

Perrigo Company Announces Approvals to Market Three New Products

PRNewswire-FirstCall
ALLEGAN, Mich.

The Perrigo Company (NASDAQ: PRGO) today announced that it will begin marketing three new products following U.S. Food and Drug Administration (FDA) approvals. More specifically, these new additions to the Perrigo line of products are:

1. Ibuprofen/Pseudoephedrine Oral Suspension (Children's Motrin® Cold)
2. Loratadine Syrup, 5 mg (Children's Claritin® Syrup)
3. Loratadine Orally Disintegrating Tablets, 10 mg (Claritin® RediTabs®)

These approvals were granted to the Company and its alliance partners through the Abbreviated New Drug Approval (ANDA) process regulated by the FDA, and are summarized as follows:

Ibuprofen/Pseudoephedrine Oral Suspension

The FDA determined that Ibuprofen/Pseudoephedrine Hydrochloride Oral Suspension, 100 mg/15 mg per 5 mL produced by Perrigo, is bioequivalent to Children's Motrin Cold Oral Suspension, marketed by McNeil Consumer and Specialty Pharmaceuticals.

Children's Motrin Cold is a liquid medication indicated to provide relief from cold, sinus and flu symptoms such as nasal and sinus congestion, sore throat and fever. Annual sales for the brand are approximately \$30 million.

Loratadine Syrup

Through an agreement with Teva Pharmaceutical Industries Ltd., Perrigo will have the right to manufacture, market and distribute Loratadine Syrup, 5 mg/5 mL. Teva has received FDA approval of its ANDA for Loratadine Syrup, 5 mg/5 mL, with FDA determining it to be bioequivalent to Children's Claritin Syrup, marketed by Schering-Plough Corporation.

Children's Claritin Syrup is a liquid antihistamine for the relief of symptoms due to hay fever or other upper respiratory allergies. Sales for the over-the-counter brand since its launch in December 2002 are approximately \$15 million.

Loratadine Orally Disintegrating Tablets

As announced by Andrx Corporation on November 4, 2003, the FDA approved its ANDA for Loratadine Orally Disintegrating Tablets, 10 mg, determining it bioequivalent to Schering-Plough Corporation's Claritin RediTabs. In January 2003, Andrx and Perrigo entered into an agreement where Perrigo will market Andrx's bioequivalent versions of Claritin products, including Claritin-D® 24, Claritin RediTabs and, when approved, Claritin-D® 12.

Claritin RediTabs is a quickly-dissolving tablet antihistamine for the relief of symptoms due to hay fever or other upper respiratory allergies. Sales for the loratadine quickly-dissolving branded business since launch in December 2002 are approximately \$90 million.

John Hendrickson, Executive Vice President and General Manager, Perrigo Consumer Healthcare, stated, "We are pleased with these approvals, which bring us medications for children and important additions to the cough/cold/allergy/sinus product category. We congratulate Teva and Andrx on their ANDA approvals and are optimistic that our product alliances will be successful while delivering health care value to consumers."

Mr. Hendrickson also noted, "These new products are expected to begin shipping in early 2004. With the Children's Ibuprofen Cold and Children's Loratadine Syrup approvals, the FDA has granted 180 days of market exclusivity."

Perrigo Company is the nation's largest manufacturer of over-the-counter (non-prescription) pharmaceutical and nutritional products sold by supermarket, drug, and mass merchandise chains under their own labels. The Company's products include over-the-counter pharmaceuticals such as analgesics, cough and cold remedies, gastrointestinal, and feminine hygiene products, and nutritional products, such as vitamins, nutritional supplements and nutritional drinks. Visit Perrigo on the Internet (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. Please see the "Cautionary Note Regarding Forward-Looking Statements" on pages 25-30 of the Company's Form 10-K for the year ended June 28, 2003 for a discussion of certain important factors that relate to forward-looking statements contained in this press release. Although the Company believes that the expectations reflected in these forward-looking statements are reasonable, it can give no assurance that such expectations will prove to be correct. 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.

Motrin® is a registered trademark of McNeil Consumer and Specialty Pharmaceuticals.

Claritin®, Claritin-D® and Claritin® RediTabs® are registered trademarks of Schering-Plough Corporation.

SOURCE: Perrigo Company

CONTACT: Ernest J. Schenk, Manager, Investor Relations and Communication of Perrigo Company, +1-269-673-9212, E-mail: eschenk@perrigo.com

Web site: <http://www.perrigo.com/>

<https://investor.perrigo.com/2003-11-14-Perrigo-Company-Announces-Approvals-to-Market-Three-New-Products>