DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556	1/31/2018-2/8/2018* FEI NUMBER 3014174643

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Bret Snow, Regional Director of Pharmacy

FIRM NAME	STREET ADDRESS
New England Life Care, Inc.	4 Constitution Way Suite J
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Woburn, MA 01801-1042	Producer of Sterile Drug 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 I OBSERVED:

OBSERVATION 1

Personnel moved rapidly in the vicinity of open sterile units and instruments, which disrupted the airflow and increased the risk of bringing lesser quality air into the ISO 5 classified aseptic processing area.

Specifically,

I observed the following:

- On January 31, 2018, Pharmacy Technician (b) (6) had prepared materials and supplies for aseptic processing and filling activities in the unclassified Pharmacy area with her bare hands after sanitizing the materials and supplies with (b) (4)

- On January 31, 2018, Pharmacy Technician (b) (6) was sterile processing TPN products in Hood (b) (4) RX# (b) (6) I observed that (b) (6) consistently put the top of her head (exposing the skin from her neck and face) into the hood along with parts of her shoulders. I also noted on February 1, 2018, an instance in which (b) (6) left the ISO 5 hood for supplies in the ISO 8 area and upon her return to the ISO 5 (b) (6) neglected to change and/or sanitize her gloves prior to entry into the ISO 5 Hood. (b) (6) had processed RX#'s (b) (6) (b) (6) that day.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Robert J Martin, Investigator X Robert J Martin Investigator Signed By: Robert J. Martin -S Date Signed: 02-08-2018 10:12:16	2/8/2018

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- On January 31, 2018, Pharmacy Technician (b) (6) was sterile processing and filling Imipenem-Cilastatin 500mg/100mL NS, Cefepime 2000mg/20mL SWFI, Iron Sucrose 20mg/10mL NS and Ampicillin 12g/620mL NS (RX#'s (b) (6) (b) (6) in Hood (b) (4) I observed (b) (6) consistently put the top of his head (exposing the skin from his neck and face) into the hood along with parts of his shoulders. Also noted was whe (b) (6) would reach for supplies located on the top of the hood his chest would routinely break the plane of the hood. On February 2, 2018, I noted that while (b) (6) was processing TPN products within Hood (b) (4) (RX#'s (b) (6) non-sterile sleeves came in contact with the aseptic connection for the (b) (4) machine.

- On January 31, 2018, Pharmacy Technician (b) (6) was sterile processing TPN products in Hood (b) (4) RX# (b) (6) and I observed (b) (6) consistently put the top of her head (exposing the skin from her neck and face) into hood along with parts of her shoulders.

OBSERVATION 2

You had inadequate HEPA filter coverage and airflow over the area to which sterile product was exposed.

Specifically,

The requalifications of the (b) (4) ISO 5 Laminar Flow Hoods (Models (b) (4) (b) (4) were inadequate in that the static and dynamic smokes studies conducted did not demonstrate the actual setup and aseptic operations within the Laminar Flow Hoods as used by the firm during routine processing operations. For example, the August 2017 requalification of these hoods indicates that static and dynamic smoke studies were conducted; however, there was inadequate documentation of said activities within the report. Furthermore, Hood (b) (4) s routinely used for TPN processing operations which contains a (b) (4) unit with numerous accessories which comprise

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approximately (b) (4) % of the hood's capacity and without adequately documenting the airflow smoke pattern it cannot be determined that this setup would have an effect on the unidirectional airflow within the hood to ensure that the sterility of the product is maintained.

OBSERVATION 3

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

Specifically,

The firm's cleanroom design and operational procedures do not provide adequate segregation of Beta-Lactam antibiotic products from general drugs produced. Beta-Lactam antibiotics are processed in the same laminar flow hoods (Hoods (b) (4) as other general drug products separated only by a wipe down with (b) (4) . For example:

- On January 31, 2018, Pharmacy Technician (b) (6) processed the following products in Hood (b) (4) 10:00am - Imipenem-Cilastatin 500mg in 100mL NS (RX# (b) (6) , 12:00pm – Cefepime 2000mg in 20mL SWFI (RX# (b) (6) , 12:30pm – Iron Sucrose 20mg in 10mL NS (RX# (b) (6) and 1:30pm – Ampicillin 12g in 620mL NS (RX# (b) (6)
- On February 1, 2018, Pharmacy Technician (b) (6) processed the following products in Hood (b) (4) 10:30am Ceftriaxone 2000mg in 20mL SWFI (RX# (b) (6) , 11:00am – Ceftriaxone 2g in 20mL SWFI (RX# (b) (6) and 3:00pm – Methadone 50mmg in 100mL NS (RX# (b) (6) .

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Furthermore, the firm does not have a specific process to decontaminate any Beta-Lactam product spillage that may occur within the Laminar Flow Hoods during production or filling operations.

OBSERVATION 4

Non-microbial contamination was observed in your production area.

Specifically,

On January 31, 2018, I observed several ceiling tiles within the Pharmacy that had what appeared to be water stains and/or had stains that had been painted over. Also noted was an unknown material splashed on the exterior side to the door leading into the ISO 8 Gowning Room.

OBSERVATION 5

Disinfecting agents and cleaning pads and cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.

Specifically,

The firm uses non-sterile disinfectants for (b) (4) sanitization of the interior surfaces of the ISO 5 Hoods (b) (4). For example, technicians will sanitize and disinfect the ISO 5 Hoods on a (b) (4) basis using (b) (4) Brand (b) (4) Disinfectant Cleaner which is non-sterile. These ISO 5 Hoods are used for sterile compounding and filling operations.

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*DATES OF INSPECTION

1/31/2018(Wed), 2/01/2018(Thu), 2/02/2018(Fri), 2/05/2018(Mon), 2/08/2018(Thu)

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