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PERRIGO CO
Form 8-K
May 04, 2001

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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):
May 3, 2001

PERRIGO COMPANY

(Exact name of registrant as specified in charter)

| | | |
|--|-----------------------------|---|
| MICHIGAN | 0-19725 | 38-2799573 |
| ----- | ----- | ----- |
| (State of 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

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ITEM 5. Other Events

Government Regulations - Food and Drug Administration

On May 2, 2001, the Company was notified by the FDA Detroit District Office that it has recommended that Abbreviated New Drug Applications (ANDAs) for two of the Company's products be approved for manufacturing at its Allegan, Michigan facility. This recommendation

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grew out of an FDA inspection and follow-up review that was conducted in March 2001, following the FDA's issuance of a Warning Letter in August 2000. It is now anticipated that final approval of the Company's ANDAs will not be withheld due to issues identified in the August 2000 Warning Letter.

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 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 "Current Good Manufacturing Practices" (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.

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 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 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.

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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)

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By: /s/ Douglas R. Schrank

Dated: May 3, 2001

Douglas R. Schrank
Executive Vice President and
Chief Financial Officer