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	09/05/2007 - 09/13/2007 FEI NUMBER 1811666

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Louis W. Yu, Ph.D., Senior Vice President Global Quality & Compliance

FIRM NAME	STREET ADDRESS
L. Perrigo Co.	515 Eastern Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Allegan, MI 49010-9070	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

Labeling and packaging materials are not representatively sampled and examined upon receipt and before use in packaging and labeling of a drug product.

In the case of liquid drug dosing cups, there are two equipment lines utilized in the production of a "batch" or run. Your sampling plan does not attempt representative sampling of these (b) (4) production lines. Current sampling plan failed to detect the presence of experimental cups, lacking the (b) (4) dosing measure, found to be present in the portion of your supplier's batch (b) (4) received as Perrigo batch #'s (b) (4) and (b) (4). Examples: (b) (4) .

OBSERVATION 2

Written procedures for the sampling of packaging and labeling materials are not followed.

SOP (b) (4) ", SOP (b) (4) " and it's associated (b) (4)) were not followed with regard to selecting six different cavity numbers and recording (identifying) which cup (cavity) mold numbers were inspected for Dosing Cup (b) (4). Examples include:

Supplier Batch #	MFG Date(s)	Perrigo Batch #	Received	Inspected
(b) (4)	7/24-25/07	(b) (4)	7/25/07	7/26/07
"	7/26-27/07	(b) (4)	7/31/07	7/31/07
"	7/31/07	(b) (4)	8/02/07	8/02/07
"	7/27/07	(b) (4)	8/14/07	8/15/07
"	7/27-28/07	(b) (4)	8/14/07	8/15/07
"	7/28-31/07	(b) (4)	8/17/07	8/17/07

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FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:

Patsy J Domingo, Investigator

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