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	6/24/2019-7/2/2019+
	FEI NUMBER 3002614375

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Richard A. Sheriff, Owner/President/Pharmacist

FIRM NAME	STREET ADDRESS
Shertech Pharmacy	221 Cooper Ln Ste A
CITY, STATE, ZIP CODE, COUNTRY Easley, SC 29642-8283	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drug Products

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

Personnel engaged in aseptic processing were observed wearing non-sterile gloves.

Specifically, your firm failed to utilize sterile gloves during the preparation of all sterile drug products (indicated for sterile injection). For example, on 6/24/19, your Pharmacist stated that no sterile gloves were used during the preparation of the (b) (4), lot (b) (4) which was used to produce finished radiological drug product, Mertiatide-Tc99m LEU, lot #K-20190624-007.

OBSERVATION 2

Sporicidal agents were not used in your facility's cleanrooms and/or ISO 5 classified aseptic processing area.

Specifically, your firm's Pharmacist stated he only uses (b) (4) (non-sterile surface disinfectant and decontaminant cleaner) and non-sterile (b) (4) within your classified ISO 3-LAFH. No sporicidal agent is used.

OBSERVATION 3

Your facility design allowed the influx of poor quality air into a higher classified area.

Specifically,

a. Your firm's classified ISO-3 LAFH ((b) (4) hoods defined as Hood (b) (4) and Hood (b) (4) are located within the classified ISO-8 Pharmacy Area. Your firm failed to demonstrate through smoke studies that an influx of

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poor-quality air is not entering your classified ISO-3 LAFH during the production of sterile drug products. In addition, your firm's Pharmacist stated the (b) (4)-classified ISO-3 LAFH are shut off overnight and prior to resuming production activities only wipes down the hoods with non-sterile (b) (4).

b. Your firm failed to monitor the differential pressure between areas with different air classifications (such as the classified ISO-8 Pharmacy Area to the unclassified gowning room) prior or during sterile drug production.

c. The set-up of the classified ISO-8 Pharmacy Area can potentially increase particulate counts. For example, the room contains a refrigerator adjacent to the classified ISO-3 LAFH (Hood (b) (4)), a table top fan was observed on the counter between Hood (b) (4) and the (b) (4) Hood (used for (b) (4) processing), air conditioning vents (non-HEPA) were observed in close proximity to Hood (b) (4) and Hood (b) (4) and all hoods were observed cluttered containing supplies and equipment.

OBSERVATION 4

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

Specifically, your firm lacked environmental monitoring (EM) procedures and documentation to demonstrate that EM was conducted during sterile processing operations. For example, your firm's President/Pharmacist stated that on 6/24/19, no EM was conducted during the (b) (4) of (b) (4) (b) (4).

OBSERVATION 5

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

Specifically, your firm failed to conduct media fills that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations. For example, according to your firm's President/Pharmacist your firm (b) (4) the (b) (4) (b) (4) into (b) (4) (b) (4) (b) (4) the drug product with radiological activity, technetium).

OBSERVATION 6

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

Specifically, on 06/24/2019, your firm filled Rx # (b) (6) for Mertiatide-Tc99m LEU (sterile injectable), lot #K-20190624-007 (8.539 mCi, Quantity: (b) (4) Volume: 0.74mL), Use By D/T: 06/25/2019, from the (b) (4) contained in the sterile tube, but failed to test the finished drug product for sterility. According to your firm's President/Owner, sterility testing is not being conducted on the finished product, Mertiatide when (b) (4) (b) (4) are being used.

OBSERVATION 7

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

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Specifically, according to your firm's President/Pharmacist, on 6/24/19, your firm (b) (4) the (b) (4) from an unknown supplier into (b) (4) (b) (4) the drug product with radiological activity, technetium). Your firm failed to demonstrate that the (b) (4) (amounts were not weighed or verified) consistently meets predetermined specifications established by the manufacturer.

OBSERVATION 8

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

Specifically, your firm's President/Pharmacist stated he was receiving (b) (4) (Mertiatide) from an alternate distribution channel (unknown source); however, your firm failed to ensure through appropriate analytical testing or documentation from the manufacturer that the (b) (4) purchased meets specifications for identity, strength, quality, and purity. According to your firm's Kit Information Report, your firm used these components to produce and dispense the following number of finished drug product units of Mertiatide-Tc99m LEU (sterile injectable) within 2019:

- (b) (4) units in January 2019,
- (b) (4) units in February 2019,
- (b) (4) units in March 2019,
- (b) (4) units in April 2019,
- (b) (4) units in May 2019.

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OBSERVATION 9

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, according to your firm's President/Pharmacist, potency testing of the active ingredient has not been conducted by your firm for the finished radiological drug product, Mertiatide-Tc99m LEU, which utilized (b) (4) from an alternate distribution channel (unknown source).

OBSERVATION 10

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

Specifically, according to your firm's President/Pharmacist your firm applies the same expiration date of the original drug product to the (b) (4) (b) (4) without having any data to support the stability of this product after further manipulations.

In addition, on 6/24/19 your firm filled Rx #(b) (6) for Mertiatide-Tc99m LEU (sterile injectable), lot #K-20190624-007 (8.539 mCi, Quantity: (b) (4) Volume: 0.74mL), and assigned a Use by Date of 06/25/2019 (24 hours); however a manufacturer's product insert found within the Pharmacy states the technetium Tc 99m mertiatide preparation must be used within (b) (4) of preparation. Your firm lacked data to support this product retains the required activity for 24-hours.

OBSERVATION 11

Records associated with drug product components, containers, closures, labeling, production, control and distribution and within the retention period for such records, were not made readily available for authorized inspection.

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Specifically, your firm failed to provide complete documentation including a Certificate of Analysis (COA) for the receipt and approval (b) (4) from your firm's suppliers. According to your (b) (4), the following batches of (b) (4) were received from three different suppliers: (b) (4) and (b) (4) but no documentation was provided to demonstrate the products were supplied by these suppliers. For example:

- On 1/26/18, your firm received container (b) (4) consisting of (b) (4) vials (b) (4), lot (b) (4) with the vendor listed as (b) (4) stated via email to your firm's Pharmacist that their company does not produce (b) (4)) or (b) (4).

- On 08/24/18, your firm received container (b) (4) consisting of (b) (4) vials of (b) (4) (b) (4) lot (b) (4) with the vendor listed as (b) (4) stated via email to your firm's Pharmacist that their company did not produce or dispense (b) (4) or (b) (4), lot (b) (4).

- On 04/19/19, your firm received container (b) (4) consisting of (b) (4) vials of (b) (4) lot (b) (4) with the vendor listed as (b) (4) stated via email to your firm's Pharmacist that their company did not ship or dispense any (b) (4) or (b) (4) to your Easley site in 2019.

This practice of incomplete and inaccurate information of vendors supplying (b) (4) or (b) (4) batches to your firm's Easley site has been occurring from 1/23/18 through 5/16/19 according to your firm's Received Containers Report.

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*DATES OF INSPECTION

6/24/2019(Mon), 6/25/2019(Tue), 6/26/2019(Wed), 6/27/2019(Thu), 6/28/2019(Fri), 7/01/2019(Mon), 7/02/2019(Tue)

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