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	07/19/2005 - 07/28/2005* FEI NUMBER 1811666

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: David T. Gibbons, Chairman, President & Chief Executive Officer

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:

Records were reviewed for the following products:
00805 (0.5 fl oz Cherry Flavored Infant APAP)
00810 (1.0 fl oz Cherry Flavored Infant APAP)
28905 (0.5 fl oz Grape Flavored Infant APAP)
28910 (1.0 fl oz Grape Flavored Infant APAP)
48705 (0.5 fl oz cold and cough without APAP)
51405 (0.5 fl oz cold and cough with APAP)

OBSERVATION 1

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

Specifically, SOP 054-362 effective date May 02, 2005:
a- states that (b) (4) is responsible for notifing the Consumers Affairs Manager the next business day of potentially serious product issues. Serious is defined in the SOP 054-362 dated 05/02/05 as any inpateint hospitalization. There is no documentation on the comlaint case status update report to show that Consumers Affairs Manager was notified the next business day for complaint PCA0170441 which resulted in an infant hospitalization.

b- states that all complaints are to be reviewed in a timley manner. Documentation shows of lack of timeliness for several complaints including but not limited to PCA0167857 complaint received 5/28/05 response sent to complainant 7/20/05; PCA0157600 received 6/22/05 response sent to complainant 7/20/05; PCA0089577 received 6/2/05 response sent to complainant 7/5/05; and PCA0168920 received 6/30/05 response sent to complainant 07/20/05.

c- states that significant trends are to be identified by Consumer Affairs. No trending was identified for the significance of complaints received by product line for products 008 and 289. Significance of complaints being the actual overdose and hospitalization of an infant and the complaints dealing with the possible overdose of infants.

d- states that all complaints go through a management review by a member of the consumers affairs team. At the start of the inspection, there was is no documentation of this review being conducted for at least 7 of 13 complaints received after 5/2/05 for products 008,289,487, and 514 including but not limited to PCA0170441, PCA0190216, PCA0188486, and PCA0167857.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313) 393-8139	07/19/2005 - 07/28/2005* FEI NUMBER 1811666

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: David T. Gibbons, Chairman, President & Chief Executive Officer

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

e- states that the evaluation of complaints is to be conducted. There was no documentation for the evaluation of complaints for 12 of 13 reviewed for product 008 and 289 including justification for not conducting an investigation and the name of the individual who made that decision.

f- Consumer Affairs Manager approval of completed and closed complaint files was not documented for 13 of 13 complaints received after 5/2/05 for products 008 and 289.

g- states that customers are to be informed of progress every two weeks. This was not documented for complaints received after 05/02/05 for product 008 and 289. This includes but is not limited to complaints PCA0168920, PCA0167857 and PCA0089577.

OBSERVATION 2

Written procedures describing the handling of complaints do not include provisions for review by the quality control unit of any complaint involving the possible failure of a drug product to meet any of its specifications and a determination as to the need for an investigation of any unexplained discrepancy.

Specifically, written policy under SOP 054-362 dated 05/02/05 only allows for Quality Control Units review of batch records for a particular manufacturing batch or packaging lot number. The SOP does not allow for the quality control group to review complaints received by product line that involve the possible failure to meet any of its specifications or unexplained descrepancies.

OBSERVATION 3

Complaint records are deficient in that they do not document the reason and the individual making the decision not to conduct a complaint investigation.

Specifically, there was no written justification to explain the lack of investigation conducted for 12 of 12 complaints received regarding confusing labeling and risk of possible infant overdose for products 008,289,487, and 514.

OBSERVATION 4

Complaint records are deficient in that they do not include the known reply to complainant.

Specifically, complaints received for the APAP products 008 and 289 did not always include documentation of the follow up with the complainant. This occured in at least 7 of 13 complaints reviewed including but not limited to PCA0070776, PCA0145931, and PCA0168920. The reply was documented on 7/20/05 after the initiation of the inspection.

SEE REVERSE OF THIS PAGE

DATE ISSUED
07/28/2005

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	07/19/2005 - 07/28/2005* FEI NUMBER 1811666

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: David T. Gibbons, Chairman, President & Chief Executive Officer

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

OBSERVATION 5

The written record did not include the reason an investigation was found not to be necessary and name of the responsible person making the determination not to conduct an investigation when an investigation into unexplained discrepancies was not conducted.

Specifically, no investigation was conducted as a result of complaints received for products 008 and 289.

OBSERVATION 6

Investigations of an unexplained discrepancy did not extend to other drug products that may have been associated with the specific failure or discrepancy.

Specifically, no investigation was initiated and document changes were not discussed regarding possible additional products with the same syringe delivery systems that is used with products 008, and 289. These other products include 514 and 487.

OBSERVATION 7

Procedures describing the handling of written and oral complaints related to drug products are deficiently written or followed.

Specifically, a complaint received by the sales department on 7/22/05 was not directly forwarded to Consumers Affairs as required by SOP 054-370 dated 05/02/05. This was reported on 7/22/05 to the Director Quality Assurance.

OBSERVATION 8

Complaint procedures are deficient in that written complaint files are not maintained at the manufacturing site nor were they readily available from their off-site location.

Specifically, complaint files after 05/02/05 for products 008,289,487, and 514 were not readily available for review. Records were requested at the start of the inspection. At the end of the day, only a summary of the complaints and a limited amount of hardcopy complaints were available for review. The firm was aware of the complaints but did not have immediate access to the records.

*** DATES OF INSPECTION:**
07/19/2005(Tue), 07/21/2005(Thu), 07/25/2005(Mon), 07/28/2005(Thu)

SEE REVERSE OF THIS PAGE

DATE ISSUED
07/28/2005

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	07/19/2005 - 07/28/2005*
	FEI NUMBER 1811666

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: David T. Gibbons, Chairman, President & Chief Executive Officer

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

FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:

Martha Sullivan Myrick, Investigator

SEE REVERSE OF THIS PAGE

DATE ISSUED
07/28/2005