

Enforcement Report - Week of October 18, 2023

Class I Drugs Event

Event ID:

93113

Product Type:

Drugs

Status:

Ongoing

Date Terminated:**Recall Initiation Date:**

09/25/2023

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

10/06/2023

Initial Firm Notification of Consignee or Public:

E-Mail

Recalling Firm:

Scynexis, Inc.
1 Evertrust Plz Fl 13
Jersey City NJ United States

Distribution Pattern:

Nationwide in the US.

Associated Products

Product Description:

BREXAFEMME (Ibexafungerp) tablets 150 mg, 4 count cartons, Rx Only, Manufactured for and distributed by SCYNEXIS, Inc., Jersey City, NJ 07302 NDC 75788-115-04

Product Quantity:

17,376

Reason for Recall:

Cross Contamination with Other Products: Potential cross-contamination of ibexafungerp citrate drug substance with ezetimibe (a non-antibacterial beta-lactam compound).

Recall Number:

D-0042-2024

Code Information:

Lot# LF21000008, Exp. 11/30/2023 Lot# LF22000051, Exp. 11/30/2025