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	07/18/2007 - 08/02/2007* FEI NUMBER 1000140268

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Edward G. Finnegan, Jr., President

FIRM NAME	STREET ADDRESS
Unico Holdings, Inc.	2201 Fourth Ave. North
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lake Worth, FL 33461	Medical Food Manufacturer (Pediatric OES)

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

All reasonable precautions are not taken to ensure that production procedures do not contribute contamination from any source.

Specifically, your firm did not ensure that controls were in place to prevent microbial contamination of pediatric OES, in that;

a) The following lots manufactured on 2/26/07 failed in-house microbiological testing on 3/2/07, and were subsequently distributed to customers in the United States and Canada even though Quality Control Hold Form identified the microbiological failure on 3/2/07 and reported product destruction on 3/14/07:
Lot GR70774: (b) (4) bottles), (b) (4) bottles), (b) (4) bottles)
Lot GR70775: (b) (4) . bottles) (b) (4) . bottles), (b) (4) bottles)

b) During the inspection, review of a customer complaint (Complaint Investigation Form, code 102006-01, dated 10-20-06) reported microbial contamination in pediatric OES Lot GR62459. The complaint record reported that 6,048/8 oz. bottles of pediatric OES product was voluntarily destroyed onsite by the customer ((b) (4)). My review of batch records revealed that a total of (b) (4) bottles of OES product were manufactured under Lot GR62459. You did not expand investigation and disposition on this complaint to account for the remaining 1,792/8 oz. bottles (b) (4)) that were also manufactured under Lot GR62459 and distributed to other customers (USA).

OBSERVATION 2

Failure to maintain equipment, containers and utensils used to convey food in a manner that protects against contamination.

Specifically, you did not regularly perform preventive maintenance and sanitation control on various components in the production line. The pediatric OES-filled bottles were openly exposed to a variety of unmaintained and unsanitary sources of adulteration and/or contamination. The following observations enumerated and illustrated the conditions found in the pediatric OES production (b) (4):

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1) The mechanical bottle capping equipment and assembly was severely corroded and tarnished. There was also an accumulation of dust and dirt on various areas of the equipment. The exposed OES-filled bottles conveyed on the line were in close proximity to the bottle capping equipment.

2) The conveying line directly adjacent to the bottle capping equipment, include an overhead plexiglass covering that was encrusted with an accumulation of debris from above. Prior to capping, the pediatric OES-filled bottles were exposed to this possible source of contamination.

3) Various mechanical components of the conveyor belt, which move the bottles from the hopper to the filler room, were not routinely cleaned and sanitized on a regular basis. Prior to filling, the empty bottles were exposed to the accumulation of dust and dirt on the conveyor line components.

OBSERVATION 3

Failure to operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food.

Specifically, your firm's rotating bottle sorter with individual air-blowing injectors was not routinely cleaned. Each automated air-blowing injector had an accumulation of dust near its surroundings. In addition, there was a comprehensive build-up of dust and filth inside the plexiglass cover which encapsulated both sides of the rotating OES bottle sorter and air-blowing injectors. There were no preventive maintenance and cleaning schedule of this air-blowing apparatus in order to control and minimize the potential for microbial contamination.

OBSERVATION 4

Failure to store finished food under conditions that would protect against deterioration of the food and its container.

Specifically, your (b) (4) storage and distribution warehouse lacked properly functioning fans and adequate ventilation. Three ventilation fans in the north section of the warehouse were non-functional, while the rest of the fans in the southern end were inadequate to efficiently ventilate the facility. The ambient temperature recorded on 7/19/2007 fluctuated between 93º and 94º F. This warehouse facility stores finished product, such as pediatric OES, while awaiting final distribution.

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*** DATES OF INSPECTION:**
07/18/2007(Wed), 07/19/2007(Thu), 07/20/2007(Fri), 07/23/2007(Mon), 07/24/2007(Tue), 07/27/2007(Fri), 08/02/2007(Thu)

FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:

Albertfiel A Salvador, Investigator

SEE REVERSE OF THIS PAGE

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08/02/2007