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	01/22/2008 - 02/11/2008* FEI NUMBER 1000140268

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Edward G. Finnegan, Board Member and President

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

MEDICAL FOODS

OBSERVATION 1

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

Specifically, your firm failed to follow procedure # L400 (Product Recall Policy) which requires a complete follow-up of recalled lots in the market (e.g., notification to FDA, follow up to recall notifications, product accounting, etc.). Your firm recalled (medical foods) lots GR70774 and GR70775 on July 10, 2007; and GR62459 on November 27, 2007. However, no follow-up was given to these three lots that, either, failed your microbiological test specifications or where linked to a customer complaint indicating microbial contamination. Your firm's only action was the distribution of recall notification letters to specific wholesale accounts. No additional follow-up/actions are observed. THIS IS A RECURRENT OBSERVATION.

LABORATORY CONTROL SYSTEM

OBSERVATION 2

Reserve samples from representative sample lots or batches of drug products selected by acceptable statistical procedures are not examined visually at least once a year for evidence of deterioration.

Specifically, your firm failed to follow procedure L712 (Retention Sample Program; section 4.3) which requires periodic visual examinations of all finished products' reserve samples. This encompasses all OTC drug products that are currently manufactured by your firm. A review of the finished product retention sample logbook disclosed that your firm does not examine retain samples on a yearly basis -according to your procedure.

SEE REVERSE OF THIS PAGE

DATE ISSUED 02/11/2008

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax:(407) 475-4768	01/22/2008 - 02/11/2008* FEI NUMBER 1000140268

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Edward G. Finnegan, Board Member and President

FIRM NAME	STREET ADDRESS
Unico Holdings, Inc.	2201 4th Ave N
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lake Worth, FL 33461-3835	Medical Food and OTC Drug Manufacturer

FACILITIES AND EQUIPMENT SYSTEM

OBSERVATION 3

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

Specifically, your firm has not implemented a program in order to assess the adequacy, and to control and monitor the air handling and compressed air systems used in the manufacture of OTC drug and medical food products.

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	01/22/2008 - 02/11/2008* FEI NUMBER 1000140268

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Edward G. Finnegan, Board Member and President

FIRM NAME	STREET ADDRESS
Unico Holdings, Inc.	2201 4th Ave N
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lake Worth, FL 33461-3835	Medical Food and OTC Drug Manufacturer

*** DATES OF INSPECTION:**
01/22/2008(Tue), 01/24/2008(Thu), 01/25/2008(Fri), 01/30/2008(Wed), 01/31/2008(Thu), 02/01/2008(Fri), 02/04/2008(Mon), 02/07/2008(Thu), 02/11/2008(Mon)

FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:

German Rivera, Investigator

SEE REVERSE OF THIS PAGE

DATE ISSUED
02/11/2008