Rolaids Extra Strength Softchews, Rolaids Extra Strength plus Gas Softchews, Rolaids Multi-Symptom plus Anti-Gas Softchews: Recall - Foreign Materials in Products

U.S. Food & Drug Administration

AUDIENCE: Consumer

ISSUE: McNeil Consumer Healthcare, Division of McNEIL-PPC, Inc. recalled all lots of Rolaids Extra Strength Softchews, Rolaids Extra Strength plus Gas Softchews, and Rolaids Multi-Symptom plus Anti-Gas Softchews distributed in the United States, following consumer reports of foreign materials in the product, including metal and wood particles.

BACKGROUND: The company’s investigation determined that the materials were potentially introduced into the product during the manufacturing process at a third party manufacturer. While the investigation is ongoing, production of these products has been suspended and will not restart until corrective actions have been implemented.

RECOMMENDATION: Consumers who purchased product included in this recall should contact McNeil Consumer Healthcare, either at http://www.rolaids.com [1]

[2] or by calling 1-888-222-6036 for instructions about receiving a refund. Consumers who have medical concerns or questions should contact their healthcare provider.

Consumers are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [3]
- Download form [4] 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

[12/14/2010 - Press Release [5] - McNeil Consumer Healthcare]

SOURCE [6]

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http://www.mdtmag.com/news/2010/12/rolaids-extra-strength-softchews-rolaids-extra-strength-plus-gas-softchews-rolaids-multi-symptom-plus-anti-gas-softchews-recall-foreign-materials-products

Links:
[1] http://www.rolaids.com
[2] http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm
[3] http://www.fda.gov/MedWatch/report.htm
[4] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[5] http://www.fda.gov/Safety/Recalls/ucm236715.htm
[6] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm236907.htm