp. date 30/11/2021 H805253, exp. date30/11/2021 H805641, exp. date30/11/2021 H805642, exp. date30/11/2021 H805643, exp. date 30/11/2021 H901581, exp. date 30/04/2021 H902139, exp. date 30/04/2022 H902140, exp. date 30/04/2022

Product Description:
Irbesartan Tablets USP, 300 mg a) 30 count (NDC 68180-412-06) and b) 90 count NDC# 68180-412-09) bottles, Rx only

Product Quantity:
119,544 bottles

Reason for Recall:
CGMP Deviations: impurity N-nitrosoirbesartan detected in API

Recall Number:
D-0088-2022

Code Information:
a) Lot# H804310, exp. date 31/08/2021 H900050, exp. date 30/11/2021 H902262, exp. date 31/05/2022 b) Lot# H000845, exp. date 28/02/2023 H000846, exp. date 28/02/2023 H000965, exp. date 31/03/2023 H805345, exp. date 30/11/2021 H805346, exp. date 30/11/2021 H805347, exp. date 30/11/2021 H805724, exp. date 30/11/2021 H900061, exp. date 31/12/2021 H900062, exp. date 31/12/2021 H900445, exp. date 31/01/2022 H901489, exp. date 31/03/2022 H901490, exp. date 31/03/2022 H901491, exp. date 31/03/2022 H902261, exp. date 31/05/2022

Product Description:
Irbesartan and Hydrochlorothiazide Tablets USP, 150/12.5 mg a) 30 count (NDC 68180-413-06) and b) 90 count (NDC 68180-413-09) bottles, Rx only

Product Quantity:
63,408 bottles

Reason for Recall:
CGMP Deviations: impurity N-nitrosoirbesartan detected in API

Recall Number:
D-0089-2022

Code Information:
a) Lot# H804537, exp. date 30/09/2021 H805148, exp. date 31/10/2021 H900063, exp. date 31/10/2021 H900522, exp. date 31/12/2021 H901582, exp. date 31/01/2022 b) Lot# H000963, exp. date 30/04/2022 H804507, exp. date 30/04/2022 H804536, exp. date 30/09/2021 H805070, exp. date 31/10/2021 H805149, exp. date 31/10/2021 H900064, exp. date 31/12/2021 H900523, exp. date 31/01/2022 H901583, exp. date 30/04/2022 H902530, exp. date 30/04/2022

Product Description:
Irbesartan and Hydrochlorothiazide Tablets USP, 300/12.5 mg a) 30 count (NDC 68180-414-06) and b) 90 count (NDC 68180-414-09) bottles, Rx only

Product Quantity:
98,052 bottles

Reason for Recall:
CGMP Deviations: impurity N-nitrosoirbesartan detected in API

Recall Number:
D-0090-2022

Code Information:
a) Lot# H804192, exp. date 31/08/2021 H805348, exp. date 30/11/2021 H900065, exp. date 31/12/2021 H902264; exp. date 31/05/2022 b) Lot# H804082, exp. date 31/08/2021 H804121, exp. date 31/08/2021 H804338, exp. date 31/08/2021 H804538, exp. date 30/09/2021 H804539, exp. date 30/09/2021 H805349, exp. date 30/11/2021 H805350, exp. date 30/11/2021 H900066, exp. date 31/12/2021 H900067, exp. date 31/12/2021 H902265, exp. date31/05/2022 H902275, exp. date31/05/2022 H902276, exp. date31/05/2022 H902531, exp. date 30/04/2022 H902532, exp. date 30/04/2022