

## **Perrigo Initiates Nationwide Voluntary Product Recall Of Acetaminophen Infant Suspension Liquid, 160 mg/5 mL, Due To A Potential Defect With The Co-Packaged Oral Syringe**

ALLEGAN, Mich., Nov. 1, 2013 /PRNewswire/ -- The Perrigo Company (NYSE: PRGO; TASE) announced today that it has initiated a voluntary, nationwide product recall to the retail level of 18 batches of its acetaminophen infant suspension liquid, 160 mg/5 mL, sold in 2 oz. and 4 oz. bottles with syringes in a box under the store brand products listed below. The recall is being initiated because of the remote potential that a small number of packages might contain an oral dosing syringe without dose markings. The correct syringe should have a white or yellow plunger with specific dose markings for 1.25 mL, 2.5 mL, 3.75 mL, and 5 mL. If the product's syringe has these dose markings, consumers can continue to use the product while following labeled use instructions.

(Photo: <http://photos.prnewswire.com/prnh/20131101/DE09003>)

(Logo: <http://photos.prnewswire.com/prnh/20120301/DE62255LOGO>)

Using an oral syringe without dose markings can result in inaccurate dosing, especially in infants who could mistakenly get too high a dose.

Commenting on this market action, Perrigo's Chairman, President and CEO Joseph C. Papa stated, "There are no issues or concerns with respect to the safety or efficacy of the product, only the potential that the oral dosing device in a relatively small number of packages could be unmarked. Out of an abundance of caution, we are taking this measure to maintain the highest possible product quality standards for our retail customers and consumers. While we cannot be certain that any of these unmarked dosing devices were released into our customers' supply chains, taking this action is the right thing to do." Perrigo has not received any reports or complaints related to this defect nor have they found any product with missing dose markings on re-examination of product on hand.

This OTC product is indicated for the relief of fever and minor aches and pains and can be used in infants, children and adults. These recalled products are sold by distributors nationwide and distributed through retail stores.

Perrigo is notifying its distributors and customers by verbal and e-mail communication today, followed by formal FedEx-delivered communication. It also is arranging for return of all recalled products. Distributors/retailers that have the acetaminophen infant suspension liquid that is being recalled should stop distribution and return product.

If the oral dosing device contained in the package has dose markings, no action is required, and the consumer can continue to use the product consistent with the label instructions. If the package contains an oral dosing device **that does not have dose markings**, the consumer should not use the product and should call Perrigo's Consumer Affairs Department, toll free, 1-800-719-9260. Consumers should contact their physician or healthcare provider if they have any questions, or if they or their children experience any problem that could possibly be related to this drug product.

Adverse events that may be related to the use of this product may be reported to FDA's MedWatch Adverse Event Reporting Program either online, by regular mail or by fax:

- **Online:** [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- **Regular Mail:** use postage-paid FDA form 3500 available at:

- Fax: 1-800-FDA-0178

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

Recalled lots, along with their corresponding branded labels, are listed below:

<b>Label</b>	<b>Batches</b>
BABIES R US	3KK0606
CARE ONE	3HK0564
EQUALINE	3HK0672
EQUATE	3HK0672, 3JK0433, 3JK0594, 3JK0595, 3JK0653, 3JK0673, 3KK0815, 3KK0817
HARMON FACE VALUES	3JK0594
HEALTH MART	3HK0671
HEALTHY ACCENTS	3HK0671, 3KK0606
HEB	3KK0606
KROGER	3GK0645, 3GK0704, 3HK0671, 3JK0433, 3JK0595, 3JK0653, 3JK0433, 3JK0595, 3GK0645, 3GK0704, 3JK0595
LEADER DRUG	3JK0433, 3JK0594
MEIJER	3JK0594, 3JK0597
PUBLIX	3JK0595
RITE AID	3GK0704
TOPCARE	3KK0359, 3KK0494
UP & UP	3HK0672
WALGREEN	3GK0704, 3HK0564, 3HK0671, 3JK0433, 3JK0595, 3JK0610, 3KK0360

Mr. Papa concluded by stating, "While patient safety remains our top priority, we do not expect this issue to have a material financial impact on the company, and we are reaffirming our Fiscal 2014 full-year's earnings guidance provided October 31, 2013."

## **About Perrigo**

From its beginnings as a packager of generic home remedies in 1887, Perrigo Company, based in Allegan, Michigan, has grown to become a leading global healthcare supplier. The Company develops, manufactures and distributes over-the-counter ("OTC") and generic prescription ("Rx") pharmaceuticals, nutritional products and active pharmaceutical ingredients ("API") and is the world's largest manufacturer of OTC pharmaceutical products for the store brand market. Perrigo's mission is to offer uncompromised "quality, affordable healthcare products", and it does so across a wide variety of product categories primarily in the United States, United Kingdom, Mexico, Israel and Australia, as well as certain other markets throughout the world, including Canada, China and Latin America. Visit Perrigo on the Internet (<http://www.perrigo.com>).

*Note:* Certain statements in this press release are forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and are

subject to the safe harbor created thereby. These statements relate to future events or the Company's future financial performance and involve known and unknown risks, uncertainties and other factors that may cause the actual results, levels of activity, performance or achievements of the Company or its industry to be materially different from those expressed or implied by any forward-looking statements. In some cases, forward-looking statements can be identified by terminology such as "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "potential" or other comparable terminology. The Company has based these forward-looking statements on its current expectations, assumptions, estimates and projections. While the Company believes these expectations, assumptions, estimates and projections are reasonable, such forward-looking statements are only predictions and involve known and unknown risks and uncertainties, many of which are beyond the Company's control. These and other important factors, including those discussed under "Risk Factors" in the Company's Form 10-K for the year ended June 28, 2013, as well as the Company's subsequent filings with the Securities and Exchange Commission, may cause actual results, performance or achievements to differ materially from those expressed or implied by these forward-looking statements. The forward-looking statements in this press release are made only as of the date hereof, and unless otherwise required by applicable securities laws, the Company disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Contact:  
Perrigo Consumer Affairs Department  
(800) 719-9260

SOURCE Perrigo Company

For further information: Arthur J. Shannon, Vice President, Investor Relations and Global Communications, (269) 686-1709, E-mail: [ajshannon@perrigo.com](mailto:ajshannon@perrigo.com); Bradley Joseph, Director, Investor Relations and Global Communications, (269) 686-3373, E-mail: [bradley.joseph@perrigo.com](mailto:bradley.joseph@perrigo.com)

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