April 17, 2020 **COM-2020-029**

RECALL NOTIFICATION

DATE:
April 15, 2020

DRUG NAME:
Nizatidine Oral Solution 15 mg/mL

COMPANY:
Amneal Pharmaceuticals, LLC

REASON:
Presence of NDMA (Nitrosodimethylamine) impurity

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 #	Expiration date
60846-301-15	**Nizatidine Oral Solution (15mg/mL)**	06598004A	04/2020
		06599001A	12/2020
		06599002A	12/2020

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 and advise them to stop using, return the drug, and contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using the recalled drug product.

Contact information:

- Customers: Call Inmar at (855) 319-4807, Monday – Friday, 8:00 am – 6:00 pm, EST, or e-mail at DrugSafety@amneal.com
- Consumers: Call Inmar at 855-319-4807, Monday – Friday, 8:00 am – 5:00 pm, EST

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/amneal-pharmaceuticals-llc-issues-voluntary-nationwide-recall-nizatidine-oral-solution-15-mgml-due?utm_campaign=FDA%20MedWatch%20-%20Nizatidine%20Oral%20Solution%2C%2015%20mg%2FmL%20by%20Amneal%3A%20Recall&utm_medium=email&utm_source=Eloqua

Best regards,

PharmPix Clinical Department

Reference:

- Center for Drug Evaluation and Research. (2020, April 15). Amneal Pharmaceuticals, LLC. Issues Voluntary Nationwide Recall of Nizatidine Oral Solution, 15 mg/mL, Due to Potential Levels of N-nitrosodimethylamine (NDMA) Impurity Amounts Above the Levels Established by FDA. Retrieved April 17, 2020, from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/amneal-pharmaceuticals-llc-issues-voluntary-nationwide-recall-nizatidine-oral-solution-15-mgml-due?utm_campaign=FDA MedWatch - Nizatidine Oral Solution, 15 mg/mL by Amneal: Recall&utm_medium=email&utm_source=Eloqua

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