Date: June 2, 2020 **COM-2020-041**

RECALL NOTIFICATION

DATE:
June 1, 2020

DRUG NAME:
Metformin Hydrochloride Extended Release Tablets, USP, 500 mg and 750 mg

COMPANY:
Amneal Pharmaceuticals LLC

REASON:
Due to detection of N-Nitrosodimethylamine (NDMA) amounts above acceptable FDA levels

Dear provider of pharmaceutical services,

At PharmPix, we are committed to the health and well-being of patients. The clinical team wants to communicate you with the latest up-to-date information on the Food and Drug Administration (FDA) drug recalls.

Affected product(s):

NDC	Product description	Lot #
53746-178-01	Metformin Hydrochloride Extended Release Tablets, USP, 500 mg	All
53746-178-05		
53746-178-10		
53746-178-90		
53746-178-Bulk		
65162-178-09		
65162-178-10		
65162-178-50		
65162-178-11		
53746-179-01	Metformin Hydrochloride Extended Release Tablets, USP, 750 mg	All
53746-179-Bulk		
65162-179-10		

Pharmacy required action:

- Identify if they have the product in inventory and immediately stop using and dispensing it.
- Contact all members that in the previous 90 days received the recalled medication.
- Advise patients to contact their physician before drug discontinuation and if they have experienced any problems that may be related to taking or using the recalled drug product.

Contact information:

- Consumers: Contact Amneal at 1-833-582-0812, Monday - Friday from 8:00 am to 5:00 pm EST.
- Wholesalers, Distributors, and Retailers should cease dispensing and contact Inmar at 855-532-1851 or via email at Rxcalls@inmar.com, Monday – Friday from 8:00 am to 5:00 pm, EST, to arrange for product return.

Note:
Remember that any adverse event related to this or any other pharmaceutical product can be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax:

- Online: Complete MedWatch Online Voluntary Reporting Form.
- Regular Mail or Fax: Download FORM FDA 3500 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Additional information:
https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/amneal-pharmaceuticals-llc-issues-voluntary-nationwide-recall-metformin-hydrochloride-extended

Best regards,

PharmPix Clinical Department

Reference:

- *Center for Drug Evaluation and Research. (2020, June 1). Amneal Pharmaceuticals LLC Issues Voluntary Nationwide Recall of Metformin Hydrochloride Extended Release Tablets, USP, 500 mg and 750 mg, Due to Detection of N-Nitrosodimethylamine (NDMA) Impurity*. Retrieved 2 June 2020, from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/amneal-pharmaceuticals-llc-issues-voluntary-nationwide-recall-metformin-hydrochloride-extended.

2 Street 1, Suite 500 Guaynabo, PR 00968 | Tel. 787.522.5252 | Fax 1.866.912.2830 | www.pharmpix.com