RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Ranitidine capsules Recall Alert

Date of Notice: 01/07/2020

Brief Description of Recall

On January 7, 2020, Appco Pharma LLC issued a voluntary recall of all ranitidine capsules due to the presence of N-nitrosodimethylamine (NDMA).

NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
ranitidine capsules, USP 150mg	62559-690-05	1905226VD	04/2021
		1906298UD	05/2021
	62559-690-60	1905225VN	04/2021
		1906295UN 1906296UN 1906297UN	05/2021
ranitidine capsules, USP 300mg	62559-691-30	1905227UE 1905228UE	04/2021

Prescriber Information

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online
- Regular Mail or Fax: Download form 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

Member Information

Members that have the drug which is being recalled should stop using/return to place of purchase and speak to their prescriber or pharmacist about alternate treatment options.

Members with questions regarding this recall can contact Appco at: (732) 253-7735 between 8 am and 6 pm (EST) (Monday-Friday) or e-mail: pv@appcopharma.com or at ANI Pharmaceuticals, Inc. at

1-800-308-6755 or PVSupport@safetycall.com.

Members should contact their prescriber if they have experienced any problems that may be related to taking or using this drug product.

RxAdvance Response

RxAdvance is in the process of contacting members and prescribers to advise them of this recall.