



Ohio Department of Agriculture
and
Ohio Department of Health



Governor Ted Strickland
Lieutenant Governor Lee Fisher

ODA Director Robert J. Boggs
ODH Director Alvin D. Jackson, M.D.

Date: December 14, 2010
TO: Health Commissioners, Directors of Environmental Health and Interested Parties
Subject: Recall Announcement (ODA/ODH) 2010 – 111

McNeil Consumer Healthcare Announces Voluntary Recall Of All Lots Of Rolaid® Extra Strength Softchews, Roldaid® Extra Strength Plus Gas Softchews, And Roldaid® Multi-Symptom Plus Anti-Gas Softchews Sold In The United States

December 9, 2010 - 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 <http://www.rolaids.com>¹⁰ 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: <http://www.fda.gov/MedWatch/report.htm>¹¹
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: <http://www.fda.gov/MedWatch/getforms.htm>¹². 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).

Product Information: Product NDC numbers can be located on the label of the package above the brand name. Lot Numbers and Expiration Dates can be found on back, side or bottom label of the package. If you cannot find the NDC number, lot number, or expiration date on the label, Click here¹³ for examples or call the Consumer Care Center at 1-888-222-6036.

FULL RECALLED PRODUCT LIST:

Product Name	Lot Number	UPC
ROLAIDS® Extra Strength Softchews, Wild Cherry		
ROLAIDS® Extra Strength Softchews, Wild Cherry, 6 count	9015A, 9016A, 9019A, 9140A, 9138A, 9210A, 9211A, 9315A, 9316A	312547655200
ROLAIDS® Extra Strength Softchews, Wild Cherry, 18 count (3 packs of 6 count)	9075A, 9076A, 9103A, 9098A, 9104A, 9239A, 9240A, 9348A	312547655255
ROLAIDS® Extra Strength Softchews, Wild Cherry, 42 count (7 packs of 6 count)	9065A, 9068A, 9069A, 9131A, 9132A, 9208A, 9209A, 9286A, 9287A	312547655316
ROLAIDS® Extra Strength Softchews, Cherry		
ROLAIDS® Extra Strength Softchews, Cherry, 6 count	0109A, 0114A, 0115A, 0134A, 0135A, 0165A, 0238B, 0239A, 0239C, 0262A, 0264A	312547655200
ROLAIDS® Extra Strength Softchews, Cherry, 18 count bag	9349AG2, 9350AG1, 0015AG2, 0015AG3, 0050AG1, 0051AG1, 0053BG2, 0106BG2, 0107AG1, 0108AG1, 0108BG3, 0108CG1, 0129BG1, 0133AG1, 0133AG2, 0165BG2, 0191BG1, 0191CG1, 0191DG1, 0213AG2, 0238AG1, 0238AG2, 0246AG1	300450649188
ROLAIDS® Extra Strength Softchews, Cherry, 36 count bag	9350AG2, 0012AG1, 0013AG1, 0014AG1, 0015AG1, 0015AG4, 0050AG2, 0053AG2, 0053BG1, 0053BG2, 0094AG1, 0106AG1, 0106BG1, 0108AG2, 0108BG2, 0191AG1, 0139BG2, 0165BG1, 0191BG1, 0207AG1, 0207AG2, 0213AG1, 0227AG1, 0246AG2, 0247AG1, 0265AG1, 0266AG1	300450649362

ROLAIDS® Extra Strength plus Gas Softchews, Tropical Fruit		
ROLAIDS® Extra Strength plus Gas Softchews, Tropical Fruit, 6 count	9005A, 9006A	312547065733
ROLAIDS® Extra Strength plus Gas Softchews, Tropical Fruit, 12 count (2 packs of 6 count)	9022A, 9027A, 9118A, 9119A, 9195A, 9196A	312547065757
ROLAIDS® Extra Strength plus Gas Softchews, Tropical Fruit, 36 count (6 packs of 6 count)	9166A, 9167A	312547065771
ROLAIDS® Multi-Symptom plus Anti-Gas Softchews, Tropical Fruit		
ROLAIDS® Multi-Symptom plus Anti-Gas Softchews, Tropical Fruit, 6 count	0017B, 0095A, 0096B, 0259A, 0260A	300450657060
ROLAIDS® Multi-Symptom plus Anti-Gas Softchews, Tropical Fruit, 12 count bag	9351BG1, 9352AG1, 0016AG1, 0059AG2, 0059BG1, 0059BG2, 0060AG2, 0167AG2, 0167AG3, 0203AG1, 0204AG1	300450657121
ROLAIDS® Multi-Symptom plus Anti-Gas Softchews, Tropical Fruit, 24 count bag	9352AG2, 9352BG2, 0016AG2, 0017AG1, 0057BG1, 0058AG1, 0059AG1, 0059BG3, 0060AG1, 0129AG1, 0132AG1, 0167AG1, 0167BG1, 0204AG2, 0205AG1, 0230AG1, 0231AG1	300450657244

For additional information http://www.rolaids.com/page.jhtml?id=/rolaids/include/lot_finder.inc