DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313) 393-8139	03/21/2006 - 03/28/2006* FEI NUMBER 1811666

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: John T. Hendrickson, Executive VP and GEN MGR of Perrigo Consumer Healthcare

FIRM NAME	STREET ADDRESS
L. Perrigo Company	515 Eastern Ave.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Allegan, MI 49010	Drug Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Complaint records are deficient in that they do not include the findings of the investigation.

Specifically, complaint number (b) (4) dated 02/07/2006 resulting in deviation investigation (b) (4) did not include complete written documentation of the investigation including the justification as to why no investigation was needed at the contract manufacturing facility.

OBSERVATION 2

Procedures describing the handling of all written and oral complaints regarding a drug product are not followed.

Specifically, SOP (b) (4) dated FEB 16,2006 was not completely followed for complaints received before but closed after the effective date of the SOP. More specifically, complaints that were opened before but closed after the effective date, including complaints (b) (4) opened 10/24/05 closed 03/13/06 and PCA (b) (4) opened 01/20/06 closed 03/13/06 did not include the investigation summary report as required by the SOP.

OBSERVATION 3

Employees are not given training in written procedures required by current good manufacturing practice regulations.

Specifically, there is no documentation to show that the contract employees in charge of complaint handling have been trained in the (b) (4)

*** DATES OF INSPECTION:**
03/21/2006(Tue), 03/22/2006(Wed), 03/23/2006(Thu), 03/24/2006(Fri), 03/28/2006(Tue)

SEE REVERSE OF THIS PAGE		DATE ISSUED 03/28/2006

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313) 393-8139	03/21/2006 - 03/28/2006* FEI NUMBER 1811666

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: John T. Hendrickson, Executive VP and GEN MGR of Perrigo Consumer Healthcare

FIRM NAME	STREET ADDRESS
L. Perrigo Company	515 Eastern Ave.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Allegan, MI 49010	Drug Manufacturer

FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:

Martha Sullivan Myrick, Investigator

SEE REVERSE OF THIS PAGE

DATE ISSUED
03/28/2006