Major – Recall of metformin extended-release (ER)

- On July 1, 2020, Major Pharmaceuticals 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 the acceptable daily intake limit.

    — The FDA recommended the recall of one lot of Major's metformin ER due to NDMA levels; however, out of an abundance of caution, Apotex 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 from Major's Indianapolis warehouse between November 2, 2018 and January 22, 2019.

Product Description	NDC#	Lot#
Metformin hydrochloride extended-release 500 mg tablets, 10X10 unit dose	0904-5794-61	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.

  Contact Major Pharmaceuticals by phone at **1-800-616-2471** for further information regarding this recall.