Enforcement Report - Week of September 29, 2021

Class I Drugs Event

Event ID:
88530

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/18/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/21/2021

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Phe Inc
302 Meadowlands Dr
Hillsborough NC United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
X RATED HONEY FOR MEN, packaged in 15g packets, 4 packets per box, UPC 6 13682 41232 2

Product Quantity:
15000 packets

Reason for Recall:
Marketed without an approved NDA/ANDA: Product found to be tainted with Tadalafil.

Recall Number:
D-0819-2021

Code Information:
All lots, Exp. 12/2025

Class I Drugs Event

Event ID:
88617

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/27/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/23/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
DuPont Nutrition USA, Inc
1301 Ogletown Rd
Newark DE United States

Distribution Pattern:
Product was distributed to one account that may have used it as a component in finished drug formulations, and further distributed Nationwide in the USA.

Associated Products

Product Description:
Avicel RC-591 NF (MCC/Carboxymethylcellulose Sodium) NF, bulk powder, 80.0 KG drum, Manufactured by: DuPont Nutrition USA, Inc., 1301 Ogletown Road, Newark, DE 19711

Product Quantity:
80 kg

Reason for Recall:
Microbial Contamination of Non-Sterile Product: Out-of-specification results obtained for total aerobic microbial count (TAMC).

Recall Number:
D-0830-2021

Code Information:
Lot # 2173766940

Class II Drugs Event

Event ID:
88497

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/13/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/17/2021

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Pfizer Inc.
235 East 42nd Street
New York NY United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Chantix (varenicline) tablets 0.5mg/1mg, 56 Tablets, Rx only, Distributed by Pfizer Labs, Division of Pfizer Inc. NY, NY 10017, Made in Ireland, NDC 00069-0471-03. carton containing one blister pack of 11 0.5 mg tablets and one blister pack containing 42.1 mg tablets.

Product Quantity:

Reason for Recall:
CGMP Deviations: Presence of the N-nitroso-varenicline impurity above FDA s acceptable interim acceptable intake limit

Recall Number:
D-0808-2021

Code Information:
Lots 00018522, 00018523, 00018739, 00018740, 00020231, 00020232, 00020357, 00020358, 00020716, 00020813, 00021288, 00021289, 00021420, 00021687, 00021688, 00021788, 00021789, 00021790, 00021791, 00021792, 00022819, 00022851, 00023136, 00023137, 00023190, 00023448, DM0275, DM0276, DM0277, DY4470, EC5911, EC5912, ED6814, ET1600, ET1603, ET1607, ET1609, ET1611 EXPIRATION DATE: August 2021 January 2023

Product Description:
Chantix (varenicline) tablets 0.5mg, 56 Tablets, Rx only, Distributed by Pfizer Labs, Division of Pfizer Inc. NY, NY 10017, Made in Ireland, NDC 0069-0468-56.

Product Quantity:

Reason for Recall:
CGMP Deviations: Presence of the N-nitroso-varenicline impurity above FDA s acceptable interim acceptable intake limit

Recall Number:
D-0809-2021

Code Information:
Lots , CY6861, DM9007, DM9008, EN5725, EN8362, EN8467 EXPIRATION DATE: January 2022 - May 2023

Product Description:
Chantix (varenicline) tablets 1 mg, 56 Tablets, Rx only, Distributed by Pfizer Labs, Division of Pfizer Inc. NY, NY 10017, Made in Ireland, NDC 0069-0469-56.

Product Quantity:

Reason for Recall:
CGMP Deviations: Presence of the N-nitroso-varenicline impurity above FDA s acceptable interim acceptable intake limit

Recall Number:
D-0810-2021

Code Information:
Lots 00018777, 00019289, 00019593, 00019682, 00019846, 00019977, 00020295, 00020448, 00020458, 00020480, 00021024, 00021073, 00021074, CW1565, CW1566, CW1567, CW1568, CW1569, CW1570, CW1571, CW1572, CW1573, CW1574, CW1575, CW1578, CW1579, CW1581, DF5277, DF5278, DF5279, DF5280, DF5281, DF5282, DR5086, DR5092, DR5093, DR5094, DT3885, DW4148, DW4152, DY7987, EC9841, EC9842, EC9847, EC9848, EE1011, EM1069, EM1070, EN5694, EN5695, EP1717, EP1718, EP1719, EW2012, EW3854, EW3865, EX2102, EX2103 EXPIRATION DATE: September 2021 December 2023

Product Description:
Chantix (varenicline) tablets 1 mg, Carton containing 4 blister packs of 14 tablets each,, Rx only, Distributed by Pfizer Labs, Division of Pfizer Inc. NY, NY 10017, Made in Ireland, NDC 0069-0469-03. EXPIRATION DATE: September 2021 June 2023

Product Quantity:

Reason for Recall:
CGMP Deviations: Presence of the N-nitroso-varenicline impurity above FDA s acceptable interim acceptable intake limit

Recall Number:
D-0811-2021

Code Information:
Lots 00019431, 00019542, 00019543, 00019544, 00020814, 00020815, 00020907, 00020965, 00021421, 00021422, 00021423, 00022136, 00022174, 00022175, 00022176, 00022177, 00022765, 00022766, 00023134, 00023135, 00023747, 00023748, DL3896, DL7779, DR2614, DX4576, DX5870, DX5871, DX5872, DX5873, DX7805, DY6078, DY7060, DY9367, DY9473, DY9475, DY9476, DY9505, EC5910, EC5913, EE9391, EF2346, EM4805, EM4807, EN2005, ET1601, ET1605, ET1606 EXPIRATION DATE: September 2021 December 2023

Class II Drugs Event

Event ID:
88539

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/26/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/23/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AVRIO HEALTH L.P
201 Tresser Blvd
Stamford CT United States

Distribution Pattern:
Product was distributed nationwide.

Associated Products

Product Description:
Betadine Solution Swabstick Povidone-Iodine Solution USP, 10 % single and three count Antispetic Non-Sterile Solution Avrio Health LP Stamford, CT 06901-3431 NDC 67618-153-01, NDC 67618-153-03

Product Quantity:
75,828 shippers

Reason for Recall:
Subpotent Drug

Recall Number:
D-0828-2021

Code Information:
Lot # 11901232, Exp. Date 09/30/2021 11901549, Exp. Date 11/30/2021 12000585, Exp. Date 03/31/2022 12000964, Exp. Date 5/31/2022 12001457, Exp. Date 7/31/2022 12002142, Exp. Date 12/31/2022 12100407, Exp. Date 03/31/2023 11901231, Exp. Date 09/30/2021 11901548, Exp. Date 11/30/2021 12000584, Exp. Date 03/31/2022 12000963, Exp. Date 05/31/2022 12001185, Exp. Date 06/30/2022 12001456, Exp. Date 07/31/2022 12002150, Exp. Date 12/31/2022 12100406, Exp. Date 03/31/2023

Class II Drugs Event

Event ID:
88583

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/06/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/17/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
The Harvard Drug Group
17187 N Laurel Park Dr Ste 300
Livonia MI United States

Distribution Pattern:
NC

Associated Products

Product Description:
Carbamazepine 200mg Tablets, USP, 200 mg, 100 Count Unit Dose Cartons, Rx only, Manufactured by: Torrent Pharmaceuticals Ltd., Bharuch-392130, India; Manufactured for: Torrent Pharma, Inc., Basking Ridge, NJ 07920; Distributed by: MAJOR PHARMACEUTICALS, 17177 N. Laurel Park Dr., Suite 233, Livonia, MI 48152 USA. NDC 0904-6172-61

Product Quantity:
4 Cartons of 100 count each

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0807-2021

Code Information:
Lot R01562; Exp. 10/2022

Class II Drugs Event

Event ID:
88591

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/27/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/21/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Glenmark Pharmaceuticals Inc., USA
750 Corporate Dr
Mahwah NJ United States

Distribution Pattern:
Nationwide.

Associated Products

Product Description:
Fulvestrant Injection 250 mg/5 mL (50 mg/mL) For Intramuscular Use Only Contains 2 single-dose pre-filled syringes Rx only NDC 68462-317-32

Product Quantity:
28658 cartons

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0820-2021

Code Information:
Lots: 30200014 Exp. 04/30/2022; 30200015 Exp. 05/31/2022; 30200015 Exp. 05/31/2022; 30200016 Exp. 05/31/2022; 30200036 Exp. 09/30/2022; 30200038 Exp. 09/30/2022; 30200039 Exp. 09/30/2022; 30200040 Exp. 09/30/2022; 30210001 Exp. 12/31/2022; 30210002 Exp. 12/31/2022; 30210003 Exp. 01/31/2023; 30210004 Exp. 01/31/2023; 30210005 Exp. 01/31/2023; 30210006 Exp. 01/31/2023; 30210014 Exp. 02/28/2023; 30210022 Exp. 02/28/2023; 30210028 Exp. 02/28/2023; 30210029 Exp. 02/28/2023; 30210030 Exp. 02/28/2023; 30210031 Exp. 02/28/2023

Product Description:
Naproxen Sodium Tablets, USP 275 mg 100 Tablets Rx Only NDC 68462-178-01 Manufactured by: Glenmark Pharmaceuticals Inc., USA 4147 Goldmine Road Monroe, NC 28110 Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430

Product Quantity:
9552 bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-0821-2021

Code Information:
Lots: 29190087 Exp. 10/31/2021; 29190088 Exp. 10/31/2021; 29190089 Exp. 10/31/2021; 29200077 Exp. 11/30/2022; 29200078 Exo, 11/30/2022

Product Description:
Naproxen Sodium Tablets, USP 550 mg Rx Only Manufactured by: Glenmark Pharmaceuticals Inc., USA 4147 Goldmine Road Monroe, NC 28110 Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430 a) 100 Tablets NDC 68462-179-01; b) 500 Tablets NDC 68462-179-05

Product Quantity:
a) 31248 bottles; b) 300 bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-0822-2021

Code Information:
Lots: a) 29190082 Exp. 09/30/2021; 29190083 Exp. 09/30/2021; 29190084 Exp. 10/31/2021; 29190085 Exp. 10/31/2021; 29200001 Exp. 12/31/2021; 29200003 Exp. 01/31/2022; 29200004 Exp. 01/31/2022; 29200005 Exp. 01/31/2022; 29200012 Exp. 02/28/2022; 29200013 Exp. 02/28/2022; b) 29200010 Exp. 02/28/2022

Product Description:
Chlorzoxazone Tablets USP 375 mg 100 Tablets Rx Only NDC 68462-724-01 Manufactured by: Glenmark Pharmaceuticals Inc., USA 4147 Goldmine Road Monroe, NC 28110 Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430

Product Quantity:
1800 bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-0823-2021

Code Information:
Lots: 29200022 Exp. 03/31/2022; 29200024 Exp. 03/31/2022; 29200035 Exp. 06/30/2022

Product Description:
Chlorzoxazone Tablets USP 750 mg 100 Tablets Rx Only NDC 68462-725-01 Manufactured by: Glenmark Pharmaceuticals Inc., USA 4147 Goldmine Road Monroe, NC 28110 Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430

Product Quantity:
4752 bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-0824-2021

Code Information:
Lots: 29200023 Exp. 03/31/2022; 29200025 Exp. 03/31/2022; 29200036 Exp. 06/30/2022; 29200056 Exp. 09/30/2022; 29200070 Exp. 11/30/2022

Product Description:
Zonisamide Capsules USP 50 mg 100 Capsules Rx Only NDC 68462-129-01 Manufactured by: Glenmark Pharmaceuticals Inc., USA Monroe, NC 28110 Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430

Product Quantity:
15936 bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-0825-2021

Code Information:
Lots: 29190043 Exp. 05/31/2022; 29190044 Exp. 05/31/2022; 29190045 Exp. 05/31/2022

Product Description:
Zonisamide Capsules USP 100 mg Rx Only Manufactured by: Glenmark Pharmaceuticals Inc., USA Monroe, NC 28110 Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430 a) 100 Capsules NDC 68462-130-01; b) 500 Capsules NDC 68462-130-05

Product Quantity:
a) 216,454 bottles; b) 2166 bottles

Reason for Recall:
CGMP Deviations

Recall Number:
D-0826-2021

Code Information:
Lots: a) 29200014 Exp. 02/28/2023; 29200015 Exp. 03/31/2023; 29200016 Exp. 03/31/2023; 29200030 Exp. 05/31/2023; 29200031 Exp. 05/31/2023; 29200032 Exp. 05/31/2023; 29200033 Exp. 06/30/2023; 29200037 Exp. 06/30/2023; 29200038 Exp. 06/30/2023; 29200039 Exp. 07/31/2023; 29200041 Exp. 07/31/2023; 29200042 Exp. 07/31/2023; 29200048 Exp. 08/31/2023; 29200049 Exp. 08/31/2023; 29200050 Exp. 08/31/2023; 29200072 Exp. 11/30/2023; 29200073 Exp. 11/30/2023; 29200074 Exp. 11/30/2023; 29200075 Exp. 11/30/2023; 29200076 Exp. 11/30/2023; b) 29200014 Exp. 02/28/2023; 29200015 Exp. 03/31/2023; 29200016 Exp. 03/31/2023

Product Description:
Arformoterol Tartrate Inhalation Solution 15 mcg*/2 mL For Oral Inhalation Only Rx Only Manufactured by: Glenmark Pharmaceuticals Inc., USA Monroe, NC 28110 Manufactured for: Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430 a) 60x2 mL Sterile Unit-Dose Vials NDC 68462-833-65; b) 30x2 mL Sterile Unit-Dose Vials NDC 68462-833-35

Product Quantity:
a) 5362 inhalers; b) 5593 inhalers

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0827-2021

Code Information:
Lots: a) 30210041 Exp. 03/31/2023; 30210045 Exp. 04/30/2023; 30210046 Exp. 04/30/2023; 30210050 Exp. 03/31/2023; 30210051 Exp. 04/30/2023; 30210058 Exp. 04/30/2023; b) 30210042 Exp. 03/31/2023; 30210047 Exp. 04/30/2023; 30210048 Exp. 04/30/2023; 30210052 Exp. 04/30/2023; 30210053 Exp. 04/30/2023; 30210054 Exp. 04/30/2023; 30210059 Exp. 04/30/2023; 30210060 Exp. 04/30/2023; 30210061 Exp. 04/30/2023; 30210062 Exp. 04/30/2023; 30210063 Exp. 04/30/2023; 30210064 Exp. 05/31/2023

Class II Drugs Event

Event ID:
88629

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/03/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/20/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Morton Grove Pharmaceuticals, Inc.
6451 Main St
Morton Grove IL United States

Distribution Pattern:
Nationwide USA and China

Associated Products

Product Description:
Promethazine Syrup Plain, 6.25 mg/5 mL (Promethazine Hydrochloride Syrup, USP), 1 Pint (473 mL), Rx Only, Manufactured For: Wockhardt USA, LLC, Parsippany, NJ 07054; Manuractured By: Morton Grove Pharmaceuticals, Inc, Morton Grove, IL 60053. NDC: 60432-608-16

Product Quantity:
116,400 bottles

Reason for Recall:
CGMP Deviations: Potential concern with products manufactured using liquid sugar batches contaminated with microbial organisms.

Recall Number:
D-0814-2021

Code Information:
Lot #: UV1335; UV1352; and UV1373

Product Description:
Promethazine With Codeine Oral Solution, (Promethazine Hydrochloride 6.25 mg/5mL & Codeine Phosphate 10 mg/5 mL), 1 Pint (473 mL), Rx Only, Manufactured For: Wockhardt USA, LLC, Parsippany, NJ 07054; Manuractured By: Morton Grove Pharmaceuticals, Inc, Morton Grove, IL 60053. NDC: 60432-606-16

Product Quantity:
14,904 bottles

Reason for Recall:
CGMP Deviations: Potential concern with products manufactured using liquid sugar batches contaminated with microbial organisms.

Recall Number:
D-0815-2021

Code Information:
Lot #: UV1198

Product Description:
Valproic Acid Oral Solution USP, (250 mg/5 mL), 1 Pint (473 mL), Rx Only, Manufactured For: Wockhardt USA, LLC, Parsippany, NJ 07054; Manuractured By: Morton Grove Pharmaceuticals, Inc, Morton Grove, IL 60053. NDC: 60432-621-16

Product Quantity:
38,748 bottles

Reason for Recall:
CGMP Deviations: Potential concern with products manufactured using liquid sugar batches contaminated with microbial organisms.

Recall Number:
D-0816-2021

Code Information:
Lot #: UV1159

Class II Drugs Event

Event ID:
88638

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
07/29/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/17/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
The Harvard Drug Group

17187 N Laurel Park Dr Ste 300
Livonia MI United States

Distribution Pattern:
CO, FL, MO, OH

Associated Products

Product Description:
Entacapone Tablets, USP, 200 mg, Rx only, 30 Tablets per unit dose cartons, Distributed by: Major Pharmaceuticals, 17177 N. Laurel Park Dr., Suite 233, Livonia, MI 48152. NDC 0904-6822-04

Product Quantity:
1,632 cartons

Reason for Recall:
Failed Dissolution Specifications

Recall Number:
D-0806-2021

Code Information:
Lot, expiry: N00187, 05/2022; N00245, 06/2022; N00273, 07/2022; N00355, 11/2022

Class II Drugs Event

Event ID:
88639

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/09/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/20/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Aurobindo Pharma USA Inc.
279 Princeton Hightstown Rd
East Windsor NJ United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Metoprolol Tartrate Tablets USP 100 mg, 1000-count bottles, Rx only, Distributed by: Aurobindo Pharma USA Inc. 279 Princeton-Highstown Road East Windsor, NJ 08520, NDC 65862-064-99

Product Quantity:
2,820 bottles

Reason for Recall:
Presence of Foreign Substance: Product complaints received for the presence of metal wire in one tablet.

Recall Number:
D-0812-2021

Code Information:
Lot: MJ1019025-A, Exp. date 04/2022

Class II Drugs Event

Event ID:
88749

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/14/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/23/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Direct Rx
94 Worldwide Dr
Dawsonville GA United States

Distribution Pattern:
FL only

Associated Products

Product Description:
Zonisamide 100 mg Capsules, 30-count bottles, Packaged and Distributed By: Direct Rx Dawsonville, GA 30534 Mfg. For Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430, NDC 61919-0775-30

Product Quantity:
2 bottles

Reason for Recall:
CGMP deviations: Gaps in the quality system in the Quality Control microbiology laboratory.

Recall Number:
D-0829-2021

Code Information:
Lot #: 17JU2118 Exp. 5/31/23

Class III Drugs Event

Event ID:
88598

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/01/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/20/2021

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Monarch PCM, LLC
7333 Jack Newell Blvd N Ste 100
Fort Worth TX United States

Distribution Pattern:
OH, TN

Associated Products

Product Description:
Sodium Sulfacetamide, 10%, Wash, packaged in bottles: a) 6 fl oz (177 mL) NDC 42808-103-06 UPC 3 42808 10306 5; b) 12 fl oz (354.8 mL) NDC 42808-103-12 UPC 3 42808 10312 6, Rx only, Manufactured in the U.S.A. for Exact-Rx, Inc., Melville, NY 11747

Product Quantity:
a) 3305 bottles; b) 840 bottles

Reason for Recall:
Subpotency: one product for active ingredient assay and another one for preservative assay

Recall Number:
D-0817-2021

Code Information:
Lots: a) 21FP1737 Exp 05/2023; b) 21FP1738 Exp 05/2023

Product Description:
Hydroquinone, USP, 4% Skin Bleaching Cream, packaged in 1 oz (28.35g) tube, Rx only, Manufactured for: Westminster Pharmaceuticals, LLC Nashville, TN 37217, NDC 69367-174-01 UPC 3 69367 17401 5

Product Quantity:
6305 tubes

Reason for Recall:
Subpotency: one product for active ingredient assay and another one for preservative assay

Recall Number:
D-0818-2021

Code Information:
Lot: 21FP1731 Exp 05/2023

Class III Drugs Event

Event ID:
88650

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
05/12/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/20/2021

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
American Health Packaging
2550 John Glenn Ave Ste A
Columbus OH United States

Distribution Pattern:
Nationwide within the USA

Associated Products

Product Description:
Sirolimus Tablets 1 mg, 30 Tablets (5 blister cards x 6 unit doses), Rx only, Packaged and Distributed by: American Health Packaging Columbus, OH 43217, NDC 68084-915-25

Product Quantity:
290 cartons

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0813-2021

Code Information:
Lot #: 1000789, Exp. Date 10/31/2022