APPCO PHARMA

URGENT: DRUG RECALL

01/07/2020

Peddanna Gumudavelli
Vice President – QA/RA
APPCO PHARMA LLC
262 Old New Brunswick Road, Suite N,
Piscataway, NJ – 08854.

Dear Valued Customer:

This is to inform you of a product recall involving:

Product Name:

Ranitidine HCl Capsules 150 mg and Ranitidine HCl Capsules 300mg

Brand Name:

Not applicable

Description:

Ranitidine HCl Capsules 150 mg: Opaque caramel hard gelatin capsules, imprinted with "AC" on cap and "535" on body in black ink, filled with pale yellow to brownish powder.

Ranitidine HCl Capsules 300 mg: Opaque caramel hard gelatin capsules, imprinted with "AC" on cap and "536" on body in black ink, filled with pale yellow to brownish powder.

UPC Codes:

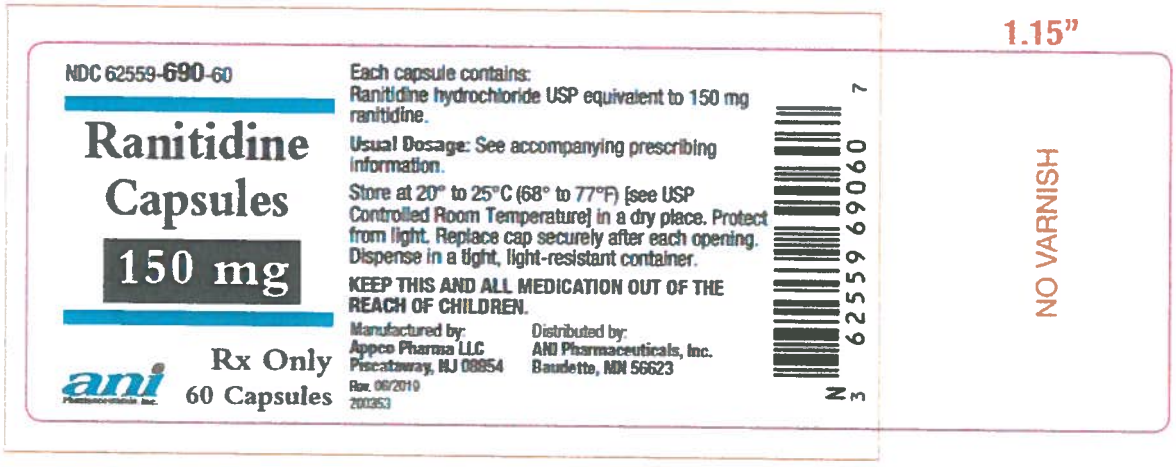
Description	Strength	Type	Pack Size	NDC
Ranitidine Capsules 150 mg	150 mg	Rx	60 CT bottle	62559-690-60
Ranitidine Capsules 150 mg	150 mg	Rx	500 CT bottle	62559-690-05
Ranitidine Capsules 300 mg	300 mg	Rx	30 CT bottle	62559-691-30

Lot Numbers:

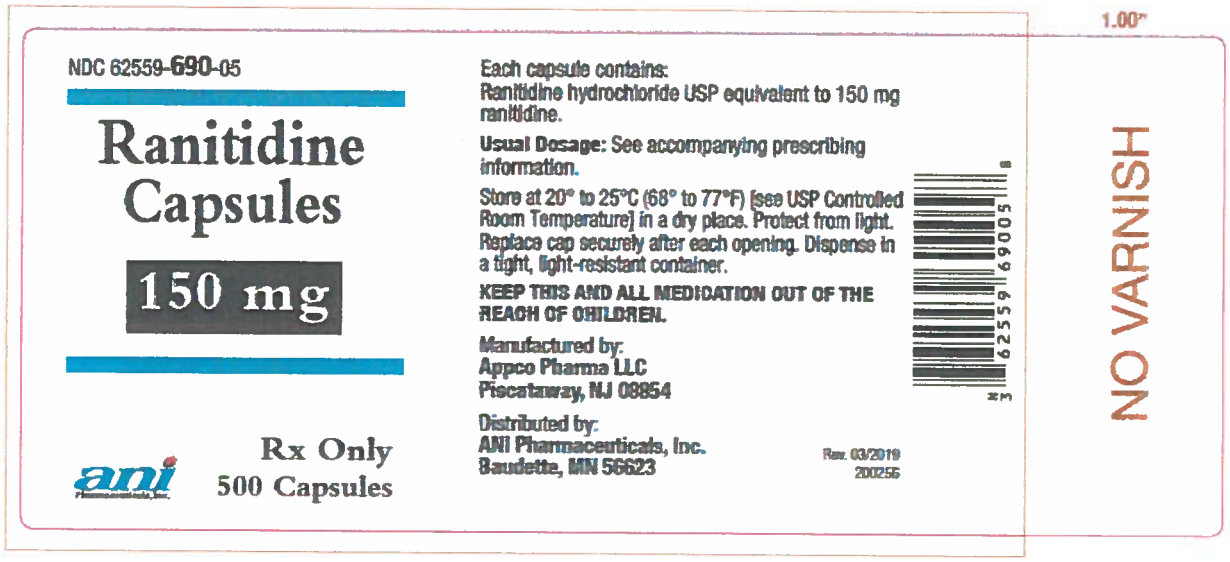
Description	Batch #	NDC Number	Label Claim	Expiration date
Ranitidine Capsules 300 mg	1905227UE	62559-691-30	300 mg	Apr-21
	1905228UE	62559-691-30	300 mg	Apr-21
Ranitidine Capsules 150 mg	1905225VN	62559-690-60	150 mg	Apr-21
	1905226VD	62559-690-05	150 mg	Apr-21
	1906295UN	62559-690-60	150 mg	May-21
	1906296UN	62559-690-60	150 mg	May-21
	1906297UN	62559-690-60	150 mg	May-21
	1906298UD	62559-690-05	150 mg	May-21

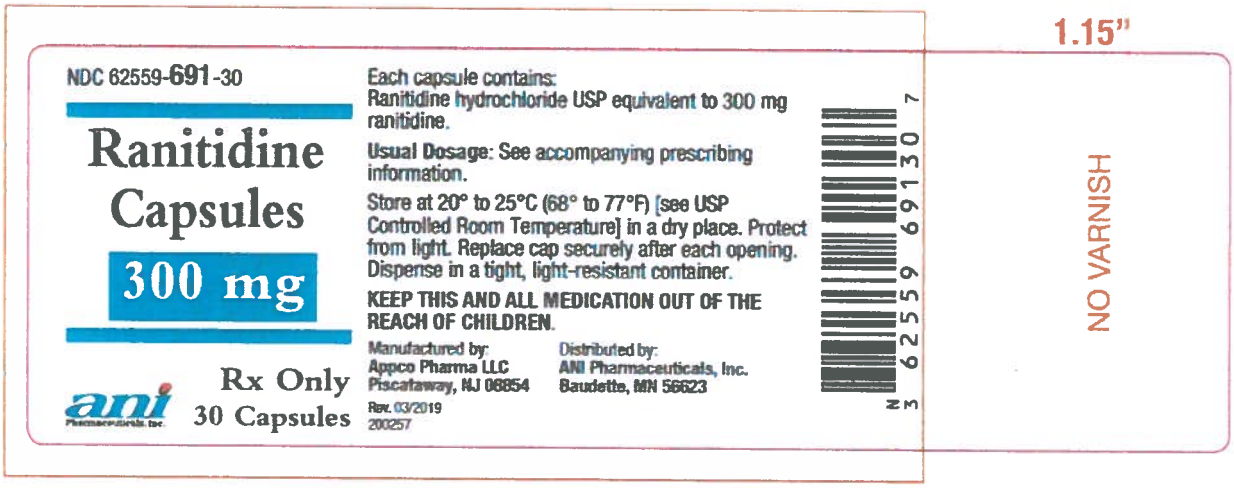
See below product label for ease in identifying the product at retail. **(Class II).**

Ranitidine Capsules 150 mg and 300 mg Labeling:



Appco Pharma LLC
Piscataway Address: 262 Old New Brunswick Road, Suite N, Piscataway, NJ – 08854,
Tel: 732-253-7735 Fax: 732-469-1000
info@appcopharma.com www.appcopharma.com





This voluntary recall is being initiated based on USFDA alert notice regarding low levels of N-nitrosodimethylamine (NDMA) impurity found in some samples of Ranitidine medicines. Subsequent preliminary test results at Appco for some of the Drug Substance (API) lots used in Drug Product manufacturing have levels of NDMA that could potentially contribute to elevated levels of NDMA in Drug Product with respect to the maximum allowable daily limit.

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Risk Statement: 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.

Ranitidine drug Product lot numbers to be recalled are mentioned above under Lot Numbers.

The product Distribution dates are: **June 2019 – September 2019.**

Recall Instructions:

Please perform the following activities:

- Examine your inventory immediately for lot listed above and immediately discontinue distribution and sales of the product lot being recalled. Please quarantine the affected lot of this product.
- In addition, if the listed product was further distributed, please identify the customers and notify them immediately of this product recall. The notification to the customers may be expedited by including a copy of this recall notification letter
- Promptly complete the attached recall stock response form even if you have no product to return.

Completed Recall Stock Response form can be submitted by any of the below methods:

Fax: 218-634-3540

Email: stephen.bitter@anipharmaceuticals.com

Mail:

ANI Pharmaceuticals
Attn: Stephen Bitter
210 Main Street West
Baudette, MN 56623

For questions regarding the return of the recalled product please call Stephen Bitter at 218-634-3655 or email at stephen.bitter@anipharmaceuticals.com. Office hours 9 am to 5 pm (EST) Monday through Friday.

Upon receipt of your Recall Response Form, a "Return Kit" will be sent to you. This kit will include:

- Pre-paid shipping label(s)
- Processing labels
- Shipping instructions

This recall is being made with the knowledge of the Food & Drug Administration.

Your cooperation and prompt response to this notice are much appreciated. If you have Customer Service-related questions, please contact ANI Pharmaceuticals, Inc. at 1-800-308-6755 or PVSupport@safetycall.com or Appco at: (732)-253-7735 between 8 am and 6 pm (Monday-Friday) or e-mail: pv@appcopharma.com.

This recall is being made with the knowledge of the Food and Drug Administration.

Enclosure(s):

1. Recall Return Response Form **(Refer enclosed attachment "Recall Return Response Form-attach-8a")**

Recall Response Form:

Appco Pharma LLC
262 Old New Brunswick Rd, NJ 08854

Product Details: **Ranitidine Capsules 150 mg and Ranitidine Capsules 300 mg**

Effected Lot details:

Description	Batch #	NDC Number	Label Claim	Expiration date
Ranitidine Capsules 300 mg	1905227UE	62559-691-30	300 mg	Apr-21
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	1906297UN	62559-690-60	150 mg	May-21
	1906298UD	62559-690-05	150 mg	May-21

Please check ALL appropriate boxes.

☐ I have read and understand the recall instructions provided in the [date of] letter.

☐ I have checked my stock and have quarantined inventory consisting of [ ] units or cases.

☐ Indicate disposition of recalled product: returned

Qty.: Date: Method:

☐ Destroyed Qty.:_____

☐ Quarantined pending correction (Qty.:);

Attached is a list of customers who received/ may have received this product. We notified these customers also about this recall.

Any adverse events associated with recalled/failed product? Yes No
If yes, please explain:

☐ I have checked my stock and have performed the appropriate method of disposition to the inventory consisting of _____ [units, cases, etc.].

Please check the appropriate box(es) to describe the nature of your business:

☐ Wholesaler
☐ Others_____

Name:
Title:
Email ID:
Firm Name:
Address:

PLEASE FAX COMPLETED RESPONSE FORM TO Tel. # [218-634-~~3655~~]3540 SB 9 Jan 2020, ATTN: [Stephen Bitter] OR MAIL TO: [ANI Pharmaceuticals, Attn: Stephen Bitter, 210 Main Street West Baudette, MN 56623] or email to stephen.bitter@anipharmaceuticals.com.

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