Enforcement Report - Week of January 29, 2020

Class II Drugs Event

Event ID:
83757

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/24/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/22/2020

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Tuscano and Delucia Group (DBA Entropic Labs)
2150 S West Temple Apt 413
Salt Lake City UT United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Entropic Labs SARM RAD-140, 20mg Capsules, 30-count bottles, Entropic Labs UPC#: 651074545302

Product Quantity:
60

Reason for Recall:
Marketed Without An Approved NDA/ANDA: product contains Selective Androgen Receptor Modulators (SARMs)

Recall Number:
D-0800-2020

Code Information:
All lots

Class II Drugs Event

Event ID:
84607

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/07/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/20/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Mylan Pharmaceuticals Inc.
781 Chestnut Ridge Rd
Morgantown WV United States

Distribution Pattern:
Product was distributed to wholesalers, distributors , retail pharmacies, charitable organizations and mail order pharmacies throughout the United States and the product may have been further distributed.

Associated Products

Product Description:
Nizatidine Capsules, USP 150 mg, Rx Only, Mylan Pharmaceuticals Inc., NDC 0378-5150-91.

Product Quantity:
31,736 bottles of 60 capsules

Reason for Recall:
CGMP Deviations: Trace amounts of an impurity, N-nitrosodimethylamine (NDMA) was detected in the API Nizatidine.

Recall Number:
D-0791-2020

Code Information:
Lot Number: 3086746, exp. date May 2020

Product Description:
Nizatidine Capsules, USP 300 mg, Rx Only, Mylan Pharmaceuticals Inc., NDC 0378-5300-93.

Product Quantity:
16,944 bottles of 30 capsules

Reason for Recall:
CGMP Deviations: Trace amounts of an impurity, N-nitrosodimethylamine (NDMA) was detected in the API Nizatidine.

Recall Number:
D-0792-2020

Code Information:
Lot # 3082876, exp. date January 2020 Lot # 3082877, exp. date January 2020

Class II Drugs Event

Event ID:
84637

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/06/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/20/2020

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
H J Harkins Company Inc dba Pharma Pac
1400 W Grand Ave Ste F
Grover Beach CA United States

Distribution Pattern:
Distributed to Physicians in the following states: CA, FL, NC, and SC.

Associated Products

Product Description:
Ranitidine, 150 mg Tablets, a) 7 count, b) 14 count, c) 20 count, d) 30 count, e) 60 count; Rx, Only, H.J. Harkins Company, Inc. dba Pharma Pac Grover Beach, CA 93433 NDC #s: 52959-0502-07, 52959-0502-14, 52959-0502-20, 52959-0502-30 and 52959-0502-60

Product Quantity:
7,212 tablets

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0793-2020

Code Information:
Lot #s: RAN63KG Exp. 05/20, RAN64KG Exp. 10/20, RAN65KG Exp. 11/20, RAN66KG Exp. 05/21

Class II Drugs Event

Event ID:
84657

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/20/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/20/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Denton Pharma, Inc.
119 Creamery Rd
North Blenheim NY United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Ranitidine Tablets, USP 150 mg , a). 4 count bottle (NDC 70934-017-04), b). 20-count bottle (NDC 70934-017-20), c). 24-count bottle (NDC 70934-017-24) d). 30-count bottle (NDC 70934-017-30) e). 90-count bottle (NDC 70934-017-90), Rx Only, Repackaged by: Northwind Pharmaceuticals North Brenheim, NY 12131.

Product Quantity:
1,341 bottles

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0794-2020

Code Information:
a). N102851902, Exp. 04/30/2021 b). D102851801, Exp. 04/2021 c). N102851901, Exp. 11/30/2021 N102851903, Exp. 12/31/2021 N102851906, Exp. 03/31/2022 d). N102851904, Exp. 02/28/2022 N102851905, Exp. 12/31/2021 e). C102851901, Exp. 11/30/2021 C102851902, Exp. 11/30/2021 C102851903, Exp. 11/30/2021 C102851904, Exp. 05/31/2021 C102851905, Exp. 02/28/2022 C102851906, Exp. 02/28/2022 C102851907, Exp. 03/31/2022

Product Description:
Ranitidine Tablets, USP 300 mg a). 15-count bottles (NDC 70934-287-15), b). 90-count bottles (NDC 70934-287-90), Rx Only, Repackaged by: Northwind Pharmaceuticals North Brenheim, NY 12131

Product Quantity:
467 bottles

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0795-2020

Code Information:
a). N106851901, Exp. 11/30/2021 N106851902, Exp. 10/31/2021 b). C106851901, Exp. 11/30/2021 C106851902 Exp. 10/31/2021 C106851903 Exp. 02/28/2022 C106851904 Exp. 11/30/2021 C106851905 Exp. 05/31/2022

Class II Drugs Event

Event ID:
84671

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/07/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/20/2020

Initial Firm Notification of Consignee or Public:
Telephone

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

Distribution Pattern:
Distribution to physicians in the following states: AL, AZ, CA, FL, GA, IN, and SC

Associated Products

Product Description:
Preferred Pharmaceuticals, Inc, Ranitidine Tablets, 150 mg, a) 30 count bottles (NDC: 68788-7388-3), b) 60 count bottles (NDC: 68788-7388-6), c) 90 count bottles (NDC: 68788-7388-9), d) 100 count bottles (NDC: 68788-7388-1)

Product Quantity:
221,710 tablets

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0796-2020

Code Information:
Lot #: All lots within expiry

Product Description:
Preferred Pharmaceuticals, Inc, Ranitidine Tablets, 300 mg, Rx Only, a) 14 count bottles (NDC: 68788-6382-1), b) 30 count bottles (NDC: 68788-6382-3), c) 90 count bottles (NDC: 68788-6382-9), d) 100 count bottles (NDC: 68788-6382-0)

Product Quantity:
39,172 tablets

Reason for Recall:
CGMP Deviations: Presence of NDMA impurity detected in product.

Recall Number:
D-0797-2020

Code Information:
Lot #: All lots within expiry

Class II Drugs Event

Event ID:
84685

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/10/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/22/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Advanced Accelerator Applications USA, Inc.
57 E Willow St
Millburn NJ United States

Distribution Pattern:
Nationwide in the US and Canada

Associated Products

Product Description:
NETSPOT, (kit for the preparation of Ga 68 dotatate injection) 40 mcg dotatate, For Intravenous Use Only, Rx Only, Manufactured for: Advanced Accelerator Applications USA, Inc. by Gipharma S.r.l. Strada Crescentino snc, 13040 Saluggia (Vc), Italy, NDC 69488-001-40.

Product Quantity:
4295 Kits

Reason for Recall:
Defective Container: loose aluminum cap crimp for the dilution buffer vial present in the NETSPOT Kit (vial 2).

Recall Number:
D-0799-2020

Code Information:
Lot #: PG1919025, Exp. 07/11/2020; PG1919026, PG1919027, Exp. 07/16/2020.

Class II Drugs Event

Event ID:
84696

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/11/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/20/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
RemedyRepack Inc.
625 Kolter Dr Ste 4
Indiana PA United States

Distribution Pattern:
Product was distributed to two facilities in CA and NY.

Associated Products

Product Description:
Ranitidine 150 mg tablet Original Supplier's NDC 65162-0253-10 Remedy Repackaged NDC 70518-1714-00

Product Quantity:
4,486 tablets

Reason for Recall:
CGMP Deviation; Received notice from supplier of potential -Nitrosodimethylamine (NDMA) amounts above established levels.

Recall Number:
D-0798-2020

Code Information:
Lot #: J0376034-052319, exp. date 05/2020 Lot #: J0406133-093019, exp. date 10/2020 Lot #: J038005-082719, exp. date 08/2020 Lot #: J0390280-072519, exp. date 07/2020 Lot #: J0390277-072519, exp. date 07/2020 Lot #: J0349352-012519, exp. date 01/2020

Class III Drugs Event

Event ID:
84676

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/14/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/23/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Hikma Pharmaceuticals USA Inc.
2 Esterbrook Ln
Cherry Hill NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
methylPREDNISolone Sodium Succinate For Injection, USP, 500 mg*/vial, Rx Only, Mfd by: HIKMA FARMACEUTICA (PORTUGAL), SA; Dist by: WEST-WARD, Eatontown, NJ 07724, NDC 0143-9850-01.

Product Quantity:
4840 vials

Reason for Recall:
Labeling: Incorrect Instructions: Vial label incorrectly instructs healthcare professional to reconstitute product with 16 mL rather than the correct volume of 8 mL of Bacteriostatic Water for Injection with Benzyl Alcohol.

Recall Number:
D-0801-2020

Code Information:
Lot #: 1901113.1, Exp JUL 2021