DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	11/27/2018-12/14/2018* FEI NUMBER 3011888866

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sean M. Barclay, Owner

FIRM NAME	STREET ADDRESS
Barclay, Luke, & Pillai Specialty Pharmacy, PLLC	8352 W Warm Springs Rd Ste 120
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Las Vegas, NV 89113-3629	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

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

Specifically,

A. Your firm's (b) (4) is inadequate in that you did not obtain the recommended (b) (4) (b) (4) as specified on the accompanied brochure during the (b) (4) test. Your test resulted in (b) (4) than recommended.

Your firm used a (b) (4) to (b) (4) drug product produced by your firm. The recommend (b) (4) for this type of (b) (4) was (b) (4). However, during the (b) (4) test of the following drug products that used the same type and lot number of the (b) (4) the following was observed:

1) Meta PT Eye Drops Lot # 102918(b) (6) with (b) (4) test result of (b) (4). This product has a BUD of 200 days.

2) Testosterone Cypionate 200 mg/mL in Grapeseed Oil for IM Injection Lot # 092418(b) (6) with (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Uttaniti Limchumroon, Investigator	X Uttaniti Limchumroon Investigator Signed By: Uttaniti Limchumroon - S Date Signed: 12-14-2018 11:54:17	12/14/2018

(b) (4) test result of (b) (4) This product has a BUD of 100 days.

B. Your latest certification dated May 8, 2018 of ISO 5 laminar flow hood indicated that the certification was conducted under the dynamic conditions. The airflow visualization test was conducted of the ISO 5 laminar flow hood. However, the certification report does not document how the dynamic conditions were simulated. You did not record the airflow visualization test conducted during the ISO 5 laminar flow hood certification. The dynamic conditions cannot be verified during the certification.

C. The media fill challenge test has not been conducted every (b) (4) as required by your procedure SOP STRL P1.140, "Media Fill Challenge", version 1.0.2, effective date 04/28/2017. The last media fill challenge test for all (b) (4) operators were conducted on 05/12/2018.

D. Your firm do not (b) (4) in the (b) (4) used to house the drug products. (b) (4) are not processed or subjected to the same conditions as the drug products therefore there is no assurance that the (b) (4) parameters utilized to sterilize the drug products are adequate. In addition, your firm has not validated the (b) (4) and parameters that are used to sterilize Stanozolol 50 mg/mL drug products. Your firm used (b) (4) parameter of (b) (4).

OBSERVATION 2

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

Specifically,

A. Your firm does not perform environmental and personnel monitoring during the production of sterile drug products. Your firm conducts environmental monitoring including viable, non-

viable, and surface monitoring on (b) (4) basis along with the cleanroom, anteroom, and ISO 5 laminar flow hood certifications. Your firm conducts personnel fingertip monitoring every (b) (4) following (b) (4) test.

B. Your firm has not performed the (b) (4) certification of ISO 7 cleanrooms, ISO 7 anteroom, and ISO 5 laminar flow hood. The last certification was conducted May 8, 2018.

OBSERVATION 3

You did not have a HEPA filter over the area to which sterile product was exposed.

Specifically,

Your firm produces and packs pellets purportedly to be sterile within the non-sterile area prior to the sterilization process. This room is a negative pressure and unclassified room. The firm produces the following pellet drug products:

A. Testosterone Sterile Pellets
B. Estradiol Sterile Pellets
C. Progesterone Sterile Pellets
D. Naltrexone Sterile Pellets

OBSERVATION 4

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

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	11/27/2018-12/14/2018* FEI NUMBER 3011888866

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Sean M. Barclay, Owner	
FIRM NAME Barclay, Luke, & Pillai Specialty Pharmacy, PLLC	STREET ADDRESS 8352 W Warm Springs Rd Ste 120
CITY, STATE, ZIP CODE, COUNTRY Las Vegas, NV 89113-3629	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drugs

Specifically,

Your firm uses a non-sterile lint free wipe and non-sterile mop head for cleaning the ISO 5 laminar flow hood before and after the production.

OBSERVATION 5

Clothing of personnel engaged in the of drug products is not appropriate for the duties they perform.

Specifically,

A. On 11/27/2018, Operator (b) (6) was observed having exposed skin around the goggle while producing Methyl cobalamin (B12) 12.5 mg/mL IM Inj Lot # 112718(b) (6) and Glutathione 20% Injection Lot # 112718(b) (6)

B. On 12/06/2018, Operator (b) (6) was observed having exposed skin around the goggle while producing High dose vitamin C Myer Cocktail IV admixture Lot # 120618(b) (6)

OBSERVATION 6

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,

Your firm did not investigate the discrepancy between the (b) (4) test results obtained during the test and the (b) (4) manufacturer recommended (b) (4) . You obtained (b) (4) test results as specified below. The recommend (b) (4) .

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Uttaniti Limchumroon, Investigator X Uttaniti Limchumroon Investigator Signed By: Uttaniti Limchumroon - S Date Signed: 12-14-2018 11:54:17	DATE ISSUED 12/14/2018

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	11/27/2018-12/14/2018* FEI NUMBER 3011888866

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Sean M. Barclay, Owner	
FIRM NAME Barclay, Luke, & Pillai Specialty Pharmacy, PLLC	STREET ADDRESS 8352 W Warm Springs Rd Ste 120
CITY, STATE, ZIP CODE, COUNTRY Las Vegas, NV 89113-3629	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drugs

A. Meta PT Eye Drops Lot # 102918(b) (6) with (b) (4) test result of (b) (4). This product has a BUD of 200 days.

B. Testosterone Cypionate 200 mg/mL in Grapeseed Oil for IM Injection Lot # 092418(b) (6) with (b) (4) (b) (4) test result of (b) (4). This product has a BUD of 100 days.

OBSERVATION 7

Equipment and utensils are not cleaned, maintained and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

A. Your firm does not depyrogenate the glassware including (b) (4) that are used to weigh non-sterile bulk drug substance and mix all components before sterilization inside the ISO 5 laminar flow hood. The (b) (4) are used in drug products such as

1) Meta PT Eye Drops
2) Testosterone Cypionate 200mg/mL in Grapeseed Oil for IM Injection

B. Your firm has not determined the hold time of the cleaned (b) (4) that are stored inside the ISO 7 anteroom. These (b) (4) are stored uncovered and exposed to the ISO 7 anteroom environment. They can be stored on the cart indefinitely before use. The (b) (4) are used in drug products such as

1) Meta PT Eye Drops

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	11/27/2018-12/14/2018* FEI NUMBER 3011888866

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Sean M. Barclay, Owner	
FIRM NAME Barclay, Luke, & Pillai Specialty Pharmacy, PLLC	STREET ADDRESS 8352 W Warm Springs Rd Ste 120
CITY, STATE, ZIP CODE, COUNTRY Las Vegas, NV 89113-3629	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drugs

2) Testosterone Cypionate 200mg/mL in Grapeseed Oil for IM Injection
3) Stanozolol 50 mg/mL

The ISO 7 anteroom is being used by the firm to gown up for sterile drug production.

OBSERVATION 8

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,

Your stability programs are inadequate in that they did not include sterility testing at the end of products' shelf life to ensure that the drug products remain sterile throughout its shelf life. For example,

A. Meta PT Eye Drops Solution Lot # 112716 (b) (6) with BUD of (b) (4) storage condition.

B. Meta PMK Eye Drops Lot # 022317 (b) (6) with BUD of (b) (4) storage condition.

C. Testosterone Cypionate 200 mg/mL in Grapeseed Oil for IM Injection Lot # 041018sb with BUD of (b) (4) (b) (4) storage condition.

OBSERVATION 9

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	11/27/2018-12/14/2018* FEI NUMBER 3011888866

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Sean M. Barclay, Owner	
FIRM NAME Barclay, Luke, & Pillai Specialty Pharmacy, PLLC	STREET ADDRESS 8352 W Warm Springs Rd Ste 120
CITY, STATE, ZIP CODE, COUNTRY Las Vegas, NV 89113-3629	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drugs

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically,

You firm does not perform sterility and endotoxin testing on each lot of sterile drug product produced. For example,

A. Glutathione 20% Injection Lot # 112718(b) (6) was not tested for sterility and endotoxin prior to release.

B. Methylcobalamin (B12) 12.5 mg/mL IM Injection Lot # 112718(b) (6) was not tested for sterility and endotoxin prior to release.

C. Biotin 5mg/mL Solution for Injection Lot # 110718(b) (6) was not tested for sterility and endotoxin prior to release.

OBSERVATION 10

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,

A. You firm does not perform potency testing on each lot of sterile drug products produced. For example,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Uttaniti Limchumroon, Investigator	X Uttaniti Limchumroon Investigator Signed By: Uttaniti Limchumroon - S Date Signed: 12-14-2018 11:54:17	12/14/2018

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	11/27/2018-12/14/2018* FEI NUMBER 3011888866

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Sean M. Barclay, Owner	
FIRM NAME Barclay, Luke, & Pillai Specialty Pharmacy, PLLC	STREET ADDRESS 8352 W Warm Springs Rd Ste 120
CITY, STATE, ZIP CODE, COUNTRY Las Vegas, NV 89113-3629	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drugs

1) Meta PT Eye Drops Solution Lot # 102918(b) (6) was not tested for potency prior to release.

2) Glutathione 20% Injection Lot # 112718(b) (6) was not tested for potency prior to release.

3) Methylcobalamin (B12) 12.5 mg/mL IM Injection was not tested for potency prior to release.

B. Your firm does not test the preservative content in the batches at the time of release. For example,

1) Meta PT Eye Drop Solution contains (b) (4) as a preservative.

2) Glutathione 20% Injection contains (b) (4) as a preservative.

3) Methylcobalamin (B12) 12.mg/mL IM Injection contains (b) (4) as a preservative.

C. Your firm has not conducted preservative effectiveness study to determine whether the amount of preservative used in the formulation are adequate to preserve the drug products throughout the shelf life. For example,

1) Meta PT Eye Drop Solution contains (b) (4) as a preservative.

2) Glutathione 20% Injection contains (b) (4) as a preservative.

3) Methylcobalamin (B12) 12.mg/mL IM Injection contains (b) (4) as a preservative.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Uttaniti Limchumroon, Investigator X Uttaniti Limchumroon Investigator Signed By: Uttaniti Limchumroon - S Date Signed: 12-14-2018 11:54:17	DATE ISSUED 12/14/2018

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	11/27/2018-12/14/2018*
	FEI NUMBER 3011888866

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sean M. Barclay, Owner

FIRM NAME	STREET ADDRESS
Barclay, Luke, & Pillai Specialty Pharmacy, PLLC	8352 W Warm Springs Rd Ste 120
CITY, STATE, ZIP CODE, COUNTRY Las Vegas, NV 89113-3629	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drugs

OBSERVATION 11

Batch production and control records are not prepared for each batch of drug product produced and do not include complete information relating to the production and control of each batch.

Specifically,

Your firm did not create production records for Fentanyl Injection 50 mcg/mL produced at the facility. The commercially available fentanyl 2500 mcg/50 mL bottle was used to draw up (b) (4) syringes as requested by the customer. There is no information as to what equipment and components were used for the batch.

***DATES OF INSPECTION**

11/27/2018(Tue), 11/28/2018(Wed), 11/29/2018(Thu), 11/30/2018(Fri), 12/03/2018(Mon), 12/04/2018(Tue), 12/06/2018(Thu), 12/14/2018(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Uttaniti Limchumroon, Investigator X Uttaniti Limchumroon Investigator Signed By: Uttaniti Limchumroon - S Date Signed: 12-14-2018 11:54:17	12/14/2018