DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612)334-4100 Fax:(612)334-4134	8/27/2018-8/31/2018
	FEI NUMBER 3008927138

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Stephen C. Morton, CEO

FIRM NAME	STREET ADDRESS
Morton Drug Company dba Morton LTC	201 E Bell St
CITY, STATE, ZIP CODE, COUNTRY Neenah, WI 54956-5096	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Products

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 WE OBSERVED:

OBSERVATION 1

You produced beta-lactam drugs without providing adequate cleaning of work surfaces to prevent cross-contamination.

Specifically, you aseptically processed beta-lactam antibiotics in the ISO 5 (b) (4) in the past three months. Your cleaning procedure does not identify the use of appropriate cleaning agents to reduce the risk of cross-contamination for these products.

OBSERVATION 2

Materials or supplies were not disinfected prior to entering the aseptic processing areas.

Specifically, on August 27, 2018, we observed the operator wipe supplies in the ISO 8 area with (b) (4) and continue to transfer them into the ISO 5 aseptic processing area with no additional wipe down of the supplies. These supplies were used in the aseptic processing of daptomycin 425 mg in 100 mL of 0.9% NaCl, prescription (b) (6)

OBSERVATION 3

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically, your firm's practice of media fills does not include using a microbiological growth medium in place of the product. Your firm injects (b) (4).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Sandra A Hughes, Investigator Tenzin Jangchup, Investigator	X Sandra A Hughes Investigator Signed By: Sandra A Hughes -S Date Signed: 08-31-2018 10:58:08	DATE ISSUED 8/31/2018

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X Tenzin Jangchup
Investigator
Signed By: Tenzin Jangchup -S5
Date Signed: 08-31-2018 10:56:49

	EMPLOYEE(S) SIGNATURE		DATE ISSUED
SEE REVERSE OF THIS PAGE	Sandra A Hughes, Investigator Tenzin Jangchup, Investigator	X Sandra A Hughes Investigator Signed By: Sandra A. Hughes -S Date Signed: 08-31-2018 10:56:08	8/31/2018