

*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.*

Torrent Pharmaceuticals Limited is initiating a recall of Fluoxetine Tablets, USP 20 mg to the Retail level. No other strengths or batches of this product are subject to this recall. This recall is being conducted with the knowledge of the Food and Drug Administration.

This recall is based on detection of N-Nitroso Fluoxetine levels on this batch which exceed the recently published recommended interim acceptable intake. This impurity has been classified as a probable human carcinogen. There were no adverse event or product complaint cases received for this batch. The impurity level observed is marginally high in this batch, hence there is no immediate risk based on the available data.

<b>NDC</b>	<b>Product Name, Strength and Package Count</b>	<b>Batch Number</b>	<b>Expiration Date</b>
13668-473-30	Fluoxetine Tablets, USP 20 mg - 30s count		
13668-473-91 (Carton) 13668-473-70 (Blister)	Fluoxetine Tablets USP 20 mg- 7's Alu-Alu Blister	BDX6K001	June-2025