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	8/2/2017-8/22/2017* FEI NUMBER 3010371376

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Hina Patel , Director of Pharmacy

FIRM NAME	STREET ADDRESS
New England Life Care,Inc., dba Advanced Compounding Solutions	4 Constitution Way, Suite L
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Woburn, MA 01801-8510	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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically,

From June 22, 2017 to July 24, 2017 the firm failed to conduct potency testing for Phenylephrine drug products (40mcg/mL, 80mcg/mL and 100mcg/mL) prefilled syringes. The Quality Unit had released (16) batches without potency testing of which the firm has distributed (4) batches (approximately 1,100 prefilled syringes) to client hospitals.

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

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a. The firm does not perform active air sampling for viable and non-viable particulates within the ISO 5 Laminar Flow Hood during aseptic operations. The firm will only conduct active air sampling along with surface sampling post aseptic operations. Furthermore, the placement of the settle plate which is used for passive sampling in the ISO 5 Laminar Flow Hood during aseptic operations is not located near the majority of aseptic manipulations but located directly under the wall mounted laptop which is used for the electronic batch records.

b. The firm does not monitor differential pressure of the ISO 5 Laminar Flow Hoods during sterile to sterile operations but will only take one reading at the beginning of operations. The firm uses four ISO 5 Laminar Flow Hoods to produce sterile products on a routine basis. Since June 22, 2017 the firm has produced (87) lots of sterile products of which two including Phenylephrine 40mcg/mL and Phenylephrine 100mcg/mL have been commercially distributed to Massachusetts hospitals/medical centers.

OBSERVATION 3

Equipment for adequate control over air pressure and micro-organisms is not provided when appropriate for the manufacture, processing, packing or holding of a drug product.

Specifically,

The requalifications of the four Baker ISO 5 Laminar Flow Hoods 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 sterile to sterile operations. For example, static and dynamic smoke studies were conducted with a smoke stick and in some areas did not show unidirectional air flow. Additionally, routine set up conditions were not captured in these studies.

OBSERVATION 4

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Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically,

The firm's aseptic process simulations (media fills) were inadequate in that the media fills were not representative of all critical process procedures and were not done at an appropriate scale to demonstrate commercial sterile operations. For example:

Aseptic media fills conducted under Qualification Procedure (PP# 03-07.02) indicates that operators will fill a mini-bag by adding 20 portions to the partially filled bag and then fill (10) syringes to qualify for aseptic simulations however, the average batch size of commercial sterile products are (500) to (600) syringes. The firm had no documented justification for the simulation size. This simulation only represents approximately 2% of routine fills and was not representative of all sterile to sterile operations. This method was used to qualify Operator (b) (6) on June 1, 2017 and (b) (6) n July 13, 2017.

OBSERVATION 5

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

Specifically,

On August 4, 2017 we observed the following:

• Operato (b) (6) was conducting sterile to sterile operations for Neostigmine 1mg/ml, 3mL lot number 20170804-6FF7DF and it was observed that (b) (6) movements within the LHF were not slow and deliberate.

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• Operato (b) (6) was conducting sterile to sterile operations for Phenylephrine 80mcg/mL, 10ml lot number 20170804-53D817 and it was observed tha (b) (6) movements were not slow and deliberate. Furthermore throughout the sterile to sterile operations (b) (6) ad several instances in which the top of her head went into LHF along with parts of her shoulders.

• Operator (b) (6) was conducting sterile to sterile for Neostigmine 1mg/ml, 3mL lot number 20170804-420BC5 and it was noted tha (b) (6) movements were not slow and deliberate. Furthermore throughout the sterile to sterile operations (b) (6) had several instances in which her shoulders had entered the LHF.

• On August 3, 2017 we observed that personnel movements were not consistent with sterile operations in that operators dressed in sterile gowning were moving between the ISO 7 Ante Room (used for sterile gowning) to the ISO 8 Gowning Room while conducting cleaning operations instead of moving from clean area to dirty area in a single direction.

OBSERVATION 6

Each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality.

Specifically,

The firm's process for evaluating incoming raw material and drug products are inadequate in that the firm's procedure requires that incoming sterile and pathogenic free materials are evaluated via the Certificate of Analysis and incoming drug products also require that the potency, sterility and pathogenicity is confirmed via Certificate of Analysis however the firm does not always receive a Certificate of Analysis even though the incoming receipt forms have Certificate of Analysis reviewed. For example the following was noted:

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The firm received 750 units of Ephedrine Sulfate 50mg/mL (Lot# 00020A) on 05/05/2017, 25 units of Phenylephrine HCL 10mg/mL (Lot# 10015A) on 07/06/2017, 48 units of Phenylephrine HCL 10mg/mL (Lot# 00011A) on 06/12/2017, 4,020 units of Neostigmine Methylsulfate 1mg/mL (Lot# 10187A) on 07/06/2017, and 640 units of CP3000 Pinnacle 3000mL EVA Mixing Containers (Lot# 17A26) received on 5/22/2017. Each of the aforementioned lots was received without a specific accompanying Certificate of Analysis detailing the results of the testing including: potency, sterility and endotoxins.

OBSERVATION 7

Procedures describing the handling of all written and oral complaints regarding a drug product are not written.

Specifically,

The firm's complaints procedure (PP#: 04-01.01) was created in April of 2017; however, the procedure was not approved until August 7, 2017, which was during the current inspection. In addition, the complaints procedure lacks instructions for the processing of adverse drug events. Furthermore, the firm's adverse events procedure (PP# 04-07.01) lacks specific details including: timeframes for the submittal of adverse event information to the FDA, submittal of follow-up reports and description of the four data elements (Identifiable patient, Identifiable reporter, Suspect drug product and serious adverse event).

***DATES OF INSPECTION**

8/02/2017(Wed),8/03/2017(Thu),8/04/2017(Fri),8/07/2017(Mon),8/08/2017(Tue),8/09/2017(Wed),8/11/2017(Fri),8/17/2017(Thu),8/22/2017(Tue)

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