Amneal – Recall of metformin extended-release (ER)

- On June 3, 2020, Amneal announced a voluntary, consumer-level recall of all lots of metformin ER tablets due to the detection of N-nitrosodimethylamine (NDMA) levels in excess of acceptable FDA levels.
    - The FDA recommended the recall of seven lots of Amneal's metformin ER due to NDMA levels; however, Amneal decided to recall all lots of metformin ER.
- NDMA is classified as a probable human carcinogen based on results from laboratory tests. NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables.
- The recalled lots were distributed nationwide in the U.S.

Product Description	NDC#	Lot#
Metformin Hydrochloride Extended-Release 500 mg tablets	53746-178-01; 53746-178-05; 53746-178-10; 53746-178-90; 53746-178-Bulk; 65162-178-09; 65162-178-10; 65162-178-11; 65162-178-50	All
Metformin Hydrochloride Extended-Release 750 mg tablets	53746-179-01; 53746-179-Bulk; 65162-179-10	All

- Metformin ER tablets are indicated as an adjunct to diet and exercise to improve blood glucose control in adults with type 2 diabetes mellitus.
- Patients who have the recalled metformin ER should continue taking it and contact their physician or healthcare provider to prescribe a replacement.
- Health care professionals should continue to prescribe metformin when clinically appropriate. FDA testing has not shown NDMA in immediate release (IR) metformin products (the most commonly prescribed type of metformin).
- Anyone with an existing inventory of the recalled product should stop distribution and quarantine the product immediately.
- The FDA continues to evaluate the safety of metformin and will provide more information as it becomes available. Updates can be found here.

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- Contact Amneal by phone at **1-833-582-0812** or by email at **amnealproductrecallds@amneal.com** for further information regarding this recall.