

Enforcement Report - Week of August 4, 2021

Class II Drugs Event

Event ID:
88289

Status:
Ongoing

Recall Initiation Date:
07/15/2021

Center Classification Date:
07/28/2021

Recalling Firm:
API Solutions Inc.
25309 Friendship Rd
Daphne AL United States

Distribution Pattern:
AL, AZ, CO, FL, VA

Product Type:
Drugs

Date Terminated:

Voluntary / Mandated:
Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:
Letter

Associated Products

Product Description:

Estriol USP41 Micro 25 Grams, Distributed by: A.P.I. Solutions 25309 Friendship Rd Daphne, AL Distributed by: Syntec Pharma Corp., NY
MFT by: Wuhan Fortune Chemical Co., Ltd., China, NDC: 46144-300-01

Product Quantity:
20 bottles

Reason for Recall:
cGMP Deviations

Recall Number:
D-0695-2021

Code Information:
Lot #: ETL181001, Exp 10/09/2021

Product Description:

Azelaic Acid 99.0+% Micro 500 Grams, Distributed By: A.P.I. Solutions Daphne Alabama Manufactured by: Yicheng Chemicals Corp. China
Distributed by: Syntec Pharma Corp New York

Product Quantity:
1 bottle

Reason for Recall:
cGMP Deviations

Recall Number:
D-0696-2021

Code Information:
Lot #: AZA181105, Exp 11/09/2021