Enforcement Report - Week of September 14, 2022

Class I Drugs Event

Event ID:
90398

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
06/07/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/06/2022

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

Recalling Firm:
Plastikon Healthcare LLC
3780 Greenway Cir
Lawrence KS United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
MILK OF MAGNESIA USP, 2400 mg/30 mL, Magnesium Hydroxide, 30 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr., Suite 233, Livonia, MI 48152, NDC 0904-6846-73.

Product Quantity:
24,400 cups

Reason for Recall:
Microbial Contamination of Non-Sterile Products

Recall Number:
D-1476-2022

Code Information:
Lot# 20071A, EXP Jul. 2022

Product Description:
MILK OF MAGNESIA USP, 2400 mg/10 mL, Magnesium Hydroxide, 30 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr., Suite 233, Livonia, MI 48152, NDC 0904-6840-72.

Product Quantity:
7,700 cups

Reason for Recall:
Microbial Contamination of Non-Sterile Products.

Recall Number:
D-1477-2022

Code Information:
Lot # 20074A, EXP Jul. 2022

Product Description:
Magnesium Hydroxide 1200 mg, Aluminum Hydroxide 1200 mg, Simethicone 120 mg per 30 mL, 30 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr., Suite 233, Livonia, MI 48152, NDC 0904-6838-73

Product Quantity:
220,500 cups

Reason for Recall:
Microbial Contamination of Non-Sterile Products.

Recall Number:
D-1478-2022

Code Information:
Lot# 20076A, EXP Jul. 2022, 20079A, 20081A, EXP Aug. 2022; 21096A, EXP Oct. 2022; 21115A, 21103A, EXP Sep. 2022.

Product Description:
Magnesium Hydroxide 2400 mg, Aluminum Hydroxide 2400 mg, Simethicone 240 mg MAX, per 30 mL Oral Suspension, 30 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr., Suite 233, Livonia, MI 48152, NDC 0904-6839-73

Product Quantity:
43,200 cups

Reason for Recall:
Microbial Contamination of Non-Sterile Products.

Recall Number:
D-1479-2022

Code Information:
Lot #: 20051A, EXP Aug. 2022; 20088A, EXP Sep. 2022.

Class II Drugs Event

Product Description:
MILK OF MAGNESIA USP, 2400 mg/30 mL, Magnesium Hydroxide, 30 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr., Suite 233, Livonia, MI 48152, NDC 0904-6846-73.

Product Quantity:
502,600 cups

Reason for Recall:
CGMP Deviations: products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.

Recall Number:
D-1480-2022

Code Information:
Lot # 20072A, 20075A, EXP Jul. 2022; 20087A, EXP Aug. 2022; 20089A, 20090A, EXP Sep. 2022; 20100A, 20102A, EXP Oct. 2022; 20106A, 20107A EXP Nov. 2022; 20109A, EXP Dec. 2022; 21010A, EXP Jan. 2023; 21028A, 21030A, 21032A, EXP Mar. 2023; 21045A, 21046A, EXP Apr. 2023; 21054A, EXP May. 2023; 21078A, 21079A, 21085A, EXP Jul. 2023; 21088A, EXP Aug. 2023

Product Description:
MILK OF MAGNESIA USP, 2400 mg/10 mL, Magnesium Hydroxide, 30 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr., Suite 233, Livonia, MI 48152, NDC 0904-6840-72.

Product Quantity:
92,200 cups

Reason for Recall:
CGMP Deviations: products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.

Recall Number:
D-1481-2022

Code Information:
Lot # 20085A, EXP Aug. 2022; 20099A, EXP Oct. 2022; 21039A, 21052A, EXP May. 2023; 21114A, EXP Oct. 2023; 21130A, 21132A, EXP Dec. 2023.

Product Description:
Magnesium Hydroxide 1200 mg, Aluminum Hydroxide 1200 mg, Simethicone 120 mg per 30 mL, 30 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr., Suite 233, Livonia, MI 48152, NDC 0904-6838-73

Product Quantity:
521,700 cups

Reason for Recall:
CGMP Deviations: products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.

Recall Number:
D-1482-2022

Code Information:
Lot # 20077A, 20080A, 20082A, EXP Aug. 2022; 21016A, EXP Feb. 2023; 21026A, EXP Mar. 2023; 21042A, 21047A, 21050A, EXP Apr. 2023; 21057A, 21059A, 21060A,EXP May. 2023; 21061A, 21067A, 21070A, 21072A, EXP Jun. 2023; 21095A, 21097A, 21099A, EXP Sep. 2023; 21107A, 21109A, 21111A, 21113A, EXP Oct. 2023; 21138A, EXP Dec. 2023; 22002A, 22004A, 22005A, EXP Jan. 2024

Product Description:
Magnesium Hydroxide 2400 mg, Aluminum Hydroxide 2400 mg, Simethicone 240 mg MAX, per 30 mL Oral Suspension, 30 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr., Suite 233, Livonia, MI 48152, NDC 0904-6839-73

Product Quantity:
88,500 cups

Reason for Recall:
CGMP Deviations: products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.

Recall Number:
D-1483-2022

Code Information:
Lot # 20084A, 20086A, EXP Aug. 2022; 21074A, 21077A, EXP Jul. 2023

Product Description:
Acetaminophen Oral Solution 160 mg / 5 mL, 5 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr., Suite 233, Livonia, MI 48152, NDC 0904-6738-70

Product Quantity:
290,270 cups

Reason for Recall:
CGMP Deviations: products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.

Recall Number:
D-1484-2022

Code Information:
Lot# 20078A, 20083A EXP Aug. 2022; 20092A, EXP Sep. 2022; 21058A, 21048C, EXP May. 2023; 21063C, EXP Jun. 2023; 21093B, EXP Sep. 2023; 22001C, EXP Jan. 2024; 22017A, EXP Mar. 2024.

Product Description:
Acetaminophen Oral Solution, 325 mg / 10.15 mL, 10.15 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr. Suite 233, Livonia, MI 48152, NDC 0904-6739-71

Product Quantity:
848,500 cups

Reason for Recall:
CGMP Deviations: products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.

Recall Number:
D-1485-2022

Code Information:
Lot # 20062A, 20067A, EXP Jun. 2022; 20092A, 20093A, EXP Sep. 2022; 20101A, 21110A, EXP Oct. 2022; 20108A, EXP Nov. 2022; 21012A, EXP Jan. 2023; 21044A, 21048B, EXP Apr. 2023; 21053A, EXP May. 2023; 21063B, 21068B, EXP Jun. 2023; 21084B, EXP Jul. 2023; 21090A, EXP Aug. 2023; 21119A, EXP Nov. 2023; 21122B, EXP Dec. 2023; 22001B, 22006A, EXP Jan. 2024; 22017B, EXP Mar. 2024

Product Description:
Acetaminophen Oral Solution 650 mg / 20.3 mL, 20.3 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr. Suite 233, Livonia, MI 48152, NDC 0904-6820-76

Product Quantity:
3,507,740 cups

Reason for Recall:
CGMP Deviations: products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.

Recall Number:
D-1486-2022

Code Information:
Lot # 20064A, 20066A, EXP Jun. 2022; 20069A, 20073A, EXP Jul. 2022; 20094A, 20094B, 20095A, 20095B, EXP Sep. 2022; 20103A, EXP Oct. 2022; 20105A, EXP Nov. 2022; 20111A, 20111B, EXP Dec. 2022; 21005A, 21005B, EXP Jan. 2023; 21019A, 21019B, EXP Feb. 2023; 21035A, 21035B, 21038A, EXP Mar. 2023; 21048A, 21048D, EXP Apr. 2023; 21058B, EXP May. 2023; 21063A, 21068A, EXP Jun. 2023; 21084A, EXP Jul. 2023; 21090B, EXP Aug. 2023; 21093A, EXP Sep. 2023; 21124A, 21126A, EXP Nov. 2023; 21136A,20112A, 21122A,21122C, 20112B, EXP Dec. 2023; 22001A, 22001D, 22006B, 22006C, EXP Jan. 2024; 22010A, 22011A, 22011B, EXP Feb. 2024; 22014A, 22015A, 22021A, EXP Mar. 2024.

Product Description:
CALCIUM CARBONATE ORAL SUSPENSION, 1250 mg/5 mL, 5 mL cup, packaged in 10 cups per tray, 4 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr. Suite 233, Livonia, MI 48152, NDC 0904-7098-94

Product Quantity:
49,280 cups

Reason for Recall:
CGMP Deviations: products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.

Recall Number:
D-1487-2022

Code Information:
Lot # 21021A, 21023A, 21024A, EXP Feb. 2023; 21064A, EXP Jun. 2023; 21073A, 21075A, EXP Jul. 2023; 21100A, EXP Sep. 2023; 21118A, 21120A, EXP Nov. 2023; 21128A, 21129A, 21131A, 21135A, EXP Dec. 2023; 22019A, EXP Mar. 2024.

Product Description:
Diphenhydramine HCl Oral Solution 12.5 mg / 5 mL, 5 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr. Suite 233, Livonia, MI 48152, NDC 0904-6740-70

Product Quantity:
217,700 cups

Reason for Recall:
CGMP Deviations: products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.

Recall Number:
D-1488-2022

Code Information:
Lot # 20063A, EXP Jun. 2022; 20098A, EXP Oct. 2022; 21055B, EXP May. 2023; 21066A, EXP Jun. 2023; 21083B, EXP Jul. 2023; 21112B, EXP Oct. 2023; 22009A, EXP Feb. 2024.

Product Description:
Diphenhydramine HCl Oral Solution, 25 mg / 10 mL, 10 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr. Suite 233, Livonia, MI 48152, NDC 0904-6741-72

Product Quantity:
349,100 cups

Reason for Recall:
CGMP Deviations: products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.

Recall Number:
D-1489-2022

Code Information:
Lot # 20065A, EXP Jun. 2022; 20068A, 20070A, EXP Jul. 2022; 20097A, 20098A, EXP Oct. 2022; 21055A, EXP May. 2023; 21083A, EXP Jul. 2023; 21091A, EXP Aug. 2023; 21112A, EXP Oct. 2023

Product Description:
GUAIFENESIN AND DEXTROMETHORPHAN 100 mg-10 mg/5 mL, 5 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr. Suite 233, Livonia, MI 48152. NDC 0904-6844-70

Product Quantity:
280,500 cups

Reason for Recall:
CGMP Deviations: products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.

Recall Number:
D-1490-2022

Code Information:
Lot # 20091A, EXP Sep. 2022; 20104A, EXP Nov. 2022; 21013A, EXP Feb. 2023; 21041A, EXP Apr. 2023; 21102A, EXP Sep. 2023; 21121A, 21127A, EXP Nov. 2023; 22003A, 22007A, EXP Jan. 2024; 22016A, EXP Mar. 2024

Product Description:
GUAIFENESIN AND DEXTROMETHORPHAN 200-20 mg/10 mL, 10 mL cup, packaged in 10 cups per tray, 10 trays per carton, For Institutional Use Only, Major Pharmaceuticals, 17177 N Laurel Park Dr. Suite 233, Livonia, MI 48152, NDC 0904-6980-72

Product Quantity:
246,200 cups

Reason for Recall:
CGMP Deviations: products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.

Recall Number:
D-1491-2022

Code Information:
Lot # 20091A, EXP Sep. 2022; 20104A, EXP Nov. 2022; 21017A, EXP Feb. 2023; 21034A, 21036A EXP Mar. 2023; 21092A, EXP Aug. 2023; 21105A, 21106A, EXP Oct. 2023; 21134A, EXP Dec. 2023; 22007B, EXP Jan. 2024; 22012A, EXP Feb. 2024; 22016B, EXP Mar. 2024

Product Description:
CORRECTDOSE Children's ALLERGY RELIEF (Diphenhydramine HCl 12.5 mg per 5 mL), 2.04 FL. OZ (60 mL) packaged in 12- 5mL individual doses, Distributed by Correct Dose Inc, Braintree MA 02184. NDC 62320-302-05 UPC 8 60003 67144 3

Product Quantity:
7,200 ampoules

Reason for Recall:
CGMP Deviations: products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.

Recall Number:
D-1492-2022

Code Information:
Lot # 21011A, EXP Jan. 2023

Product Description:
CORRECTDOSE Children's PAIN RELIEF & Fever Reducer, Cherry, (Acetaminophen 160 mg per 5 mL), 2.04 FL.OZ (60mL), packaged in 12-5mL individual doses, Distributed by Correct Dose Inc, Braintree MA 02184. NDC 62320-311-05 UPC 8 60003 67145 0

Product Quantity:
1,464 ampoules

Reason for Recall:
CGMP Deviations: products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.

Recall Number:
D-1493-2022

Code Information:
Lot # 20096A, EXP Oct. 2022

Product Description:
CORRECTDOSE Children's COUGH & CHEST CONGESTION DM (Guaifenesin 100 mg / Dextromethorphan 5 mg per 5 mL) 2.04FL. OZ (60mL), packaged in 12-5 individual doses, Distributed by Correct Dose Inc, Braintree MA 02184. NDC 62320-321-05 UPC 8 60003 67146 7

Product Quantity:
1,464 ampoules

Reason for Recall:
CGMP Deviations: products manufactured under conditions which reflect manufacturing processes that were not adequately controlled.

Recall Number:
D-1494-2022

Code Information:
Lot # 21014A, EXP Feb. 2023

Class II Drugs Event

Event ID:
90796

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/22/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/07/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
CIPLA
10 Independence Blvd
Warren NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Difluprednate Ophthalmic Emulsion, 0.05%, 5 mL bottle, RX only, Manufactured for Exelan Pharmecuticals, Inc., Boca Raton, FL 33432, NDC 76282-708-50.

Product Quantity:
3,468 bottles

Reason for Recall:
Lack of Assurance of Sterility: customer complaint for defective container where breakage of the protective cap exposes tip of eye drop which could compromise sterility.

Recall Number:
D-1498-2022

Code Information:
Lot # DEG5BD2, Exp 07/2023

Product Description:
Difluprednate Ophthalmic Emulsion, 0.05%, 5 mL bottle, RX only, Manufactured by Cipla Ltd., India, Manufactured for: Cipla USA, Inc., NJ 07059, NDC 69097-341-35.

Product Quantity:
117,844 bottles

Reason for Recall:
Lack of Assurance of Sterility: customer complaint for defective container where breakage of the protective cap exposes tip of eye drop which could compromise sterility.

Recall Number:
D-1499-2022

Code Information:
Lot #: DEG1HC2, DEG2HC2, DEG3HC2, DEG4HC2, DEG5HC2, DEG6HC2, Exp 01/2023; DEG1IC2, DEG2IC2, DEG3IC2, DEG4IC2, Exp 02/2023; DEG1LC2, DEG2LC2, Exp 05/2023; DEG1BD2, DEG2BD2, DEG3BD2, Exp 07/2023

Class II Drugs Event

Event ID:
90813

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
08/31/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
09/06/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Akorn, Inc.
5605 Centerpoint Ct Ste A
Gurnee IL United States

Distribution Pattern:
USA nationwide

Associated Products

Product Description:
Lidocaine Hydrochloride Jelly USP, 2%, Sterile, 30mL tube, Rx only, Manufactured by: Akorn, Inc., Lake Forest, IL 60045, NDC 17478-711-31

Product Quantity:
82,689 tubes

Reason for Recall:
cGMP Deviations: Turbidity discovered in Artificial Tears Ointment during sterility testing. Scope expanded to include other lots and products which potentially share the same root cause.

Recall Number:
D-1495-2022

Code Information:
Lot # 9J36A, 9J36B, 9J39A, 9J39B, 9J39C, 9J39D, 9J39E, 9J42B, 9J42C, Exp 8/31/2022; 9K62A, 9K62B, 9K62C, Exp 9/30/2022; 9M04A, 9M04B, Exp 11/30/2022

Product Description:
Sodium Chloride Ophthalmic Ointment USP, 5%, Sterile, Net Wt 3.5 g (1/8 oz) tube, Mfg by: Akorn, Inc., Lake Forest , IL 600405, NDC 17478-622-35

Product Quantity:
48,636 tubes

Reason for Recall:
cGMP Deviations: Turbidity discovered in Artificial Tears Ointment during sterility testing. Scope expanded to include other lots and products which potentially share the same root cause.

Recall Number:
D-1496-2022

Code Information:
Lot#: 9J58A, 9J58B, Exp 8/31/2022