DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA Florida District 555 Winderley Place, Suite 200 Maitland FL 32751 (407) 475-4700 Industry Information: www.fda.gov/oc/industry	10/11-10/14/16, 10/17/16 & 10/21/16
	FEI NUMBER FEI: 3011827553

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Kevin P. O'Connell, Owner

FIRM NAME	STREET ADDRESS
Tri-Coast Pharmacy, Inc.	14125 U.S. Hwy 1
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Juno Beach, FL 33408	Producer of Sterile Drug Products

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

Observation 1: Actionable microbial contamination was present in the ISO 5 area or in adjacent areas during aseptic production without adequate product evaluation and remedial action.

Specifically, on July 7, 2016 your firm detected high levels of gram-negative rods, coagulase positive staphylococcus, molds and yeast during routine Environmental Monitoring (EM) which is conducted every (b) (4) within the (b) (4). This is evident by the following examples:

(b) (4) (Active Air Samples)
Location (b) (4) 5cfus total: 3cfus of coagulase-negative staph., 1 cfu of dermacoccus spp. and 1 cfu of bacillus spp.
Location (b) (4) - 3 cfus total: 2 cfus of gram positive coryneform bacillus and 1 cfu of bacillus spp.
Location (b) (4) -4 cfus total: 3 cfus of micrococcus luteus and 1 cfu coagulase-negative staph.

(b) (4) (Active Air Samples)
Location (b) (4) -3 cfus total: 2 cfus of coagulase-negative staph. and 1 cfu of micrococcus spp.
Location (b) (4) - 6 cfus total: 3 cfus of gram-positive coryneform bacillus, 2 cfus of coagulase-negative staph, and 1 cfu of bacillus spp.
Location (b) (4) - 18 cfus total: 12 cfus of micrococcus luteus, 3 cfus of coagulase-negative staph., 3 cfus of acinetobacter radioresistens
Location (b) (4) (b) (4) - 29 cfus total: 23 cfus of micrococcus luteus, 3 cfus of micrococcus spp., 2 cfus of coagulase negative staph. and 1 cfu of acinetobacter radioresistens
Location (b) (4) - 17 cfus total: 10 cfus of acinetobacter

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	Jessica L. Pressley	Jessica L. Pressley, Drug Investigator Jennifer L. Huntington, Drug Investigator	10/21/2016

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radioresistens, 3 cfus of micrococcus spp., 2 cfus of coagulase negative staph. and 2 cfus of bacillus spp.
Location (b) (4) (b) (4) 17 cfus total: 11 cfus of coagulase negative staph., 5 cfus of acinetobacter radioresistens and 1 cfu of non sporulating dematiaceous fungus

(b) (4) (Surface Samples)
Location (b) (4) (b) (4))-6 cfus total: 3 cfus of micrococcus luteus and 3 cfus of coagulase negative staph.

Furthermore, your firm conducts (b) (4) surface sampling (b) (4) within the (b) (4) (b) (4) located in the (b) (4) and the (b) (4) (b) (4) (b) (4) . Collecting surface samples (b) (4) does not represent environmental conditions during the aseptic operations.

During this time, your firm continued to produce sterile drug products within the (b) (4) (b) (4), (b) (4) without evaluating the implication of the fungal and bacterial growth detected during the active air and surface sampling.

In addition, your firm had two lots fail sterility testing in September 2016. L-Carnitine 250mg/ml inj. lot # 09082016A (batch size: (b) (4) vials) and Glutamine/Arginine/Carnitine 25/100/200mg/ml inj. lot # 09152016D (batch size: (b) (4) l vials).

Observation 2: Your firm failed to conduct (b) (4) (b) (4) (b) (4) . Your firm has used this (b) (4) since approximately December 2015 to sterilize all large batches including HCG 11,000 IU inj. lot # 08052016A, BUD: 02/01/17 ((b) (4) vials) and Testosterone Cypionate/ Propionate 200mg/50mg/ml inj. lot #01192016C, BUD: 07/17/16 ((b) (4) vials).

Observation 3: Personnel failed to disinfect or change gloves frequently enough to prevent contamination.

Specifically, on 10/13/16 during the preparation of Testosterone Propionate 100mg/ml inj. lot # 10132016A, your firm's operator was observed entering the negative pressure clean room, touching the door handle with (b) (6), (b) (7) (C) sterile (b) (4) gloves and without changing or disinfecting the gloves begins preparing to (b) (4)

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(b) (4) (b) (4). In addition, the operator began filling sterile product into the finished product vials without changing or disinfecting (b) (5), (b) (7)(C) gloves.

Furthermore, on 10/14/16 during the production of Methylcobalamin 1,000mcg/ml inj. lot # 10132016F, BUD: 04/11/17 your firm's operator was observed touching the inner surfaces of the stoppers with (b) (5), (b) (7)(C) gloved hand while applying them on (b) (4) finished product vials.

Observation 4: There is no HEPA filter (laminar air flow) over the area to which sterile product is exposed.

Specifically, on 10/11/16 during the current FDA inspection, we observed Sermorelin plus 27mg lot #10102016K, BUD: 04/08/17 (batch size: (b) (4) vials) within the (b) (4) located in the ISO 5 negative pressure clean room. Your firm's operator stated that this lot was produced within the ISO 5 positive pressure clean room. (b) (6), (b) (7)(C) stated that since there was no room in the (b) (4) within the ISO 5 positive pressure clean room (b) (5), (b) (7)(C) transported the (b) (4) vials from the positive clean room through the ante room (not under a HEPA filter) and into the negative pressure room (b) (4) (operator had to open the door to the positive pressure clean room and the door to the negative pressure clean room to place the vials into the negative pressure room (b) (4) which in total is approximately a (b) (4) . distance).

Observation 5: The HEPA filters located in the laminar air flow (b) (4) Hood (b) (4) and Hood (b) (4) within the ISO 5 positive clean room contain significant brown stains. Your firm's operator stated that approximately one year ago during production within Hood (b) (4) the (b) (4) broke and the product splattered onto the HEPA filter. Your firm's operator also stated that the significant brown stains (approximately 12 x 5 inches) located in Hood (b) (4) have been that way for approximately two years. Your firm has continued to produce sterile products within Hood (b) (4) and Hood (b) (4) without evaluating the impact on product sterility and taking the appropriate corrective actions such as replacing the HEPA filters.

Observation 6: Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

Specifically,
a) On 10/13/16, your firm's operators were observed donning their sterile hood, sterile mask and (b) (4)

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goggles on with their bare hands prior to washing their hands. Both operators were also observed donning their sterile gowns on with their bare hands and leaning against the ante room wall allowing their sterile gowns to come in contact with the wall.

b) On 10/14/16, your firm's operators were observed donning their sterile mask and sterile gowns with their bare hands. In addition, your firm's operators stated that they re-use their sterile gowns for one day while working on different products within the ISO 5 positive pressure clean room. They stated that when they finish a batch they will hang their sterile gowns in the ante room.

In addition, on 10/14/16 during the production operations of Methylcobalamin 1,000mcg/ml inj. lot # 10132016F, BUD: 04/11/17 your firm's operator was observed working directly over the open vials containing sterile product within the LAFW Hood therefore blocking the movement of first air around the open unit. Also, the operator's sleeve was observed touching the open finished product vials which contained sterile product potentially contaminating the batch.

Observation 7: Wipes used in the ISO 5 hoods (negative and positive pressure clean rooms) are not sterile. On 10/12/16 during the routine (b) (4) cleaning of the positive pressure ISO 5 clean room your firm's operator was observed using non-sterile wipes and spraying them with (b) (4) and (b) (4) to clean the interior surfaces of the (b) (4) LAFW hoods.

Observation 8: The ISO 5 positive pressure clean room is not operated appropriately to ensure adequate air flow within the room.

Specifically, on 10/14/16 during the production of Methylcobalamin 1,000mcg/ml inj. lot # 10132016F, BUD: 04/11/17 within the ISO 5 positive pressure clean room we observed 10 out of the (b) (4) air return vents to be closed. Your firm's operators stated that during the cleaning of the walls some air return vents have a tendency to close.

Observation 9: One (1) vial out of (b) (4) vials of Calm Me Injection from Lot # 08032016C, BUD: 01/30/2017 was found to contain an unknown foreign material.

Specifically, on 10/14/16 during the product inspection (released batches) of Calm Me Injection Lot #08032016C,

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BUD: 01/30/2017 30mL amber vials, we observed 1 vial out of (b) (4) vials to contain a round, white-like foreign material. According to Calm Me specifications, the amber 30mL vial should contain a clear solution.

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