

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> One Montvale Avenue Stoneham, MA 02180 (781) 587-7500 Fax: (781) 587-7556	<small>DATE(S) OF INSPECTION</small> 2/26/2018-3/2/2018 <small>FEI NUMBER</small> 1000159373	
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Bret M. Snow, Regional Director of Pharmacy		
<small>FIRM NAME</small> New England Life Care, Inc.	<small>STREET ADDRESS</small> 108a Industrial Way	
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Portland, ME 04103-1082	<small>TYPE ESTABLISHMENT INSPECTED</small> Producer of Sterile Drug Products	
<p>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.</p>		
<p>DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1</p> <p>You had inadequate HEPA filter coverage and airflow over the area to which sterile product was exposed.</p> <p>Specifically:</p> <p>The following observations relate to inadequate qualification, operation, and maintenance of ISO 5 classified (b) (4) laminar flow hoods (b) (4) and biological safety cabinet (b) (4) used to produce sterile drugs for human use:</p> <p>A. ISO 5 classified areas were not certified under dynamic conditions. Specifically, uni-directional airflow was not verified under operational conditions in dynamic airflow pattern studies in ISO 5 (b) (4) laminar flow hoods (b) (4) and biological safety cabinet (b) (4) used to produce sterile drugs for human use.</p> <p>B. Your aseptic simulation (media fill) program is not designed to include performance in each ISO 5 laminar flow hood (b) (4) used for production and filling of sterile drugs and aseptic simulations are never performed in the ISO 5 biosafety cabinet (b) (4) used to process and fill cytotoxic drugs.</p>		
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<p>C. The air pressure differential across the HEPA filter in hazardous drug (cytotoxic) production biological safety cabinet (b)(4) is not read and recorded from the system Magnehelic differential pressure gauge.</p> <p>D. On 02/27/2018 I observed approximately 5 light yellow to brown colored dime sized stains on the HEPA filter face at working height in ISO 5 laminar flow hoods (b)(4) and approximately 10 light yellow to brown colored dime to quarter sized stains and one faint approximately 3 cm x 20 cm stain at working height on the HEPA filter face adjacent to the (b)(4) (b)(4) in ISO 5 laminar flow hood (b)(4) used for general aseptic production of sterile drugs for human use. You do not have written procedures for (b)(4) evaluation and acceptance criteria for the condition of HEPA filters in use in the ISO 5 classified areas.</p> <p>E. Reports of HEPA Certification testing performed by your contractor do not present as found data and your firm does not receive as found data even when adjustments (b)(4) or repairs (leak repair) are performed prior to obtaining the final (reported) results. Furthermore, HEPA Filter leaks detected during certification testing are not followed up with investigations to include product risk assessment and root cause determination. For example:</p> <ul style="list-style-type: none"> a. On 03/24/2017 a HEPA filter leak was detected and repaired in laminar flow hood (b)(4) during routine HEPA certification testing and you did not perform an investigation to include product risk assessment and root cause determination. b. On 03/24/2017 a HEPA filter leak was detected and the filter was replaced in laminar flow hood (b)(4) during routine HEPA certification testing and you did not perform an investigation to include product risk assessment and root cause determination. <p>F. HEPA Filter replacement in the ISO 5 classified areas (laminar flow hoods (b)(4) and biosafety cabinet (b)(4) is not preceded by end of use or as found performance testing to include leak check and air velocity prior to removal and replacement for reasons other than failed</p>		
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certification testing such as visible staining.		
<p>OBSERVATION 2 You produced beta-lactam drugs without providing adequate containment, segregation and cleaning of work surfaces to prevent cross-contamination.</p> <p>Specifically:</p> <p>Your cleanroom design and operational procedures do not provide adequate containment and segregation of Beta-Lactam antibiotic products from general drugs produced. Beta-Lactam antibiotics are routinely processed in the same laminar flow hoods (b) (4) as other general drug products separated only by a wipe down of hood surfaces with sterile (b) (4). For example:</p> <p>On 02/27/2018 I observed a Pharmacy Technician process RX (b) (6) Oxacillin Sodium in laminar flow hood (b) (4). According to your records the next order processed in hood (b) (4) was a TPN for RX # (b) (6).</p> <p>Furthermore, you do not have a specific process to deactivate and remove any Beta-Lactam product spillage that may occur within the laminar flow hoods or facility during handling, processing, or filling operations.</p>		
<p>OBSERVATION 3 Materials or supplies were not disinfected prior to entering the aseptic processing areas.</p> <p>Specifically:</p>		
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<p>You do not sanitize drug product components and process equipment stored in the ISO 7 classified buffer area immediately before entry to the ISO 5 laminar flow hoods. For example:</p> <p>On 02/26/2018 and 02/27/2018 I observed numerous times that components stored in the ISO 7 cleanroom including (b) (4) and process equipment including syringes were not sanitized immediately before placing them, still in the outer wrapping, into ISO 5 laminar flow hoods.</p>		
<p>OBSERVATION 4 Personnel engaged in aseptic processing were observed with exposed hair.</p> <p>Specifically:</p> <p>On 02/26-28/2018 I observed numerous times that Pharmacy Technician's faces, heads, and shoulders entered the plane of ISO 5 laminar flow hoods during production operations and cleaning. Technicians are not required to wear goggles or glasses so the face and forehead is exposed above the dust mask.</p>		
<p>OBSERVATION 5 Disinfecting agents and cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.</p> <p>Specifically:</p>		
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<p>Commercial cleaning and disinfection agents used within ISO 5 classified (b) (4) laminar flow hoods (b) (4) and biological safety cabinet (b) (4) used to produce sterile drugs for human use are not claimed to be sterile. For example:</p> <ul style="list-style-type: none"> The labeling provided for (b) (4) does not claim sterility (b) (4) is (b) (4) and applied with non-sterile wipes for daily cleaning and disinfection of surfaces inside the ISO 5 hoods and biological safety cabinet. (b) (4) is directly applied with non-sterile wipes for (b) (4) cleaning and disinfection of surfaces inside the ISO 5 hoods and biological safety cabinet. <p>Furthermore, you do not provide sufficient disinfection agent contact (dwell) time on surfaces within the ISO 5 classified (b) (4) laminar flow hoods (b) (4) and biological safety cabinet (b) (4). The manufacturer's directions for use of (b) (4) indicate that the minimum effective contact time is (b) (4) (b) (4) and manufacturer's directions for (b) (4) specify a (b) (4) contact time. According to your Lead Pharmacy Technician ISO 5 area surfaces are wiped down with sterile (b) (4) on non-sterile wipes "right after" application of the (b) (4) (b) (4)</p>		
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