

Enforcement Report - Week of September 28, 2022

Class III Drugs Event

Event ID:

90709

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

09/19/2022

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

09/22/2022

Initial Firm Notification of Consignee or Public:

Letter

Recalling Firm:

UNICHEM PHARMACEUTICALS USA INC

1 Tower Center Blvd Ste 2200

East Brunswick NJ United States

Distribution Pattern:

Distributed Nationwide in the USA

Associated Products

Product Description:

Clonidine Hydrochloride Tablets, USP, 0.3 mg, 100-count bottle, Rx Only, Manufactured by: UNICHEM LABORATORIES LTD. Pilerne Ind. Estate, Pilerne, Bardez, Goa 403 511, India Manufactured for: UNICHEM PHARMACEUTICALS (USA), INC. East Brunswick, NJ 08816. NDC# 29300-137-01

Product Quantity:

18,960 bottles of 100

Reason for Recall:

Product mix-up: 0.2 mg strength Clonidine Hydrochloride Tablets, USP in a 100-count bottle of 0.3 mg strength Clonidine Hydrochloride Tablets,

Recall Number:

D-1541-2022

Code Information:

Lot # GCLH22005, exp. date 02/29/2024