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	02/06/2006 - 02/14/2006
	FEI NUMBER 1000140268

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Christopher Bohlman, President

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

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Appropriate training in food handling techniques and food protection principles has not been provided to food handlers and supervisors.

FOOD
Specifically,
The QA manager stated that all training was done on the job at your facility. I observed the following:

Inadequate training:
1. The operator who ran the (b) (4) filler stated he was not sure what the parameter settings were and he was not sure what the manually adjustable speed dial did. He stated the night crew sets the machine up and he just turns it on.

2. The operator who ran the capper machine in the (b) (4) fill room stated they were unsure of what the adjustment knobs ((b) (4) on the machine did. They stated they just turned the machine on and called maintenance if there were any problems.

3. (b) (4) fill line: Upon asking the plant manager and personnel running the RF sealler machine they were unable to state what the knobs, switches, and water fill lines function were on the RF sealer, and what settings and height they should be at for proper functioning.

4. Your firm has (b) (4) large PSI gauges in your (b) (4) pasteurizer and the plant manager and personnel who run the pasteurizer were unable to explain what they did and why. The gauges were not calibrated. While reviewing your firm's pasteurization validation 2001 I found the gauges were critical in the pasteurization startup and to assure adequate flow by assessing if certain gauges had greater PSI than

other gauges on the system during production. The production manager and the employee who runs the pasteurizer were unable to describe the flow of the raw (b) (4) solution through the pasteurizer. I was unable to assess if raw (b) (4) product was commingled with pasteurized (b) (4)

OBSERVATION 2

Failure to perform mechanical manufacturing steps so as to protect food against contamination.

FOOD
Specifically,
(b) (4) production equipment (2/6&7/06): I observed all the bottles of (b) (4) exiting from the filler had several ounces difference in the head space, the capper machine did not cap approximately every fourth bottle and all bottles were falling onto their sides when exiting the machine (upon asking the personnel who ran this machine if this was normal operation they stated, "no it had only been going on for the last few days"), approximately every fourth bottle leaving the tamper evident band applicator machine were missing the tamper evident band, and upon asking the plant manager I was unable to ascertain what level the (b) (4) machine was supposed to be from the cap heads, whereas the following machines (run approximately (b) (4)) on the (b) (4) processing line were not maintained at or above the level of maintenance recommended in the manufacture's manual. The manuals called for hourly, daily, weekly, and sometimes monthly maintenance. Your firm's PM for the machines is performed weekly (per the QA manager, and documentation) and some machines did not have a prescribed PM schedule (tamper evident band applicator machine and the foil sealer, per your firm's QA manager):

a. filler machine
b. capper machine
c. Foil cap sealer
d. Neck Band Applicator (tamper evident cap)

Your firm's pasteurization is dependent on time, temperature, and flow rate of the (b) (4) solution through the system. Upon asking your production manager, the employee who operates the machine, and your QA manager none could not state what the flow rate through the pasteurizer was. Your firm's only time and temperature wheel is not calibrated for time. The pasteurizer (b) (4) not have a flow meter. I was unable to assess at what flow rate the (b) (4) solution is passing through the pasteurizer. I was unable to assess at what temperature the (b) (4) solution is at when it is going through the pasteurizer because the only thermometer is located after the (b) (4) that increased the amount of time the (b) (4) is being pasteurized.

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The plant manager and the employee who operates the (b) (4) pasteurizer were unable to state the function of the (b) (4) PSI gauges on your pasteurizing system. The PSI gauges were not calibrated. Your firm's process validation documentation (2001) for the pasteurizer stated the PSI gauges are needed to correctly prime and verify the pasteurizer was creating adequate flow pressure. For instance, the prime is dependent on a certain PSI pressure and the adequate pressure of the entire system when primed is checked by verifying certain PSI gauges have a higher PSI reading then others: (b) (4) (b) (4) . PSI gauges: PI (b) (4)

(b) (4) production line that was producing (b) (4) on 2/8/06: The bottle inverter that is vacuum assisted had a (b) (4) shop vacuum hooked up to the machine that was not operating or able to operate after calling the maintenance personnel. Your firm was unable to produce the manual for the maintenance of the machine so I could not assess if (b) (4) was enough force to provide a vacuum in an open (to the warehouse air) system. I was unable to assess if your firm's maintenance had been correctly performed on this machine due to the lack of maintenance references and lack of PM maintenance documentation for this machine.

2/8/06: I observed that your firm's Filler Machine (that is pneumatically driven with PSI requirements for performance) has a constant fluctuation of fill and overfills consistently spilling (b) (4) product onto the floor. The machine has (b) (4) PSI gauges that were not calibrated.

(b) (4) line: the air supply line for the equipment (requiring a certain PSI to perform) in the whole (b) (4) line is inadequate. The supply is 100PSI and supplies both the (b) (4) line and the cosmetic line. The filler machine manual states "air requirements 80-100PSI, the capper machine requires 40PSI. There are multiple machines (almost every one) that require a certain PSI to function. The QA managers were unable to provide the PSI requirements for all the machines in the (b) (4) line.

(b) (4) machine had 2 red zip ties on the entry gate and an elastic band on the gate control valve (2/6/06). The gate controller (that stops the bottles to be at a precise location to be filled by the filler) had threads on the both ends of metal that stopped the bottles with nothing attached to the threads providing an area that is difficult to clean/sanitize. Upon asking the operator they stated something screwed onto the gate controller threads a long time ago but was no longer there.

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OBSERVATION 3

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

FOOD
Specifically,
1. (b) (4) Line: (2/6/06) Employees were observed emptying 3-4 liter bottles of (b) (4) solution directly onto the floor 2 feet from the production line with (b) (4) solution splashing onto them, their shoes, and the production line. The QA manager verified that (b) (4) bottles were emptied onto the floor from 6:30AM to 11:30AM and that this was your firm's standard procedure. (b) (4) of the floor in the (b) (4) fill room was wet with (b) (4) solution. Wet feet tracks of (b) (4) solution ran to and from the warehouse from the (b) (4) filling room. Employees tracking (b) (4) on their feet were observed to be frequently coming in and out of the (b) (4) fill room.

2. (b) (4) Line: 2/7/06 Fruit flavored (b) (4) labels in use in production were stored in a cardboard box that was directly on the floor which had wet (b) (4) solution on the floor 4 inches from the box.

3. (b) (4) tank processing Room for mixing (b) (4) solution:
   a. Steady leak from closed processing (b) (4) joint where finished product (b) (4) to holding tanks then to pasteurization system.
   b. The supply line of (b) (4) water has a steady leak on left side of the water pump providing (b) (4) water to the tanks used to mix the (b) (4) solution.
   c. Green hose used for cleaning the (b) (4) mixing room was directly on the floor (2/6/06) near the (b) (4) tank.

OBSERVATION 4

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

FOOD
Specifically,

1. (2/6/06): empty (b) (4) bottles being put in the bottle hopper in the (b) (4) fill line were in plastic bags in

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cardboard boxes stored directly on the floor.

2. (b) (4) Filling line:
a. On 2/6/06 #4 & #11 filler heads filling the (b) (4) bottles did not stop their flow and overflowed into the holding bin which emptied its fluid directly o he floor approximately 3 feet directly below the filler line. After your firm provided maintenance to the filler different heads were observed to do the same on 2/7/06 (#12) and after more maintenance was performed I observed the same conditions on 6/8/06 regarding #1, #2, & #3 heads.
b. Filling Machine: on 2/6, 7, & 8/06 multiple hoses (clear and blue) that go from the fill controller (located one side of the fill line) to the filling heads (located on the other side of the fill line) were lying on the floor where (b) (4) solution spilled onto them from the bin under the fill machine.

OBSERVATION 5

Failure to provide hand washing facilities at each location in the plant where needed.

FOOD
Specifically,
Your firm (b) (4) not have a hand washing facility for a twenty four hour operation employing (b) (4) people on two manufacturing shifts and one cleaning shift. When asked if your firm had hand washing facility your firm's QA manager stated the employee bathrooms are the hand washing facilities for your firm.

OBSERVATION 6

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

FOOD
Specifically,
2/7/06: There was a large fan in the warehouse blowing directly onto open bottles on the (b) (4) production line traveling to the fill room where the bottles were being filled with Fruit Flavor (b) (4) (non-preservative).

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OBSERVATION 7

Failure to inspect, segregate, and handle raw materials to ascertain that they are clean and suitable for processing into food.

FOOD
Specifically,

Your firm had one bottle of "(b) (4) " in your lab (a raw material used in (b) (4) (b) (4) with an expiration date of 6/18/05.

OBSERVATION 8

Failure to take effective measures to protect against the inclusion of extraneous material in food.

FOOD
Specifically,

1. There were multiple (to numerous to count) large, droplet shaped, blackish brown, particles on the ceiling directly over the (b) (4) pasteurizer (2/8/06).

2. (b) (4) line: Your firm's (b) (4) filler room (b) (4) not have a cleanable ceiling. It is a drop ceiling that cannot be washed or sanitized. There was condensation drips on a white metal vent that was directly above the (b) (4) processing line running (b) (4) (2/8/06).

3. (b) (4) line: 2/6/7 the upper filling hose for (b) (4) filler had a glove stuck in the entry hose and (b) (4) solution was spraying down directly over the 12 filling nozzles and into the uncapped bottles that were filled with pasteurized (b) (4)

4. (b) (4) line: The (b) (4) had a plexiglass cover that had 3 pieces of tape hanging directly over the empty bottles and had dozens of patches of tape residue on the inside lid directly over the empty bottles going into the (b) (4) line (2/7/06) to be filled with Fruit Flavored (b) (4) (non-preservative). After your firm stated the plexiglass was cleaned I observed areas to numerous to count that had darkened gum like residue still on the inside of the plexiglass directly in contact with the empty bottles heading down the line to be filled with (b) (4) solution.

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5. (b) (4) line: 2/6/06: The bottle hopper, with a plexiglass cover, located in a large warehouse, was overfilled and exposing the empty bottles to the warehouse environment prior to being filled with pasteurized (b) (4) solution. There were four other areas on the line (which was 90% covered in plexiglass) which were uncovered and open to the overhead environment (the QA manager stated it is not the firm's normal practice to have the hamper open and two areas that normally have plexiglass to be uncovered).

OBSERVATION 9

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

FOOD
Specifically,
Your firm's stability studies that support a shelf life of two years for your (b) (4) was performed at room temperature (b) (4) per your firm's QA manager). Your firm's warehouse where the (b) (4) solution and retention samples are stored had a documented temperature reading in the coldest section of the warehouse of up to (b) (4) in Sept 2005 (one of the hottest months in Florida) and was at (b) (4) in Feb 2006 (one of the coldest months in Florida).

OBSERVATION 10

Failure to remove litter and waste that may constitute an attractant, breeding place, or harborage area for pests, within the immediate vicinity of the plant buildings or structures.

FOOD
Specifically:
Grounds:
a. A metal old collapsed shed, 3- 55 gallon rusted canisters, and a large assortment of wood, metal and shelving were on the ground circling a large area directly outside your firm's dumpster which is located approximately 75 feet from your firm's delivery door.

b. 2 trailer trucks (both missing doors) were full of miscellaneous items that included metal, wood, toilets, and several old wooden pallets scattered under the trucks were located approximately 100ft from the loading dock.

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OBSERVATION 11

Failure to provide adequate screening or other protection against pests.

FOOD
Specifically,
Your firm has an open vent (1X1ft.) 10 feet from your firm's (b) (4) pasteurizer which was only half screened on 2/7/06 leaving the facility open to the possible entry of pests. After your firm's QA personnel stated it had been repaired I observed the same vent on 2/8/06 with a corner of the screen detached.

OBSERVATION 12

Toilet doors open into areas where food is exposed to airborne contamination, and there are no alternative means taken to prevent such contamination.

FOOD
Specifically,
Both female and male bathrooms are located in the processing area and open directly into the processing area.

OBSERVATION 13

A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated and approved according to established procedures.

DRUG
Specifically,
Your firm conducted a process validation for (b) (4) and your (b) (4) lines of production without adequate IQ installation and verification of air supply and demand. Pr is required for multiple machines on your production lines, for instance: your firm's air supply produces (b) (4) and supplies four lines of production that require at least (b) (4) PSI to function correctly (the (b) (4) PSI does not include 5 machines that require air pressure on your lines).

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OBSERVATION 14

Equipment and utensils are not cleaned, maintained, and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

DRUG
Specifically,
(b) (4) Line:

a. On the filling machine (that had been used last the previous day and cleaned post production, per the operator) there was approximately 2-3 tablespoons of a white/grey/black crystallized buildup of fluid on the entry line and dripping below the entry line (2/10/06). More crystallized buildup was observed on 2/13/06.
b. The (b) (4) filler machine also had white particulates in a spider web like pattern covering a 6 X 1.5 inch area below the filler intake on 2/10 & 13/06.
c. The clear air pressure hose to shut of the fill head that was approximately 10 inches long had a clear hose that was half filled with blackened material. Also the gate controller clear air hose had 3 inches of black material inside the hose.

OBSERVATION 15

The plumbing system contains defects that could contribute to the contamination of drug products.

DRUG

Specifically,
(b) (4) water: there was a water leak in the (b) (4) water line. The (b) (4) pump, located on the floor beside the purified water holding tank has a steady dripping leak of purified water that is running clear fluid from the pump in a steady stream along the floor to the floor drain approximately 8 ft away from the pump.

The "reject" water for the purification system runs to the floor drain and is in direct contact with the floor drain (the floor drain was broken to allow the waste pipe entry) and has no p-trap in the system.

(b) (4) bucket containing “quality assurance pipettes” (per the operator) that were not in use had a constant drip of water going into the tall plastic bucket. The bucket was located inside the (b) (4) and

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(b) (4) mixing room. The operator stated they were "there all the time" and not used constantly. There was a constantly drip from a bleeder going into the bucket that overflows onto the floor. There was a small stream of water running along the floor to the floor drain approximately 6 ft. away keeping the floor constantly wet (2/10/06).

OBSERVATION 16

Equipment for adequate control over temperature is not provided when appropriate for the manufacture, processing, packing or holding of a drug product.

DRUG
Specifically,
Inappropriate storage of raw materials and finished product: the following materials for (b) (4) and (b) (4) production were stored in your warehouse which has its coldest point at (b) (4) on 2/10/06 (record review documents the warehouse being (b) (4) in September 2005):

a. (b) (4) raw material: multiple (b) (4) of (b) (4) used in (b) (4) production was stored beside the (b) (4) mixing tanks (label states to "store in cool dry place).
b. (b) (4) raw material: Unico Natural Lemon Flavor (b) (4) states on the label store at room temperature. Your firm's QA manager stated the (b) (4) room temperature your firm uses is (b) (4) (b) (4).
c. Finished product: the label states to store the following products at (b) (4) (1. VagiGuard providone Iodine medicated douche, and Fresh Pure providone Iodine medicated douche are stored in your firm's warehouse until release (approximately 5 days).

OBSERVATION 17

Washing and toilet facilities are not provided and easily accessible to working areas.

DRUG
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2/6/06: Your firm has no hand washing facility for approximately (b) (4) employees (b) (4) per shift). The only place for an employee to wash their hands in your firm are in the male and female bathrooms (one female, one male) that also allow only one person to use the bathroom at a time. Your QA manager stated your hand washing facilities are located in the above bathrooms.

OBSERVATION 18

For components removed from the original containers, the new container fails to be identified with component name or item code, weight or measure, and batch for which component was dispensed including product name, strength and lot number.

DRUG
Specifically,
(b) (4) Batch for 2/10/06:
The following materials were measured/weighed out and placed in unmarked (and one had a different label than the material inside) containers set aside and waiting to be run in the next batch of (b) (4)

1. plastic bucket labeled (b) (4)
2. metal container: contained (b) (4) flavor
3. white bucket: contained (b) (4)
4. small cup: (b) (4).

OBSERVATION 19

Routine inspection and checking of automatic and mechanical equipment is not performed according to a written program designed to assure proper performance.

DRUG
Specifically,
1. 2/10/06: There was no PSI gauge on your firm's air pipe supply for the (b) (4) filler machine (requires (b) (4) PSI supply), (b) (4) capper (I was unable to determine PSI requirement, upon asking your firm twice on two different days your firm did not provide the PSI requirements for multiple machines including the (b) (4) capper), and the (b) (4) filler head ((b) (4) PSI required for two air line supplies) that are pneumatically driven and require a certain amount of pressure to perform (2/10/06). There were no PSI gauges on the air entry lines for any of the machines (that all require a certain PSI to perform) in the (b) (4) line. Your QA manager and production manager stated the air storage tank which is supplied by two compressors has an output of (b) (4) PSI. This storage tank supplies (per your firm's production manager) both OTC lines ((b) (4) and enema), one food line (minimum (b) (4) PSI which (b) (4) not including all the equipment), and (b) (4) cosmetic line (requires (b) (4) PSI).

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2. (b) (4) water system: I was unable to assess if your firm was performing maintenance activities appropriately. Your firm does not have written (b) (4) water maintenance specifications which state when the following maintenance is to occur:

a. Four RO filters: no documentation of when to change
b. (b) (4) filter (b) (4) microns Recirculation loop: no documentation of when to change
c. (b) (4) tank replacement (2 in system): no documentation of when to change.

FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:

Sean T. Creighton, Investigator

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