Metformin Hydrochloride Extended Release Tablets – Amneal Pharmaceuticals

On May 29, 2020, the U.S. Food and Drug Administration (FDA) announced that Amneal Pharmaceuticals, Inc. is voluntarily recalling Metformin Hydrochloride Extended-Release Tablets, 500mg and 750mg.

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 and 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.

- 500mg tablets: 53746-0178-01; 53746-0178-05; 53746-0178-10; 53746-0178-90; 65162-0178-09; 65162-0178-10; 65162-0178-11; 65162-0178-50
- 750mg tablets: 53746-0179-01; 65162-0179-10

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