Enforcement Report - Week of May 22, 2019

Class III Drugs Event

Event ID:
82715

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
04/29/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
05/13/2019

Initial Firm Notification of Consignee or Public:

Recalling Firm:
Pfizer Inc.
235 E 42nd St
New York NY United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Relpax (eletriptan HBr) 40 mg, a) 12 tablets 2 cards x six 40 mg tablets per blister pack, NDC 0049-2340-05; b) 6 tablets 1 card x six 40 mg tablets per blister pack, NDC 0049-2340-45, Rx Only, Made in Ireland, Distributed by Roerig, Division of Pfizer Inc, NY NY 10017.

Product Quantity:
100277 tablets

Reason for Recall:
Labeling: Label Error on Declared Strength: an artwork error on the secondary packaging of Relpax 40 mg Tablets, indicates that each tablet contains eletriptan hydrobromide equivalent to 20mg eletriptan, instead of 40mg, on one side of the carton.

Recall Number:
D-1278-2019

Code Information:
Lot #s: a) W38322, Exp 10/2020, W98482, Exp 03/2021; b) W64062, Exp 01/2021, X27517, Exp 03/2021, AJ3674, Exp 11/2021.