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FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 1 of 7 PAGES	FORM EDA 481 (00/06)		INSPECTIONAL	BSERVATIONS	PAGE 1 of 7 PAGES	

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FIRMNAME	lerin, owner/President/	STREET ADDRESS		
Shertech Phan	macy	221 Coop	ber Ln Ste A	
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Easley, SC 29	642-8283	Producer	of Sterile Drug Pro	ducts
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Specifically, you EM was conduct	ing areas are deficient regardin firm lacked environmental mon ed during sterile processing ope o EM was conducted during the	nitoring (EM) proc erations. For exa	edures and documentation t mple, your firm's President	o demonstrate that
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FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL	OBSERVATIONS	PAGE 2 of 7 PAGES

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Specifically, yo incorporating, a	adequate validation of the a ur firm failed to conduct me s appropriate, worst-case ac example, according to your (b) (4) into	edia fills that closely	ons that provide a challenge	e to aseptic
(b) (4)				
(b) (4)			the drug	product with
radiological act	ivity, technetium).			
injectable), lot # from the (b) (4) test the finished	06/24/2019, your firm filled K-20190624-007 (8.539 m drug product for sterility. A acted on the finished product	Ci, Quantity: Vo	lume: 0.74mL), Use By D/ contained in the sterile tube irm's President/Owner, ster	Γ: 06/25/2019, e, but failed to
	itten procedures for product ne identity, strength, quality			
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	407) 475-4700 Fax: (407) 475-4768		3002614375	
NAME AND TITLE OF INDIVIDUA	L TO WHOM REPORT ISSUED			
Richard A. Sh	eriff, Owner/President/N	Pharmacist		
FIRM NAME		STREET ADDRESS		
Shertech Phar	-		r Ln Ste A	
CITY STATE ZIP CODE COUNT Easley, SC 29		Producer	of Sterile Drug Prod	ucts
Specifically, acc	cording to your firm's Preside		6/24/19, your firm(b) (4 known supplier into(b) (
(b) (4)	th radiological activity, techne (amounts were not weight tablished by the manufacture	etium). Your firm ed or verified) con	failed to demonstrate that	(b) (4) the at the
OBSERVATIO	NO			
State of the second sec	t is not tested for conformity v	with all appropriate	e written specifications for	or purity,
alternate distribut appropriate anal specifications for Report, your firm	ar firm's President/Pharmacist ation channel (unknown source ytical testing or documentatio r identity, strength, quality, an n used these components to pro- Mertiatide-Tc99m LEU (steri	e); however, your on from the manufa nd purity. Accordin roduce and dispension	firm failed to ensure thro acturer that the (b) (4) p ng to your firm's Kit Info se the following number	ough urchased meets ormation
• (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.	.5		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Jessica L Pressley, Inv Jared P Stevens, Invest	estigator igator 561	Jessona L. Pressley Trivestigatur Dale Signed: 07-02-2019 14:25-37 X	DATE ISSUED 7/2/2019
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	. INSPECTIONAL OB	SERVATIONS	PAGE 4 of 7 PAGES

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DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200	6/24/2019-7/2/2019*
Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	3002614375
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Richard A. Sheriff, Owner/Presid	dent/Pharmacist
	dent/Pharmacist
Richard A. Sheriff, Owner/Presid	
Richard A. Sheriff, Owner/President President	STREET ADDRESS

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: 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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 EMPLOYEE(s) SIGNATURE Jessica L Pressley, Investigator Jared P Stevens, Investigator
 Jessica L Pressley, Signed B Stevens, Investigator
 Jessica L Pressley, Signed B Stevens, Investigator
 Date ISGUED
 7/2/2019

 FORM FDA 483 (09/08)
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 PAGE 5 of 7 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Plac		DATE(S) OF IN	SPECTION 019-7/2/2019*		
Maitland, FL 32751	, 32751		4375		
(407)475-4700 Fax:	(407) 475-4768	500201	4373		
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED					
Richard A. Sheriff	, Owner/President/Pharm	acist STREET ADDRESS			
Shertech Pharmacy		221 Cooper Ln S	te A		
CITY STATE ZP CODE, COUNTRY Easley, SC 29642-8	202	TYPE ESTABLISHMENT INSPECTED Producer of Ste	rile Drug Produ	acte	
Edsley, 50 23042-0	205	FIGURCET OF SEE	TITE DING FLOOD	ieus	
 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 from your firm's suppliers. According 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) from your firm's Pharmacist that their company does not produce (b) (4) stated via email to your firm's Pharmacist that their company does not produce (b) (4) is stated via email to your firm's Pharmacist that their company does not produce (b) (4) is of (b) (4) (4) (b) (4) with the vendor listed as (b) (4) is stated via email to your firm's Pharmacist that their company did not produce or dispense (b) (4) or (b) (4) is the vendor listed as (b) (4) is email to your firm's Pharmacist that their company did not produce or dispense (b) (4) or (b) (4) is the vendor listed as (b) (4) is stated via email to your firm's Pharmacist that their company did not produce or dispense (b) (4) or (b) (4) is the vendor listed as (b) (4) is stated via email to your firm's Pharmacist that their company did not produce or dispense (b) (4) or (b) (4) is the vendor listed as (b) (4) is stated via email to your firm's Pharmacist that their company did not ship or dispense any (b) (4) is of (b) (4) is or (b) (4) is your firm's Pharmacist that their company did not ship or dispense any (b) (4) is or (b) (4) is your firm's Pharmacist that their company did not ship or dispense any (b) (4) is your firm's Easley site in 2019. This practice of incomplete and inaccurate information of vendors supplying (b) (4) is or (b) (4) is or (b) (4) is do your firm's Easley site has been occurring from 1/23/18 through 5/16/19 according to your firm's Received Containers Report. 					
SEE REVERSE Jess:	(8)SIGNATURE ica L Pressley, Investig d P Stevens, Investigato	gator SPC	Jessica L. Pressley investigator Bignet By Jesson L. Presser - 5 Dale Signet 07-02/2019 14:25:37 X	DATE ISSUED 7/2/2019	
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ALTH AND HUMAN SERVICES UG ADMINISTRATION
DATE(S) OF INSPECTION 6/24/2019-7/2/2019*
FEI NUMBER 3002614375
rmacist
STREET ADDRESS
221 Cooper Ln Ste A
TYPE ESTABLISHMENT INSPECTED
Producer of Sterile Drug Products

***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)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Jessica L Pressley, J Jared P Stevens, Inve		DATE ISSUED
FORM EDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS	PAGE 7 of 7 PAGES