

Enforcement Report - Week of August 30, 2017

Class I Drugs Event

Event ID: 77082	Product Type: Drugs	Status: Ongoing	Date Terminated:
Recall Initiation Date: 04/20/2017	Voluntary / Mandated: Voluntary: Firm Initiated	Center Classification Date: 08/22/2017	Initial Firm Notification of Consignee or Public: Press Release
Recalling Firm: C. O. Truxton 136 Harding Ave Bellmawr NJ United States		Distribution Pattern: Nationwide	

Associated Products

Product Description: Phenobarbital Tablets USP, 15 mg, 1000 count bottles, Rx Only, Manufactured by West-ward Pharmaceutical Corp. Eatontown, NJ 07724, Distributed by Truxton, Inc., Bellmawr, NJ 08031, NDC 0463-6160-10	Product Quantity: unknown
Reason for Recall: Labeling: Labeled Error on Declared Strength; report of a 1000 ct bottle labeled as Phenobarbital 15 mg tablets actually contained 30 mg tablets	Recall Number: D-1111-2017
Code Information: Lot # 70952A; Exp. 11/17	
Product Description: Phenobarbital Tablets USP, 30 mg, 1000 count bottles, Rx Only, Manufactured by West-ward Pharmaceutical Corp. Eatontown, NJ 07724, Distributed by Truxton, Inc., Bellmawr, NJ 08031, NDC 0463-6145-10	Product Quantity: unknown
Reason for Recall: Labeling: Label Mixup; potentially mislabeled	Recall Number: D-1112-2017
Code Information: Lot # 70926A; Exp. 11/17 Lot # 70981A; Exp. 01/18 Lot # H15A59; Exp. 08/18	

Class I Drugs Event

Event ID: 77375	Product Type: Drugs	Status: Ongoing	Date Terminated:
Recall Initiation Date: 05/25/2017	Voluntary / Mandated: Voluntary: Firm Initiated	Center Classification Date: 08/22/2017	Initial Firm Notification of Consignee or Public: Press Release
Recalling Firm: Brian P. Richardson 3410 Delafield Ln Dallas TX United States		Distribution Pattern: TX	

Associated Products

Product Description: CaverFlo Natural Herbal Coffee, 25 g, supplied in boxes of 10 packets, manufacture for Caverflo Texas Trading -- UPC: 9555671709987	Product Quantity: Unknown
Reason for Recall: Marketed without an Approved NDA/ANDA; FDA analysis result found product to contain sildenafil, tadalafil and undeclared milk	Recall Number: D-1117-2017
Code Information: all lots within expiry.	

Class II Drugs Event

Event ID: 77082	Product Type: Drugs	Status: Ongoing	Date Terminated:
Recall Initiation Date: 04/20/2017	Voluntary / Mandated: Voluntary: Firm Initiated	Center Classification Date: 08/22/2017	Initial Firm Notification of Consignee or Public: Press Release
Recalling Firm: C. O. Truxton 136 Harding Ave Bellmawr NJ United States		Distribution Pattern: Nationwide	

Associated Products

Product Description: Phenobarbital Tablets USP, 60 mg, 1000 count bottles, Rx Only, Manufactured by West-ward Pharmaceutical Corp. Eatontown, NJ 07724, Distributed by Truxton, Inc., Bellmawr, NJ 08031, NDC 0463-6151-10	Product Quantity: unknown
Reason for Recall: Labeling: Label Mixup; potentially mislabeled	Recall Number: D-1113-2017
Code Information: Lot # 71416A; Exp. 05/20 Lot # 70881A; Exp. 07/17 Lot # H15A68; Exp. 01/18 Lot # 70980A; Exp. 02/18	
Product Description: Phenobarbital Tablets USP, 100 mg, a) 100 count bottles (NDC 0463-6152-01), b) 1000 count bottles (NDC 0163-6152-10), Rx Only, Manufactured by West-ward Pharmaceutical Corp. Eatontown, NJ 07724, Distributed by Truxton, Inc., Bellmawr, NJ 08031	Product Quantity: unknown
Reason for Recall: Labeling: Label Mixup; potentially mislabeled	Recall Number: D-1114-2017
Code Information: a) Lot # 70989A; Exp. 02/18, Lot # 70973A; Exp. 01/18 b) Lot # 70973A; Exp. 01/18, Lot # H15A76; Exp. 02/18, Lot # 71346A; Exp. 12/19, Lot # 70989A; Exp. 02/18	
Product Description: Amitriptyline HCL Tablets, USP 50 mg, 100 count bottles, Rx Only, Manufactured for: Qualitest Pharmaceuticals Huntsville, AL 35811, Distributed by: Truxton, Inc. Bellmawr, NJ 08031, NDC: 0463-6352-10	Product Quantity: unknown
Reason for Recall: Labeling: Label Mixup; potentially mislabeled	Recall Number: D-1115-2017
Code Information: Lot # C0260416A; Exp. 03/18	
Product Description: Phenobarbital Tablets USP, 15 mg, 1000 count bottles, Rx Only, Manufactured by West-ward Pharmaceutical Corp. Eatontown, NJ 07724, Distributed by Truxton, Inc., Bellmawr, NJ 08031, NDC 0463-6160-10	Product Quantity: unknown
Reason for Recall: Labeling: Label Mixup; potentially mislabeled	Recall Number: D-1116-2017
Code Information: Lot # 71162A; Exp. 10/18 Lot # 70915A; Exp. 08/17 Lot # H15A55; Exp. 11/17	

Class II Drugs Event

Event ID: 77869	Product Type: Drugs	Status: Ongoing	Date Terminated:
Recall Initiation Date: 08/02/2017	Voluntary / Mandated: Voluntary: Firm Initiated	Center Classification Date: 08/24/2017	Initial Firm Notification of Consignee or Public: Press Release

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

Distribution Pattern:
Nationwide in the USA

Associated Products

<p>Product Description: Rugby Diocto Liquid, Docusate Sodium 50 mg/ 5 mL, Stool Softener Laxative, One Pint (473 mL) plastic bottles, Dist. by: Rugby Laboratories, 17177 N. Laurel Park Dr., Suite 233, Livonia, MI 48152 --- NDC: 0536-0590-85</p> <p>Reason for Recall: Microbial contamination of Non-sterile Products; presence of yeast and potential B. cepacia contamination</p> <p>Code Information: Item# 370010, Lot: 20351701</p>	<p>Product Quantity: 7,308 bottles</p> <p>Recall Number: D-1119-2017</p>
<p>Product Description: Rugby Diocto Syrup, Docusate Sodium 60 mg/15 mL, Stool Softener Laxative, One Pint (473 mL) plastic bottles, Dist. by: Rugby Laboratories, 31778 Enterprise Drive, Livonia, MI 48150. NDC: 0536-1001-85</p> <p>Reason for Recall: Microbial contamination of Non-sterile Products; presence of yeast and potential B. cepacia contamination</p> <p>Code Information: Item# 370282, Lot: 22941701</p>	<p>Product Quantity: 7,272 bottles</p> <p>Recall Number: D-1120-2017</p>
<p>Product Description: Major Senna Syrup Natural Vegetable Laxative, Sennoside 8.8 mg, 8 fl. oz. (237 mL) plastic bottles, Dist. by: Major Pharmaceuticals, 17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152 USA. NDC: 00904-6289-09</p> <p>Reason for Recall: Microbial contamination of Non-sterile Products; presence of yeast and potential B. cepacia contamination</p> <p>Code Information: Item # 263923, all lots</p>	<p>Product Quantity: 26,891 bottles</p> <p>Recall Number: D-1121-2017</p>
<p>Product Description: Rugby Aller-chlor (Chlorpheniramine Maleate Syrup, USP), 2 mg, 4 fl. oz. (120 mL) plastic bottles, Distributed by: Rugby Laboratories 17177 N. Laurel Park Drive, Suite 233, Livonia, MI 48152 USA --- NDC: 0536-1025-47</p> <p>Reason for Recall: Microbial contamination of Non-sterile Products; presence of yeast and potential B. cepacia contamination</p> <p>Code Information: Item # 370339, all lots</p>	<p>Product Quantity: 4,715 bottles</p> <p>Recall Number: D-1122-2017</p>
<p>Product Description: Rugby Senexon Liquid Natural Vegetable Stimulant,(Sennosides) 8.8 mg, 8 fl oz (237 mL) plastic bottles, Distributed by: Rugby Laboratories, 17177 N Laurel Park Drive, ?Suite 233, Livonia, MI 48152 --- NDC 0536-1000-59</p> <p>Reason for Recall: Microbial contamination of Non-sterile Products; presence of yeast and potential B. cepacia contamination</p> <p>Code Information: Item# 370281 all lots</p>	<p>Product Quantity: 32,413 bottles</p> <p>Recall Number: D-1123-2017</p>