PERRIGO CO
Form 8-K
March 06, 2001

1

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):
March 6, 2001

PERRIGO COMPANY
(Exact name of registrant as specified in charter)

MICHIGAN	0-19725	38-2799573
(State or other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

515 Eastern Avenue, Allegan, Michigan	49010
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code:
(616) 673-8451

2

ITEM 5. Other Events

Government Regulations - Food and Drug Administration

The manufacturing, testing, packaging, distribution, labeling, advertising and sale of the Company's products are subject to regulation by one or more United States agencies, including the Food and Drug Administration (FDA). The FDA exercises authority over three aspects of the Company's business: (i) the

operation of manufacturing, testing and packaging facilities, (ii) the labeling and marketing of over-the-counter (OTC) pharmaceutical drug products, and (iii) the labeling and marketing of dietary supplements.

On an on-going basis, the FDA reviews the safety and efficacy of OTC pharmaceutical products and monitors the labeling, advertising and other matters related to the promotion and sale of such products. The FDA also regulates the facilities and procedures used to manufacture OTC pharmaceuticals and all facilities must be registered with the FDA and all products made in those facilities must be manufactured in accordance with "Current Good Manufacturing Practices" (cGMP) established by the FDA. Compliance with cGMP guidelines entails a dedication of substantial resources and requires significant costs.

The FDA performs periodic inspections to ensure that the Company's facilities remain in compliance with cGMP regulations. The failure of a facility to be in compliance may lead to regulatory action that could result in production interruptions, product recalls or delays in new drug approvals. The impact of one or more of these actions could have a material adverse effect on the Company's business.

In August 2000, the Company received a Warning Letter from the FDA primarily related to manufacturing issues identified during the FDA's April 2000 inspection of its Allegan, Michigan manufacturing facilities. The Warning Letter also identified certain issues related to the Company's Quality Systems. In response to the Warning Letter, the Company met with the FDA to discuss the manufacturing and Quality Systems issues. The Company is implementing remedial action to address the manufacturing issues and has completed a Global Improvement Plan ("GIP") with the help of outside consultants to ensure that the Company's Quality Systems comply with cGMP on an on-going basis. The GIP Plan includes a review of the Quality Systems, formulation of revisions to the Quality Systems, a plan to implement identified changes and a plan to audit and measure the effectiveness of the corrective action taken. The Company has already taken comprehensive corrective action as outlined in the GIP Plan and will continue to implement the GIP Plan on an on-going basis to ensure compliance with cGMP.

Based on discussions with the FDA, a reinspection of the Allegan facilities to review the actions taken to correct the manufacturing issues cited in

the Warning Letter was expected. The FDA initiated their inspection and follow-up review on March 5, 2001. The Company cannot predict that its remedial actions will resolve the FDA's concerns or whether the FDA will take any further action.

4

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)

By: /s/ Douglas R. Schrank

Dated: March 6, 2001

Douglas R. Schrank
Executive Vice President and
Chief Financial Officer