The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

Ajanta Pharma USA Inc. would like to inform you of a product recall involving Duloxetine Delayed Release Capsules. Please refer to the table below.

This recall has been initiated due to the identification of N-Nitroso Duloxetine (NDX), a nitrosamine drug substance-related impurity (NDSRI), at levels exceeding the US FDA recommended NDX limit of 0.83 ppm (ppm) in the below-listed batches, as identified during ongoing long-term stability monitoring and confirmatory testing. Use of or consumption of this product may pose a theoretical incremental long-term carcinogenic risk due to the presence of N-Nitroso Duloxetine (NDX) impurity above the Acceptable Intake limit. There is no risk of acute or immediate adverse health effects. A Health Hazard Evaluation has concluded that the probability of serious adverse health consequences is remote.

Sr. No.	**Product Name**	**Batch No.**	**NDC No.**	**Mfg. Date**	**Exp. Date**	**Pack Size**
1	Duloxetine Delayed Release Capsules 20 mg	PA10734	27241-097-06	Jul-24	Jun-26	60’s
2	Duloxetine Delayed Release Capsules 30 mg	PA10774	27241-098-09	Jun-24	May-26	90’s
3	Duloxetine Delayed Release Capsules 30 mg	PA10794	27241-098-03	Jul-24	Jun-26	30’s
4	Duloxetine Delayed Release Capsules 30 mg	PA12174	27241-098-03	Jul-24	Jun-26	30’s
5	Duloxetine Delayed Release Capsules 30 mg	PA10804	27241-098-10	Jul-24	Jun-26	1000’s

6	Duloxetine Delayed Release Capsules 60 mg	PA07434	27241-099-03	Jun-24	May-26	30’s