

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 01/14/2009 - 01/27/2009*
	FEI NUMBER 1000140268

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Walter A. Mason, Vice President, Quality Assurance / Quality Control

FIRM NAME Perrigo Florida Inc dba Unico	STREET ADDRESS 2201 4th Ave N
CITY, STATE, ZIP CODE, COUNTRY Lake Worth, FL 33461-3835	TYPE ESTABLISHMENT INSPECTED Medical Food, OTC Drug, and Cosmetic 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 WE OBSERVED:

OBSERVATION 1

An adverse event report for a nonprescription drug was not submitted to the Secretary of HHS within 15 business days of receipt of the report.

Specifically, you did not submit a report to FDA within 15 days of receipt of Complaint #071808-1, received on 7/18/08, for a serious and unexpected event associated with Longs Wellness Preparation Cleansing Kit, Flavored Oral Saline Laxative, Lot #PK70010, exp date 07/09.

OBSERVATION 2

Failure to manufacture foods under conditions and controls necessary to minimize the potential for growth of microorganisms.

Specifically, after (b) (4) filling and capping you do not invert the bottles of Pediatric Oral Electrolyte Solution on all production lines to control the growth of microorganisms.

OBSERVATION 3

Failure to perform filling and packaging in a manner that protects food from becoming contaminated.

Specifically,

a) Plastic containers were loaded onto a hopper in an uncovered open warehouse area prior to their entry into the enclosed OES Fill Room for filling with Pediatric Oral Electrolyte Solution.

b) The cap and collar area of bottles of Pediatric Oral Electrolyte Solution were wiped with cloth rags immediately as they exited (b) (4) fill and capping operations in the OES Fill Room on Lines 1 and 2 (Line 3 was not in operation).

AMENDED

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Mary F. Bodick, Investigator Ethan P. Stegman, Investigator	DATE ISSUED 01/27/2009
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OBSERVATION 4

Failure to take apart equipment as necessary to ensure thorough cleaning.

Specifically, you do not take apart the filler nozzles (used to fill containers of Pediatric Oral Electrolyte Solution) for cleaning, sanitizing, and inspection.

OBSERVATION 5

Instruments used for measuring conditions that control or prevent the growth of undesirable microorganisms are not adequately maintained.

Specifically, calibration was not completed for hand held thermometer S/N (b) (4) due date of 11/27/08.

*** DATES OF INSPECTION:**

01/14/2009(Wed), 01/15/2009(Thu), 01/20/2009(Tue), 01/21/2009(Wed), 01/23/2009(Fri), 01/27/2009(Tue)

AMENDED

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