Granules Pharmaceuticals – Recall of metformin extended-release (ER)

- On July 6, 2020, Granules 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 acceptable FDA levels.

- 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.

- Granules Pharmaceuticals began shipping this product on March 21, 2019.

Product Description	NDC#	Lot#
Metformin Hydrochloride Extended-Release 750 mg tablets	70010-492-01; 70010-492-05	4920003A, 4920004A, 4920005A, 4920005B, 4920009A, 4920010A, 4920011A, 4920012A, 4920013A, 4920014A, 4920015A, 4920016A

- 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 Inmar (appointed company for Granules) by phone at **1-888-985-9117** or by email at **recalls@inmar.com** for further information regarding this recall.