Date: May 29,2020 **COM-2020-039**

RECALL NOTIFICATION

DATE:
May 28, 2020

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

COMPANY:
Apotex Corp

REASON:
Due to detection of N-Nitrosodimethylamine (NDMA)

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:

NDC	Product description	Lot #
60505-0260-01	Metformin Hydrochloride Extended-Release Tablets, USP 500mg	All

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 Apotex Customer Service at 1-888-985-9014, Monday - Friday from 9:00 am to 5:00 pm EST.
    - Questions regarding this recall contact Apotex Corp. by phone at 1-800-706-5575 (8:30am – 5:00pm, EST Monday thru Friday).
- Wholesalers, Distributors, and Retailers should return the recalled product to the place of purchase.

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:

- Online: www.fda.gov/medwatch/report.htm

- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm 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/apotex-corp-issues-voluntary-nationwide-recall-metformin-hydrochloride-extended-release-tablets

Best regards,

PharmPix Clinical Department

Reference:

- *Center for Drug Evaluation and Research. (2020, May 28). Apotex Corp. Issues Voluntary Nationwide Recall of Metformin Hydrochloride Extended-Release Tablets 500mg Due to the Detection of N-nitrosodimethylamine (NDMA)*. Retrieved 29 May 2020, from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/apotex-corp-issues-voluntary-nationwide-recall-metformin-hydrochloride-extended-release-tablets .

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