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	07/19/2005 - 07/22/2005
	FEI NUMBER 1000140268

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Christopher A. Bohlman, President

FIRM NAME	STREET ADDRESS
Unico Holdings, Inc.	1830 2nd Ave N
CITY, STATE, ZIP CODE, COUNTRY Lake Worth, FL 33461-4202	TYPE ESTABLISHMENT INSPECTED OTC drug , cosmetic, and medical food 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:

QUALITY SYSTEM

OBSERVATION 1

Results of stability testing are not used in determining expiration dates.

Specially, the firm assigned a tentative 2 year expiration date to their newly formulated product "Vagi.Gard Povidone-Iodine Medicated Douche Concentrate" based on laboratory results that do not match the specifications established for the product per Protocol 010605.

OBSERVATION 2

Drug product production and control records, are not reviewed by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed.

Specifically, the review of QC Raw Material Inspection/Testing Reports for Phosphoric Acid (ULN 062905-2 & 041204-03) and Disodium Phosphate (ULN 061305-4) by the Quality Control Unit is inadequate in that:

- These raw materials were documented as "Released to Production" before the Identity Test and Microbial Testing Results were available for review by the Quality Control Unit.
- The QC Raw Material Inspection/Testing Report Cover Sheet (Section 6) documents incorrect dates for the results of the Material I.D. Tests.
- According to SOP L500, section 5.1.7 (b) (4) However, the disposition of the materials does not identify the product as (b) (4)

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PRODUCTION SYSTEM

OBSERVATION 3

Written production and process control procedures are not documented at the time of performance.

Specifically, a comparative review of the following Batch Production and Control Records and "Batches, Warehouse, Mechanics, and Porters" sign-in/sign-out sheets found discrepancies related to the presence of the second person during the weigh/mixing of the batch.

For the **Sodium Phosphate Enema**:

- Batch #(b) (4), Exp. 12/06, manufactured on 12/13/04 - the Batch Production and Control Record documents the batch was mixed by "(b) (4)" from 5:15 am to 5:45 am, and was verified by (b) (4) who, according to the sign-in sheet, started work at 6:45 am.
- Batch #(b) (4), Exp. 02/07, manufactured on 02/15/05 - the Batch Production and Control Record documents the batch was mixed by (b) (4) from 5:00 am to 5:30 am, and was verified by (b) (4) who, according to the sign-in sheet started, work at 6:50 am.

For the **Oral Saline Laxative**:

- Batch #(b) (4), Exp. 12/06, manufactured on 12/21/01 - the Batch Production and Control Record documents the batch was mixed by (b) (4) " from 9:10 am to 9:55 am, and was verified by (b) (4) who, according to the sign-out sheet, left work at 8:30 am.

OBSERVATION 4

Written procedures are lacking which describe in sufficient detail the approval of components.

Specifically, the firm does not have written procedures that describes in details the tracking and final approval of components that have been released to production under "Conditional Approval".

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MATERIALS SYSTEM

OBSERVATION 5

Drug products are not stored under appropriate conditions of so that their identity, strength, quality, and purity are not affected.

Specifically, the temperature of the warehouse where raw materials and finished products are stored is not controlled. On 7/19/05, the temperature of the warehouse was observed at [redacted] (b)(4), close to where finished product was stored.

FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:

Ana del P. Cintron, Investigator

SEE REVERSE OF THIS PAGE

DATE ISSUED
07/22/2005