

Pharmacy_Subscriberlist@DCA

From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Friday, January 15, 2016 11:38 AM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Recall notice - Zydus Pharmaceuticals USA Inc.

Zydus Pharmaceuticals USA Inc. has decided to initiate a recall of the below drug product based on OOS result in retention sample of Risperidone OD Tablet, 2 mg, 30 count bottle (Lot Number MP4967) for Risperidone CIS-N-Oxide impurity during stability testing. As part of firm's impact assessment and based on the trend of this impurity, risk of stability failure in other unexpired lot numbers may be anticipated as mentioned in above table.

Please immediately check your inventory, quarantine, discontinue distribution of the affected product, and contact your wholesaler for directions.

Product Name	Lot No.	Expiry	Pack Size	NDCNo.	Distribution Start Date	Distribution End Date
Risperidone OD Tablets, 2mg	MP4967	04/16	30's	68382-156-06	Aug 28, 14	Aug 04, 15
Risperidone OD Tablets, 0.5mg	MP6917	06/16	30's	68382-154-06	Oct 09, 14	Jul 14, 15
Risperidone OD Tablets, 0.5mg	MP4965	04/16	30's	68382-154-06	Aug 29, 14	Oct 09, 14
Risperidone OD Tablets, 0.5mg	MP2943	02/16	30's	68382-154-06	Jun 09, 14	Sep 04, 14
Risperidone OD Tablets, 1 mg	MP6918	06/16	30's	68382-155-06	Jan 20, 15	Aug 19, 15
Risperidone OD Tablets, 1 mg	MP4966	04/16	30's	68382-155-06	Sep 12, 14	Jan 20, 15
Risperidone OD Tablets, 1 mg	MP2944	02/16	30's	68382-155-06	Jun 23, 14	Sep 15, 14