

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.

Granules Pharmaceuticals Inc. is recalling 12 lots of Metformin HCl Extended Release Tablets, USP 750mg, 100 and 500 count, listed below. The recall is initiated due to presence of N-Nitrosodimethylamine (NDMA) amounts above the established levels by FDA. NDMA is classified as a probable human carcinogen. This recall is to the patient level.

The product began shipping on 03/21/2019.

#	NDC #	Batch Number	Exp. Date
1	70010-492-01	4920003A	May-21
2	70010-492-01	4920004A	Jun-21
3	70010-492-01	4920005A	Jun-21
4	70010-492-05	4920005B	Jun-21
5	70010-492-01	4920009A	Nov-21
6	70010-492-01	4920010A	May-22
7	70010-492-01	4920011A	Jun-22
8	70010-492-01	4920012A	Jun-22
9	70010-492-01	4920013A	Jul-22
10	70010-492-01	4920014A	Jul-22
11	70010-492-01	4920015A	Aug-22
12	70010-492-01	4920016A	Jan-23