Perrigo Initiates Voluntary Product Recall In The U.S. Of Children's Guaifenesin Grape Liquid And Guaifenesin DM Cherry Liquid Due To A Potential Defect With The Dosage Cup

DUBLIN, Jan. 11, 2016 /PRNewswire/ -- Perrigo Company plc (NYSE: PRGO; TASE) announced today that, following the recent recall of certain dosing cups by its supplier, it has initiated a voluntary product recall in the US to the retail level of 2 batches of its children's guaifenesin grape liquid (100mg/5 mL) and 3 batches of its children's guaifenesin DM cherry liquid (100mg guaifenesin and 5mg dextromethorphan HBr/ 5 ml) sold in 4 oz. bottles with dosage cup in a box under the store brand products listed below. This recall is being initiated because some packages contain an oral dosing cup with incorrect dose markings.

Use of these products according to labeled instructions with an affected dosing cup is unlikely to result in serious side effects, and no reports related to overdose have been received to date. Consumers should be aware that an overdose of Guaifenesin DM may cause hyper excitability, rapid eye movements, changes in muscle reflexes, ataxia, dystonia, hallucinations, stupor, and coma. Other effects have included nausea, vomiting, tachycardia, irregular heartbeat, seizures, respiratory depression, and death. Gastric decontamination is recommended after acute ingestion of greater than 10 mg/kg, if administered soon after ingestion. At risk populations such as those who are poor metabolizers of dextromethorphan may experience an overdose by a factor of 3, if incorrect measuring levels are used. Additionally, small children who are poor metabolizers of dextromethorphan and use the product regularly over a period of several days at the mistaken dose, may develop cumulative toxicity. Moreover, adverse reactions to guaifenesin when given in high or excessive dosage may include nausea/vomiting, diarrhea, and/or abdominal pain. Therefore, an extreme overdose in an at risk population may need medical intervention, but in most cases adverse health consequences are temporary and reversible.

Commenting on this market action, Perrigo's Chairman and CEOJoseph C. Papa stated, "There have been no reports of adverse events to Perrigo as a result of the incorrect dosage markings. Perrigo is taking this action to maintain the highest possible product quality standards for our retail customers and consumers. We are taking this action because it is the right thing to do."

These OTC products are indicated for helping loosen phlegm (mucus) and thin bronchial secretions and making coughs more productive, as well as in the case of the DM product to temporarily relieve: coughs due to minor throat irritations, the intensity of coughing, and the impulse to cough. 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, followed by formal FedEx-delivered communication. It also is arranging for return of all recalled products. Distributors/retailers that have the affected batches of children's guaifenesin grape liquid and/or children's guaifenesin DM cherry that is being recalled should stop distribution and return product.

Consumers that have product with the corresponding labels and batch numbers listed below should discard the dosing device and product and may call Perrigo, toll free, Monday through Friday from 8:00 AM to 10:00 PM EST, at 1-888-345-0479, or visit

mucusreliefrecall.com. 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 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.

- **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail**: use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm, then complete and return to the 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.

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

GUAIFENESIN GRAPE LIQ 4 OZ

Label	Lot number	Expiry
H.E.B	5LK0592	08/2017
CVS	5MK0340	08/2017

GUAIFENESIN DM CHRY LIQ 4 OZ

Label	Lot number	Expiry
Sunmark	5LK0528, 5LK0630	03/2017
Rite-Aid	5LK0528, 5LK0630	03/2017
Topcare	5LK0528, 5LK0630, 5LK0779	03/2017
Kroger	5LK0528, 5LK0630	03/2017
GoodSense	5LK0528	03/2017
Dollar General	5LK0630	03/2017
Care One	5LK0630	03/2017
CVS	5LK0630	03/2017

About Perrigo

Perrigo Company plc is a top five global over-the-counter ("OTC") consumer goods and leading specialty pharmaceutical company, offering patients and customers high- quality products at affordable prices. From the Company's beginning in 1887 as a packager of home remedies, it has grown to become the world's largest manufacturer of OTC healthcare products and supplier of infant formulas for the store brand market. The Company is also a leading provider of generic extended topical prescription products, and it receives royalties from sales of the multiple sclerosis drug Tysabri®. The Company provides "Quality Affordable Healthcare Products®" across a wide variety of product categories and geographies, primarily in North America, Europe and Australia, as well as

in other markets, including Israel and China. Visit Perrigo online at (http://www.perrigo.com).

Forward Looking Statements

Certain statements in this press release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and 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, including but not limited to, the successful integration of the Omega Pharma Invest NV business. These and other important factors, including those discussed under "Risk Factors" in the Company's Form 10-K for the year ended June 28, 2015, 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.

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SOURCE Perrigo Company plc

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