Enforcement Report - Week of July 8, 2020

Class I Drugs Event

Event ID:
85839

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/09/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/26/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
MasterPharm LLC
11502 Liberty Ave Fl 2
South Richmond Hill NY United States

Distribution Pattern:
FL and MD

Associated Products

Product Description:
Minoxidil/Biotin/Spironolactone 1.25/5/25 mg capsule, 90 capsules per bottle, This is a compounded drug not for resale, Store at room temperature, MasterPharm, 115-02 Liberty Ave, Richmond Hill, NY 11419.

Product Quantity:
300 capsules

Reason for Recall:
Super-potent Drug: This recall has been initiated due to the elevated presence of minoxidil and biotin.

Recall Number:
D-1363-2020

Code Information:
Lot #: 01-09-2020:13@8, Exp. 7/7/2020

Class II Drugs Event

Event ID:
85784

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/12/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/26/2020

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Beaming White LIc
1205 Ne 95th St Suite A
Vancouver WA United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Koala Hand Sanitizer, Soothing Eucalyptus, 16 FL OZ., Antibacterial, (Ethyl Alcohol 68%), Manufactured by Beaming White LLC, 1205 NE 95th St., Vancouver, WA 98665

Product Quantity:

Reason for Recall:
Subpotent Drug: active ingredient ethanol tested below label claim and there is presence of undeclared isopropyl alcohol.

Recall Number:
D-1357-2020

Code Information:
Lot #: 40820, Exp. Date 4/8/23

Product Description:
Koala Hand Sanitizer, Menthol, 16 FL OZ., Antibacterial, (Ethyl Alcohol 69%), Manufactured by Beaming White LLC, 1205 NE 95th St., Vancouver, WA 98665

Product Quantity:

Reason for Recall:
Subpotent Drug: active ingredient ethanol tested below label claim and there is presence of undeclared isopropyl alcohol.

Recall Number:
D-1358-2020

Code Information:
Lot #: 40920, Exp. Date 4/9/23; 41320, Exp. Date 4/13/23; 41420, Exp, Date 4/14/23; 41620, Exp. Date 4/16/23; 41720, 41720-2, Exp. Date 4/17/23

Product Description:
Koala Hand Sanitizer, Unscented, 16 FL OZ., Antibacterial, (Ethyl Alcohol 70%), Manufactured by Beaming White LLC, 1205 NE 95th St., Vancouver, WA 98665

Product Quantity:

Reason for Recall:
Subpotent Drug: active ingredient ethanol tested below label claim and there is presence of undeclared isopropyl alcohol.

Recall Number:
D-1359-2020

Code Information:
Lot#: 42220, Exp. Date 4/22/23

Class II Drugs Event

Event ID:
85848

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/16/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/26/2020

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Glaxosmithkline Consumer Healthcare Holdings
184 Liberty Corner Rd
Warren NJ United States

Distribution Pattern:
Nationwide in the US

Associated Products

Product Description:
Childrens Robitussin Honey Cough and Chest Congestion DM, dextromethorphan (cough suppressant), guaifenesin (expectorant), 4 FL OZ. bottle

(118 mL), Distributed by: Pfizer, Madison, NJ 07940 USA, UPC: 50300318760128, NDC: 0031-8760-12.

Product Quantity:
132,336 bottles

Reason for Recall:
Defective Delivery System: the dosing cups are missing graduations applicable to certain age groups.

Recall Number:
D-1361-2020

Code Information:
Lot #s: 02177, 02178, Exp. 01/31/2022

Product Description:
Childrens Dimetapp Cold & Cough, For ages 6 yrs. & over, 8 FL OZ. bottle, (237 mL), Distributed by: Pfizer Madison, NJ 07940, Made in Canada, UPC: 60300312234196, NDC: 0031-2234-19.

Product Quantity:
78,132 bottles

Reason for Recall:
Defective Delivery System: the dosing cups are missing graduations applicable to certain age groups.

Recall Number:
D-1362-2020

Code Information:
Lot CL8292, Exp. 09/30/2021

Class II Drugs Event

Event ID:
85861

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/12/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/26/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
The Harvard Drug Group
17177 N Laurel Park Dr Ste 233
Livonia MI United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Metformin Hydrochloride Extended-Release Tablets, USP, 500 mg, 100 Tablets (10 x 10) unit dose cartons, Rx only, Manufactured by: Apotex, Inc., Toronto, Ontario, Canada, Manufactured for: Apotex Corp. Weston, FL, Distributed by: Major Pharmaceuticals, Livonia, MI 48152 NDC 00904-5794-61

Product Quantity:
1,906 Cartons

Reason for Recall:
CGMP Deviation: Potential presence of Nitrosodimethylamine (NDMA) Impurity above the established levels.

Recall Number:
D-1360-2020

Code Information:
Lot T-02134, exp 09/2020

Class II Drugs Event

Event ID:
85880

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/17/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
06/26/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Preferred Pharmaceuticals, Inc.
1250 N Lakeview Ave Ste O
Anaheim CA United States

Distribution Pattern:
Product was distributed to two medical clinics located in FL.

Associated Products

Product Description:
Metformin HCl Extended Release Tablets, USP, 500 mg, Generic for Glucophage XR, Pkg Size 100, Mfg: Time-Cap, Labs Inc., Farmingdale, NY, Preferred Pharmaceuticals, Anaheim, CA NDC: 68788-6932-01

Product Quantity:
144 bottles

Reason for Recall:
CGMP Deviations: FDA analysis detected N-Nitrosodimethylamine (NDMA) levels in excess of the Acceptable Daily Intake Limit.

Recall Number:
D-1364-2020

Code Information:
J0119M, K1419L, K2719J, A0220H; Exp. Date 12/2020

Not Yet Classified Drugs Event

Event ID:
85742

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/19/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Flexion Therapeutics, Inc.
10 Mall Rd Ste 301
Burlington MA United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Zilretta (triamcinolone acetonide extended-release injectable suspension), 32mg per vial, 5mL vials, Single-dose Kits, Rx Only, Manufactured for: Flexion Therapeutics, Inc. 10 Mall Road, Suite 301, Burlington, MA 01803, NDC 70801-003-01

Product Quantity:
792 kits

Reason for Recall:
Temperature Abuse: Product was stored at room temperature longer than 6 weeks and was inadvertently distributed instead of discarded

Recall Number:

Code Information:
Lot # ZA19014, exp. date 05/2021