

# Enforcement Report - Week of August 28, 2019

## Class II Drugs Event

**Event ID:**

83417

**Product Type:**

Drugs

**Status:**

Ongoing

**Date Terminated:**
**Recall Initiation Date:**

07/26/2019

**Voluntary / Mandated:**

Voluntary: Firm initiated

**Center Classification Date:**

08/16/2019

**Initial Firm Notification of Consignee or Public:**

Letter

**Recalling Firm:**

Medtech Products, Inc.  
660 White Plains Rd Ste 250  
Tarrytown NY United States

**Distribution Pattern:**

Nationwide in the USA and Puerto Rico, St. Michael, Barbados, Guyana, St. Johns, Antigua and Barbuda, Kingston 5, and Jamaica.

## Associated Products

**Product Description:**

Clear eyes REDNESS RELIEF (Glycerin 0.25%, Naphazoline hydrochloride 0.012%) eye drops, packaged in a) 0.5 FL OZ (15 mL) bottle (UPC 6 78112 25415 6); b) 1 FL OZ (30 mL) bottle (UPC 6 78112 25419 4); c) 0.2 FL OZ (6 mL) bottle, Handy Pocket Pal (UPC 6 78112 25418 7); Distributed by Medtech Products Inc., Tarrytown, NY 10591; A Prestige Brands Company.

**Product Quantity:**

6,661,188 bottles

**Reason for Recall:**

CGMP Deviations: concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility that could impact the product quality of the finished products.

**Recall Number:**

D-1822-2019

**Code Information:**

Lot #: a) 16195, Exp 07/19; 16211, 16216, Exp 08/19; b) 16205, Exp 07/19; 16211, Exp 08/19; c) 16192, 16203, Exp 07/19; 16242, Exp 09/19; 16280, 16285, Exp 10/19; 16300, Exp 11/19; 16336, Exp 12/19; 17002, 17012, Exp 01/20; 17051, Exp 02/20; 17130, Exp 04/20; 17147, Exp 05/20

**Product Description:**

Clear eyes REDNESS RELIEF (Glycerin 0.25%, Naphazoline hydrochloride 0.012%) eye drops, Handy Pocket Pal, 0.2 FL OZ (6 mL) bottle, Dist. by Lil' Drug Store Products Inc., 1201 Continental Place NE, Cedar Rapids, IA 52402; Medtech Products Inc., Tarrytown, NY 10591, UPC 7 92554 70103 7.

**Product Quantity:**

1,621,200 bottles

**Reason for Recall:**

CGMP Deviations: concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility that could impact the product quality of the finished products.

**Recall Number:**

D-1823-2019

**Code Information:**

Lot #: 16321, Exp 11/19; 16336, Exp 12/19; 17012, Exp 01/20; 17034, 17051, Exp 02/20; 17147, Exp 05/20

**Product Description:**

Clear eyes MAXIMUM ITCHY EYE RELIEF (Glycerin 0.25%, Naphazoline hydrochloride 0.012%, Zinc Sulfate 0.25%) eye drops, 0.5 FL OZ (15 mL) bottle, Distributed by Medtech Products Inc., Tarrytown, NY 10591, A Prestige Brands Company, UPC 6 78112 65920 3.

**Product Quantity:**

927,108 bottles

**Reason for Recall:**

CGMP Deviations: concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility that could impact the product quality of the finished products.

**Recall Number:**

D-1824-2019

**Code Information:**

Lot #: 16302, Exp 11/19; 16331, 16344, Exp 12/19; 17011, 17016, Exp 01/20.

**Product Description:**

Clear eyes MAXIMUM REDNESS RELIEF (Glycerin 0.5%, Naphazoline hydrochloride 0.03%) eye drops, 0.5 FL OZ (15 mL) bottle, Distributed by Medtech Products Inc., Tarrytown, NY 10591, A Prestige Brands Company, UPC 6 78112 66577 8.

**Product Quantity:**

1,872,984 bottles

**Reason for Recall:**

CGMP Deviations: concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility that could impact the product quality of the finished products.

**Recall Number:**

D-1825-2019

**Code Information:**

Lot #: 16234, 16247, Exp 08/19; 16286, Exp 10/19; 16314, Exp 11/19

**Product Description:**

Clear Eyes Assorted IRC Display; each display contains 6 each of a) Clear eyes REDNESS RELIEF (Glycerin 0.25%, Naphazoline hydrochloride 0.12%) eye drops, 0.5 FL OZ (15 mL) bottle (UPC 6 78112 25415 6); b) Clear eyes MAXIMUM REDNESS RELIEF (Glycerin 0.5%, Naphazoline hydrochloride 0.03%), 0.5 FL OZ (15 mL) bottle (UPC 6 78112 66577 8); and c) Clear eyes MAXIMUM ITCHY EYE RELIEF (Glycerin 0.25%, Naphazoline hydrochloride 0.012%, Zinc Sulfate 0.25%), 0.5 FL OZ (15 mL) bottle (UPC 6 78112 65920 3); Distributed by Medtech Products Inc., Tarrytown, NY 10591, A Prestige Brands Company, display UPC 6 78112 10452 9.

**Product Quantity:**

20,808 bottles

**Reason for Recall:**

CGMP Deviations: concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility that could impact the product quality of the finished products.

**Recall Number:**

D-1826-2019

**Code Information:**

Lot #: Display 17E23A, Exp 12/19; lot and expiry for individual products within this display are captured in each individual product Code Information

**Product Description:**

Clear Eyes Maximum Redness and Itchy Eye Relief Sidekick Display; each display contains 12 each of a) Clear eyes MAXIMUM REDNESS RELIEF (Glycerin 0.5%, Naphazoline hydrochloride 0.03%) eye drops, 0.5 FL OZ (15 mL) bottle, (UPC 6 78112 66577 8); and b) Clear eyes MAXIMUM ITCHY EYE RELIEF (Glycerin 0.25%, Naphazoline hydrochloride 0.012%, Zinc Sulfate 0.25%) eye drops, 0.5 FL OZ (15 mL) bottle, (UPC 6 78112 65920 3); Distributed by Medtech Products Inc., Tarrytown, NY 10591, A Prestige Brands Company, case UPC 00678112105434.

**Product Quantity:**

66,168 bottles

**Reason for Recall:**

CGMP Deviations: concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility that could impact the product quality of the finished products.

**Recall Number:**

D-1827-2019

**Code Information:**

Lot #: Display 17C30A, Exp 10/19; lot and expiry for individual products within this display are captured in each individual product Code Information

**Product Description:**

Clear Eyes Assorted Sidekick Floor Stand Display; each display contains 6 each of a) Clear eyes REDNESS RELIEF (Glycerin 0.25%, Naphazoline hydrochloride 0.12%) eye drops, 0.5 FL OZ (15 mL) bottle (UPC 6 78112 25415 6); b) Clear eyes MAXIMUM REDNESS RELIEF (Glycerin 0.5%,

Naphazoline hydrochloride 0.03%), 0.5 FL OZ (15 mL) bottle (UPC 6 78112 66577 8); and c) Clear eyes MAXIMUM ITCHY EYE RELIEF (Glycerin 0.25%, Naphazoline hydrochloride 0.012%, Zinc Sulfate 0.25%), 0.5 FL OZ (15 mL) bottle (UPC 6 78112 65920 3); Distributed by Medtech Products Inc., Tarrytown, NY 10591, A Prestige Brands Company, case UPC 00678112106905.

**Product Quantity:**

25,992 bottles

**Reason for Recall:**

CGMP Deviations: concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility that could impact the product quality of the finished products.

**Recall Number:**

D-1828-2019

**Code Information:**

Lot #: Display 17E12A, Exp 09/19; lot and expiry for individual products within this display are captured in each individual product Code Information

**Product Description:**

Clear Eyes Redness Relief Club Pack Display; each display contains 18 3-Pack bottles (UPC 6 78112 10552 6) of Clear eyes REDNESS RELIEF (Glycerin 0.25%, Naphazoline hydrochloride 0.12%) eye drops, 0.5 FL OZ (15 mL) bottle (individual bottle UPC 6 78112 25415 6); Distributed by Medtech Products Inc., Tarrytown, NY 10591, A Prestige Brands Company.

**Product Quantity:**

124,038 bottles

**Reason for Recall:**

CGMP Deviations: concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility that could impact the product quality of the finished products.

**Recall Number:**

D-1829-2019

**Code Information:**

Lot #: 3-pack Q16299D2, Exp 07/19; Q162300D1, Q16260B1, Q16261B1, Q16263B1, Q16301D1, Q16302D1, Q16303D1, Q16308D1, Q16309D1, Q16336D1, Q16337D1, Q16340D1, Q16342D1, Q16343D1, Q16344D1, Exp 08/19; lot and expiry for individual products within this display are captured in each individual product Code Information

**Product Description:**

Clear Eyes Maximum Itchy Eye Relief Sidekick Floor Stand Display; each display contains 12 each of Clear eyes MAXIMUM ITCHY EYE RELIEF (Glycerin 0.25%, Naphazoline hydrochloride 0.012%, Zinc Sulfate 0.25%) eye drops, 0.5 FL OZ (15 mL) bottle, (UPC 6 78112 65920 30); Distributed by Medtech Products Inc., Tarrytown, NY 10591, A Prestige Brands Company, case UPC 10678112106995.

**Product Quantity:**

1,752 bottles

**Reason for Recall:**

CGMP Deviations: concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility that could impact the product quality of the finished products.

**Recall Number:**

D-1830-2019

**Code Information:**

Lot #: 16331, 16344, EXP 12/19

**Product Description:**

Clear Eyes Maximum Redness Relief Club Pack Display; each display contains 18 3-Pack bottles (UPC 6 78112 10859 6) of Clear eyes MAXIMUM REDNESS RELIEF (Glycerin 0.5%, Naphazoline hydrochloride 0.03%) eye drops, 0.5 FL OZ (15 mL) bottle, (UPC 6 78112 66577 8); Distributed by Medtech Products Inc., Tarrytown, NY 10591, A Prestige Brands Company.

**Product Quantity:**

17,316 bottles

**Reason for Recall:**

CGMP Deviations: concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility that could impact the product quality of the finished products.

**Recall Number:**

D-1831-2019

**Code Information:**

Lot #: Q16322M1, Q16323M1, Q16323M2, Q16326M1, Exp 08/19; lot and expiry for individual products within this display are captured in each

## individual product Code Information

**Product Description:**

Clear Eyes Maximum Itchy Eye Relief Sidekick Floor Stand Display; each display (case UPC 10678112736383) contains 12 each of Clear eyes MAXIMUM ITCHY EYE RELIEF (Glycerin 0.25%, Naphazoline hydrochloride 0.012%, Zinc Sulfate 0.25%) eye drops, 0.5 FL OZ (15 mL) bottle, (UPC 6 78112 65920 3), Distributed by Medtech Products Inc., Tarrytown, NY 10591, A Prestige Brands Company.

**Product Quantity:**

1,836 bottles

**Reason for Recall:**

CGMP Deviations: concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility that could impact the product quality of the finished products.

**Recall Number:**

D-1832-2019

**Code Information:**

Lot #: 16331, 16344, Exp 12/19

**Product Description:**

Clear Eyes Redness Relief Handy Pocket Pal Club Pak Display; each display (case UPC 30300742541283) contains 48 each of Clear eyes REDNESS RELIEF (Glycerin 0.25%, Naphazoline hydrochloride 0.012%) eye drops, 0.2 FL OZ (6 mL) bottle, Handy Pocket Pal (UPC 6 78112 25418 7); Distributed by Medtech Products Inc., Tarrytown, NY 10591; A Prestige Brands Company.

**Product Quantity:**

793,872 bottles

**Reason for Recall:**

CGMP Deviations: concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility that could impact the product quality of the finished products.

**Recall Number:**

D-1833-2019

**Code Information:**

Lot # 16242, Exp 09/19; 16280, Exp 10/19; 17051, Exp 02/20; 17130, Exp 04/20

**Product Description:**

Clear eyes REDNESS RELIEF (Glycerin 0.25%, Naphazoline hydrochloride 0.012%) eye drops, Handy Pocket Pal, 0.2 FL OZ (6 mL) bottle, Distributed by Select Corporation, Carrolton, TX 75007; Medtech Products Inc., Tarrytown, NY 10591, A Prestige Brands Company, UPC 6 55708 01039 6.

**Product Quantity:**

1,030,128 bottles

**Reason for Recall:**

CGMP Deviations: concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility that could impact the product quality of the finished products.

**Recall Number:**

D-1834-2019

**Code Information:**

Lot #: 16192, 16203, Exp 07/19; 16321, Exp 11/19; 17002, Exp 01/20; 17034, Exp 02/20

**Product Description:**

Clear Eyes Redness Relief Hand Pocket Pal Tray Display; each display (UPC 6 78112 25418 7) contains 48 each of Clear eyes REDNESS RELIEF (Glycerin 0.25%, Naphazoline hydrochloride 0.012%) eye drops, 0.2 FL OZ (6 mL) bottle, Handy Pocket Pal (UPC 6 78112 25418 7); Distributed by Medtech Products Inc., Tarrytown, NY 10591 A Prestige Brands Company.

**Product Quantity:**

314,112 bottles

**Reason for Recall:**

CGMP Deviations: concerns regarding the sufficiency of Quality Assurance controls over critical systems in the manufacturing facility that could impact the product quality of the finished products.

**Recall Number:**

D-1835-2019

**Code Information:**

Lot #: 17051, Exp 02/20; 17130, Exp 04/20; 17147, Exp 05/20

**Class II Drugs Event****Event ID:**

83501

**Status:**

Ongoing

**Recall Initiation Date:**

07/29/2019

**Center Classification Date:**

08/19/2019

**Recalling Firm:**

Upsher Smith Laboratories, Inc.  
6701 Evenstad Dr N  
Maple Grove MN United States

**Distribution Pattern:**

KY, OH, NJ, LA

**Product Type:**

Drugs

**Date Terminated:****Voluntary / Mandated:**

Voluntary: Firm initiated

**Initial Firm Notification of Consignee or Public:**

Telephone

**Associated Products****Product Description:**

Bexarotene Capsules, 75 mg, 100 capsules per bottle, Rx Only, Manufactured for: Upsher-Smith Laboratories, LLC, Maple Grove, MN 55369. NDC: 0832-0285-00

**Product Quantity:**

166 bottles

**Reason for Recall:**

Failed Dissolution Specifications

**Recall Number:**

D-1836-2019

**Code Information:**

Lot: A2610. exp 3/2020

**Class II Drugs Event****Event ID:**

83580

**Status:**

Ongoing

**Recall Initiation Date:**

08/16/2019

**Center Classification Date:**

08/26/2019

**Recalling Firm:**

SCA Pharmaceuticals, LLC  
755 Rainbow Rd Ste B  
Windsor CT United States

**Distribution Pattern:**

Nationwide in the U.S.

**Product Type:**

Drugs

**Date Terminated:****Voluntary / Mandated:**

Voluntary: Firm initiated

**Initial Firm Notification of Consignee or Public:**

Letter

**Associated Products**

**Product Description:**

Ketamine 50 mg/5 mL in 0.9% Sodium Chloride Injection for IV or IM Use (concentration = 10 mg/mL), 6 mL Syringe, Rx Only, SCA Pharmaceuticals, Windsor, CT 06095, NDC 70004-0430-09.

**Product Quantity:**

922 syringes

**Reason for Recall:**

Lack of Assurance of Sterility.

**Recall Number:**

D-1843-2019

**Code Information:**

Lot #: 1219010961, Exp. 10/24/2019