Enforcement Report - Week of March 30, 2022

Class I Drugs Event

Event ID:
89481

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/25/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/18/2022

Initial Firm Notification of Consignee or Public:
Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

Recalling Firm:
Blaine Labs Inc
11037 Lockport Pl
Santa Fe Springs CA United States

Distribution Pattern:
Nationwide in 17 States to 45 doctors.

Associated Products

Product Description:
REVITADERM WOUND CARE GEL, (Benzalkonium Chloride in a gel containing transforming growth factor-b), 0.1%, packaged in 29.6 mL (1.0 FL OZ) bottles (NDC 63347-120-02) and 88.7 mL (3.0 FL OZ) tubes (NDC 63347-120-01), Blaine Labs Inc., Santa Fe Springs, CA 90670

Product Quantity:
1119 (1 oz.) bottles/ 772 (3 oz.) tubes

Reason for Recall:
Microbial Contamination of Non-sterile Product; FDA analysis found the product to be contaminated with Bacillus cereus.

Recall Number:
D-0668-2022

Code Information:
Lot/Batch #: BL 2844, Expiration date 2/19/2023

Class II Drugs Event

Event ID:
89717

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/08/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/29/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Olympia Compounding Pharmacy dba Olympia Pharmacy
6700 Conroy Rd Ste 155
Orlando FL United States

Distribution Pattern:
Nationwide in the USA including Puerto Rico.

Associated Products

Product Description:
Sermorelin Acetate Lyophilized powder for reconstitution, Multi-Dose 9 mg per vial, Each ML contains: 5% Mannitol USP, Sterile Water for Injection USP, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0059-00

Product Quantity:
2283 vials

Reason for Recall:
Sub Potent

Recall Number:
D-0718-2022

Code Information:
Lots: D44026 Exp. 4/26/22; F42104 Exp. 6/4/22

Product Description:
NAD+ Nicotinamide Adenine Dinucleotide, Lyophilized powder for reconstitution, Multi-Dose 500 mg per vial, Each ML contains: 0.288% Sodium Phosphate Monobasic USP, 0.42% Sodium Phosphate Dibasic USP, 5% Mannitol USP, Sterile Water for Injection USP, Rx Only, Olympia Pharmaceuticals 6700 Conroy Rd., Ste. 155, Orlando, FL 32835 NDC: 73198-0083-00

Product Quantity:
2634 vials

Reason for Recall:
Product found to be Sub Potent or Exceeded reconstitution time

Recall Number:
D-0719-2022

Code Information:
Lot: D24005 Exp. 4/5/22; C41008 Exp. 3/8/22

Product Description:
Sincalide Lyophilized powder for reconstitution Each ML contains: Mannitol 170mg, Arginine 30mg, Lysine 15mg, Potassium Phosphate 9mg, Methionine 4mg, Edetate Disodium Dihydrate 2mg, Polysorbate mcg, Water for Injection, Multiple Dose Injection 5 mcg Vial, Rx Only, Olympia Compounding Pharmacy Compounded by: Olympia Pharmacy Conroy Rd., Ste. 155, Orlando, FL 32835, NDC 73198-0082-00 Revised Label: Sincalide Lyophilized powder for reconstitution, 5mcg per multi dose vial, Each ML contains: 16.7% Mannitol, 3% Arginine, 1.5% Lysine, 0.9% Potassium Phosphate, 0.4% Methionine, 0.2% Edetate Disodium Dihydrate, 0.004% Sodium Metabisulfate, 0.0005% Polysorbate. Water for injection. Rx only, Olympia Pharmaceuticals NDC 73198-0082-00

Product Quantity:
836 vials

Reason for Recall:
Super Potent and Failed Reconstitution Time

Recall Number:
D-0724-2022

Code Information:
Lot: D24001 Exp. 4/1/22

Class II Drugs Event

Event ID:
89774

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/10/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/23/2022

Initial Firm Notification of Consignee or Public:
Other

Recalling Firm:
Rock Town Distillery, Inc.
1201 Main St
Little Rock AR United States

Distribution Pattern:
Distributed in Arkansas USA

Associated Products

Product Description:
ROCK TOWN - DISTILLERY - HAND SANITIZER, Alcohol Antiseptic 70%, Topical Solution packaged in a) 375 mL (12.7 fl. oz.), NDC 74492-0002-1; b) 3785 mL/1 gallon NDC 74492-0002-2; c) 236 mL/8 oz. NDC 74492-0002-3; d) 473 mL/16 oz. NDC 74492-0002-4; Made in USA Rock Town Distillery, 1201 Main Street Little Rock, Arkansas 72202

Product Quantity:
35,468 containers

Reason for Recall:
CGMP Deviations: FDA analysis found product to contain acetal and acetaldehyde above specification limits.

Recall Number:
D-0715-2022

Code Information:
No lot number or expiration date.

Class II Drugs Event

Event ID:
89779

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/14/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/21/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Athenex Pharma Solutions, LLC
11342 Main St
Clarence NY United States

Distribution Pattern:
USA nationwide.

Associated Products

Product Description:
Norepinephrine Bitartrate Injection 4mg per 250 mL in 0.9% Sodium Chloride, 4 mg, 250 mL excel bag, Rx only, Athenex Pharma Solutions, LLC, Clarence, NY, 14031, NDC 76154-474-15

Product Quantity:
4,270 bags

Reason for Recall:
Defective container

Recall Number:
D-0706-2022

Code Information:
Lot #: F2101628, F2101629, F2101630, F2101631, Exp 4/28/22; F2101632, F2101633, Exp 4/29/22; F2101795, F2101796, Exp 5/27/22

Product Description:
Norepinephrine Bitartrate Injection 16 mg per 250 mL added to 0.9% Sodium Chloride, 16 mg, 250 mL excel bag, Rx only, Athenex Pharma Solutions, LLC, Clarence, NY, 14031, NDC 76154-476-15

Product Quantity:
5,320 bags

Reason for Recall:
Defective container

Recall Number:
D-0707-2022

Code Information:
Lot #: F2101634, Exp 3/30/22; F2101665, F2101666, Exp 4/02/22; F2101788, F2101789, Exp 4/26/22; F2101811, F2101812, F2101815, Exp 4/29/22

Product Description:
Norepinephrine Bitartrate Injection 8 mg per 250 mL in 0.9% Sodium Chloride, 8 mg, 250 mL excel bag, Rx only, Athenex Pharma Solutions, LLC, Clarence, NY, 14031, NDC 76154-475-15

Product Quantity:
9,800 bags

Reason for Recall:
Defective container

Recall Number:
D-0708-2022

Code Information:
Lot #: F2101639, F2101642, F2101644, F2101645, Exp 4/30/22; F2101674, F2101675, F2101676, Exp 5/05/22; F2101790, F2101791, F2101792, F2101793, F2101794, Exp 5/26/22; F2101813, Exp 5/29/22

Product Description:
Phenylephrine HCl Injection 40 mg per 250 mL in 0.9% Sodium Chloride, 40 mg, 250 mL excel bag, Rx only, Athenex Pharma Solutions, LLC, Clarence, NY, 14031, NDC 76154-493-15

Product Quantity:
670 bags

Reason for Recall:
Defective container

Recall Number:
D-0709-2022

Code Information:
Lot #: F2101651, Exp 5/30/22

Product Description:
Phenylephrine HCl Injection 50 mg per 250 mL in 0.9% Sodium Chloride, 50 mg, 250 mL excel bag, Rx only, Athenex Pharma Solutions, LLC, Clarence, NY, 14031, NDC 76154-494-15

Product Quantity:
1,800 bags

Reason for Recall:
Defective container

Recall Number:
D-0710-2022

Code Information:
Lot #: F2101652, F2101653, Exp 5/30/22; F2200111, Exp 7/27/22

Product Description:
Phenylephrine HCl Injection in 0.9% Sodium Chloride, 20 mg, 250 mL excel bag, Rx only, Athenex Pharma Solutions, LLC, Clarence, NY, 14031, NDC 76154-491-15

Product Quantity:
1,980 bags

Reason for Recall:
Defective container

Recall Number:
D-0711-2022

Code Information:
Lot #: F2101654, Exp 5/30/22; F2101834, Exp 7/03/22; F2200110, Exp 7/27/22

Product Description:
Epinephrine Injection 8 mg per 250 mL in 0.9% Sodium Chloride, 8mg, 250 mL excel bag, Rx only, Athenex Pharma Solutions, LLC, Clarence, NY, 14031, NDC 76154-814-15

Product Quantity:

Reason for Recall:
Defective container

Recall Number:
D-0712-2022

Code Information:
Lot #: F2101780, F2101781, Exp 6/21/22

Class II Drugs Event

Event ID:
89798

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/15/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/21/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Teligent Pharma, Inc.
105 Lincoln Avenue
Buena NJ United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Betamethasone Dipropionate Lotion USP, 0.05%* (Augmented), packaged in a) 30 mL (29 grams) bottles, NDC 52565-023-29; b) 60 mL (58 grams) bottles, NDC 52565-023-59, Rx Only, Teligent Pharma, Inc., Buena, NJ 08310

Product Quantity:
43,218 bottles

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0669-2022

Code Information:
Batch: a) 15998, Exp. 3/31/2022; b) 16104, Exp. 4/30/2022; 16133, Exp. 5/31/2022; 16391, Exp. 8/31/2022; 15440, Exp. 9/30/2022

Product Description:
Clobetasol Propionate Cream USP, 0.05%, packaged in a) 15 grams tube, NDC 52565-051-15; b) 30 grams tube, NDC 52565-051-30; c) 45 grams

tube, NDC 52565-051-45; d) 60 grams tube, NDC 52565-051-60; Rx only, Manufactured by: Teligent Pharma, Inc., Buena, NJ 08310.

Product Quantity:
207,933 tubes

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0670-2022

Code Information:
Batch: a) 15803, Exp. 7/31/2022; 16237, Exp. 11/30/2022; b) 15803, Exp. 7/31/2022; 16388, Exp. 2/28/2023; c) 15605, Exp. 7/31/2022; 16237, Exp. 11/30/2022; 16388, Exp. 2/28/2023; d) 15605, Exp. 7/31/2022; 15860, Exp. 8/31/2022; 16001, Exp. 9/30/2022; 16237, Exp. 11/30/2022; 16344, Exp. 1/31/2023; 16294, Exp. 2/28/2023; 16474, Exp. 2/28/2023; 16543, Exp. 2/28/2023.

Product Description:
Clobetasol Propionate Cream USP, 0.05% (Emollient), packaged in a) 15 grams tube, NDC 52565-094-15; b) 30 grams tube, NDC 52565-094-30; c) 45 grams tube, NDC 52565-094-45; d) 60 grams tube, NDC 52565-094-60, Rx only, Manufactured by: Teligent Pharma, Inc., Buena, NJ 08310.

Product Quantity:
105,200 tubes

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0671-2022

Code Information:
Batch: a) 15377, Exp. 3/31/2022; 15927, Exp. 9/30/2022; 16130, Exp. 11/30/2022; b) 15117, Exp. 2/28/2022; 16028, Exp. 9/30/2022; 16945, Exp. 5/31/2023; c) 15377, Exp. 3/31/2022; 15927, Exp. 9/30/2022; 16683, Exp. 5/31/2022; d) 15116, Exp. 2/28/2022; 15117, Exp. 2/28/2022; 16130, Exp. 11/30/2022; 16228, Exp. 11/30/2022; 16348, Exp. 1/31/2023

Product Description:
Clobetasol Propionate Lotion, 0.05%, packaged in a) 2 fl. oz. (59 mL) bottles, NDC 52565-055-02; b) 4 fl. oz. (118 mL) bottles, NDC 52565-055-04, Rx Only, Manufactured by: Teligent Pharma, Inc., Buena, New Jersey 08310.

Product Quantity:
35,180 bottles

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0672-2022

Code Information:
Batch: a) 15599, Exp. 4/30/2022; 16108, Exp. 10/31/2022; 16471, Exp. 2/28/2023; 16680, Exp. 3/31/2023; b) 15120, 15126, 15592, Exp. 2/28/2022; 15599, Exp. 4/30/2022; 16108, 16145, Exp. 10/31/2022; 16261, Exp. 12/31/2022; 16456, 16471, Exp. 2/28/2023; 16552, 16680, Exp. 3/31/2023

Product Description:
Clobetasol Propionate Ointment USP, 0.05%, packaged in a) 15 grams tube, NDC 52565-039-15; b) 30 grams tube, NDC 52565-039-30; c) 45 grams tube, NDC 52565-039-45; d) 60 grams tube, NDC 52565-039-60, Rx only, Manufactured by: Teligent Pharma, Inc., Buena, NJ 08310.

Product Quantity:
72,826 tubes

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0673-2022

Code Information:
Batch: a) 15856, Exp. 8/31/2022; 17026, Exp. 6/30/2023; b) 15856, Exp. 8/31/2022; 17026, Exp. 6/30/2023; 17046, Exp. 6/30/2023; c) 15856, Exp. 8/31/2022; d) 15856, Exp. 8/31/2022; 17026, Exp. 6/30/2023

Product Description:
Clobetasol Propionate Gel, 0.05%, packaged in a) 15 grams tube, NDC 52565-082-15; b) 30 grams tube, NDC 52565-082-30; c) 60 grams tube, NDC 52565-082-60, Rx Only, Teligent Pharma, Inc., Buena, NJ 08310.

Product Quantity:
81,883 tubes

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0674-2022

Code Information:
Batch: a) 15063, Exp. 2/28/2022; 15928, Exp. 9/30/2022; 16432, Exp. 2/28/2023; 16769, Exp. 4/30/2023; b) 15243, Exp. 2/28/2022; 16628, Exp. 3/31/2023; c) 15064, 15286, 15287, Exp. 2/28/2022; 16173, Exp. 11/30/2022; 16628, Exp. 3/31/2023

Product Description:
Desonide Ointment, 0.05%, packaged in a) 15 g tubes, NDC 52565-038-15; b) 60 g tubes, NDC 52565-038-60, Rx Only, Manufactured by: Teligent Pharma, Inc., Buena, NJ 08310.

Product Quantity:
36,426 tubes

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0675-2022

Code Information:
Batch: a) 15495, Exp. 4/30/2022; 16955, Exp. 5/31/2023; b) 15249, 15250, 15446, Exp. 3/31/2022; 15495, Exp. 4/30/2022; 16377, Exp. 1/31/2023

Product Description:
Desoximetasone Ointment USP, 0.05%, Net Wt. 100 grams tubes, Rx only, Manufactured for: SOLA Pharmaceuticals, Baton Rouge, LA 70810, NDC 70512-037-10.

Product Quantity:
6850 tubes

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0676-2022

Code Information:
Batch: 15996, 15997, Exp. 9/30/2022

Product Description:
Desoximetasone Ointment USP, 0.05%, packaged in a) 100 grams tubes, NDC 52565-045-99; b) 60 grams tubes, NDC 52565-045-60, Rx only, Manufactured by: Teligent Pharma, Inc., Buena, New Jersey 08310.

Product Quantity:
54,897 tubes

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0677-2022

Code Information:
Batch: a) 15196, Exp. 2/28/2022; 16605, Exp. 3/31/2023; b)15190, Exp. 2/28/2022; 16660, Exp. 4/30/2023; 17037, Exp. 6/30/2023; 17163, Exp. 8/31/2023

Product Description:
Desoximetasone Ointment USP, 0.25%, packaged in a) 100 grams tubes, NDC 52565-030-99; b) 60 grams tubes, NDC 52565-030-60; c) 15 grams tubes, NDC 52565-030-15, Rx Only, Teligent Pharma, Inc., Buena, New Jersey 08310.

Product Quantity:
13,989 tubes

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0678-2022

Code Information:
Batch: a) 15496, Exp. 4/30/2022; 16347, Exp. 1/31/2023; b) 15496, Exp. 4/30/2022; 16298, Exp. 1/31/2023; c) 15496, Exp. 4/30/2022; 16298, Exp. 1/31/2023

Product Description:
Diclofenac Sodium Topical Solution USP, 1.5% w/w, 5 fl. oz. (150 mL) bottle, Rx only, Teligent Pharma, Inc., Buena, New Jersey 08310, NDC 52565-002-05.

Product Quantity:
16,643 bottles

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0679-2022

Code Information:
Batch: 15066, 15389 Exp. 3/31/2023; 15437, Exp. 12/31/2023; 16823, Exp. 4/30/2024; 16825, 16826, Exp. 4/30/2024

Product Description:
Diclofenac Sodium Topical Solution USP, 1.5% w/w, 5 fl. oz. (150 mL) bottles, Rx Only, Manufactured for: SOLA Pharmaceuticals, Baton Rouge, LA 70810, NDC 70512-025-05.

Product Quantity:
36,018 bottles

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0680-2022

Code Information:
Batch: 15384, Exp. 3/31/2023; 15646, Exp. 5/31/2023; 15971, Exp. 9/30/2023; 16206, 16226, Exp. 11/30/2023; 16268, Exp. 12/31/2023; 16342, 16343, Exp. 1/31/2024; 16503, 16504, Exp. 3/31/2024; 16632, Exp. 4/30/2024; 16715, 16731, Exp. 5/31/2024

Product Description:
Diflorasone Diacetate Ointment USP, 0.05%, Net Wt 60 g tubes, Rx only, Manufactured for: SOLA Pharmaceuticals, LLC Baton Rouge, LA 70809, NDC 70512-031-60.

Product Quantity:
24,304 bottles

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0681-2022

Code Information:
Batch: 15800, Exp. 7/31/2022; 15876, 15904, 15917, 15922, Exp. 8/31/2022; 16202, 16203, Exp. 11/30/2022.

Product Description:
Econazole Nitrate Cream, 1%, packaged in a) 15 grams tubes, NDC 52565-022-15; b) 85 grams tubes, NDC 52565-022-85; c) 30 grams tubes, NDC 52565-022-30, Rx Only, Manufactured by: Teligent Pharma, Inc., Buena, New Jersey 08310.

Product Quantity:
151,975 tubes

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0682-2022

Code Information:
Batch: a) 16410, 16438, Exp. 1/31/2023; 16882, Exp. 4/30/2023; b) 15349, Exp. 2/28/2022; 16410, 16438, Exp. 1/31/2023; 16882, Exp. 4/30/2023;

c) 16410, 16438, Exp. 1/31/2023

Product Description:
Fluocinonide Cream USP, 0.1%, 120 grams tube, Rx Only, Manufactured by: Teligent Pharma, Inc., Buena, New Jersey 08310, NDC 52565-079-11.

Product Quantity:
13,905 tubes

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0683-2022

Code Information:
Batch: 15288, Exp. 3/31/2022; 16065, Exp. 10/31/2022; 16430, 16431, Exp. 2/28/2023; 16675, Exp. 3/31/2023

Product Description:
Fluocinonide Gel USP, 0.05%, packaged in a) 15 g tubes, NDC 52565-054-15; b) 60 g tubes, NDC 52565-054-60; c) 30 g tubes, NDC 52565-054-30, Rx Only, Teligent Pharma, Inc., Buena, NJ 08310.

Product Quantity:
51,748 tubes

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0684-2022

Code Information:
Batch: a) 15122, Exp. 2/28/2022; 15475, Exp. 3/31/2022; b) 15119, Exp. 2/28/2022; 15122, Exp. 2/28/2022; 15380, Exp. 3/31/2022; c) 15380, Exp. 3/31/2022

Product Description:
Fluocinonide Topical Solution USP, 0.05%, packaged in a) 20 mL bottles, NDC 52565-025-20; b) 60 mL bottles, NDC 52565-025-59, Rx only, Teligent Pharma, Inc., Buena, New Jersey 08310.

Product Quantity:
7169 bottles

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0685-2022

Code Information:
Batch: 17138, Exp. 2/28/2023

Product Description:
Gentamicin Sulfate Cream USP, 0.1%, packaged in a) 15 g tubes, NDC 52565-085-15, b) 30 g tubes, NDC 52565-085-30, Rx Only, Manufactured by: Teligent Pharma, Inc., Buena, NJ 08310.

Product Quantity:
355,672 tubes

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0686-2022

Code Information:
Batch: a) 15342, 15343, 16686, Exp. 3/31/2023; b) 15259, 15260, Exp. 3/31/2022; 15282, Exp. 4/30/2022; 15283, Exp. 5/31/2022; 15725, 15745, 15764, Exp. 6/30/2022; 16066, Exp. 10/31/2022

Product Description:
Gentamicin Sulfate Ointment USP 0.1%, packaged as a) 15 grams tube, NDC 52565-090-15; b) 30 grams tube, NDC 52565-090-30, Rx Only, Manufactured by: Teligent Pharma, Inc., Buena, NJ 08310.

Product Quantity:
43,956 tubes

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0687-2022

Code Information:
Batch: a) 16878, 16912, Exp. 5/31/2023; b)16878, Exp. 5/21/2023

Product Description:
Halobetasol Propionate Ointment, 0.05%, Net Wt. 50 grams tube, Rx only, Manufactured for: SOLA Pharmaceuticals, Baton Rouge, LA 70809, NDC 70512-033-50.

Product Quantity:
35,185 tubes

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0688-2022

Code Information:
Batch: 15128, Exp. 2/28/2022; 15721, Exp. 6/30/2022; 16171, Exp. 10/31/2022; 16819, Exp. 4/30/2023; 17124, Exp. 7/31/2023

Product Description:
Halobetasol Propionate Ointment, 0.05%, packaged as a) 15 g tubes, NDC 52565-073-15; b) 50 g tubes, NDC 52565-073-51, Rx Only, Manufactured by: Teligent Pharma, Inc., Buena, NJ 08310.

Product Quantity:
161,331 tubes

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0689-2022

Code Information:
Batch: a) 15280, Exp. 2/28/2022; 16539, Exp. 3/31/2023; 16907, Exp. 5/31/2023; b) 15381, Exp. 3/31/2022; 15382, 15501, 15523, Exp. 4/30/2022; 15812, Exp. 7/31/2022; 15972, 16034, 16037, Exp. 9/30/2022; 16105, 16143, Exp. 10/31/2022; 16539, 16746, 16747, Exp. 3/31/2023; 16906, Exp. 5/31/2023; 16962, 17041, Exp. 6/30/2023; 17110, Exp. 7/31/2023

Product Description:
Hydrocortisone Butyrate Lotion 0.1%, 4 fl. oz. (118 mL) bottle, Rx only, Distributed by: Mayne Pharma, Greenville, NC 27834, NDC 51862-159-04.

Product Quantity:
6431 bottles

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0690-2022

Code Information:
Batch: 15435, Exp. 3/31/2022; 16960, Exp. 5/31/2023

Product Description:
Halobetasol Propionate Ointment, 0.05%, Net Wt. 50 grams tube, Rx Only, Manufactured by: Teligent Pharma, Inc., Buena, NJ 08310, Distributed by: McKesson Corporation, dba Sky Packaging, 4971 Southridge Blvd., Suite 101, Memphis, TN 38141, NDC 63739-998-67.

Product Quantity:
21,323 tubes

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0691-2022

Code Information:
Batch: 15720, Exp. 6/30/2022; 16449, 16450, Exp. 2/28/2023

Product Description:
Hydrocortisone Butyrate Lotion, 0.1%, packaged in a) 2 fl oz (59 mL) bottles, NDC 52565-087-02; b) 4 fl oz (118 mL) bottles, NDC 52565-087-04, Rx only, Manufactured by: Teligent Pharma, Inc., Buena, NJ 08310.

Product Quantity:
30,497 bottles

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0692-2022

Code Information:
Batch: a) 16293, Exp. 1/31/2023; 16436, 16451, Exp. 2/28/2023; b) 15105, Exp. 2/28/2022; 15290, 15291, 15292, Exp. 3/31/2022; 16293, Exp. 1/31/2023; 16436, 16451, 16472, Exp. 2/28/2023

Product Description:
Lidocaine Cream, 4%, packaged in a) Net Wt. 15 grams tubes, NDC 52565-122-15; b) Net Wt. 30 grams tubes, NDC 52565-122-30; c) 5 x 5 gram tubes, NDC 52565-122-07; Manufactured by: Teligent Pharma, Inc. Buena, New Jersey 08310; Manufactured by: Teligent Pharma, Inc., Buena, New Jersey 08310.

Product Quantity:
136,960 tubes

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0693-2022

Code Information:
Batch: a) 15192, Exp. 2/28/2022; 16278, Exp. 1/31/2023; b) 15124, 15192, Exp. 2/28/2022; 15296, 15336, 15337, 15439, Exp. 3/31/2022; 16278, Exp. 1/31/2023; 16603, 16664, Exp. 3/31/2023;17023, Exp. 6/30/2023; c) 15067, Exp. 2/28/2022; 16664, Exp. 3/31/2023

Product Description:
Lidocaine Ointment USP, 5%, Net Wt 35.44 g (1 1/4 oz) tube, Rx Only, Teligent Pharma, Inc., Buena, New Jersey 08310, NDC 52565-008-14.

Product Quantity:
100,256 tubes

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0694-2022

Code Information:
Batch: 16389, Exp. 2/29/2024; 16452, Exp. 2/29/2024

Product Description:
Nystatin and Triamcinolone Acetonide Ointment, USP, packaged in a) 15 grams tubes, NDC 52565-042-15; b) 30 grams tubes, NDC 52565-042-30; c) 60 grams tubes, NDC 52565-042-60, Rx Only, Manufactured by: Teligent Pharma, Inc., Buena, NJ 08310.

Product Quantity:
217,184 tubes

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0695-2022

Code Information:
Batch: a) 15125, Exp. 2/28/2022; 15385, Exp. 3/31/2022; 15613, Exp. 5/31/2022; 16027, Exp. 9/30/2022; 16204, Exp. 11/30/2022; 16376, Exp.

1/31/2023; 16707, Exp. 3/31/2023; b) 15385, Exp. 3/31/2022; 15752, Exp. 6/30/2022; 15346, Exp. 9/30/2022; 16188, Exp. 11/30/2022; 16567, Exp. 2/28/2023; 16730, Exp. 4/30/2023; c)15752, Exp. 6/30/2022; 16188, Exp. 11/30/2022

Product Description:
Triamcinolone Acetonide Ointment USP, 0.5%, Net Wt. 15 grams tube, Rx Only, Teligent Pharma, Inc., Buena, New Jersey 08310, NDC 52565-048-15.

Product Quantity:
159,994 tubes

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0696-2022

Code Information:
Batch: 15608, Exp. 5/31/2022; 16026, Exp. 9/30/2022; 16224, Exp. 11/30/2022

Product Description:
Triamcinolone Acetonide Cream USP, 0.1%, packaged in a) 15 grams tubes, NDC 52565-056-15; b) 30 grams tubes, NDC 52565-056-30; c) 80 grams tubes, NDC 52565-056-80, d) 1 lb (454 g) jars, NDC 52565-056-26; Rx Only, Teligent Pharma, Inc., Buena, New Jersey 08310.

Product Quantity:
721,225 tubes; 90,893 jars

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0697-2022

Code Information:
Batch: a) 15123, Exp. 2/28/2022; 15875, Exp. 8/31/2022; 16115, Exp. 10/31/2022; b) 15123, 15201, Exp. 2/28/2022; 15477, Exp. 4/30/2022; 15897, Exp. 8/31/2022; 16090, Exp. 10/31/2022; 16374, Exp. 1/31/2023; 16676, Exp. 3/31/2023; 17109, Exp. 7/31/2023; c) 15241, Exp. 2/28/2022; 16610, Exp. 3/31/2023; d) 15121, 15127, 15191, 15201, 15278, Exp. 2/28/2022;15386, 15567, Exp. 4/30/2022; 15875, Exp. 8/31/2022; 16050, 16051, 16115, Exp. 10/31/2022; 16165, 16201, Exp. 11/30/2022; 16609, 16610, 16624, Exp. 3/31/2023; 16700, Exp. 4/30/2023; 16732, Exp. 5/31/2023; 17081, 17108, Exp. 7/31/2023

Product Description:
Triamcinolone Acetonide Lotion USP, 0.025%, 60 mL (60 grams) bottle, Rx only, Teligent Pharma, Inc., Buena, New Jersey 08310, NDC 52565-010-59.

Product Quantity:
112,769 bottles

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0698-2022

Code Information:
Batch: 14796, Exp. 12/31/2022; 14797, Exp. 1/31/2023; 14534, 15571, 15572, Exp. 4/30/2023; 15746, 15756, Exp. 6/30/2023; 15982, Exp. 9/30/2023; 16043, 16144, 16149, Exp. 10/31/2023; 16433, 16434, Exp. 2/29/2024; 16656, 16679, Exp. 3/31/2024; 16784, Exp. 5/31/2024

Product Description:
Triamcinolone Acetonide Ointment USP, 0.1%, packaged in a) 15 grams tubes, NDC 52565-014-15; b) 80 grams tubes, NDC 52565-014-80; c) 1 lb (454 g) jars, NDC 52565-014-26; Rx only, Teligent Pharma, Inc., Buena, New Jersey 08310.

Product Quantity:
482,003 tubes; 45,583 jars

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0699-2022

Code Information:
Batch: a) 15000, Exp. 1/31/2023; 15591, Exp. 4/30/2023; 15946, Exp. 9/30/2023; b) 14674, Exp. 11/30/2022; 14760, 14798, Exp. 12/31/2022;

14896, Exp. 1/31/2023; 15000, Exp. 1/31/2023; 15591, Exp. 4/30/2023; 15802, 15833, Exp. 7/31/2023; 15872, Exp. 8/31/2023; 15946, Exp. 9/30/2023; 16069, Exp. 10/31/2023; 16199, Exp. 11/30/2023; 16429, Exp. 2/29/2024; 16608, 16712, Exp. 3/31/2024; 17080, Exp. 7/31/2024; c)15065, Exp. 2/28/2023; 15072, Exp. 2/28/2023; 15436, Exp. 3/31/2023; 15810, Exp. 7/31/2023; 15877, Exp. 8/31/2023; 15974, Exp. 9/30/2023; 16045, Exp. 10/31/2023; 16269, Exp. 12/31/2023; 16270, Exp. 12/31/2023; 16566, Exp. 3/31/2024; 16713, Exp. 3/31/2024; 17042, Exp. 6/30/2024; 17068, Exp. 7/31/2024

Product Description:
Clobetasol Propionate Cream USP, 0.05%, packaged in 60 grams tube, Rx only, Manufactured for SOLA Pharmaceuticals, Baton Rouge, LA 70809; NDC 70512-028-60.

Product Quantity:
26,326 tubes

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0700-2022

Code Information:
Batch: 16001 Exp. 9/30/2022; 16089 Exp. 11/30/2022

Product Description:
Diflorasone Diacetate Ointment USP, 0.05%, Net Wt 60 g tubes, Rx only, Manufactured by: Teligent Pharm, Inc., Buena, New Jersey 08310, NDC 52565-063-60.

Product Quantity:
4532 tubes

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0701-2022

Code Information:
Batch: 15876, Exp 8/31/2022; 16205, Exp. 11/30/2022

Product Description:
Gentamicin Sulfate Cream USP, 0.1%, packaged in 30 grams tubes, Rx Only, Manufactured for: SOLA Pharmaceuticals, LLC, Baton Rouge, LA 70810, NDC 70512-036-30.

Product Quantity:
31,489 tubes

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0702-2022

Code Information:
Batch: 15725, Exp. 6/30/2022; 16113, Exp. 10/31/2022

Product Description:
Hydrocortisone Butyrate Lotion, 0.1%, 4 fl oz (118 mL) bottle, Rx only, Manufactured for: SOLA Pharmaceuticals, Baton Rouge, LA 70809, NDC 70512-032-04.

Product Quantity:
6874 bottles

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0703-2022

Code Information:
Batch: 16896, 16897 Exp. 5/31/2023

Product Description:
Lidocaine Cream 4%, Net Wt. 30 grams tube, Distributed by: RUGBY LABORATORIES, 17177 N. Laurel Park Dr., Suite 233, Livonia, MI 48152, NDC 0536-1281-28.

Product Quantity:
48,907 tubes

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0704-2022

Code Information:
Batch: 15722, Exp. 6/30/2022; 16274, Exp. 12/31/2022; 16947, Exp. 5/31/2023; 17140, Exp. 8/31/2023

Product Description:
Lidocaine Ointment USP, 5%, Net Wt 35.44 g (1 1/4 Oz) tube, Rx Only, Manufactured for: Hi-Tech Pharmacal Co., Inc., Amityville, NY 11701, NDC 50383-341-35.

Product Quantity:
49,081 tubes

Reason for Recall:
cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.

Recall Number:
D-0705-2022

Code Information:
Batch: 16695, Exp 4/30/2024

Class II Drugs Event

Event ID:
89807

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/07/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/22/2022

Initial Firm Notification of Consignee or Public:
Letter

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

Distribution Pattern:
Nationwide within the United States

Associated Products

Product Description:
Diclofenac Sodium Topical Solution 1.5%, 150 mL, Rx only, Packaged and Distributed by: Direct Rx Dawsonville, GA 30534 Mfg. For SOLA Pharmaceuticals Baton Rouge, LA, NDC 61919-675-05

Product Quantity:
312 bottles

Reason for Recall:
Defective Container: Leaking containers.

Recall Number:
D-0714-2022

Code Information:
Lot #: 24MA2010 Exp. 1/31/2023

Class II Drugs Event

Event ID:
89836

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
09/08/2021

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/24/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Akorn, Inc.
1925 W Field Ct Ste 300
Lake Forest IL United States

Distribution Pattern:
Nationwide within theUSA

Associated Products

Product Description:
TheraTears Extra (sodium carboxymethylcellulose) 0.25% Lubricant Eye Drops, 30 Sterile Single-Use Vials per box, Akorn Consumer Health, A Division of Akorn, Inc., Ann Arbor, MI 48105. NDC 58790-010-30

Product Quantity:
62,331 box

Reason for Recall:
Lack of Assurance of Sterility

Recall Number:
D-0717-2022

Code Information:
Lot #: 913012, 913013, 913014, Exp. Date 1/31/2023

Class III Drugs Event

Event ID:
89717

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/08/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
03/29/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Olympia Compounding Pharmacy dba Olympia Pharmacy
6700 Conroy Rd Ste 155
Orlando FL United States

Distribution Pattern:
Nationwide in the USA including Puerto Rico.

Associated Products

Product Description:
Formula F9, Papaverine 0.9 mg/mL, Phentolamine 0.1 mg/mL, PGE 20 mcg/mL, Atropine 0.01 mg/mL, Multi-Dose 10 mL vial, Each ML contains: 0.5% Chlorobutanol NF, 0.005% Edetate Disodium Dihydrate USP, 2.74% Benzyl Alcohol NF, 5% Mannitol USP, 1% Sodium Metabisulfite NF, 1% Ethyl Alcohol USP, Sterile Water for Injection USP, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0004-10

Product Quantity:
493 vials.

Reason for Recall:
Sub Potent

Recall Number:
D-0720-2022

Code Information:
Lot: D41C19 Exp. 4/19/22

Product Description:
T-105, Papaverine 30 mg/mL Phentolamine 1 mg/mL PGE 10 mcg/mL packaged as a) 5 mL Multi-dose NDC 73198-0005-05; b) 10 mL Multi-dose NDC 73198-0005-10; Each ML contains: 0.5% Chlorobutanol NF, 0.0005% Edetate Disodium Dihydrate USP, 1.84% Benzyl Alcohol NF, 5% Mannitol USP, 1% Sodium Metabisulfite NF, 0.5% Ethyl Alcohol USP, Sterile Water for Injection USP, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155, Orlando, FL 32835.

Product Quantity:
1093 vials

Reason for Recall:
Super Potent

Recall Number:
D-0721-2022

Code Information:
Lots: a) E41F10 Exp. 5/10/22; b) E41G10 Exp. 5/10/22

Product Description:
SB-4, Papaverine 30mg/mL, Phentolamine 3mg/mL, Alprostadil 40mcg/mL, packaged in a) 5 mL Multi-dose vial NDC 73198-0023-05; b) 10 mL Multi-dose vial NDC 73198-0023-10, Each ML contains: 0.5% Chlorobutanol NF, 0.0005% Edetate Disodium Dihydrate USP, 1.84% Benzyl Alcohol NF, 5% Mannitol USP, 1% Sodium Metabisulfite NF, 2% Ethyl Alcohol USP, Sterile Water for Injection USP, Rx Only, Olympia Pharmaceuticals, Conroy Rd., Ste. 155, Orlando, FL 32835

Product Quantity:
1032 vials

Reason for Recall:
Sub Potent

Recall Number:
D-0722-2022

Code Information:
Lots: a) E41C18 Exp. 5/18/22; b) E41D18 Exp. 5/18/22

Product Description:
Hydroxocobalamin B12 1mg/mL, Multi-Dose 30 mL vial, Each ML contains: 0.82% Sodium Chloride USP, 0.9% Benzyl Alcohol NF, Sterile Water for Injection USP, Rx Only, Olympia Pharmaceuticals Conroy Rd., Ste. 155, Orlando, FL 32835 NDC 73198-0080-30

Product Quantity:
1613 vials

Reason for Recall:
Sub Potent

Recall Number:
D-0723-2022

Code Information:
Lot: E47025 Exp. 5/21/22

Not Yet Classified Drugs Event

Event ID:
89705

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
03/03/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
Tennessee Technical Coatings, Corp.
1421 Higgs Rd
Lewisburg TN United States

Distribution Pattern:
Distributed in AL, TN

Associated Products

Product Description:
HAND SANITIZER Isopropyl Alcohol Antiseptic 75%, Net contents: 1 U.S. Gallon/3.785 Liters Tennessee Technical Coatings Corporation, 1421 Higgs Road (P.O. Box 1698) Lewisburg, TX 37091, NDC 76921-000-01

Product Quantity:
169.2 gallons

Reason for Recall:
Chemical Contamination: FDA analysis found 1 lot of HAND SANITIZER Isopropyl Alcohol Antiseptic 75%, to contain methanol.

Recall Number:

Code Information:
Batch #:00806001, No EXP date on label.

Product Description:
HAND SANITIZER Isopropyl Alcohol Antiseptic 75%, Net contents: 1 U.S. Gallon/3.785 Liters Tennessee Technical Coatings Corporation, 1421 Higgs Road (P.O. Box 1698) Lewisburg, TX 37091, NDC 76921-000-01

Product Quantity:

Reason for Recall:
CGMP Deviations: lots and products of hand sanitizer are being recalled because they were manufactured under the same conditions as the product lot found to contain methanol.

Recall Number:

Code Information:
Batch #: 00421002, 00422001, 00429001, 00521001, 00622003, No EXP date on label.