COMPANY ANNOUNCEMENT

Appco Pharma LLC Issues Voluntary Nationwide Recall of Ranitidine Hydrochloride Capsules 150 mg and 300 mg Due to an Elevated Amount of Unexpected Impurity, N-Nitrosodimethylamine (NDMA)

Summary

Company Announcement Date:

January 07, 2020

FDA Publish Date:

January 07, 2020

Product Type:

Drugs

Reason for Announcement:

NDMA (Nitrosodimethylamine) impurity

Company Name:

Appco Pharma LLC

Brand Name:

ani

Product Description:

Ranitidine Tablets 150mg and 300mg

Company Announcement

Appco Pharma LLC (Appco) is voluntarily recalling all quantities and lots, within expiry, of Ranitidine Hydrochloride Capsules to the Consumer level. Ranitidine Hydrochloride Capsules are being recalled because of the presence or potential presence of N-nitrosodimethylamine

(NDMA) levels above the acceptable daily intake levels established by the FDA, based on FDA-validated tests. To date, Appco has not received any reports of adverse events related to use of the product as part of this recall.

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 Hydrochloride in strengths of 150 mg and 300 mg, is a prescription-only oral medication indicated for the treatment of duodenal ulcer, benign gastric ulcer, reflux esophagitis, post-operative peptic ulcer, Zollinger-Ellison Syndrome, and other conditions where reduction of gastric secretion and acid output is desirable.

The products subject to recall are listed below and are packaged in bottles. The product can be identified by checking the product name, count/bottle, manufacturer details and batch or lot number on the bottle containing these products.

Description	Strength	NDC	Batch #	Counts	Expiration date
Ranitidine Capsules 300 mg	300 mg	62559-691-30	1905227UE	30's	Apr-21
	300 mg	62559-691-30	1905228UE	30's	Apr-21
Ranitidine Capsules 150 mg	150 mg	62559-690-60	1905225VN	60's	Apr-21
	150 mg	62559-690-05	1905226VD	500's	Apr-21
	150 mg	62559-690-60	1906295UN	60's	May-21
	150 mg	62559-690-60	1906296UN	60's	May-21
	150 mg	62559-690-60	1906297UN	60's	May-21
	150 mg	62559-690-05	1906298UD	500's	May-21

Ranitidine Capsules 150 mg & Ranitidine Capsules 300 mg were distributed nationwide.

Appco is notifying their marketing partner (ANI Pharmaceuticals, Inc.) by phone, email or other communication with recall notification communication. ANI Pharmaceuticals Inc., on behalf of Appco Pharma LLC, will be notifying its distributors and customers by phone and in writing to immediately discontinue distribution of the specific lots being recalled and to notify their sub-accounts. Appco is arranging for return of all recalled products to ANI Pharmaceuticals, Inc. Instructions for returning recalled products are given in the recall letter. Anyone with an existing inventory will be asked to immediately stop distribution and return any stock to ANI

Pharmaceuticals, Inc. by contacting Stephen Bitter at stephen.bitter@anipharmaceuticals.com (mailto:stephen.bitter@anipharmaceuticals.com) or 218-634-3655 (between 8 to 5PM CST). All the recalled product shall be sent to:

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

Consumers that have product which is being recalled should stop using/return to place of purchase and speak to their physician or pharmacist about alternate healthcare treatment options.

Consumers 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 (mailto:pv@appcopharma.com) or at ANI Pharmaceuticals, Inc. at 1-800-308-6755 or PVSupport@safetycall.com (mailto:PVSupport@safetycall.com). Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

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 (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)
- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) 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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Company Contact Information

Consumers:

Appco

732-253-7735

pv@appcopharma.com (mailto:pv@appcopharma.com)

Media:

Stephen Bitter

218-634-3655

stephen.bitter@anipharmaceuticals.com (mailto:stephen.bitter@anipharmaceuticals.com)

Product Photos

More Recalls, Market Withdrawals, & Safety Alerts (/safety/recalls-market-withdrawals-safety-alerts)