

Enforcement Report - Week of May 20, 2020

Class I Drugs Event

Event ID:

85619

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

04/14/2020

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

05/19/2020

Initial Firm Notification of Consignee or Public:

Telephone

Recalling Firm:

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

Distribution Pattern:

Nationwide in the U.S.

Associated Products

Product Description:

Finasteride Plus 1.25 mg Capsule, a) 30-count bottle, b) 90-count bottle, Compounded Product Not for Resale, MasterPharm, 115-02 Liberty Ave, Richmond Hill, NY 11419.

Product Quantity:

7260 capsules

Reason for Recall:

Cross Contamination with Other Products; Finasteride Plus 1.25mg capsules were found to contain minoxidil.

Recall Number:

D-1269-2020

Code Information:

Lot #02-27-2020:04@11, Exp. August 25, 2020.

Class III Drugs Event

Event ID:

85500

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

04/20/2020

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

05/13/2020

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

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

Distribution Pattern:

Nationwide

Associated Products

Product Description:

ChapStick Total Hydration Moisture + Tint + SPF15 Peachy Keen Net Wt. 0.08 OZ (2.2g) Marketed by: Pfizer, Madison, NJ 07940 USA, NDC 0573-0871-08

Product Quantity:

288 packages

Reason for Recall:

Labeling: Not elsewhere classified: Observed separation in the secondary packaging in the blister and the backer card

Recall Number:

D-1266-2020

Code Information:

Lot #: 9344AA, 9345AA

Product Description:

ChapStick Total Hydration Moisture + Tint + SPF15 Very Berry Net Wt. 0.08 OZ (2.2g) Marketed by: Pfizer, Madison, NJ 07940 USA NDC 0573-0872-08

Product Quantity:

288 packages

Reason for Recall:

Labeling: Not elsewhere classified: Observed separation in the secondary packaging in the blister and the backer card

Recall Number:

D-1267-2020

Code Information:

Lot #: 9346AA, 9347AA

Product Description:

ChapStick Total Hydration Moisture + Tint + SPF15 Pretty in Pink Net Wt. 0.08 OZ (2.2g) Marketed by: Pfizer, Madison, NJ 07940 USA NDC 0573-0873-08

Product Quantity:

360 packages

Reason for Recall:

Labeling: Not elsewhere classified: Observed separation in the secondary packaging in the blister and the backer card

Recall Number:

D-1268-2020

Code Information:

Lot #: 9343AA, 9343BA

Class III Drugs Event

Event ID:

85566

Status:

Ongoing

Recall Initiation Date:

04/24/2020

Center Classification Date:

05/13/2020

Recalling Firm:

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

Distribution Pattern:

AL, FL, IA, NY, OH, TX

Product Type:

Drugs

Date Terminated:**Voluntary / Mandated:**

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Letter

Associated Products

Product Description:

Memantine Hydrochloride Extended-Release Capsules, 28 mg, 100 capsules per unit dose cartons, Rx only, Manufactured by: Lupin Limited, Pithampur (M.P.)-454 775, India; Distributed by: Major Pharmaceuticals, 17177 N Laurel Park Dr., Suite 233, Livonia, MI 47152 USA. NDC: 0904-6735-61

Product Quantity:

678 cartons

Reason for Recall:

Failed dissolution specifications: Low stage 3 results obtained for dissolution during routine stability testing.

Recall Number:

D-1262-2020

Code Information:

Lot #: M02199D, M02246D, Exp 5/2020