Enforcement Report - Week of May 17, 2023

Class I Drugs Event

Event ID:
91808

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/13/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/08/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Camber Pharmaceuticals Inc.
800 Centennial Ave Ste 1
Piscataway NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Atovaquone Oral Suspension USP, 750 mg/5 mL, Packaged in 210 mL bottle, Manufactured for: Camber Pharmaceuticals, Inc., Piscataway, NJ 08854, Manufactured by: Hetero Labs Limited, Jeedimetla, Hyderabad - 500 055, India, NDC# 31722-629-21.

Product Quantity:
1568 bottles

Reason for Recall:
Microbial Contamination of Non-Sterile Product: Objectionable organism, identified as Bacillus cereus, found in product during testing of repackaged product.

Recall Number:
D-0567-2023

Code Information:
Lot# E220182, Exp. 12/31/2023

Class II Drugs Event

Event ID:
92208

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/26/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/09/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Apotex Corp.
2400 N Commerce Pkwy Ste 400
Weston FL United States

Distribution Pattern:
Nationwide throughout the United States

Associated Products

Product Description:
Calcitonin Salmon (synthetic origin) Nasal Spray, 2200 USP Calcitonin Salmon Units/mL, 200 USP Calcitonin Salmon Units/spray, 3.7 mL bottle, Rx only, Manufactured by: Apotex Corp., Toronto, Ontario, Canada, M9L 1T9, NDC 60505-0823-6

Product Quantity:
82,375 bottles

Reason for Recall:
Presence of Foreign Substance: Glass splinter particle entrapped inside the pump ball seat rendered the pump inoperable.

Recall Number:
D-0568-2023

Code Information:
Lot #: TH5645, Exp. 01/2025

Class III Drugs Event

Event ID:
92174

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/24/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/10/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
The Harvard Drug Group
341 Mason Rd
La Vergne TN United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Gabapentin Tablets, USP 600 mg, packaged in Cartons of 100 tablets (10 tablets per blister pack x 10), Rx Only, Distributed by: Aurobindo Pharma USA, Inc. East Windsor, NJ 08520 Distributed by: Major Pharmaceuticals 17177 N Laurel Park Dr., Suite 233 Livonia, MI 48152 USA, NDC 0904-6823-61

Product Quantity:
3984 cartons

Reason for Recall:
Product mixup: one foreign tablet found in product.

Recall Number:
D-0570-2023

Code Information:
Lot: T04468, Exp 10/2024