Edgar Filing: PERRIGO CO - Form 8-K

PERRIGO CO Form 8-K November 24, 2004

> UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

> > FORM 8-K

CURRENT REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): November 23, 2004

PERRIGO COMPANY

(Exact name of registrant as specified in its charter)

MICHIGAN (State of other Jurisdiction of Incorporation) 0-19725 -----(Commission File Number)

38-2799573 -----(IRS Employer Identification No.)

Registrant's telephone number, including area code: (269) 673-8451

Not Applicable

(Former name or address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- [] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- [] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- [] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange
 Act (17 CFR 240.14d-2(b))
- [] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange
 Act (17 CFR 240.13e-4(c))

ITEM 8.01. Other Events

Product Recall

The Company has initiated a retail-level recall of all lots of loratadine syrup, a liquid antihistamine indicated for the relief of symptoms due to hay fever or other upper respiratory allergies.

During post-marketing stability studies, the Company detected a difference in the stability profiles of the batches used to support FDA approval and the batches initially manufactured. The Company has made the decision to recall all product from the retailer and wholesaler channels. An independent medical consultant has indicated that there is "no indication that this would result in any patient toxicity or negative effects". The subject recall is not safety related. There have been no reports of injury or illness related to the use of this product.

The value of the Company's on-hand inventories and the cost of return and disposal is estimated to be between \$7.5 and \$8.5 million, which is expected to reduce earnings \$0.07 to \$0.08 per share for the fiscal second quarter ending December 25, 2004. In addition, the impact of not having the product available for sale will reduce earnings no more than an additional \$0.02 in the second half of fiscal year 2005.

Certain statements in this 8-K 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 27 - 33 of the Company's Form 10-K for the year ended June 26, 2004 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.

SIGNATURES

Pursuant to the requirement of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PERRIGO COMPANY (Registrant)

Edgar Filing: PERRIGO CO - Form 8-K

Dated: November 24, 2004