Pharmacy_Subscriberlist@DCA

From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Wednesday, May 11, 2016 3:10 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Product Recall - Gavis Pharmaceuticals LLC

Gavis Pharmaceuticals LLC is recalling two (2) lots of ZOLPIDEM TARTRATE SUBLINGUAL TABLETS 1.75 mg and 3.5mg (30 count cartons). These lots are being recalled as the current packaging for this product may not meet the child-resistance standards as required by the Poison Prevention Packaging Act (PPPA).

There is no risk to the consumer to use the drug as directed since the product continues to meet all quality requirements specified by the FDA. However, the child-resistance of the packaging may not meet PPPA standards, increasing the chance that young children could gain unintended access to the tablets, posing a risk of overdose.

This recall should be carried out to the ***Consumer Level.*** Lots were distributed between March 21, 2016 to May 6, 2016 to wholesalers and distributors nationwide. Your assistance is appreciated and necessary to prevent further distribution of these product lots:

Product	NDC	Lot Number	Exp. Date
ZOLPIDEM TARTRATE SUBLINGUAL TABLETS 1.75 mg	43386-762-30	M16140A	02/2018
ZOLPIDEM TARTRATE SUBLINGUAL TABLETS 3.5 mg	43386-761-30	M16144A	02/2018

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