DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	4/25/2019-5/9/2019* FEI NUMBER 3004483463

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Timothy J Bresnahan, President

FIRM NAME	STREET ADDRESS
Coast Quality Pharmacy, LLC dba Anazao Health	5710 Hoover Blvd
CITY, STATE, ZIP CODE, COUNTRY Tampa, FL 33634-5339	TYPE ESTABLISHMENT INSPECTED Producer of sterile and non-sterile drugs

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

You did not make adequate product evaluation and take remedial action where actionable microbial contamination was found to be present in an area adjacent to the ISO 5 classified aseptic processing area during aseptic production.

Specifically,

A. For OOS-2019-0003: a sterility failure (*Bacillus subtilus*) was received by your firm on 01/31/19 for ACD solution, Lot ACD190129RA, produced on 01/29/19 in ISO 5 Hood (b) (4) located in non-radiopharmaceutical room, (b) (4). Per OOS-2019-0003, the root cause of the sterility failure was identified as "the environment in room (b) (4) The (b) (4) table was contaminated with *B. subtilus* group". In addition, *Bacillus subtilus* was cultured on 01/16/19 from surface sampling taken of the (b) (4) table used to prep vials prior to placement into the ISO 5 Hood and to (b) (4) vials after the placement of the cap after lyophilization. ACD solution, Lot ACD190129RA was discarded however your firm failed to evaluate the potential impact on additional sterile drug products produced in room (b) (4) from 01/16/19 to 01/29/19. Additional batches produced in room (b) (4) from 01/16/19 to 01/29/19 and later distributed include:

- On 01/16/19: (b) (4) bags of Lysine Arginine Batch, Lot LA-B190116DS-A
- On 01/16/19: (b) (4) bags of Lysine Arginine Batch, Lot LA-B190116DS-B
- On 01/18/19: (b) (4) vials of DTPA, Lot DTPA190118AC
- On 01/18/19: (b) (4) bags of Lysine Arginine Batch, Lot LA-B190118AC
- On 01/21/19: (b) (4) Lysine Arginine (b) (4) Lot LA190121DS-2
- On 01/21/19: (b) (4) bags of Lysine Arginine Batch, Lot LA-B190121DS-A
- On 01/21/19: (b) (4) bags of Lysine Arginine Batch, Lot LA-B190121DS-B
- On 01/22/19: (b) (4) vials of HMPAO, Lot EX190122AC

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- On 01/22/19 (b) (4) of Lysine Arginine (b) (4) Lot LA190122AC
- On 01/23/19: (b) (4) of Lysine Arginine (b) (4) Lot LA190123DS-A
- On 01/23/19 (b) (4) of Lysine Arginine (b) (4) Lot LA190123DS-B
- On 01/23/19: (b) (4) vials of Sincalide (CCK), Lot SINC190123RA-A
- On 01/23/19: (b) (4) vials of Sincalide (CCK), Lot SINC190123RA-C
- On 01/24/19 (b) (4) bags of Lysine Arginine Batch, Lot LA-B190124AC-A
- On 01/24/19 (b) (4) bags of Lysine Arginine Batch, Lot LA-B190124AC-B
- On 01/28/19: (b) (4) of Lysine Arginine Bag, Lot LA190128DS-A
- On 01/28/19: (b) (4) of Lysine Arginine Bag, Lot LA190128DS-B
- On 01/29/19: (b) (4) of Lysine Arginine (b) (4) Lot LA190129RA-1
- On 01/29/19: (b) (4) of Lysine Arginine (b) (4) Lot LA190129RA-2
- On 01/29/19: (b) (4) of Lysine Arginine (b) (4) ot LA190129RA-3
- On 01/29/19: (b) (4) of Lysine Arginine (b) (4) Lot LA190129RA-4
- On 01/29/19: (b) (4) of Lysine Arginine (b) (4) Lot LA190129RA-5

B. EM (Environmental Monitoring) OOS 19-09: an actionable organism (b) (4) cfu, *Bacillus cereus*) was cultured from active air sampling performed in the middle of room (b) (4) on 01/23/19. Sincalide (CCK), Lot SINC190123RA-B and Sincalide (CCK), Lot SINC190123RA-D were discarded however your firm failed to evaluate the potential impact on additional sterile drug products produced in room (b) (4) on 01/23/19 and released for distribution:

- (b) (4) of Lysine Arginine (b) (4) Lot LA190123DS-A
- (b) (4) of Lysine Arginine (b) (4) LA190123DS-B
- (b) (4) vials of Sincalide (CCK), Lot SINC190123RA-A
- (b) (4) vials of Sincalide (CCK), Lot SINC190123RA-C

C. For EM OOS 06/12/18: an action level of (b) (4) cfu (fungal organism, *Penicillium decumbens*) was observed in the ISO 5 laminar airflow workbench (LAFW) in the non-radiopharmaceutical room (b) (4) for active air sampling performed on 06/12/18. The fungus was discovered on 06/15/18 and the hood and room were

cleaned with a sporicidal. Two lots, MEB-180612BM and PYP-180612BM, were discarded however your firm failed to evaluate the potential impact on additional sterile drug products produced in room (b) (4) from 06/12/18 to 06/14/18. Additional batches produced in room (b) (4) on 06/12/18 and dispensed on 06/12/18 include:

- (b) (4) of L-Lysine/L-arginine, Lot LA-180612BM-A
- (b) (4) of L-Lysine/L-arginine, Lot LA-180612BM-B
- (b) (4) of L-Lysine/L-arginine, Lot LA-180612BM-C
- (b) (4) of L-Lysine/L-arginine, Lot LA-180612BM-D
- (b) (4) of L-Lysine/L-arginine, Lot LA-180612BM-E
- (b) (4) of L-Lysine/L-arginine, Lot LA-180612BM-F

The following lots were produced in room (b) (4) on 06/14/18:

- (b) (4) vials of SINC-180614BM-A released for distribution
- (b) (4) vials of SINC-180614BM-B released for distribution
- SINC-180614BM-C (discarded due to potency failure)
- SINC-180614BM-D (discarded due to potency failure)

OBSERVATION 2

You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically, your firm failed to use pharmaceutical-grade components for which there is a USP/NF monograph:

- (b) (4) used to prepare radiopharmaceuticals such as In-111-DTPA for cisternography
- Diethylenetriaminepentaacetic acid (DTPA) used to prepare radiopharmaceuticals such as In-111-DTPA and non-radiopharmaceuticals such as DTPA Cold Kits
- Sodium Iodide I-123 used to prepare radiopharmaceuticals such as I-123 MIBG
- Sodium Iodide I-131 used to prepare radiopharmaceuticals such as I-131 capsules
- (b) (4) used to prepare radiopharmaceuticals such as 51 Chromium Chromate

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0.100mCi/mL

This is a repeat observation from the inspection performed 04/09/18-05/07/18.

OBSERVATION 3

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

Specifically,

A. High risk media fills are not representative of the maximum batch size for aseptic operations for non-radiopharmaceutical drugs produced in vials and IV bags. For example:
   - Operators performed high risk media fills consisting of your firm's maximum batch size of (b) (4) vials only **(b) (4)** .
   - Operators performed high risk media fills consisting of your firm's maximum batch size o (b) (4) bags only **(b) (4)** .

B. Your firm lacks validations for your **(b) (4)** machines used in the production of sterile Sincalide (CCK), Sodium I-123 MIBG, Bicisate (ECD), Exametazime (HMPAO), Mebrofenin, Mertiatide, Pentetate (DTPA), Pyrophosphate (PYP), Red Blood Cell (RBC), Succimer (DMSA), Sestamibi, and Tetrofosmin.

   (*This is a repeat observation from the inspection performed 04/09/18-05/07/18.*)

C. A (b) (4) clean was not performed per your firm's procedure, *P-304 Cleaning and Disinfection of the Compounding Area*, after an actionable microorganism (b) (4) fu, *Penicillium decumbens*) was observed during active air sampling on 06/12/18 in ISO 5 Hood (b) (4) located in non-radiopharmaceutical room (b) (4) and an actionable microorganism (b) (4) cfu, Bacillus cereus) was cultured from active air sampling performed in the middle of room (b) (4) on 01/23/19.

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OBSERVATION 4

The written stability program for drug products does not include reliable, meaningful and specific test methods.

Specifically, your stability test results for radiopharmaceutical and non-radiopharmaceutical sterile drugs prepared by your firm does not include testing and results at meaningful time intervals for your established beyond use dates for the following:

- Chemical impurities
- Microorganisms
- Yeasts and molds
- Endotoxins

This is a repeat observation from the inspection performed 04/09/18-05/07/18.

OBSERVATION 5

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

Specifically, your firm failed to use sterile cleaning agents in the routine cleaning of ISO 5 LAFW and BSC hoods and the nuclear and pain medicine ISO 7 clean rooms. Examples of non-sterile cleaning agents include, but are not limited to the following:

- **(b) (4)**)
- **(b) (4)** does not appear to be high enough to be sporicidal **(b) (4)** of **(b) (4)** with **(b) (4)** of non-sterile water).

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4/25/2019(Thu), 4/26/2019(Fri), 4/29/2019(Mon), 4/30/2019(Tue), 5/02/2019(Thu), 5/03/2019(Fri), 5/09/2019(Thu)

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