Enforcement Report - Week of October 4, 2023

Class II Drugs Event

Event ID:
93073

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/22/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/26/2023

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Sofie Co dba Sofie
100 Executive Dr Ste 6
Sterling VA United States

Distribution Pattern:
Product was released to one facility in VA.

Associated Products

Product Description:
Florbetaben F-18 (Neuraceq¿) Injection Solution 1.4 to 135 mCi/mL, 50 mL in 1 multi-dose glass vial, Diagnostic-For Intravenous Use Only, Manufactured by SOFIE Co dba SOFIE, Dulles, VA 20166 for Life Molecular Imagining Ltd., NDC 54828-001-50

Product Quantity:
6 patient doses

Reason for Recall:
Lack of Assurance of Sterility: out-of-specification test results observed for Filter Integrity Test (FIT).

Recall Number:
D-1177-2023

Code Information:
Batch # FBBVA123082201, EOS: 22 Aug 2023/08:25, EXP: 22 Aug 2023/18:25

Class III Drugs Event

Event ID:
92977

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/29/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/27/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
RB Health (US) LLC
399 Interpace Pkwy
Parsippany NJ United States

Distribution Pattern:
USA nationwide

Associated Products

Product Description:
Clearasil Rapid Rescue Deep Treatment Pads (Salicylic Acid 2%), packaged in 90-count plastic jar, further packaged in case of 6 jars per case, Distributed by RB Health (US), Parsippany, NJ 07054, NDC 63824-431-90

Product Quantity:
6,072 cases/36,426 individual selling units

Reason for Recall:
Labeling: Label Error on Declared Strength: The incorrect label on the back of the product packaging.

Recall Number:
D-1179-2023

Code Information:
Lot # KT220211, Exp 07/2024

Class III Drugs Event

Event ID:
93044

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/12/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/27/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Tolmar, Inc.
701 Centre Ave
Fort Collins CO United States

Distribution Pattern:
Nationwide in the US.

Associated Products

Product Description:
Eligard (leuprolide acetate) for injectable suspension, 7.5 mg every month, Sterile, Rx Only, Must be reconstituted before use, NDC 62935-753-75, Manufactured by: Tolmar Inc., Fort Collins, CO 80526, For Tolmar Therapeutics Inc., Fort Collins, CO 80526.

Product Quantity:
2990 cartons

Reason for Recall:
Superpotent Drug - Higher than expected levels of leuprolide acetate in the constituted product.

Recall Number:
D-1178-2023

Code Information:
Lot: 13635A1, Exp. 07/31/2024