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.

Amneal Pharmaceuticals LLC Bridgewater, New Jersey (Amneal), is voluntarily recalling all lots of Metformin Hydrochloride Extended Release Tablets, USP, 500 mg and 750 mg, within expiry to the Retail Level.

Amneal was notified by the U.S. FDA that the Agency's testing of seven lots of Metformin Hydrochloride Extended Release Tablets, USP, 500 mg and 750 mg, showed N-Nitrosodimethylamine (NDMA) amounts above acceptable FDA levels. FDA recommended the recall of the seven tested lots. Amneal has agreed to this recall and has further decided to extend the recall to all lots within expiry of Metformin Hydrochloride Extended Release Tablets, USP, 500 mg and 750 mg, out of an abundance of caution. Further scientific evaluations are ongoing at Amneal.

To date, Amneal has not received any reports of adverse events that have been confirmed to be directly related to this recall.

Amneal's Metformin Hydrochloride Immediate Release Tablets, USP are not affected by this recall.

NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. NDMA is a known environmental contaminant found in water and foods, including meats, dairy products and vegetables.

Metformin HCl Extended Release Tablets, USP, 500 mg and 750 mg, manufactured by Amneal, are prescription, solid oral products that are indicated as an adjunct to diet and exercise to improve blood sugar control in adults with type 2 diabetes mellitus.

The Metformin Hydrochloride Extended Release Tablets, USP, 500 mg and 750 mg, subject to the recall, are identified by the NDC numbers stated on the product label.

Metformin HCl Extended Release Tablets, USP, 500 mg.	
53746-178-01	100 count bottles
53746-178-05	500 count bottles
53746-178-10	1000 count bottles
53746-178-90	90 count bottles
53746-178-Bulk	Bulk Box
65162-178-09	90 count bottles
65162-178-10	100 count bottles
65162-178-11	1000 count bottles

Metformin HCl Extended Release Tablets, USP, 500 mg.	
65162-178-50	500 count bottles

Metformin HCl Extended Release Tablets, USP, 750 mg	
53746-179-01	1000 count bottles
53746-179-Bulk	Bulk Box
65162-179-10	100 count bottles

The affected Metformin Hydrochloride Extended Release Tablets, USP, 500 mg and 750 mg, lots were distributed nationwide in the US directly to Wholesalers, Distributors, Retailers and Repackagers.

Amneal is notifying its direct customers via mail (UPS Standard Overnight) by mailing a recall notification letter and is arranging for return of all the recalled product. Anyone with an existing inventory of the product should quarantine the recalled lots immediately.

Customers who purchased the impacted product directly from Amneal may call Amneal at 1-833-582-0812 or email to AmnealproductrecallDS@amneal.com, Monday – Friday, 8:00 am – 5:00 pm, EST, for further information.

Retailers who have Metformin Hydrochloride Extended Release Tablets, USP, 500 mg or 750 mg, which are being recalled, should cease dispensing and contact Inmar at 855-532-1851 or via email at Rxcalls@inmar.com Monday – Friday, 8:00 am – 5:00 pm, EST, to arrange for product return.

If you would like to report any adverse reactions or quality problems experienced with the use of this product you may contact Amneal Drug Safety by phone at 1-877-835-5472, Monday - Friday, 8:00 am – 6:00 pm, EST, or via e-mail at DrugSafety@amneal.com.

Any adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online
- Regular Mail or Fax: Download form or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.