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 ORAPHARM1_RESPONSES@fda.hhs.gov	3/21/2022-4/28/2022* FEI NUMBER 3010371376

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
John A. Fantasia, Vice President	
FIRM NAME	STREET ADDRESS
New England Life Care, Inc. dba Advanced Compounding Solutions	4 Constitution Way Ste L
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Woburn, MA 01801-1042	Outsourcing Facility

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

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

A. Your firm failed to thoroughly investigate environmental monitoring excursions and has continued to produce product while investigations into environmental excursions exceeding your action limits in ISO-5 hoods are open and incomplete:

- The firm was unable to provide documentation of investigations for 21 out of 24 excursions recorded so far in 2022, five of which were logged in March 2022 prior to the on-site inspection. Open excursions include:
  - On 1/13/2022, your firm recorded two viable air excursions in ISO-5 hoods 32LFH-05 and 03LFH-03 involving the gram-positive, spore-forming organism *Bacillus licheniformis*. On that day, your firm produced Ephedrine 5 mg/mL;5mL lot (b) (4) - (b) (4), which your quality unit released into distribution on 2/1/2022.
  - On 1/14/2022, your firm recorded a personnel monitoring excursion involving the gram-positive, spore-forming organism *Brevibacillus brevis*. On that day, your firm produced Ephedrine 5mg/ml;5ml lot (b) (4), which your quality unit released into distribution on 2/1/2022.
  - On 1/18/2022, your firm recorded a viable air excursion in ISO-5 hood 34LFH-07

AMENDMENT 1

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	Jonathan G Matrisciano, Investigator Daniel L Zheng, Investigator Terry Bridgewater, Investigator	X Jonathan G Matrisciano Investigator Signed By: Jonathan G. Matrisciano -S Date Signed: 0 -28-2022 13: 1:11	4/28/2022

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involving the gram-positive organism *Staphylococcus hominis*. On that day, your firm produced Succinylcholine 20mg/mL;5mL RT lot (b) (4) which your quality unit released into distribution on 2/8/2022.

- On 1/31/2022, your firm recorded a viable air excursion in ISO-5 hood 34LFH-07 involving the gram-positive, spore-forming organism *Cytobacillus horneckiae*. On that day, your firm produced Succinylcholine 20mg/mL;5mL RT lot (b) (4), which your quality unit released into distribution on 2/25/2022.
- On 2/16/2022, your firm recorded a personnel monitoring excursion involving the gram-positive, spore-forming organism *Cytobacillus horneckiae*. On that day, your firm produced Neostigmine 1mg/mL; 3mL lot (b) (4), which your quality unit released into distribution on 3/9/2022.
- On 2/17/2022, your firm recorded a personnel monitoring excursion involving the gram-positive, spore-forming organism *Cytobacillus horneckiae*. On that day, your firm produced Ephedrine 5mg/ml;5ml lot (b) (4) which your quality unit released into distribution on 3/14/2022.

- The firm was unable to provide documentation of investigation for 11 excursions recorded between October 2021 and December 2021. Open excursions include:
  - On 12/3/2021, your firm recorded a viable air excursion in ISO-5 hood 34LFH-07 involving the gram-positive organisms *Staphylococcus epidermis* and *Corynebacterium tuberculostearicum*.
  - On 12/7/2021, your firm recorded a personnel monitoring excursion involving the gram-positive, spore-forming organism *Bacillus licheniformis*.
  - On 12/20/2021, your firm recorded a personnel monitoring excursion involving the gram-positive organism *Staphylococcus epidermis*.
  - On 12/21/2021, your firm recorded a viable air excursion in ISO-5 hood 04LFH-04 involving the gram-positive organism *Staphylococcus capitis*.

B. Your firm failed to adequately investigate production discrepancies:

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- Your firm failed to adequately investigate the presence of particulates exceeding your action limit of (b) (4). Your visual inspectors rejected 2.86% (b) (4) units) of Vancomycin 1.75g in 500mL NS, lot (b) (4), 2.84% (b) (4) units) of Dil m 125mg in 100mL NS, lot (b) (4), and 3.30% (seven units) of Norepinephrine 8mg in D5W 250mL, lot (b) (4) for particulate presence. The report concluded without documented evidence that these particulates were "not an uncommon occurrence in 503B manufacturing" and that the primary root cause was overly strict visual inspection action limits. Your investigation failed to identify the nature of the particulates present in each lot of your sterile drug products, and your investigations and root cause analyses failed to assess if your production process was a potential cause of the particulate matter contamination in each lot. This investigation was closed on 3/9/2022.
- On 9/9/2021, a spider was observed by a compounding operator in the ISO-7 compounding room (Rm 5-109) immediately next to the ISO-5 hood 32LFH-05 where sterile compounding operations were being performed. Your investigation report failed to document if any preventative action or additional cleaning was performed, and if any risk assessment was conducted to determine the potential risk to the sterile products produced in the ISO-7 room at the time.
- From 2020-2021, your firm found a flying ant in the ISO-7 hazardous room (Rm 5-106), an ant in the ISO-8 gowning room (Rm 5-102), a stinkbug in the ISO-8 finished goods room (Rm 5-112), and a large carpenter ant in the ISO-7 hazardous room (Rm 5-106). Your firm failed to conduct an investigation into the source of these pests and failed to determine adequate corrective and preventative actions to prevent pests from entering the controlled areas of your compounding suite.
- Your firm failed to investigate and follow up on findings, recommendations, and trends described in monthly reports issued by your contracted pest control company. For example, your contractor recommended installation of a second set of warehouse doors to the exterior on 6/28/2019 to reduce the chance of trapping pests inside the building. This recommendation

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remained listed as an open condition on your contractor's (b) (4) report issued on 9/22/2021. The firm was unable to provide documentation of awareness or analysis of the recommendation.

- Discrepancies were identified between the electronic and paper portions of the batch record for production of Vancomycin 750mg in 250mL NS, lot (b) (4) regarding number of drug units produced and weighed. The investigation did not include a root cause analysis.
- In a review of your manufacturing investigations from 2021 to 2022, it was determined that your quality unit released lots of sterile drug products prior to the closure of manufacturing investigations against firm procedure and without appropriate, written justification:
  - (b) (4) lots were released in October and November 2021 before closure of an investigation into a missed or undocumented cleaning of the ISO-7 compounding room (Rm 5-109).
  - (b) (4) lots were released in February 2022 before closure of an investigation into a sensor e in the firm's continuous monitoring system.
  - (b) (4) lots were released in April 2021 before closure of an investigation into potential contamination of syringe caps.

C. Your firm failed to thoroughly investigate customer complaints received for distributed commercial product:

- The firm received a customer complaint related to potency of Rocuronium 50mg/5mL, lot (b) (4) on 5/4/2021, and another for discoloration in Vancomycin 1.25g, lot (b) (4) on 7/1/2021. The firm was unable to find reports or documentation of these two complaints aside from the complaints log and initial customer emails. No investigations were conducted, and the complaints remain in open status on your complaints log.
- On 10/20/2021, a customer reported two leaking bags of Vancomycin 1.75g in 500mL NS, lot (b) (4). Your quality unit closed this complaint without an investigation, and justification for closure without investigating was not provided.
- On 2/4/2019, a customer reported a syringe of Phenylephrine 100mcg/mL; 10mL, lot (b) (4)

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(b) (4) that was underfilled. The report determined that the root cause of the underfilled syringe was the customer already having used that syringe without any evidence to support this conclusion. Additionally, the investigation did not include a document review or assessment of retain samples.

- On 1/29/2020, a customer reported five leaking bags of Diltiazem 125mg in NS 100mL, lot (b) (4). The investigation determined the root cause to be damage during shipping without evidence to support the conclusion. Your firm failed to investigate the raw material lot of fluid bags used as the container for this drug product and failed to extend the investigation to other product lines using the same container/closure system. Additionally, the investigation did not include a document review or assessment of retain samples.
- On 4/9/2019, a customer reported a syringe of Ephedrine 25mg, lot (b) (4) with a missing tamper-evident cap and a syringe of Phenylephrine 400mcg, lot (b) (4) with a loose syringe cap. The report was unable to determine a root cause for the missing tamper-evident cap and stated that the loose cap on the phenylephrine syringe had been insufficiently tightened during production. The report does not document how the root cause was determined. The investigation did not include a document review or assessment of retain samples. Additionally, the investigation noted that both batches were compounded by the same operator, but the firm did not review the operator's training as part of the investigation.
- On 8/5/2019, a customer reported a syringe of Succinylcholine 20mg/mL; 10mL, lot (b) (4) (b) (4) that was underfilled. Your firm assessed compounder error as the most likely root cause. The investigation failed to include corrective or preventative actions. Additionally, the investigation did not include a document review.
- On 11/30/2019, a customer reported receiving a leaking bag of Vancomycin 1.5g in NS 500mL, lot (b) (4). The report documented a root cause of damage during shipping without evidence to support the conclusion. Your firm failed to investigate your production process or the raw material lot of fluid bags as a potential root cause and failed to extend the investigation to other product lines using the same container/closure system. The investigation did not include a document review or assessment of retain samples.

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OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed.

Specifically,

A. On 03/21/2022, pharmacy technicians were observed conducting manufacturing operations for Media Fill Lot # (b) (4). During the operation, multiple manufacturing operators were observed with "(b) (4). The (b) (4) created a (b) (4) 's forehead exposing the operators' skin which could allow particulates to enter the ISO 5 Aseptic and ISO 7 areas of the facility.

B. On 03/24/2022, we observed the production of Phenylephrine 80mcg/mL; 10mL Lot # (b) (4) (b) (4) in LFH 2LFH-02, and Rocuronium 10mg/mL; 5mL Lot # (b) (4) in LFH 34LFH-07. During manufacturing operations, the following was observed:

1. During the production of Phenylephrine 80mcg/mL; 10mL in LFH 2LFH-02:

- Operator (b) (6) placed a hand-held particle counter meter directly against the face of the ISO 5 filter, blocking first pass air over syringe caps during manufacturing.
- Operator (b) (6) placed an air sampler directly against the face of the ISO 5 LFH filter, which was blocking first pass air over the ISO 5 work zone.
- Operator (b) (6) was observed changing tubing which blocked first pass air.
- Operator (b) (6) placed an Environmental Monitoring settling plate against the face of the ISO 5 filter directly in the path of first pass air, and not in the ISO 5 work area as required by

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procedure.

- During Personnel Monitoring, operator (b) (6) was observed touching the fingertips of her gloved hands to the Personnel Monitoring test plate and failed to "roll" her gloved fingertips on the plate while performing personnel monitoring.

2. During the production of Rocuronium 10mg/mL; 5mL in LFH 34LFH-07:

- Operator (b) (6) was observed placing his gloved hand on the work surface inside the ISO 5 Hood three times without first sanitizing his gloves.

OBSERVATION 3

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

A. Your firm failed to validate the cleaning process used to perform cleaning operations in your facility. Your firm uses sterile (b) (4), sterile (b) (4), sterile (b) (4), and sterile (b) (4) to clean and disinfect the ISO 5, ISO 7, and ISO 8 areas of your facility, and to clean and disinfect the equipment, components and materials entering into each area of the facility. Your firm failed to demonstrate that the cleaning processes and cleaning agents used are sufficient to maintain aseptic conditions in your facility during the production of sterile drug products.

B. Your aseptic processing areas were insanitary or difficult to clean:

- On 3/24/2022, investigators observed pools of an unidentified standing liquid in the ISO-7 ante room (Rm 5-107) and the ISO-7 compounding room (Rm 5-109) while both rooms were in clean status.

AMENDMENT 1

- Surfaces are difficult to clean due to damage and deterioration. On 3/24/2022, rust and paint chipping were observed on the exterior of ISO-5 hoods 02LFH-02, 04LFH-04, 33LFH-06, and 34LFH-07 in the ISO-7 environment, located within inches of the ISO-5 work surface. Rust was also observed in the grating of ISO-5 hoods 04LFH-04, 33LFH-06, and 34LFH-07 immediately adjacent to the ISO-5 work surface. Scratches were observed on the horizontal work surface inside all (b) (4) ISO-5 hoods. In the ISO-7 environment, a patch of hook and loop fastener was found adh (b) (4) d to the exterior of ISO-5 hood 03LFH-03 covered in unidentified white fibers.
- On 3/24/2022, investigators observed unidentified brown residue on the surface of a power cable inside ISO-5 hood 34LFH-07.
- The firm's ISO-5 hoods are designed with (b) (4) of the hood cabinet that facilitate cable pass-through into the ISO-5 hood. On 3/24/2022, investigators observed damage and deterioration on the (b) (4) of ISO-5 hood 04LFH-04, the (b) (4) of ISO-5 hood 33LFH-06, and the (b) (4) of ISO-5 hood 34LFH-07, as well as unidentified brown residue on the (b) (4) of ISO-5 hood 33LFH-06.
- The firm does not clean or sanitize power cables located in the ISO-5 and ISO-7 environments. On 3/24/2022, investigators observed that, during cleaning of the ISO-5 hoods, operators repositioned the repeater pump and touchscreen computer monitor within the ISO-5 cabinet, pulling cabling through the (b) (4) into the ISO-5 environment with no sanitization. In the ISO-7 compounding room (Rm 5-109), power cables are loose and piled beneath and behind hoods.

C. Your procedures for material sanitization are inadequate:

- The firm does not document dwell times for material sanitization. For documentation of material sanitization, operators record the end of line clearance before sanitization and the end of line clearance after sanitization. Your firm is not able to demonstrate through documentation that dwell times have been met. Additionally, there are no time-measurement devices in the ISO-8 gowning room (Rm 5-102) and the ISO-7 ante room (Rm 5-107) that would enable operators to

verify dwell time.

D. There is a lack of control over the cleaning contractor your firm uses for (b) (4) cleaning of the classified suite, including the ISO-7 compounding room (Rm 5-109). Your firm has not conducted any verification of the contractor's activities, including adherence to procedure and cleaning agent dwell times, beyond reviewing the contractor's cleaning log entries the (b) (4)

OBSERVATION 4

Buildings used in the manufacturing, processing, packing and holding of a drug product are not maintained in a good state of repair.

Specifically, structures intended to maintain control of the ISO-7 environment in the compounding room (Rm 5-109) exhibit damage or deterioration:

A. On 03/24/2022 and 03/31/2022, investigators observed that mechanisms for sealing doors were damaged or absent:

- Automatic drop bottoms for maintaining classified environments in the cleanroom suite are missing or damaged. Examples include doors between the unclassified warehouse and the ISO-8 gowning room (Rm 5-102), the ISO-8 gowning room (Rm 5-102) and the ISO-7 ante room (Rm 5-107), the ISO-7 ante room (Rm 5-107) and the ISO-7 compounding room (Rm 5-109), and the unclassified warehouse and the ISO-8 material wipe down room (Rm 5-104).
- The rubber gasket on the door between the ISO-8 gowning room (Rm 5-102) and ISO-7 ante room (Rm 5-107) was damaged and loose.
- The design of the sliding door between the unclassified warehouse and the ISO-8 finished product room (Rm 5-112) leaves an unsealed gap between the door and the frame when the door is in the closed position. Additional gaps were observed due to the door not being flush with the

frame and floor.

B. On 3/25/2022, investigators observed a hole in the air return ventilation shaft of the ISO-7 compounding room (Rm 5-109) leading to the unclassified maintenance mezzanine on the roof of the cleanroom suite.

C. On 3/24/2022, investigators observed damage and deterioration in the ISO-7 compounding room (Rm 5-109):

- A casing designed to encapsulate cables run from the ceiling of the ISO-7 compounding room was found loose and out of place, exposing a cut out hole in a ceiling tile.
- Paint chipping was observed on the door closer attached to the door between the compounding room and the ante room. The closer is located inside the ISO-7 environment.
- Residue observed on the door between the ISO-7 compounding room (Rm 5-109) and the unclassified office space appeared to be peeling and deteriorating plastic.
- There were gaps in the rubber floor sweeps of the airlock between the ISO-7 compounding room (Rm 5-109) and the ISO-8 hold room (Rm 5-110).

D. Facility maintenance is not controlled. There is no firm employee responsible for identifying and overseeing facility maintenance issues. The firm uses a contractor for facility maintenance. During their (b) (4) facility maintenance review, this contractor does not enter classified areas and does not assess the condition of the compounding suite.

OBSERVATION 5

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

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Specifically,

A. You conducted dynamic Air Flow Pattern Visualization testing (smoke studies) for ISO 5 Laminar Flow Hoods (LFHs) 1LFH-01, 2LFH-02 and 34LFH-07 on 10/20/2021 and for 33LFH-06 on 10/21/2021, which are used to produce sterile drug products. The smoke studies performed were deficient:

- The 10/20/2021 and 10/21/2021 studies for the LFHs do not include the transfer of all starting components and materials into the ISO 5 classified areas.
- The 10/20/2021 and 10/21/2021 studies for the LFHs failed to include all manipulations and transfers performed by the operator during production.

B. On 03/24/2022, the air returns inside the ISO-7 compounding room were observed to be blocked by large pieces of equipment.

- The air return in the southwest corner of the ISO-7 compounding room (Rm 5-109) is entirely occluded by Hood 34LFH-07.
- The air return in the northwest corner of the ISO-7 compounding room is mostly blocked by Hood 02LFH-02.

OBSERVATION 6

Samples of representative units were not collected and visually examined for correct labeling at the completion of finishing operations.

Specifically, your firm failed to visually examine finished sterile drug products at the end of finishing operations to ensure each lot of drug product was correctly labeled. Your procedures do not require a

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representative number of finished drug products be sampled and then visually examined for correct labeling prior to release. In addition, product batch records do not indicate if sterile finished drug product's labeling has been examined at the end of finishing operations to confirm each lot contains the appropriate label for the manufactured sterile drug product.

OBSERVATION 7

The labels of your outsourcing facility's drug products are deficient.

Specifically, the labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A). Specifically, the dosage form is not found on your drug product labels.

Examples of your drug product labels that do not contain this information:

- Diltiazem 125mg in 100mL bag
- Norepinephrine Bitartrate 8 mg Dextrose 5% 250 mL bag
- Vancomycin HCL 750 mg in 0.9% Sodium Chloride 250 mL bag
- Phenylephrine 20mg in 250mL bag

***DATES OF INSPECTION**

3/21/2022(Mon), 3/22/2022(Tue), 3/23/2022(Wed), 3/24/2022(Thu), 3/25/2022(Fri), 3/28/2022(Mon), 3/29/2022(Tue), 3/30/2022(Wed), 3/31/2022(Thu), 4/01/2022(Fri), 4/04/2022(Mon), 4/05/2022(Tue), 4/06/2022(Wed), 4/07/2022(Thu), 4/08/2022(Fri), 4/28/2022(Thu)

X Daniel L Zheng
Investigator
Signed By: Daniel L. Zheng -S
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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."