

Enforcement Report - Week of March 4, 2020

Class I Drugs Event

Event ID:

84916

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

02/07/2020

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

03/02/2020

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Taro Pharmaceuticals U.S.A., Inc.

3 Skyline Dr

Hawthorne NY United States

Distribution Pattern:

Distributed Nationwide in the USA.

Associated Products

Product Description:

Phenytoin Oral Suspension USP, 125 mg/5 mL potency, 8 fl oz (237 mL) Rx Only Mfd. by: Taro Pharmaceuticals Industries Ltd. Haifa Bay, Israel 2624761 Dist. by: Taro Pharmaceuticals U.S.A. Inc. Hawthorne, NY 10532, NDC 51672-4069-1

Product Quantity:

29,172 8 Fl Oz bottles

Reason for Recall:

Resuspension Problems: Two lots of Phenytoin Oral Suspension USP 125mg/5mL may coagulate and may not resuspend as per the label copy instructions.

Recall Number:

D-0863-2020

Code Information:

Lot# 327874, 327876, Exp Dec/2020

Class III Drugs Event

Event ID:

85008

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

02/12/2020

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

02/26/2020

Initial Firm Notification of Consignee or Public:

E-Mail

Recalling Firm:

Golden State Medical Supply Inc.

5187 Camino Ruiz

Camarillo CA United States

Distribution Pattern:

Distributed Nationwide in the USA

Associated Products

Product Description:

TRAMADOL HYDROCHLORIDE Tablets, USP, 50 mg, Rx Only a)100-count bottles (NDC 60429-588-01) b) 500-count bottle (NDC 60429-588-05)
Manufactured by Teva Czech Industries, s.r.o. Opava-Komarov, Czech Republic, Packaged by GSMS Incorporated, Camarillo, CA 93012

Product Quantity:

379,043 100-ct bottles and 330,997 500-ct bottles

Reason for Recall:

Labeling: Incorrect package insert - Patient leaflets for the specified lots of unscored tablets contain language relative to a 25 mg dosing titration that necessitates the use of a scored 50 mg tablet.

Recall Number:

D-0856-2020

Code Information:

Lot Numbers: a) GS021259, Exp. Date 11/31/2019; GS021742, GS022074, Exp. 2/29/2020; GS022619, GS022836, 3/31/2020; GS023243, GS023631, Exp. 4/30/2020; GS023869, GS024562, GS025492, Exp. 5/31/2020; GS025184, Exp. 6/30/2020; GS026306, Exp. 9/30/2020; GS026654, Exp.=12/31/2020; GS027566, Exp. 2/28/2020; GS028574, Exp. 4/30/2021; b) GS021570, GS021444, GS021445, GS021443, GS021447, GS021446, 11/31/2019; GS021745, GS021746, GS021744, GS022076, GS022077, GS022078, GS022075, GS021747, GS021748, Exp. 2/29/2020; GS022622, GS022623, GS022624, GS022620, GS022837, GS022838, GS022856, GS022621, Exp. 3/31/2020; GS023029, GS023028, GS023027, Exp. 4/30/2020; GS023958, GS023959, GS023960, GS025045, GS024929, GS025048, GS025047, GS025588, GS025046, Exp. Date 5/31/2020; GS025260, GS025259, Exp.6/30/2020; GS025717, GS025719, GS025718, Exp. 8/31/2020; GS023607, GS026308, GS026309, Exp. 9/30/2020; GS026912, GS026911, GS026910, Exp. 12/31/2020; GS027678, Exp. 2/28/2021; GS027836, Exp. 11/30/2020; GS027570, GS027569, Exp. 2/28/2020; GS027572, GS027571, Exp. 4/30/2021

Class III Drugs Event

Event ID:

85018

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

02/21/2020

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

02/27/2020

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 United States and Puerto Rico

Associated Products

Product Description:

Sodium Chloride Ophthalmic Ointment USP, 5%, 3.5 g tubes, Manufactured by: Akorn, Inc., Lake Forest, IL 60045. NDC 17478-622-35

Product Quantity:

720 eaches

Reason for Recall:

Presence of Particulate Matter: Brown spots observed on the inside of the tube of product, identified as tin with trace copper, which are the base of the materials of construction for the tube.

Recall Number:

D-0859-2020

Code Information:

Lot #: 8B66A, Exp. Date 01/2021; Lot 8C91A, Exp. Date 02/2021; Lots 8F07A, 8F16A, Exp. Date 05/2021; Lot 8F13A, Exp. Date 07/2021.

Product Description:

Well at Walgreens Sodium Chloride Ophthalmic Ointment USP, 5%, 3.5 g tubes, Distributed by: Walgreen Co. 200 Wilmot Rd., Deerfield, IL 60015. NDC 0363-9050-00.

Product Quantity:

24 eaches

Reason for Recall:

Presence of Particulate Matter: Brown spots observed on the inside of the tube of product, identified as tin with trace copper, which are the base of the materials of construction for the tube.

Recall Number:

D-0860-2020

Code Information:

Lot #:8G59A, Exp. Date 06/2021

Product Description:

CVS Health Sodium Chloride Ophthalmic Ointment USP, 5%, 3.5 g tubes, Distributed By: CVS Pharmacy Inc. One CVS Drive, Woonsocket, RI 02895, NDC 59779-303-01

Product Quantity:**Reason for Recall:**

Presence of Particulate Matter: Brown spots observed on the inside of the tube of product, identified as tin with trace copper, which are the base of the materials of construction for the tube.

Recall Number:

D-0861-2020

Code Information:

Lot #: 8G50A, Exp. Date 06/2021