

Enforcement Report - Week of April 11, 2018

Class III Drugs Event

Event ID:

79446

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

03/15/2018

Voluntary / Mandated:

Voluntary: Firm Initiated

Center Classification Date:

04/04/2018

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

InvaGen Pharmaceuticals, Inc.

7 Oser Ave

Hauppauge NY United States

Distribution Pattern:

Nationwide

Associated Products

Product Description:

buPROPion HCl Extended-Release Tablets, USP (SR), 100 mg, 60 count bottles, Rx Only, Manufactured for: Cipla USA Inc. 1560 Sawgrass Corporate Parkway Suite 130 Sunrise, FL 33323, Manufactured by: InvaGen Pharmaceuticals, Inc. (a subsidiary of Cipla Ltd.) Hauppauge, NY 11788 --- NDC 69097-877-03

Product Quantity:**Reason for Recall:**

Failed Dissolution Specifications; during stability testing

Recall Number:

D-0618-2018

Code Information:

Lot# I1606579 and Lot# I1606580 Exp: 05/2018; Lot# I1612114 and Lot# I1612115 Exp: 11/2018

Product Description:

buPROPion HCl Extended-Release Tablets, USP (SR), 150 mg ,a) 60 count (NDC 69097-878-03) and b) 100 count (NDC 69097-878-07) bottles, Rx Only, Manufactured for: Cipla USA Inc. 1560 Sawgrass Corporate Parkway Suite 130 Sunrise, FL 33323, Manufactured by: InvaGen Pharmaceuticals, Inc. (a subsidiary of Cipla Ltd.) Hauppauge, NY 11788

Product Quantity:**Reason for Recall:**

Failed Dissolution Specifications; during stability testing

Recall Number:

D-0619-2018

Code Information:

a) Lot I1606609 and Lot I1606610 Exp. Date 05/2018; Lot I1610639 Exp. Date 09/2018 b) Lot #I1606610 Exp Date 05/2018; Lot I1607847 and Lot I1607845 Exp Date 06/2018; Lot I1610639 Exp Date 09/2018

Class III Drugs Event

Event ID:

79604

Product Type:

Drugs

Status:

Ongoing

Date Terminated:

Recall Initiation Date:

03/21/2018

Voluntary / Mandated:

Voluntary: Firm Initiated

Center Classification Date:

03/30/2018

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

Mayne Pharma Inc

1240 Sugg Pkwy

Greenville NC United States

Distribution Pattern:

Nationwide in the USA

Associated Products

Product Description:

Fabior (tazarotene) Foam, 0.1%, 100 grams can, Rx only, Distributed by: Mayne Pharma, Greenville, NC 27834; NDC 51862-295-10.

Product Quantity:

3312 cans

Reason for Recall:

Superpotent Drug: High out of specification results for tazarotene assay at the 9-month stability time point.

Recall Number:

D-0616-2018

Code Information:

Lot: MBEB, Exp. 01/31/2019