Enforcement Report - Week of February 9, 2022

Class II Drugs Event

Event ID:
89270

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/21/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/31/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ideal Specialty Apothecary, Inc. dba Ideal Pharmacy
2333 Morris Ave Ste B101
Union NJ United States

Distribution Pattern:
nationwide in the USA

Associated Products

Product Description:
Medroxyprogesterone Acetate Injection, IM, 150 mg/mL, packaged in 1 ml Single Dose Vial, RX Only, Ideal Pharmacy, 2333 Morris Ave, Union, NJ 07083

Product Quantity:
57,994 vials

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0463-2022

Code Information:
All lots within expiry

Class II Drugs Event

Event ID:
89385

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/10/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/02/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA
400 Interpace Pkwy
Parsippany NJ United States

Distribution Pattern:
nationwide in the USA

Associated Products

Product Description:
Tretinoin Capsules, 10 mg, 100 count bottle, Rx Only, Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 0555-0808-02

Product Quantity:
1,175 Bottles

Reason for Recall:
Failed Dissolution Specifications; Low Out of specification (OOS) results for dissolution.

Recall Number:
D-0520-2022

Code Information:
Lot #: 100022970, Exp. 08/2022

Class II Drugs Event

Event ID:
89422

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/18/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/28/2022

Initial Firm Notification of Consignee or Public:

Recalling Firm:
Teva Pharmaceuticals USA
400 Interpace Pkwy
Parsippany NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Doxylamine Succinate and Pyridoxine Hydrochloride Delayed-Release Tablets 10 mg/10 mg, 100-count bottle, Rx Only, Manufactured by: Actavis Laboratories FL, Inc., Fort Lauderdale, FL 33314, USA, Distributed by: Actavis Pharma, Inc., Parsippany, NJ 007045 USA, NDC 0591-2132-01

Product Quantity:
6205 100-count bottles

Reason for Recall:
Failed Dissolution Specification: Dissolution results are below specification limits for the active ingredient

Recall Number:
D-0461-2022

Code Information:
Lot# 100025842, 100028023, Exp Date 08/2023

Class II Drugs Event

Event ID:
89464

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/24/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
01/31/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Ultra Seal Corporation
521 Main St
New Paltz NY United States

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Nasal & Sinus Decongestant (phenylephrine HCl 5mg) 2 tablets per packet, Mfd. for Cintas First Aid & Safety, Mason OH 45040

Product Quantity:
3,508,200 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0464-2022

Code Information:
Lot #: AK9491, AK9496, Exp. Date 02/2022; K9817, Exp. Date 09/2022

Product Description:
Cold Tablet Pain Reliever/Fever Reducer/Expectorant/Nasal Decongestant (acetaminophen 325 mg, Guaifenesin 200mg, Phenylephrine HCl 5 mg) 2 tablets per packet, Mfg, for Respond Industries and American First Aid, Mason, OH 45040

Product Quantity:
313,000 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0465-2022

Code Information:
Lot #: K9824, Exp. Date 09/2022

Product Description:
AERO TAB Cold Relief (acetaminophen 325 mg, Guaifenesin 200mg, Phenylephrine HCl 5mg) 2 tablet packets, Mfg. for: Aero Healthcare, Valley Cottage, NY 10989

Product Quantity:
226,390 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0466-2022

Code Information:
Lot #: AK9565, Exp. Date 04/2022

Product Description:
Maximum Strength Non Aspirin Pain Reliever/Fever Reducer (acetaminophen 500 mg) 2 tablet packets, Mfg. for: Advanced First Aid, Baltimore MD 21237, American Safety & First Aid, Osceola, IN 46561, NDC 67060-210-68

Product Quantity:
1,236,000 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0467-2022

Code Information:
Lot #: AK9495, Exp. Date 02/2022; AK9613, Exp. Date 05/2022

Product Description:
CHLORESIN (acetaminophen 325mg, dextromethorphan HBr 15mg, Guaifenesin 200mg, Phenylephrine HCl 5mg) 2 tablet packets,

Manufactured For Afassco Inc. Minden NV 89423, NDC 51532-0107-2

Product Quantity:
225,350 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0468-2022

Code Information:
Lot #: AK9492, Exp. Date 02/2022

Product Description:
Extra Strength (ES) PAIN RELIEVER (acetaminophen 500 mg) 2 tablet packets, Manufactured by Ultratab Laboratories, Inc.

Product Quantity:
297,050 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0469-2022

Code Information:
Lot #: AK9602, Exp. Date 05/2022

Product Description:
Legatrin PM Pain Reliever/Sleep Aid (acetaminophen 500 mg, diphenhydramine HCl 50mg caplets) 50-count bottles, Manufactured for: Church & Dwight Co., Inc. Ewing, NJ 08628 NDC 10237-907-50

Product Quantity:
174,852 bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-0470-2022

Code Information:
Lot #: HY9042, Exp. Date 02/2022; HY9094, HY9112, Exp. Date 04/2022; HY9134, Exp. Date 05/2022; HY9267, Exp. Date 09/2022

Product Description:
Cystex Urinary Pan Relief (NSAID) (methenamine 162mg, sodium salicylate 162.5mg tablets) packaged in a) 40-count blisters and b) 20-count blisters, Distributed by: Clarion Brands, LLC 27070 Miles Road, Suite A Solon, OH 44139, NDC 69693-512-40

Product Quantity:
a) 702,240 blisters, b) 30,180 blisters

Reason for Recall:
cGMP deviations

Recall Number:
D-0471-2022

Code Information:
Lot #: a) 19A043, 19A093, Exp. Date 01/2022; 19B062,19C079,19C080, Exp. Date 03/2022; 19D041, Exp. Date 04/2022; 19E035, 19E087, Exp. Date 05/2022; 19G084, Exp. Date 08/2022; 19H098, Exp. Date 09/2022 b) 19H098A, Exp. Date 09/2022

Product Description:
DBI 357 Super Magnum Quick Energy Stimulant (caffeine 200mg) tablets, packaged in a) 36-count bottles, b) 100-count bottles, c) 500-count bottles, and d) 3-count packets, Marketed by: DBI Distribution A Division of King Richard Promotions, Inc. P.O. Box 78546, Indianapolis, IN 46270

Product Quantity:
a) 147,528 bottles, b) 2,451 bottles, c) 2,492 bottles, d) 573,696 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0472-2022

Code Information:
Lot #: a) C19065, Exp. Date 03/2022; F19081, Exp. Date 06/2022; 19H083, Exp. Date 08/2022; b) H19083, 1H9083, Exp. Date 08/2022; c) 19F081, Exp. Date 06/2022; 19083H, Exp. Date 08/2022; d) 19C065, Exp. Date 03/2022; 19081F, Exp. Date 06/2022

Product Description:
Ephedrine Plus (Ephedrine HCl 25mg, Guaifenesin 200mg) tablets, 24-count bottles, Marketed by: DMD Pharmaceuticals A Division of Dickery Consumer Products, Inc. Noblesville, IN 46060, NDC 65193-320-24

Product Quantity:
301,842 bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-0473-2022

Code Information:
Lot#: 18M063, Exp. Date 01/2022; 19G076, Exp. Date 09/2022

Product Description:
Dologen (acetaminophen 325 mg and dexbrompheniramine maleate 1mg) caplets, packaged in a) 90-count bottles, b) 2-count packets, Manufactured in the USA for Kramer-Novis, San Juan, Puerto Rico 00917, NDC 52083-482-02

Product Quantity:
a) 9,060 bottles, b) 44,700 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0474-2022

Code Information:
Lot #: a) 19G074, 19G075, Exp. Date 07/2022; b) 19G075, Exp. Date 07/2022

Product Description:
MidNite Sleep Health (melatonin 1.5 mg) tablets, 30-count bottles, Distributed by: Mylan Consumer Healthcare, Inc. Morgantown, WV 26505 USA

Product Quantity:
2,189,232 bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-0475-2022

Code Information:
Lot #: 18L124, 18L125, 18L126, Exp. Date 02/2022; 19C037, 19C038, 19C039, 19C040, Exp. Date 03/2022; 19D029, 19D030, Exp. Date 04/2022; 19D031, Exp. Date 06/2022; 19G047, Exp. Date 07/2022

Product Description:
Back Pain-Off (caffeine 50mg, magnesium salicylate 290mg) Tablets 2-count packets, Mfd for MEDIQUE PRODUCTS, Fort Myers, FL 33967, NDC 47682-073-00

Product Quantity:
1,959,267 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0476-2022

Code Information:
Lot #: 9708, Exp. Date 07/2022; AK9810, Exp. Date 09/2022; AK9946, K9946, Exp. Date 12/2022

Product Description:
Cetafen Non-aspirin pain reliever (acetaminophen 325mg) tablets, 2-count packets, Manufactured for: HARTHealth Seattle, WA 98124

Product Quantity:
915,770 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0477-2022

Code Information:
Lot #: A-K-9668, Exp. Date 06/2022; A-K-9475, Exp. Date 02/2022

Product Description:
Multi Symptom Cold Relief (acetaminophen 325 mg, Dextromethorphan HBr 15mg, Guaifenesin 200mg, Phenylephrine HCl 5mg) tablets, 2-count packets, Dist. by Honeywell Safety Products USA, Smithfield, RI 02917

Product Quantity:
673,160 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0478-2022

Code Information:
Lot #: AK9715, K9715, Exp. Date 07/2022

Product Description:
Lite Remfresh Advanced Ion-Powered Melatonin (Melatonin 0.5mg) Tablets, 36-count blisters, Physician's Seal LLC, Boca Raton, FL 33487

Product Quantity:
25,776 blisters

Reason for Recall:
cGMP deviations

Recall Number:
D-0479-2022

Code Information:
Lot #: 19E058A, 19E058B, Exp. Date 05/2022

Product Description:
Cold Relief Severe Pain/Cough (acetaminophen 325mg, Dextromethorphan HBr 15mg, Guaifenesin 200mg, phenylephrine HCl 5mg), 2-tablet packets, Manufactured for Select Corporation, Carrollton, TX 75007

Product Quantity:
227,010 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0480-2022

Code Information:
Lot #: AK9436, Exp. Date 01/2022

Product Description:
Multi-Symptom Cramp Relief (acetaminophen 325mg and Pamabrom 25mg), 2- tablet packets, Mfd. for First Aid Direct, Mason, OH 45040

Product Quantity:
1,351,660 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0481-2022

Code Information:
Lot #: AK9453, Exp. Date 01/2022; AK9716, 07/2022

Product Description:
Backache & Muscle Relief (acetaminophen 250 mg, magnesium salicylate-tetrahydrate 290mg, caffeine 50 mg) 2 tablets per packet, Mfd.

for First Aid Direct, Mason, OH 45040, NDC 42961-111-832

Product Quantity:
5,107,565 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0482-2022

Code Information:
Lot #: K9770, AK9770 Exp. Date 08/2022; AK9958, K9958 Exp. Date 12/2022; AK9717, Exp. Date 07/2022; AK9522, AK9641 , Exp. Date 03/2022; AK9817, Exp. Date 09/2022

Product Description:
Cold Relief (acetaminophen 250 mg, guaifenesin 200mg, phenylephrine HCl 5 mg) 2 tablets per packet, Mfd. for First Aid Direct, Mason, OH 45040, NDC 42961-112-03

Product Quantity:
7,858,690 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0483-2022

Code Information:
Lot #: K9456, AK9454, 9456, AK9456, Exp. Date 01/2022; AK9524, AK9528 Exp. Date 03/2022; K9767, AK9767, Exp. Date 08/2022; AK9824, AK9823, Exp. Date 09/2022; AK9564, Exp. Date 04/2022

Product Description:
Headache & Congestion Sinus Relief (acetaminophen 250 mg, phenylephrine HCl 5 mg) 2 tablets per packet, Mfd. for First Aid Direct, Mason, OH 45040, NDC 42961-0206-02

Product Quantity:
5,741,384 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0484-2022

Code Information:
Lot #: 9445, AK9445, K9445, Exp. Date 01/2022; K9486, Exp. Date 02/2022; AK9708, Exp. Date 07/2022; AK9515, Exp. Date 03/2022; K9810, Exp. Date 09/2022; AK9658, Exp. Date 06/2022

Product Description:
Pain Away Pain Reliever/Fever Reducer (NSAID) (acetaminophen 110 mg, aspirin 162 mg, salicylamide 152mg, caffeine 32.4 mg), 2 tablets per packet, Mfg, for Respond Industries and American First Aid, Mason, OH 45040

Product Quantity:
1,186,000 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0485-2022

Code Information:
Lot #: AK9493, Exp. Date 02/2022

Product Description:
Cold/Sinus Pain Reliever/Fever Reducer Nasal Decongestant (acetaminophen 325 mg, Phenylephrine HCl 5mg), 2 tablets per packet, Mfg, for Respond Industries and American First Aid, Mason, OH 45040

Product Quantity:
301,650 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0486-2022

Code Information:
Lot #: K9708, Exp. Date 07/2022

Product Description:
COLD TERMINATOR decongestant/cold relief (acetaminophen 325 mg, Guaifenesin 200mg, 5.0 Phenylephrine HCl) 2 tablet packets, Manufactured for: Tellus Medical Products, Carlsbad, CA 92011, NDC 69103-2556

Product Quantity:
226,400 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0487-2022

Code Information:
Lot #: AK9587, Exp. Date 02/2022

Product Description:
PAIN TERMINATOR extra strength pain relief (aspirin 162 mg, acetaminophen 110 mg, Caffeine 32.4mg, Salicylamide 152 mg) 2 tablet packets, Manufactured for: Tellus Medical Products, Palm Desert, CA 92211, NDC 69103-2507

Product Quantity:
1,188,280 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0488-2022

Code Information:
Lot #: AK9451, Exp. Date 01/2022

Product Description:
SINU-PHEN PLUS sinus pain and congestion tabs (acetaminophen 500 mg, Phenylephrine HCl 5.0 mg) 2 tablet packets, Manufactured for: Tellus Medical Products, Palm Desert, CA 92211, NDC 69103-2536-00

Product Quantity:
122,400 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0489-2022

Code Information:
Lot #: AK9766, Exp. Date 08/2022

Product Description:
DILOTAB II, SINUS AND COLD RELIEF NON DROWSY (acetaminophen 325 mg, Phenylephrine HCl 5 mg) 2 tablet packets, Dist. by ZEE Medical Distributors, LLC Mason, OH 45040, NDC 42961-052-03

Product Quantity:
2,685,700 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0490-2022

Code Information:
Lot #: AK9548, (L) 106, Exp. Date 04/2022; AK9647, (L)103, Exp. Date 06/2022; AK9598, Exp. Date 05/2022

Product Description:
EXTRA STRENGTH UN-ASPIRIN (acetaminophen 500 mg) 2 Caplet packets, Dist. by ZEE Medical Distributors, LLC Mason, OH 45040, NDC 42961-041-03

Product Quantity:

1,694,200 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0491-2022

Code Information:
Lot #: AK9599, Exp. Date 05/2022; AK9648, (L) 104, Exp. Date 06/2022

Product Description:
PAINAID (acetaminophen 110 mg, aspirin 162mg, caffeine 32.4 mg, salicylamide 152mg) 2 tablet packets, Dist. by ZEE Medical Distributors, LLC Mason, OH 45040

Product Quantity:
2,336,600 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0492-2022

Code Information:
Lot #: AK9433, Exp. Date 01/2022; AK9749, Exp. Date 08/2022

Product Description:
PAINAID BRF Back Relief Formula (acetaminophen 250 mg, caffeine 50 mg, Magnesium salicylate 290 mg) 2 tablet packets, Dist. by ZEE Medical Distributors, LLC Mason, OH 45040, NDC 42961-0003-00

Product Quantity:
111,300 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0493-2022

Code Information:
Lot #: AK9698, Exp. Date 07/2022

Product Description:
PAINAID PMF Premenstrual Formula (acetaminophen 500 mg, pamabrom 25mg) 2 caplet packets, Dist. by ZEE Medical Distributors, LLC Mason, OH 45040, NDC 42961-0046-03

Product Quantity:
769,200 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0494-2022

Code Information:
Lot #: AK9434, (L)101, Exp. date 01/2022

Product Description:
CONGESTAID II Nasal Decongestant (Phenylephrine HCl 5mg) 2 tablet packets, Dist. by ZEE Medical Distributors, LLC Mason, OH 45040

Product Quantity:
447,050 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0495-2022

Code Information:
Lot #: AK9478, Exp. Date 02/2022; AK9799, Exp. Date 09/2022

Product Description:
Mint Flavored Antacid (Calcium Carbonate 420mg) 2 tablet packets, Mfg for Just American Safety, Osceola, IN 46561, NDC 67060-303-68

Product Quantity:
1,309,800 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0496-2022

Code Information:
Lot #: AK9523, K9523 Exp. Date 03/2022; AK9670, Exp. Date 06/2022

Product Description:
Pain & Sinus Reliever Pain Reliever/Nasal Decongestant (acetaminophen 500mg, Phenylephrine HCl 5mg) 2 tablet packets, Mfg for Advanced First Aid, Baltimore, MD 21237, NDC 67060-194-68

Product Quantity:
887,000 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0497-2022

Code Information:
Lot #: AK9527, Exp. Date 03/2022

Product Description:
Regular Strength Pain Reliever (acetaminophen 110 mg, aspirin 162 mg, Caffeine 32.4 mg, Salicylamide 152 mg) 2 tablet packets, Mfg for Advanced First Aid, Baltimore, MD 21237, NDC 67060-0113-00

Product Quantity:
1,180,000 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0498-2022

Code Information:
Lot #: AK9450, Exp. Date 01/2022

Product Description:
PAPENOL (acetaminophen 500 mg), 2 tablet packets, Manufactured for: Afassco Inc. Minden, NV 89423

Product Quantity:
533,100 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0499-2022

Code Information:
Lot #: K9495, Exp. Date 02/2022; AK9614, Exp. Date 05/2022

Product Description:
MAGNACAL (calcium carbonate 420 mg), 2 tablet packets, Manufactured for: Afassco Inc. Minden, NV 89423

Product Quantity:
307,000 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0500-2022

Code Information:

Lot #: AK9768, Exp. Date 08/2022

Product Description:
PEPTIME Energy (caffeine 250mg) tablets, 100-count bottles, Marketed by: DMD Pharmaceuticals, A Division of Dickery Consumer Products, Inc., Noblesville, IN 46060.

Product Quantity:

Reason for Recall:
cGMP deviations

Recall Number:
D-0501-2022

Code Information:
Lot #: 19E021, 19E022

Product Description:
PEPTIME Energy (caffeine 300mg) tablets, packaged in a) 6 count packets and b) 100-count bottles, Marketed by: DMD Pharmaceuticals, A Division of Dickery Consumer Products, Inc., Noblesville, IN 46060.

Product Quantity:
a)131,112 packets, b) 8,064 bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-0502-2022

Code Information:
Lot #: a)19E030, b)19E031

Product Description:
PEPTIME Energy (caffeine 350mg) tablets, packaged in a) 6 count packets and b) 100-count bottles, Marketed by: DMD Pharmaceuticals, A Division of Dickery Consumer Products, Inc., Noblesville, IN 46060.

Product Quantity:
a) 113,040 packets, b) 7,132 bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-0503-2022

Code Information:
Lot #: a)19E032, b)19E033

Product Description:
PEPTIME Energy (caffeine 250mg) tablets, packaged in a) 6 count packets and b) 100-count bottles, Marketed by: DMD Pharmaceuticals, A Division of Dickery Consumer Products, Inc., Noblesville, IN 46060.

Product Quantity:
a) 156,096 packets, b) 9,648 bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-0504-2022

Code Information:
Lot #: a)19E021, b)19E022

Product Description:
CVS Health Natural Sleep Aid Chewable Tablets Cherry Flavor (melatonin 1.5mg), 30-count bottles, Distributed by: CVS Pharmacy Inc. One CVS Drive, Woonsocket, RI 02895

Product Quantity:
241,560 bottles

Reason for Recall:
cGMP deviations

Recall Number:

D-0505-2022

Code Information:
Lot #: 18L124, Exp. Date 02/2022; 19D029, Exp. Date 04/2022

Product Description:
MidNite Natural sleep aid Chewable Tablets Cherry Flavor (melatonin 1.5mg), 30-count bottles, BGP Pharma ULC, Etobicoke, ON M8Z 2S6

Product Quantity:
90,072 bottles

Reason for Recall:
cGMP deviations

Recall Number:
D-0506-2022

Code Information:
Lot #: 19C038C, Exp. Date 03/2022; 19G047C, Exp. Date 07/2022; 18L124C, Exp. Date 02/2022

Product Description:
Exaprin pain reliever (acetaminophen 110 mg, aspirin 162 mg, caffeine 32.4mg, salicylamide 152mg) tablets, 2- tablet packets, Manufactured for: HARTHealth Seattle, WA 98124

Product Quantity:
1,1401,641 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0507-2022

Code Information:
Lot #: AK9796, Exp. Date 09/2022

Product Description:
Nutralox Mint Antacid (calcium carbonate 420mg) Chewable tablets, 2-count packets, Manufactured for: HARTHealth Seattle, WA 98124

Product Quantity:
1,486,050 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0508-2022

Code Information:
Lot #: AK9566, Exp. Date 04/2022; AK9612, Exp. Date 05/2022

Product Description:
FEM-PRIN MENSTRUAL RELIEF (acetaminophen 325 mg, pamabrom 25mg) tablets, 2-count packets, Manufactured for: HARTHealth Seattle, WA 98124

Product Quantity:
223,090 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0509-2022

Code Information:
Lot #: AK9695, Exp. Date 07/2022

Product Description:
CETAFEN COUGH & COLD COUGH & COLD RELIEF (Acetaminophen 325 mg, Dextromethorphan HBr 15mg, Guaifenesin 200mg, phenylephrine HCl 5mg) Coated tablets, 2-count packets, Manufactured for: HARTHealth Seattle, WA 98124

Product Quantity:
225,000 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0510-2022

Code Information:
Lot #: AK9841, Ex. Date 10/2022

Product Description:
CETAFEN Extra Non-Aspirin Pain Relieve (Acetaminophen 500 mg) caplets, 2-count packets, Manufactured for: HARTHealth Seattle, WA 98124

Product Quantity:
1,019,000 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0511-2022

Code Information:
Lot #: AK9475, Exp. Date 02/2022

Product Description:
AYPANAL Non-aspirin Pain Reliever (acetaminophen 325 mg) tablets, 2-count packets, Dist. by Honeywell Safety Products USA, Smithfield, RI 02917

Product Quantity:
216,000 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0512-2022

Code Information:
Lot #: AK9640, Exp. Date 03/2022

Product Description:
SINUS DECONGESTANT Nasal Decongestant (phenylephrine HCl 5mg) tablets, 2-count packets, Dist. by Honeywell Safety Products USA, Smithfield, RI 02917

Product Quantity:
448,300 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0513-2022

Code Information:
Lot #: AK9859, Exp. Date 10/2022

Product Description:
MIRALAC (calcium carbonate 420mg) tablets, Mint Flavor, 2-count packets, Dist. by Honeywell Safety Products USA, Smithfield, RI 02917

Product Quantity:
409,890 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0514-2022

Code Information:
Lot #: AK9486, Exp. Date 02/2022

Product Description:
ELECTROLYTE Supplement Tablets (calcium 5.2 mg, Potassium 20.8 mg, Magnesium 6 mg) 2-count packets, Dist. by Honeywell Safety Products USA, Smithfield, RI 02917

Product Quantity:
1,474,050 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0515-2022

Code Information:
Lot #: AK9797, AK9254

Product Description:
REMfresh Advanced Ion-Powered Melatonin (Melatonin 2 mg) Caplets, packaged in a) 12-count blisters b) 36-count blisters Physician's Seal LLC, Boca Raton, FL 33487

Product Quantity:
a) 308,928 blisters b) 29,808 blisters

Reason for Recall:
cGMP deviations

Recall Number:
D-0516-2022

Code Information:
Lot #: a) 19B050A, 19B050B, 19B050C, 19B050D, 19B050E, Exp. Date 06/2022; 19F063, 19F063A, 19F063B, Exp. Date 08/2022; b) 19B050-A, Exp. Date 06/2022

Product Description:
REMfresh Advanced Ion-Powered Melatonin (Melatonin 5 mg) Caplets, packaged in 36-count blisters Physician's Seal LLC, Boca Raton, FL 33487

Product Quantity:
40,344 blisters

Reason for Recall:
cGMP deviations

Recall Number:
D-0517-2022

Code Information:
Lot #: 19B011, 19B012, 19B012A, 19E023, Exp. Date 05/2022

Product Description:
Sinus Relief (acetaminophen 325mg, Guaifenesin 200mg, phenylephrine HCl 5mg), 2-tablet packets, Manufactured for Select Corporation, Carrollton, TX 75007

Product Quantity:
447,190 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0518-2022

Code Information:
Lot #: AK9651, Exp. Date 06/2022; AK9437, Exp. Date 01/2022

Product Description:
Sinus Relief Headache/Nasal (acetaminophen 325mg, phenylephrine HCl 5mg), 2 tablet packets, Manufactured for Select Corporation, Carrollton, TX 75007

Product Quantity:
227,010 packets

Reason for Recall:
cGMP deviations

Recall Number:
D-0519-2022

Code Information:

Lot #: AK9436, Exp. Date 01/2022

Class III Drugs Event

Event ID:
89368

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/07/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/02/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teva Pharmaceuticals USA
400 Interpace Pkwy
Parsippany NJ United States

Distribution Pattern:
USA Nationwide

Associated Products

Product Description:
Mimvey (estradiol and norethindrone acetate tablets USP), 1 mg/0.5 mg, packaged in cartons of 28 Tablets, Rx only, Manufactured By: Barr Laboratories, Inc., Pomona, NY 10970, Manufactured For: Teva Pharmaceuticals USA Inc. North Wales, PA 19454, NDC 0093-5455-28

Product Quantity:
218174 cartons

Reason for Recall:
Mislabeling

Recall Number:
D-0521-2022

Code Information:
Lot#: 100018611, Exp 03/2022; 100019834, Exp 06/2022; 100022226, Exp 09/2022; 100024574, Exp 01/2023

Product Description:
Mimvey (estradiol and norethindrone acetate tablets USP) 1 mg/0.5 mg, packaged in cartons of 28 Tablets, Rx Only, Manufactured By: Barr Laboratories, Inc., Pomona, NY 10970, Manufactured For: Teva Pharmaceuticals USA Inc. North Wales, PA 19454, NDC 0093-5455-42

Product Quantity:
6430 cartons

Reason for Recall:
Mislabeling

Recall Number:
D-0522-2022

Code Information:
Lot#: 100018610, Exp 03/2022; 100021521, Exp 09/2022; 100024575, Exp 01/2023