

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.

Bayshore Pharmaceuticals LLC. is recalling Metformin Hydrochloride Extended-Release Tablets USP 500mg and 750mg. This recall is being carried out due to the detection of N-Nitrosodimethylamine (NDMA) impurity. This recall is being made at the patient level and for the affected NDCs and lot numbers listed below. The affected lots were manufactured in June 2019 and distributed between July 2019 through October 2019.

Patients who have received impacted lots of Metformin Hydrochloride Extended-Release Tablets, USP 500 mg and 750 mg are advised by the FDA to continue taking their medication and contact their pharmacist, physician, or medical provider for advice regarding an alternative treatment.

Product Name	Strength	Pack Size	NDC Number	Lot Number	Expiration
Metformin Hydrochloride Extended-Release Tablets USP, 500 mg	500mg	1000's Bottle	76385-128- 10	18641	May 2021
Metformin Hydrochloride Extended-Release Tablets USP, 750 mg	750mg	100's Bottle	76385-129- 01	18657	May 2021