Enforcement Report - Week of March 25, 2020

Class I Drugs Event

Event ID:
84265

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
11/08/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/19/2020

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Med Man Distribution, Inc.
433 Pickerel River Rd
Pickerel Canada

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
UP2, Dietary Supplement, All Natural Libido for Men & Women, a) one pack, b) four pack, c) ten pack capsules per carton, Exclusively Manufactured and Formulated by: Buy Wise Marketing, 4234 I-75 Business Spur, Sault Ste Marie, MI 49783, Ultimatepleasure2.com.

Product Quantity:
1,680 cartons

Reason for Recall:
Marketed without an Approved NDA/ANDA: Product contains undeclared sildenafil which was discovered through FDA analysis.

Recall Number:
D-1036-2020

Code Information:
030419

Product Description:
Bow & Arrow, Dietary Supplement, Libido Enhancer for Men, a) Four pack, b) Ten pack capsules per carton, Exclusively Manufactured by: Medicine Man Distribution, 4234 I-75 Business Spur, Sault Ste Marie, MI 49783

Product Quantity:
1880 cartons

Reason for Recall:
Marketed without an Approved NDA/ANDA: Product contains undeclared sildenafil which was discovered through FDA analysis.

Recall Number:
D-1037-2020

Code Information:
0217

Class II Drugs Event

Event ID:
83645

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/05/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/16/2020

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
PA

Associated Products

Product Description:
Lisinopril/HCTZ 20mg/12.5mg Tablet, QTY: 30 tablets per blister card, MFG: Lupin Pharma Baltimore, MD 21202, NDC 68180-0519-02 (Original NDC of 500 count bottle); 70518-0382-03 (Repackaged NDC for blister cards).

Product Quantity:
480 tablets

Reason for Recall:
Presence of Foreign Tablets/Capsules: This is a spin-off recall of D-1581-2019 due to a product complaint where one of Lupin's Fenofibrate 145mg was observed in the 500 s count product bottle.

Recall Number:
D-1030-2020

Code Information:
Lot #: J0322819-091418, Exp: 09/30/2019

Class II Drugs Event

Event ID:
84127

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/23/2019

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/13/2020

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Perrigo Company PLC
515 Eastern Ave
Allegan MI United States

Distribution Pattern:
Nationwide USA

Associated Products

Product Description:
Regular Strength Acid Reducer, Ranitidine tablets, USP 75 mg, 30 tablets per bottle. [NDC: Brand] NDC CVS Health: 69842-293-65; NDC Equaline 41163-931-65; NDC Family Wellness: 55319-876-65; NDC Good Sense 0113-0876-65; NDC H.E.B.: 37808-876-65; NDC Harris Teeter: 69256-876-65; NDC Health Mart: 62011-0283-1; NDC Leader: 62011-0283-1; NDC Major: 0904-6715-46; NDC Signature Care: 21130-118-65; NDC Sunmark: 49348-136-44; NDC Up & Up: 11673-876-65; NDC Walgreens: 0363-1876-65

Product Quantity:

Reason for Recall:
CGMP Deviation; Possible contamination with impurity N-nitrosodimethylamine.

Recall Number:
D-1012-2020

Code Information:
Lots: 8DE1363, 8EE1558, 8FE1450, 8GE1331, 8HE1221, 8KE2825, 8JE1916, 8KE2243, 8ME2685, 9AE2785, 9AE2786, 9DE2721, 9CE3317, 9EE2579, 9FE2957, 9GE2785, 9GE3218, 9HE3577

Product Description:
Regular Strength Acid Reducer, Ranitidine tablets, USP 75 mg, 60 tablets per bottle. [NDC: Brand] NDC Health Mart: 62011-0283-2; NDC Major: 0904-6715-52; NDC Meijer: 41250-252-72; NDC Sunmark: 49348-136-12;

Product Quantity:

Reason for Recall:
CGMP Deviation; Possible contamination with impurity N-nitrosodimethylamine.

Recall Number:
D-1013-2020

Code Information:
Lots: 8DE1367, 8EE1559, 8FE1451, 8GE1340, 8HE1222, 8KE2831, 8JE1917, 8KE2245 , 8ME2724, 9AE2831, 9DE2747, 9CE3339, 9EE2636, 9FE2971, 9GE2793, 9GE3220

Product Description:
Regular Strength Acid Reducer, Ranitidine tablets, USP 75 mg, 80 tablets per bottle. [NDC: Brand] NDC Basic Care: 0113-7876-27; NDC CVS Health: 69842-293-27; NDC Leader: 70000-0375-2; NDC Up & Up: 11673-876-27; NDC Walgreens: 0363-1876-27

Product Quantity:

Reason for Recall:
CGMP Deviation; Possible contamination with impurity N-nitrosodimethylamine.

Recall Number:
D-1014-2020

Code Information:
Lots: 8CE1643, 8DE1370, 8DE1768, 8EE1560, 8FE1452, 8GE1341, 8HE1223, 8KE2832, 8KE2246, 8ME2725, 9AE2835, 9CE3378, 9DE2748, 9EE2637, 9FE2976, 9GE2795, 9GE3228, 9HE3617

Product Description:
Regular Strength Acid Reducer, Ranitidine tablets, USP 75 mg, 150 tablets per bottle. [NDC: Brand] NDC H.E.B.: 37808-876-47; NDC Equate: 49035-876-47

Product Quantity:

Reason for Recall:
CGMP Deviation; Possible contamination with impurity N-nitrosodimethylamine.

Recall Number:
D-1015-2020

Code Information:
Lots: 8CE1644, 8CE1645, 8DE1401, 8DE1402, 8DE1403, 8DE1769, 8DE1773, 8EE1561, 8EE1562, 8FE1453, 8FE1454, 8GE1342, 8HE1224, 8KE2248, 8KE2833, 8JE1918, 8KE2247, 8ME2727, 8ME2729, 9DE2750, 9AE2836, 9AE2837, 9CE3403, 9CE3404, 9DE2749, 9EE2638, 9FE2977, 9GE2796, 9GE3229

Product Description:
Regular Strength Acid Reducer, Ranitidine tablets, USP 75 mg, 160 tablets per bottle. [NDC: Brand] NDC CVS Health.: 69842-293-06

Product Quantity:

Reason for Recall:
CGMP Deviation; Possible contamination with impurity N-nitrosodimethylamine.

Recall Number:
D-1016-2020

Code Information:
Lots: 8FE1455, 8GE1343, 8HE1225, 8KE2834, 8KE2249, 8ME2730, 9AE2838, 9EE2639, 9FE2993

Product Description:
Maximum Strength Acid Reducer, Ranitidine tablets, USP 150 mg, 8 tablets. [NDC: Brand] NDC Good Sense:0113-0852-51; NDC Walgreens 0363-0852-51

Product Quantity:

Reason for Recall:
CGMP Deviation; Possible contamination with impurity N-nitrosodimethylamine.

Recall Number:
D-1017-2020

Code Information:
Lots: 8CE1429, 8CE1760, 9BE2907, 9DE3183, 9EE2900, 9JE2936

Product Description:
Maximum Strength Acid Reducer, Ranitidine tablets, USP 150 mg, 24 tablets per bottle. [Brand, NDC] NDC Being Well: 46994-852-62; NDC Care One 41520-392-02; NDC CVS Health: 59779-540-02; NDC DG Health: 55910-852-02; NDC Equaline: 41163-852-62; NDC Equate: 49035-608-02; NDC Exchange Select: 55301-852-02; NDC Family Wellness: 55319-852-02; NDC Good Neighbor Pharmacy: 46122-224-62; NDC Good Sense 0113-0852-62; NDC Harris Teeter: 69256-041-62; NDC Health Mart 49348-109-04; NDC Kroger 30142-600-02; NDC Major 0904-6716-24; NDC Meijer: 41250-852-02; NDC Publix: 56062-099-02; NDC Rite Aid 11822-0852-5; NDC Select 7: 10202-852-62; NDC Shop Rite 41190-852-62; NDC Shopko: 37012-852-62; NDC Signature Care: 21130-116-02; NDC Sound Body: 50594-852-02; NDC Sunmark: 62011-0282-1; NDC Topcare: 36800-852-02; NDC Up & Up: 11673-023-02; NDC Walgreens: 0363-0852-62

Product Quantity:

Reason for Recall:
CGMP Deviation; Possible contamination with impurity N-nitrosodimethylamine.

Recall Number:
D-1018-2020

Code Information:
Lots: 8EE1452R, 8AE1743, 8BE1340, 8CE1549, 8CE1778, 8DE1128, 8DE1313, 8DE1640, 8EE1117, 8EE1234, 8EE1452, 8CE1314, 8CE1315, 8DE1096, 8DE1530, 8EE1699, 8GE1528, 8HE1465, 8JE2199, 8LE2172, 8DE1721, 8EE1299, 8FE1634, 8GE1833, 8GE1835, 8HE1337, 8LE2173, 8LE2380, 9BE2888, 8JE2162, 8KE2495, 8KE2496, 8LE2169, 9BE2772, 9BE2889, 9CE3771, 9DE2854, 8LE2288, 8LE2592, 8LE2593, 8ME3124, 8ME3125, 9BE2773, 9BE2774, 9DE3234, 9EE2603, 9EE2903, 9FE2952, 9CE3689, 9CE3690, 9EV1891, 9FV1152, 9DE2868, 9DE2869, 9EE2760, 9FV1153, 9EE2779, 9GE2879, 9HE3558, 9JE2591, 9FE3109, 9FE3110, 9GE2869, 9HE3433, 9JE2541

Product Description:
Maximum Strength Acid Reducer, Cool Mint Ranitidine tablets, USP 150 mg, 24 tablets per bottle. [Brand, NDC] NDC Care One: 41520-609-62; NDC CVS Health: 59779-950-62; NDC DG Health: 55910-423-62; NDC Equaline: 41163-950-62; NDC Family Wellness: 55319-523-62; NDC Good Neighbor Pharmacy: 46122-041-62; NDC HEB: 37808-710-02; NDC Kroger: 30142-891-02; NDC Leader: 70000-0378-1; NDC Meijer: 41250-950-02; NDC Rite Aid: 11822-0950-0; NDC Shopko: 37012-950-62; NDC Signature Care: 21130-568-62; NDC Topcare: 36800-950-62; NDC Walgreens: 0363-0950-02

Product Quantity:

Reason for Recall:
CGMP Deviation; Possible contamination with impurity N-nitrosodimethylamine.

Recall Number:
D-1019-2020

Code Information:
Lots: 8FV1462, 8GV1289, 8BE1465, 8CE1616, 8DE1277, 8DE1580, 8DE1766, 8FE1348, 8GE1527, 8GE1733, 8GE1735, 8HE1466, 8HE1590, 8JE2232, 8KE2676, 8LE2283, 8LE2284, 8LE2345, 8ME2640, 9AE2663, 9AE2863, 9AE2864, 9BE3158, 9CE3773, 9CE3774, 9CE3879, 9EE2499, 9EE2635, 9EE2904, 9FE2821, 9FE2953, 9FE3369, 9GE2653, 9GE2905, 9GE3077, 9GE3115, 9HE3546, 9HE3559, 9JE2593

Product Description:
Maximum Strength Acid Reducer, Cool Mint Ranitidine tablets, USP 150 mg, 40 tablets per bottle. [Brand, NDC] NDC Up & Up: 11673-950-58

Product Quantity:

Reason for Recall:
CGMP Deviation; Possible contamination with impurity N-nitrosodimethylamine.

Recall Number:
D-1020-2020

Code Information:
Lots: 9BE3161, 9CE3880, 9EE2500, 9FE2823, 9GE2656, 9HE3554, 9JE2676

Product Description:
Maximum Strength Acid Reducer, Ranitidine tablets, USP 150 mg, 50 tablets per bottle. [Brand, NDC] NDC DG Health: 55910-852-71; NDC Good Neighbor Pharmacy: 46122-224-71; NDC Good Sense: 0113-0852-71; NDC Harris Teeter: 69256-041-71; NDC Kroger: 30142-600-71; NDC Major: 0904-6716-51; NDC Meijer: 41250-852-71; NDC Publix: 56062-099-71; NDC Rite Aid: 11822-0852-2; NDC Signature Care: 21130-116-71; NDC Topcare: 36800-852-71

Product Quantity:

Reason for Recall:
CGMP Deviation; Possible contamination with impurity N-nitrosodimethylamine.

Recall Number:
D-1021-2020

Code Information:
Lots: 8AE1744, 8BE1369, 8CE1377, 8CE1378, 8DE1103, 8DE1531, 8EE1700, 8FV0829, 8DE1722, 8EE1317, 8FE1635, 8GE1921, 8HE1342, 8KE2503R, 8JE2154, 8KE2503, 8LE2198, 8LE2597, 9AE2499, 9BE2862, 9BE2863, 9CE3723, 9DE2890, 9DE2891, 9EE2812, 9FE3187, 9GE2885, 9HE3435, 9JE2656

Product Description:
Maximum Strength Acid Reducer, Ranitidine tablets, USP 150 mg, 65 tablets per bottle. [Brand, NDC] NDC Care One: 41520-392-09; NDC CVS Health: 59779-540-09; NDC Family Wellness: 55319-852-09; NDC Good Neighbor Pharmacy: 46122-532-09; NDC HEB: 37808-507-09; NDC Health Mart: 49348-109-54; NDC Meijer: 41250-891-09; NDC Rite Aid: 11822-0852-3; NDC Shopko: 37012-852-09; NDC Sound Body: 50594-852-09; NDC Sunmark: 49348-109-54; NDC Up & Up: 11673-852-09; NDC Walgreens: 0363-0852-09

Product Quantity:

Reason for Recall:
CGMP Deviation; Possible contamination with impurity N-nitrosodimethylamine.

Recall Number:
D-1022-2020

Code Information:
Lots: 8AE1752, 8BE1412, 8CE1437, 8CE1439, 8DE1141, 8DE1737, 8EE1318, 8FE1690, 8GE1928, 8HE1395, 8JE2155, 8KE2516, 8LE2253, 8LE2624, 9AE2522, 9BE2933, 9BE2934, 9CE3734, 9DE3070, 9EE2830, 9FE3266, 9GE2934

Product Description:
Maximum Strength Acid Reducer, Cool Mint Ranitidine tablets, USP 150 mg, 65 tablets per bottle. [Brand, NDC] NDC Basic Care: 0113-7950-09; NDC CVS Health: 59779-950-09; NDC Equate: 49035-800-09; NDC Good Neighbor Pharmacy: 46122-533-09; NDC Kroger: 30142-891-09; NDC Topcare: 36800-950-09; NDC Up & Up: 11673-950-09; NDC Walgreens: 0363-0950-09

Product Quantity:

Reason for Recall:
CGMP Deviation; Possible contamination with impurity N-nitrosodimethylamine.

Recall Number:
D-1023-2020

Code Information:
Lots: 8AE1884, 8BE1466, 8DE1318, 8CE1617, 8DE1319, 8EE1326, 8DE1611, 8DE1767, 8FE1350, 8FE1352, 8GE1736, 8GE1840, 8GE1859, 8HE1592, 8HE1593, 8HE1594, 8JE2234, 9CE3263, 8JE2233, 8LE2360, 8KE2704, 8ME2641, 8ME2642, 9AE2675, 9AE2676, 9CE3265, 9CE3881, 9DE2585, 9EE2501, 9EE2502, 9FE2825, 9FE2827, 9GE2657, 9GE3124, 9GE3122, 9HE3555

Product Description:
Maximum Strength Acid Reducer, Ranitidine tablets, USP 150 mg, 90 tablets per bottle. [Brand, NDC] NDC Equate: 49035-608-75; NDC Up & Up: 11673-023-75

Product Quantity:

Reason for Recall:
CGMP Deviation; Possible contamination with impurity N-nitrosodimethylamine.

Recall Number:
D-1024-2020

Code Information:
Lots: 8EE1702, 8EE1703, 8EE1704, 8FE1724, 8GE1942, 8HE1396, 8HE1397, 8JE2156, 8KE2521, 8KE2523, 8LE2255, 8LE2665, 8LE2668, 9AE2541, 9AE2542, 9AE2543, 9BE2993, 9BE2994, 9BE2995, 9CE3735, 9CE3736, 9DE3108, 9DE3109, 9DE3110, 9EE2872, 9EE2880, 9FE3273, 9FE3276, 9GE2978, 9GE2979, 9HE3437, 9HE3438

Product Description:
Maximum Strength Acid Reducer, Cool Mint Ranitidine tablets, USP 150 mg, 90 tablets per bottle. [Brand, NDC] NDC Equate: 49035-800-75; NDC Up & Up: 11673-950-75

Product Quantity:

Reason for Recall:
CGMP Deviation; Possible contamination with impurity N-nitrosodimethylamine.

Recall Number:
D-1025-2020

Code Information:
Lots:8EE1514, 8EE1515, 8FE1353, 8GE1732, 8GE1864, 8HE1652, 8HE1653, 8JE2235, 8KE2724, 8KE2725, 8LE2367, 8ME2643, 8ME2644, 9AE2766, 9AE2767, 9CE3273, 9CE3274, 9DE2629, 9DE2630, 9EE2516, 9EE2517, 9FE2915, 9FE2916, 9GE2694, 9GE3144

Product Description:
Maximum Strength Acid Reducer, Ranitidine tablets, USP 150 mg, 95 tablets per bottle. [Brand, NDC] NDC Basic Care: 0113-7852-01; NDC Berkley Jensen: 68391-852-56; NDC: CVS Health: 59779-540-01; NDC DG Health: 55910-011-01; NDC Kirkland: 63981-852-56; NDC Kroger: 30142-600-56; NDC Meijer: 41250-852-01; NDC Rite Aid: 11822-0852-4; NDC Walgreens: 0363-0852-01

Product Quantity:

Reason for Recall:
CGMP Deviation; Possible contamination with impurity N-nitrosodimethylamine.

Recall Number:
D-1026-2020

Code Information:
Lots:8CE1446, 8DE1740, 8FE1238, 8FE1794, 8GE1964, 8JE2159, 8ME2546, 8ME2547, 9BE3011, 9CE3854, 9DE3158, 9FE3340, 9HE3445, 9JE2663, 8AE1779, 8BE1414, 8DE1199, 8DE1200, 8DE1532, 8EE1321, 8FE1239, 8FE1346, 8FE1793, 8HE1516, 8KE2563, 8KE2563R, 8LE2260, 9AE2610, 9AE2612, 9BE3012, 9BE3013, 9CE3852, 9DE3156R, 9DE3160, 9DE3161, 9EE2952, 9FE3338, 9GE2993, 8AV1095, 8AV1150, 8AV1235, 8AV1236, 8AV1237, 8BV0896, 8BV0897, 8BV0910, 8BV1737, 8BV1757, 8BV1758, 8CV0930, 8CV1316, 8CV1317, 8CV1319, 8CV1324, 8CV1633, 8DV1128, 8DV1129, 8DV1134, 8EV0993, 8EV0994, 8EV0995, 8EV1240, 8FV0712, 8FV0912, 8FV0913, 8FV0914, 8FV0915, 8GV0847, 8GV0849, 8GV0997, 8HV0926, 8HV0928, 8HV1534, 8HV1535, 8JV0730, 8JV0944, 8KV2339, 8KV2348, 8KV2485, 8LV1791, 8LV2205, 8MV1650, 8MV1712, 9AV2395, 9AV2679, 9AV2680, 9BV2182, 9CV1345, 9CV1346, 9CV1347, 9CV1348, 9CV1349, 9DV1511, 9DV1515, 9EV1422, 9EV1585, 9EV1596, 9FV1132, 9FV1275R, 9FV1330, 9FV1331, 9FV1332, 9FV1333, 9FV1339, 9FV1954, 9FV1972, 9GV1675, 9GV1994, 9HV1415

Product Description:
Maximum Strength Acid Reducer, Cool Mint Ranitidine tablets, USP 150 mg, 95 tablets per bottle. [Brand, NDC] NDC Basic Care: 0113-7950-01; NDC CVS Health: 59779-950-01

Product Quantity:

Reason for Recall:
CGMP Deviation; Possible contamination with impurity N-nitrosodimethylamine.

Recall Number:
D-1027-2020

Code Information:
Lots: 8BE1032, 8BE1486, 8CE1638, 8DE1361, 8DE1612, 8FE1354, 8GE1737, 8HE1654, 8JE2237, 8KE2726, 8LE2369, 8ME2645, 9AE2777, 9CE3315, 9DE2720, 9EE2578, 9FE2956, 9GE2698, 9GE3202

Product Description:
Maximum Strength Acid Reducer, Ranitidine tablets, USP 150 mg, 200 tablets per bottle. [Brand, NDC] NDC Basic Care: 0113-7852-82; NDC CVS Health: 59779-540-82; NDC HEB: 37808-507-82; NDC Signature Care: 21130-116-82; NDC Walgreens: 0363-0852-82

Product Quantity:

Reason for Recall:
CGMP Deviation; Possible contamination with impurity N-nitrosodimethylamine.

Recall Number:
D-1028-2020

Code Information:
Lots: 8AE1291, 8AE1785, 8BE1415, 8CE1525, 8DE1201, 8DE1741, 8EE1323, 8FE1806, 8GE1965, 8HE1517, 8JE2161, 8KE2565, 8LE2261, 8ME2548, 9AE2658, 9BE3018, 9CE3861, 9DE3244, 9FE2820, 9FE3373, 9GE3094, 9HE3449, 9JE2665

Class II Drugs Event

Event ID:
85128

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/02/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/19/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Noven Therapeutics, LLC
11960 Sw 144th St
Miami FL United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Daytrana (methylphenidate transdermal system) patches, Delivers 10 mg over 9 hours (1.1 mg/hr), 30-count box, Rx only, Manufactured for Noven Therapeutics, LLC. Miami, FL 33186, NDC 68968-5552-3

Product Quantity:
9513 boxes

Reason for Recall:
Defective Delivery System: Out of specification for mechanical peel and shear.

Recall Number:
D-1042-2020

Code Information:
Lot#: 86280, Exp 06/2020

Product Description:
Daytrana (methylphenidate transdermal system) patches, Delivers 15 mg over 9 hours (1.6 mg/hr), 30-count box, Rx only, Manufactured for Noven Therapeutics, LLC. Miami, FL 33186, NDC 68968-5553-3

Product Quantity:
13761 boxes

Reason for Recall:
Defective Delivery System: Out of specification for mechanical peel and shear.

Recall Number:
D-1043-2020

Code Information:
Lot#: 85942, Exp 03/2020; 86281, Exp 06/2020

Product Description:
Daytrana (methylphenidate transdermal system) patches, Delivers 20 mg over 9 hours (2.2 mg/hr), 30-count box, Rx only, Manufactured for Noven Therapeutics, LLC. Miami, FL 33186, NDC 68968-5554-3

Product Quantity:
11093 boxes

Reason for Recall:
Defective Delivery System: Out of specification for mechanical peel and shear.

Recall Number:
D-1044-2020

Code Information:
Lo#t: 86081, Exp 04/2020; 86196, Exp 06/2020

Product Description:
Daytrana (methylphenidate transdermal system) patches, Delivers 30 mg over 9 hours (3.3 mg/hr), 30-count box, Rx only, Manufactured for Noven Therapeutics, LLC. Miami, FL 33186, NDC 68968-5555-3

Product Quantity:
7469 boxes

Reason for Recall:
Defective Delivery System: Out of specification for mechanical peel and shear.

Recall Number:
D-1045-2020

Code Information:
Lot#: 86083, Exp 05/2020; 86282, Exp 06/2020

Class II Drugs Event

Event ID:
85152

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/09/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/18/2020

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Sotalol HCL Tablets, USP (AF) 80 mg, 100 count bottles, Rx Only, Mylan Pharmaceuticals Inc. Morgantown, WV 26505 USA. NDC 00378-5123-01

Product Quantity:
300 100-count bottles

Reason for Recall:
Presence of particulate matter. presence of metal particles.

Recall Number:
D-1031-2020

Code Information:
Lot # 3095754, exp. date 02/2021

Class II Drugs Event

Event ID:
85181

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/11/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/24/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Jubilant Cadista Pharmaceuticals, Inc.
207 Kiley Dr
Salisbury MD United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Pantoprazole Sodium Delayed-Release Tablets, USP, 40 mg, 90 count bottle, Rx Only, Manufactured by Jubilant Generics Ltd, Roorkee-247661 India, NDC 59746-284-90

Product Quantity:
89,376 90-count bottles

Reason for Recall:
CGMP Deviations: Presence of dark brown discoloration on edges of tablets

Recall Number:
D-1058-2020

Code Information:
Lot # PA218005A, exp. date 12/2020, PA218P010, PA218P011, exp. date 04/2021, PA218108A, PA218110A, exp. date 06/2021

Class II Drugs Event

Event ID:
85184

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/09/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/19/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Sun Pharmaceutical Industries, Inc.
270 Prospect Plains Rd
Cranbury NJ United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Atorvastatin Calcium Tablets, USP 40 mg, Rx only, 500-count bottle, Manufactured by: Sun Pharmaceutical Industries Limited Mohali, INDIA, Distributed by: Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, NDC 63304-829-05

Product Quantity:
1416 bottles

Reason for Recall:
Presence of foreign substance: Foreign matter has been identified as latex glove in one lot of Atorvastatin Calcium Tablets USP 40 mg.

Recall Number:
D-1047-2020

Code Information:
Lot#: AA33617, Exp 03/2021

Class II Drugs Event

Event ID:
85186

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/24/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/23/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Breckenridge Pharmaceutical, Inc
15 Massirio Dr Ste 201
Berlin CT United States

Distribution Pattern:
Product was distributed nationwide within the United States.

Associated Products

Product Description:
Solifenacin Succinate Tablets, 5mg, packaged in a) 30-count bottles (NDC 51991-893-33) and b) 90-count bottles (NDC 51991-893-90) Distributed by: Breckenridge Pharmaceutical, Inc. Boca Raton, FL 33487; Manufactured by: Piramal Enterprises Limited Plot No 67-70, Sector -2 Pithampur 454 775, Dist, Dhar Madhya Pradesh, INDIA

Product Quantity:
11,250 bottles

Reason for Recall:
CGMP Deviations: During manufacturing Solifenacin Succinate Tablets might convert to Solifenacin Tartrate Tablets.

Recall Number:
D-1050-2020

Code Information:
Lot #: a) 81244, 81217, Exp. Date 01/2021 and b) 81245, Exp. Date 01/2021

Product Description:
Solifenacin Succinate Tablets, 10 mg, packaged in a) 30-count bottles (NDC 51991-894-33) and b) 90-count bottles (NDC 51991-894-90), Distributed by: Breckenridge Pharmaceutical, Inc. Boca Raton, FL 33487; Manufactured by: Piramal Enterprises Limited Plot No 67-70, Sector -2 Pithampur 454 775, Dist, Dhar Madhya Pradesh, INDIA

Product Quantity:
11, 250 bottles

Reason for Recall:
CGMP Deviations: During manufacturing Solifenacin Succinate Tablets might convert to Solifenacin Tartrate Tablets.

Recall Number:
D-1051-2020

Code Information:
Lot #: a) 81253, 81272, Exp. Date 01/2021 and b) 81268, Exp. Date 01/2021

Class II Drugs Event

Event ID:
85230

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/13/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/18/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Sun Pharmaceutical Industries, Inc.
270 Prospect Plains Rd
Cranbury NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Doxycycline Capsules, USP, 75 mg, 100-count bottle, Rx only, Manufactured by: Ohm Laboratories Inc., New Brunswick, NJ 08901; Distributed by Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512; NDC 63304-615-01.

Product Quantity:
624 bottles

Reason for Recall:
CGMP Deviations: Doxycycline capsules were not manufactured under Current Good Manufacturing Practice conditions.

Recall Number:
D-1032-2020

Code Information:
Lot #: AA39490, Exp 03/2021

Product Description:
Doxycycline Capsules, USP, 100 mg, 50-count bottle, Rx only, Manufactured by: Ohm Laboratories Inc., New Brunswick, NJ 08901; Distributed by Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512; NDC 63304-616-50.

Product Quantity:
172,320 bottles

Reason for Recall:
CGMP Deviations: Doxycycline capsules were not manufactured under Current Good Manufacturing Practice conditions.

Recall Number:
D-1033-2020

Code Information:
Lot #: 3983720, Exp 10/2020; 3990461, 3990464, 3990465, 3990466, 3990470, Exp 11/2020; AA42499, AA42510, AA44468, AA44470, Exp 04/2021; AA55073, AA55074, AA55075, Exp 05/2021; AA61486, Exp 06/2021

Class III Drugs Event

Event ID:
84968

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/17/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/13/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Strides Pharma Science Limited
Krs Gardens, No.36/7 Suragajakkanahalli Indlawadi Cross, Anekal Taluk
Bangalore India

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
Potassium Chloride Extended-Release Tablets USP, 10mEq (750mg), 1000-count bottle, Rx only, Manufactured by: Strides Shasun Limited Bengaluru - 562106, India, Distributed by: Strides Pharma Inc., East Brunswick, NJ 08816, NDC 64380-861-08

Product Quantity:
2576 bottles

Reason for Recall:
Failed Tablet/Capsules Specifications: Oversized tablets were found in one lot of Potassium Chloride Tablets 750 mg.

Recall Number:
D-1029-2020

Code Information:
Lot #: 7238958A, 7238257A, Exp 7/31/2021; 7239404A, Exp 9/30/2021

Class III Drugs Event

Event ID:
85136

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/04/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/18/2020

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Par Pharmaceutical Inc.
1 Ram Ridge Rd
Chestnut Ridge NY United States

Distribution Pattern:
U.S.A. Nationwide

Associated Products

Product Description:
PrediniSONE Tablets, USP 5 mg, 48-count bottle, Rx only, Distributed by: Par Pharmaceutical Chestnut Ridge, NY 10977, NDC 0603-5337-31

Product Quantity:
13008 bottles

Reason for Recall:
Labeling: Incorrect or Missing Exp Date - An incorrect expiration date has been identified on Prednisone Tablets USP 5 mg

Recall Number:
D-1035-2020

Code Information:
Lot #: 8672518, Exp 12/21

Not Yet Classified Drugs Event

Event ID:
85228

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/05/2020

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Fresenius Medical Care Holdings, Inc.
920 Winter St Bld 950
Waltham MA United States

Distribution Pattern:
Product was distributed throughout the United States.

Associated Products

Product Description:
Sodium Chloride 0.9% Injection, USP, 1000 mL bags, Rx only, Manufactured by: Fresenius Medical Care North America, Waltham, MA 02451

Product Quantity:
32,592 bags

Reason for Recall:
CGMP Deviation: Chemical indicators were not positioned properly during sterilization process.

Recall Number:

Code Information:
Lot #: 19EG02012, 19EG02019, Exp. Date 05/2020; 19DG02050, Exp. Date 04/2020