Enforcement Report - Week of November 16, 2022

Class I Drugs Event

Event ID:
90974

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/07/2022

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
11/08/2022

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Viatris Inc
1000 Mylan Blvd
Canonsburg PA United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Octreotide Acetate Injection 500 mcg/mL, 10 x 1 mL Single-Dose Unit-of-Use Syringes, For Subcutaneous or Intravenous Use, Rx Only, Manufactured for: Mylan Institutional LLC, Morgantown, WV 26505 U.S.A., Made in Italy, NDC: 67457-246-00 (syringe), 67457-246-01 (carton).

Product Quantity:
22400 syringes

Reason for Recall:
Presence of Particulate Matter: Product complaint for the presence of glass particles in a syringe.

Recall Number:
D-0058-2023

Code Information:
Lot #: AJ21002, Exp. 03/2024