



Clifton Health Department Food Recall Notification



Public Health
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Food/Drug/Pet Recall: Apotex Corp.

Apotex Corp. is voluntarily recalling Ranitidine Tablets 75mg and 150mg (All pack sizes and Formats) to the Retail level. Apotex has learned from the U.S. Food and Drug Administration and other Global regulators that some ranitidine medicines including brand and generic formulations of ranitidine regardless of the manufacturer, contain a nitrosamine impurity called N-nitrosodimethylamine (NDMA) at low levels. To date, Apotex has not received any reports of adverse events related to use of the product.

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 Tablet is an over the counter (OTC) oral product indicated for the relief of heartburn associated with acid indigestion and sour stomach and prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods and beverages. The affected Ranitidine Hydrochloride Tablets can be identified by NDC numbers stated on the product label.

Product
Strength
Pack Size
NDC Number

Ranitidine tablets, USP 150mg- acid reducer (Rite Aid) 150 mg 50's Bottle 11822-6052-1
Ranitidine tablets, USP 150mg- acid reducer (Rite Aid) 150 mg 65's Bottle 11822-6052-2
Ranitidine tablets, USP 150mg- acid reducer (Rite Aid) 150 mg 95's Bottle 11822-4727-3
Ranitidine tablets, USP 150mg- acid reducer (Walmart) 150 mg 65's Bottle 49035-117-06
Ranitidine tablets, USP 150mg- acid reducer (Walmart) 150 mg 24's Bottle 49035-100-00
Wal-Zan® 150 RANITIDINE TABLETS, USP 150 mg / ACID REDUCER (WALGREENS) 150 mg 200's Bottle 0363-1030-07

Product
Strength
Pack Size
NDC Number

Ranitidine tablets, USP 150 mg - acid reducer (Rite Aid) 150 mg 24's Bottle 11822-6051-8
Ranitidine tablets, USP 150mg- acid reducer (Walmart) 150 mg 130's Bottle 49035-100-07
Wal-Zan® 150 RANITIDINE TABLETS, USP 150 mg / ACID REDUCER (WALGREENS) 150 mg 24's Bottle 0363-1013-02
Wal-Zan® 75 RANITIDINE TABLETS, USP 75 mg / ACID REDUCER (WALGREENS) 75 mg



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30's Bottle 0363-1029-03

Cool mint Ranitidine tablets, USP 150 mg - acid reducer (Rite Aid) 150 mg 24's Bottle 11822-6107-4

Wal-Zan® 150 RANITIDINE TABLETS, USP 150 mg / ACID REDUCER (WALGREENS) 150 mg 65's Bottle 0363-1030-06

Wal-Zan® 150 RANITIDINE TABLETS, USP 150 mg / ACID REDUCER (WALGREENS) 150 mg 95's Bottle 0363-1030-09

The affected Ranitidine Hydrochloride Tablets were distributed Nationwide to Warehousing Chains. Apotex Corp. has notified its affected direct account Warehousing Chains via mail (FedEx Standard Overnight) by mailing a recall notification letter and is arranging for return of all recalled product.

Wholesalers, Distributors and Retailers return the impacted product to place of purchase. Anyone with an existing inventory of the product should quarantine the recalled lots immediately. Customers who purchased the impacted product directly from Apotex can call Inmar Rx Solutions at 800-967-5952 (option 1) (9:00am - 5:00pm, EST Monday thru Friday), to arrange for their return.

Consumers with questions regarding this recall can contact Apotex corp. by phone-number 1-800-706-5575 (8:30am - 5:00pm, EST Monday thru Friday) or email address UScustomerservice@Apotex.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

.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

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