



McNeil Consumer Healthcare, 7050 Camp Hill Road, Fort Washington, PA 19034

URGENT VOLUNTARY DRUG RECALL

December 9, 2010

Dear Retailer Customer:

MCNEIL CONSUMER HEALTHCARE ANNOUNCES VOLUNTARY RECALL OF ALL LOTS OF ROLAIDS® EXTRA STRENGTH SOFTCHEWS, ROLAIDS® EXTRA STRENGTH PLUS GAS SOFTCHEWS, AND ROLAIDS® MULTI-SYMPTOM PLUS ANTI-GAS SOFTCHEWS SOLD IN THE UNITED STATES

Please return ALL warehouse and retail inventory of the identified products below. No product other than the ones specified should be returned.

McNeil Consumer Healthcare, Division of McNEIL-PPC, Inc. is voluntarily recalling all lots of *ROLAIDS® Extra Strength Softchews*, *ROLAIDS® Extra Strength plus Gas Softchews*, and *ROLAIDS® Multi-Symptom plus Anti-Gas Softchews* (full product details below) distributed in the United States. McNeil is taking this action following some consumer reports of foreign materials in the product, including metal and wood particles. The company's investigation has determined that the materials were potentially introduced into the product during the manufacturing process at a third party manufacturer. While the risk of serious adverse health consequences is remote, McNeil Consumer Healthcare advises consumers who have purchased these recalled products to discontinue use.

While our investigation is ongoing we have suspended production of *ROLAIDS® Extra Strength Softchews*, *ROLAIDS® Extra Strength plus Gas Softchews*, and *ROLAIDS® Multi-Symptom plus Anti-Gas Softchews* and will not restart production until corrective actions have been implemented.

Consumers who purchased product included in this recall should contact McNeil Consumer Healthcare, either at www.rolaids.com or by calling 1-888-222-6036 (Monday-Friday 8 a.m. to 8 p.m. Eastern Time, and Saturday-Sunday 9 a.m. to 5 p.m. Eastern Time) for instructions about receiving a refund. Consumers who have medical concerns or questions should contact their healthcare provider.

Any adverse reactions may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- **Online:** www.fda.gov/medwatch/report.htm
- **Regular Mail:** use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm . Mail to address on the pre-addressed form.
- **Fax:** 1-800-FDA-0178

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

The lot numbers for the recalled products can be found on the back or the bottom of the package.

Action Requested:

1. Identify all retail inventory of products listed below, remove from your shelves and return immediately as per the "Return Authorization Form" or send to your supplier or headquarter warehouse. If you have any questions regarding the form please call Stericycle at 877-546-8443 or fax to 877-546-2984.
2. If you are a Wholesaler or if you have sub-distributed any of the below products to any other locations, please take the necessary steps to have your customers return these products to you for consolidation of inventory and return to Stericycle using the attached documents. Utilize a copy of the enclosed information to facilitate and document this action with each of your sub-accounts.

We appreciate your cooperation in helping us successfully execute this voluntary recall. If you have any questions related to the return of these products, please contact Stericycle at 877-546-8443. If you have any questions about the products, please contact your McNeil Consumer Healthcare Sales Representative.

Product Name	Lot Number	UPC Code
ROLAIDS® Extra Strength plus Gas Softchews		
ROLAIDS® Extra Strength plus Gas Softchews, Tropical Fruit, 6 count	All Lots	312547065733
ROLAIDS® Extra Strength plus Gas Softchews, Tropical Fruit, 12 count (2 packs of 6 count)	All Lots	312547065757
ROLAIDS® Extra Strength plus Gas Softchews, Tropical Fruit, 36 count (6 packs of 6 count)	All Lots	312547065771
ROLAIDS® Extra Strength Softchews		
ROLAIDS® Extra Strength Softchews, Wild Cherry, 18 count (3 packs of 6 count)	All Lots	312547655255
ROLAIDS® Extra Strength Softchews, Cherry, 18 count bag	All Lots	300450649188
ROLAIDS® Extra Strength Softchews, Cherry, 36 count bag	All Lots	300450649362
ROLAIDS® Extra Strength Softchews, Wild Cherry, 42 count (7 packs of 6 count)	All Lots	312547655316
ROLAIDS® Extra Strength Softchews, Wild Cherry, 6 count	All Lots	312547655200
ROLAIDS® Extra Strength Softchews, Cherry, 6 count	All Lots	312547655200
ROLAIDS® Multi-symptom plus Anti-Gas Softchews		
ROLAIDS® Multi-Symptom plus Anti-Gas Softchews, Tropical Fruit, 12 count bag	All Lots	300450657121
ROLAIDS® Multi-Symptom plus Anti-Gas Softchews, Tropical Fruit, 24 count bag	All Lots	300450657244
ROLAIDS® Multi-Symptom plus Anti-Gas Softchews, Tropical Fruit, 6 count	All Lots	300450657060

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