Enforcement Report - Week of June 4, 2025

Class I Drugs Event

Event ID:
96833

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/06/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/29/2025

Initial Firm Notification of Consignee or Public:
Press Release

Recalling Firm:
EnShiShiXiangNiShangMaoYouXianGongSi
Unknown
Unknown
China

Distribution Pattern:
Nationwide Via Amazon Platform

Associated Products

Product Description:
ENDURANCE BOOST WITH HORNY GOAT WEED, 500mg, 20 capsules per carton, VEPEMVA Nutrition Supplement....rgy and Endurance, UPC X004BB9Z8N

Product Quantity:
600, 20-count cartons

Reason for Recall:
Marketed without approved NDA/ANDA: The product has been found to be tainted with Sildenafil and Propoxyphenylsildenafil (a sildenafil analogue).

Recall Number:
D-0453-2025

Code Information:
Lot: 250214PRO, Expiration Date: 02/14/2027.

Class II Drugs Event

Event ID:
96836

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/07/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/27/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Alembic Pharmaceuticals Limited
Formulation Division, Village Panelav, P.O. Tajpura, Near Baska, Taluka Halol
Panchmahal
India

Distribution Pattern:
US Nationwide

Associated Products

Product Description:
Bromfenac Ophthalmic Solution 0.09%, 1.7 mL bottle, Rx only, Sterile, Manufactured for: Alembic Pharmaceuticals, Inc., Bedminster, NJ 07921, USA, Manufactured by Alembic Pharmaceuticals Limitied, Gujarat, India, Made in India, NDC 62332-508-17

Product Quantity:
N/A

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0447-2025

Code Information:
Lot 7230309, Exp Date: 5/31/2025; Lot 7230310, Exp Date: 5/31/2025; Lot 7230311, Exp Date: 5/31/2025

Class II Drugs Event

Event ID:
96861

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
02/28/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/28/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Glenmark Pharmaceuticals Inc., USA
750 Corporate Dr
Mahwah, NJ 07430-2009
United States

Distribution Pattern:
U.S. Nationwide

Associated Products

Product Description:
Carvedilol Tablets USP 3.125mg Tablets a.)100-count bottle (NDC 68462-162-01), b.) 500-count bottle (NDC 68462-162-05), Rx Only, Manufactured by: Glenmark Pharmaceuticals Ltd., Manufactured for: Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430.

Product Quantity:
[100 Tablet Bottles] 59,952 bottles; [500 Tablet Bottles] 155,976 bottles

Reason for Recall:
CGMP Deviations; presence 'N-Nitroso Carvedilol I' Impurity above the recommended acceptable intake limit

Recall Number:
D-0448-2025

Code Information:
[100-Count Bottles] Lot 19231450, Exp Mar-25, 19233345, Exp Jul-25; Lot 19234275, Exp Sep-25; Lot 19240280, Exp DEC-25 [500-Count Bottles] Lot 19231450, 19231464, 19231471, 19231493, Exp Mar-25, 19232083, 19232103 Exp Apr-25, 19232658, Exp Jun-25; Lot 19233328, 19233343, 19233344, 19233345, Exp Jul-25; Lot 19234275, Exp Sep-25; Lots 19234843, 19235039, Exp Nov-25; Lots 19240280, 19240296, Dec-25

Product Description:
Carvedilol Tablets USP 6.25 mg, a.)100-count bottle (NDC 68462-163-01), b.) 500-count bottle (NDC 68462-163-05) Rx Only, Manufactured by: Glenmark Pharmaceuticals Ltd., Manufactured for: Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430.

Product Quantity:
[100 Tablet Bottles] 90,000 bottles; [500 Tablet Bottles] 324,288 bottles

Reason for Recall:
CGMP Deviations; presence 'N-Nitroso Carvedilol I' Impurity above the recommended acceptable intake limit

Recall Number:
D-0449-2025

Code Information:
[100-Count Bottles] Lot 19233369, Exp Jul-25; Lot 19234162, Exp Sep-25; Lot 19240543, Exp Jan-26 [500-Count Bottles] Lots 19231174, 19231199, 19231164, Exp Feb-25, 19231517,19231527, 19231566,19231568,19231595, 19231618,19231634,19231638, 19231448, Exp Mar-25, 19232043,19232051,19232064, Apr-25, 19232322, 19232324, 19232365, 19232380, 19232389, Exp May-25; Lots 19232736, 19232743, 19232746, 19232756, 19232757, Exp Jun-25; Lots 19233369, 19233371, 19233405, 19233416, Exp Jul-25; Lots 19234162, 19234183, 19234192, 19234204, 19234223, 19234243, 19234263, 19234165, 19234242, Exp Sep-25; Lots 19234743, 19234774, 19234993, Exp Nov-25; Lots 19240223, 19240203, 19240211, 19240214, 19240247, 19240249, 19240272, 19240319, Exp Dec-25; Lot 19240543, Exp Jan-26

Product Description:
Carvedilol Tablets USP 12.5 mg, 500-Count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Ltd., Manufactured for Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430. NDC: 68462-164-05

Product Quantity:
84,048 bottles

Reason for Recall:
CGMP Deviations; presence 'N-Nitroso Carvedilol I' Impurity above the recommended acceptable intake limit

Recall Number:
D-0450-2025

Code Information:
Lot, Exp: Lots 19231899, 19231922, 19231927, 19231967, 19231979, Exp Apr-25; Lots 19232226, 19232234, 19232265, 1923227,1 Exp May-25; Lots 19232758, 19232759, 19232762, 19232788, Exp Jun-25

Product Description:
Carvedilol Tablets USP 25 mg, 500 -Count bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Ltd., Manufactured for Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430. NDC 68462-165-05.

Product Quantity:
18,696 bottles

Reason for Recall:
CGMP Deviations; presence 'N-Nitroso Carvedilol I' Impurity above the recommended acceptable intake limit

Recall Number:
D-0451-2025

Code Information:
Lot, expiry: Lots 19231107, 19231114, 19231152, Exp Feb-25; Lot 19234866, Exp Jan-26

Class II Drugs Event

Event ID:
96867

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/15/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
05/28/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Glenmark Pharmaceuticals Inc., USA
750 Corporate Dr
Mahwah, NJ 07430-2009
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Theophylline (Anhydrous) Extended-Release Tablets, 600 mg, 100 Tablets per bottle, Rx Only, Manufactured by: Glenmark Pharmaceuticals Limited. Colvale-Bardez, Goa - 403513, India. Manufactured for: Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ 07430. NDC: 68462-356-01

Product Quantity:
8,520 100-count bottles

Reason for Recall:
OOS results reported for the Dissolution (by UV) test.

Recall Number:
D-0452-2025

Code Information:
Lots: 19234121, 19234148, Exp Sep-30-25; Lots 19242881, 19242899, Exp Jun-30-26