DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax:(407) 475-4768	07/10/2006 - 07/13/2006* FEI NUMBER 1000140268

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Christopher A. Bohlman, President

FIRM NAME	STREET ADDRESS
Unico Holdings, Inc.	1830 2nd Ave North
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lake Worth, FL 33461-4202	Pediatric Electrolyte Oral Solution 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

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

Specifically, on 7/10/2006, workers did not wash/sanitize their hands or gloves before or during manual capping of plastic bottles containing pasteurized pediatric electrolyte oral solution (Lot #UN62117). Workers repeatedly touched the conveyor equipment, and a trash barrel without washing or sanitizing hands or gloves while applying the caps to bottles of finished product.

OBSERVATION 2

Responsibility for assuring compliance with current good manufacturing practices relating to personnel has not been assigned to competent supervisory personnel.

Specifically, on 7/10/2006, the fill room supervisor directed workers to manually place caps on bottles of pediatric electrolyte oral solution (Lot #UN62117) when the automatic capping machine malfunctioned, instead of stopping the line until repairs could be made. This exposed the product to post pasteurization contamination.

OBSERVATION 3

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

Specifically, on 7/11/2006, the laboratory technician conducting pH measurements prior to release of Lot #CO62129, pediatric electrolyte solution, could not verify that unexpired buffers (4 pH and 7 pH) were used to standardize the pH meter.

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OBSERVATION 4

Lack of backflow protection from piping systems that discharge waste water.

Specifically, the waste water exit pipe located on the floor between Tank #2 (T2) and the RO (reverse osmosis) water system did not have an air gap between the outlet pipe and the drain.

*** DATES OF INSPECTION:**
07/10/2006(Mon), 07/11/2006(Tue), 07/13/2006(Thu)

FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:

Mary F. Bodick, Investigator

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DATE ISSUED
07/13/2006