

Enforcement Report - Week of February 19, 2025

Class II Drugs Event

Event ID:
96172

Product Type:
Drugs

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
01/21/2025

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/11/2025

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
AvKARE
615 N 1st St
Pulaski, TN 38478-2403
United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Irbesartan Tablets USP, 300 mg, 50 Tablets (5 x 10) Unit Dose per carton, Manufactured for: AvKARE, Pulaski, TN 38478. NDC 50268-442-15

Product Quantity:
341 cartons

Reason for Recall:
Out of Specification for Dissolution

Recall Number:
D-0224-2025

Code Information:
Lot 45279, Exp 03/31/2025