Enforcement Report - Week of October 27, 2021

Class I Drugs Event

Event ID:
88770

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/30/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/15/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Beiersdorf Inc
45 Danbury Rd
Wilton CT United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Coppertone Pure & Simple 50 Sunscreen Spray (To Deliver) Zinc Oxide 24.08%, NET WT 5 OZ (142 g) can, Beiersdorf Inc., Wilton, CT 06897 UPC 0 72140 02880 0

Product Quantity:
38,328 cans

Reason for Recall:
Chemical contamination; presence of benzene

Recall Number:
D-0010-2022

Code Information:
Lot# TN00CJ4

Product Description:
Coppertone Pure & Simple kids 50 Sunscreen Spray (To Deliver) Zinc Oxide 24.08%, NET WT 5 OZ (142 g) can, Beiersdorf Inc., Wilton, CT 06897 UPC 0 72140 02882 4

Product Quantity:
167,808 cans

Reason for Recall:
Chemical contamination; presence of benzene

Recall Number:
D-0011-2022

Code Information:
Lot# TN00854, TN00855, TN00CJV

Product Description:
Coppertone Pure & Simple baby 50 Sunscreen Spray (To Deliver) Zinc Oxide 24.08%, NET WT 5 OZ (142 g) can, Beiersdorf Inc., Wilton, CT 06897 UPC 0 72140 02881 7

Product Quantity:
124,668 cans

Reason for Recall:
Chemical contamination; presence of benzene

Recall Number:
D-0012-2022

Code Information:
Lot# TN0083J, TN0083K

Product Description:
Coppertone SPORT MINERAL 50 Sunscreen Spray (To Deliver) Zinc Oxide 24.08%, NET WT 5 OZ (142 g) can, Beiersdorf Inc., Wilton, CT 06897 UPC 0 72140 02870 1

Product Quantity:
142,236 cans

Reason for Recall:
Chemical contamination; presence of benzene

Recall Number:
D-0013-2022

Code Information:
Lot# TN008KU, TN008KV

Product Description:
Coppertone SPORT Sunscreen Spray 50, (To Deliver) Avobenzone 3%, Homosalate 10%, Octisalate 5%, Octocrylene 5%, NET WT 1.6 OZ (45 g) can, Beiersdorf Inc., Wilton, CT 06897 UPC 0 41100 00506 9

Product Quantity:
143,376 cans

Reason for Recall:
Chemical contamination; presence of benzene

Recall Number:
D-0014-2022

Code Information:
Lot# TN00BU3

Class II Drugs Event

Event ID:
88734

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/17/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/20/2021

Initial Firm Notification of Consignee or Public:

Recalling Firm:
American Health Packaging
2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:
Nationwide within the USA

Associated Products

Product Description:
GlipiZIDE Extended-Release Tablets, 2.5 mg, 30 Tablets (3 blister cards each with 10 individually blistered doses), Rx only, Manufactured by: Patheon Pharmaceuticals Inc., Cincinnati, OH 45237; Distributed by: Actavis Pharma, Inc., Parsippany, NJ 07054. Carton NDC#: 68084-295-21 (Individual Dose NDC: 68084-295-11)

Product Quantity:
2,266 cartons

Reason for Recall:
Failed Dissolution Specifications: results were above specification.

Recall Number:
D-0020-2022

Code Information:
Lot #: 194141, Exp. Date 03/31/2022

Class II Drugs Event

Event ID:
88738

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/22/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/21/2021

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
AirDuo Digihaler 113/14 (fluticasone propionate 113 mcg and salmeterol 14 mcg) Inhalation Powder, Sample Not For Sale, Rx Only, Mktd by: Teva Respiratory, LLC , Frazer, PA 19355, Manufactured in Ireland, NDC 59310-520-08

Product Quantity:
10,665 inhalers

Reason for Recall:
Subpotent drug: OOS results of Label Claimed Emitted Dose for salmeterol

Recall Number:
D-0021-2022

Code Information:
AFR17A

Product Description:
AirDuo Digihaler 232/14 (fluticasone propionate 232 mcg and salmeterol 14 mcg) Inhalation Powder, Sample Not For Sale, Rx Only, Mktd by: Teva Respiratory, LLC, Frazer, PA 19355, Manufactured in Ireland, NDC 59310-530-08.

Product Quantity:
3,240 inhalers

Reason for Recall:
Subpotent drug: OOS results of Label Claimed Emitted Dose for salmeterol

Recall Number:
D-0022-2022

Code Information:
AFR18A

Product Description:
AirDuo Digihaler 55/14 (fluticasone propionate 55 mcg and salmeterol 14 mcg) Inhalation Powder, Rx Only, Mktd by: Teva Respiratory, LLC Frazer, PA 19355, Manufactured in Ireland, NDC 59310-111-06

Product Quantity:
1,978 inhalers

Reason for Recall:
Subpotent drug: OOS results of Label Claimed Emitted Dose for salmeterol

Recall Number:
D-0023-2022

Code Information:
AFR16A

Product Description:
AirDuo Digihaler 113/14 (fluticasone propionate 113 mcg and salmeterol 14 mcg) Inhalation Powder, Rx Only, Mktd. by: Teva Respiratory, LLC, Frazer, PA 19355, Manufactured in Ireland, NDC 59310-129-06.

Product Quantity:
4,850 inhalers

Reason for Recall:
Subpotent drug: OOS results of Label Claimed Emitted Dose for salmeterol

Recall Number:
D-0024-2022

Code Information:
AFR17A

Product Description:
AirDuo Digihaler 232/14 (fluticasone propionate 113 mcg and salmeterol 14 mcg) Inhalation Powder, Rx Only, Mktd by: Teva Respiratory, LLC, Frazer, PA 19355, Manufactured in Ireland, NDC 59310-136-06

Product Quantity:
5,500 inhalers

Reason for Recall:
Subpotent drug: OOS results of Label Claimed Emitted Dose for salmeterol

Recall Number:
D-0025-2022

Code Information:
AFR17A

Class II Drugs Event

Event ID:
88754

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/21/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/15/2021

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Sanitor Corporation
8400 Cerritos Ave
Stanton CA United States

Distribution Pattern:
Distributed to one distributor located in Las Vegas, NV.

Associated Products

Product Description:
Cleaning Solutions Foaming Hand Sanitizer, Active Ingredient Benzalkonium chloride 0.1%, New Wave Cleaning Solutions LLC, 7001 W Arby Ave Suite 100, Las Vegas, NV 89113, UPC#: 8 60001 93396 3

Product Quantity:
unknown

Reason for Recall:
CGMP Deviations: Use of this product may cause possible infection/ irritation of the skin and/or soft tissues.

Recall Number:
D-0018-2022

Code Information:
Lot # 20102, 20103, Exp, Sept, 2021;

Class II Drugs Event

Event ID:
88770

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/30/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/15/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Beiersdorf Inc
45 Danbury Rd
Wilton CT United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Coppertone Pure & Simple 50 Sunscreen Spray (To Deliver) Zinc Oxide 24.08%, NET WT 5 OZ (142 g) can, Beiersdorf Inc., Wilton, CT 06897 UPC 0 72140 02880 0

Product Quantity:
36,660 cans

Reason for Recall:
cGMP Deviations

Recall Number:
D-0015-2022

Code Information:
Lot# TN00BR2

Product Description:
Coppertone Pure & Simple kids 50 Sunscreen Spray (To Deliver) Zinc Oxide 24.08%, NET WT 5 OZ (142 g) can, Beiersdorf Inc., Wilton, CT 06897 UPC 0 72140 02882 4

Product Quantity:
70,320 cans

Reason for Recall:
cGMP Deviations

Recall Number:
D-0016-2022

Code Information:
Lot# TN00857

Product Description:
Coppertone Pure & Simple baby 50 Sunscreen Spray (To Deliver) Zinc Oxide 24.08%, NET WT 5 OZ (142 g) can, Beiersdorf Inc., Wilton, CT 06897 UPC 0 72140 02881 7

Product Quantity:
14,748 cans

Reason for Recall:
cGMP Deviations

Recall Number:
D-0017-2022

Code Information:
Lot# TN009GH

Class II Drugs Event

Event ID:
88809

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/05/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/22/2021

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 USA

Associated Products

Product Description:
Omeprazole Delayed-Release Capsules, 20 mg* (equivalent to 20.6 mg omeprazole magnesium), 24 Hour, 14-count capsules per bottle within a carton, Distributed by Cardinal Health, Dublin, OH 43017, NDC 70000-0232-1

Product Quantity:
8,976 bottles

Reason for Recall:
CGMP Deviations: Customer complaint for the presence of a staple co-mingled with capsules within the bottle.

Recall Number:
D-0026-2022

Code Information:
BT001594C

Class II Drugs Event

Event ID:
88838

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/08/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/22/2021

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:
Distributed Nationwide in the USA.

Associated Products

Product Description:
Imipramine Pamoate Capsules 125 mg, 30-count bottle, Rx only, Manufactured for Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202 UNited States. Manufactured by: Lupin Limited, Pithampur, (M.P.) 454 775 India NDC# 68180-316-06

Product Quantity:
1,902 bottles

Reason for Recall:
Out of specification result observed in a dissolution test at the 9-month long term stability time point.

Recall Number:
D-0027-2022

Code Information:
lot H002205, exp. date 08/2023

Class II Drugs Event

Event ID:
88841

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/10/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
10/20/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Piramal Critical Care, Inc.
3950 Schelden Cir
Bethlehem PA United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Rocuronium Bromide Injection 50mg/5 mL, 5mL Multi-Dose Vial, Rx only, Manufactured for: Piramal Critical Care, Bethlehem, PA 18017, USA, Manufactured by: Sanovel Ilac, San. Ve Tic. A.S. Istanbul, Turkey, NDC 66794-0228-41

Product Quantity:
100 glass vials

Reason for Recall:
Labeling: Label Lacks Warning or Rx Legend: Finished product did not include the statement on the flip cap vial, "WARNING: PARALYZING AGENT"

Recall Number:
D-0019-2022

Code Information:
Lot #: 20415001, 20415002, Expiration Date 05/2022