DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 8th Street NE Atlanta, GA 30309 Phone: 404-253-1171; Email: ORAPHARM2_RESPONSES@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	06/25-07/02, 15-18/2019
	FEI NUMBER 3009042626

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Richard A. Sheriff, President

FIRM NAME	STREET ADDRESS
Shertech Pharmacy, LLC	1470 Hampton Plaza Dr.
CITY, STATE AND ZIP CODE Kernersville, NC 27284	TYPE OF 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) (WE) OBSERVED:

OBSERVATION 1

Your firm produced drugs while construction was underway in an adjacent area without adequate controls to prevent contamination of the production environment and product.

Specifically, on 06/25/2019, there was on-going construction in the non-sterile drug manufacturing area which involved the displacement of ceiling tiles, exposing fiberglass ceiling insulation. I also observed the manipulation of drywall. On 06/27/2019, construction employees were observed sanding drywall and the smell of paint was pungent. The area of construction was immediately adjacent to the area where employees don garb and other protective apparel for use in sterile nuclear and non-nuclear manufacturing operations. The construction area was neither cordoned off nor physically separated from the rest of the pharmacy to protect the production environment within this area and the surrounding sterile manufacturing areas. Your firm continued to engage in sterile and non-sterile manufacturing operations while construction was underway. In addition, your firm did not conduct any environmental monitoring to verify that the environment was suitable for aseptic production during this construction period. Your firm produced and/or distributed products on 06/26/2019 and 06/27/2019 under those conditions. Among them were:

- Rx#(b)(6) – Sincalide I.V.
- Rx#(b)(6) – Sodium Pertechnetate Tc99 (b) (4)(LEU)
- Rx#(b)(6) – HDP-Tc99m (LEU)(b) (4)
- Rx#(b)(6) - HDP-Tc99m (LEU)(b) (4)
- Rx#(b)(6) – MDP-Tc99m (b) (4)(LEU)
- Rx#(b)(6) – Sestamibi – Tc99m (b) (4)(LEU)
- Rx#(b)(6) - Sestamibi – Tc99m (b) (4)(LEU)
- Paraben Water for Injection (USP <51> Study
- Methylcobalamin 1000 MCG/mL Injectable

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OBSERVATION 2
Your facility was designed and/or operated in a way that permits poor flow of personnel and materials.

Specifically, your facility does not have any physical barriers separating classified environments, with the exception of the ISO 5 laminar airflow hood used in sterile drug manufacturing operations. In addition, I observed employees and construction workers not properly garbed entering your firm's-controlled environments. Some examples are, but not limited to:

• On 06/25/2019, I observed construction employees (not garbed) go through your firm's garbing area (identified as a "non-sterile ante area," but was not, however, classified by your contract certification entity) and enter your firm's restroom and return to the gowning area.
• On 06/26/2019, I observed a pharmacist and a pharmacy tech (not garbed) traverse the Nuclear Room (ISO 7 classified) and proceed to the "non-sterile ante area" (not classified) where they donned non-sterile garb, then again traverse the Nuclear Room (ISO 7) where they began engaging in sterile drug manufacturing operations in their respective ISO 5 classified laminar airflow hoods.
• On 06/27-28/2019, I observed administrative personnel (not garbed) working on computers located in the nuclear pharmacy (ISO-7 Classified).

OBSERVATION 3
Personnel touched equipment or other surfaces located outside of the ISO 5 classified aseptic processing area with gloved hands and then engaged in aseptic processing without changing or sanitizing gloves.

Specifically, on 06/26/2019, I observed personnel engaged in aseptic operations not sanitizing their gloved hands when moving from the Laminar Airflow Hoods (ISO 5 Classified Area) to an area of lesser air quality (ISO 7 Classified Area) and returning to the Laminar Airflow Hoods (ISO 5 Classified Area). Also, floor mats were observed on the floor at the ISO 5 working stations, the QC testing area and at support work areas in the ISO 7 nuclear pharmaceutical area. Neither the mats, nor the floor beneath the mats were observed to be cleaned and sanitized during the inspection.

In addition, I observed product delivery personnel repeatedly entering your firm's sterile processing area from an unclassified area to check on product status without donning and/or changing their protective apparel (e.g. apron,

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foot covering, hair net, sleeve covering, face mask).

According to your firm's distribution report, on 06/26/2019, your firm produced and distributed the following products:

Product Name	Lot Numbers
HDP-Tc99m (LEU) (b) (4)	K-20190626-003
The fifth I-131 Diagnostic Capsule	M-20190626-003
Iodine-123 Capsule (200 uCi) (b) (4)	60219097B
MAA-Tc99m (b) (4) (LEU)	K-20190626-010
MAA-Tc99m (b) (4) (LEU) (b) (4)	K-20190626-010
MAG3-Mertiatide Tc99m (b) (4) (LEU)	K-20190626-004
MDP-Tc99m (b) (4) (LEU)	K-20190626-001
Mebrofenin - Tc99m (b) (4) (LEU)	K-20190626-006
Myoview - Tc99m (b) (4) (LEU)	K-20190626-005
Sestamibi-Tc99m (b) (4) (LEU)	K-20190626-008
Sestamibi-Tc99m (b) (4) (LEU)	K-20190626-007
Sodium Pertechnetate Tc99m (b) (4) (LEU)	E-20190626-004
Sodium Pertechnetate Tc99m (b) (4) (LEU)	E-20190626-005
Sodium Pertechnetate Tc99m (b) (4) (LEU)	E-20190626-003
Sodium Pertechnetate Tc99m (b) (4) (LEU)	E-20190626-002
Sodium Pertechnetate Tc99m (b) (4) (LEU)	E-20190625-004
Sulfur Colloid Tc-99m (b) (4) (LEU)	K-20190626-009
Sulfur Colloid Tc-99m (b) (4) (LEU)	K-20190626-011

OBSERVATION 4
Personnel engaged in aseptic processing were observed leaving and re-entering the cleanroom from non-classified areas without first replacing gowning apparel.

Specifically, on 06/26/2019, I observed the pharmacist that had been engaged in sterile nuclear pharmaceutical manufacturing operations, leave the ISO 7 area containing the ISO 5 laminar airflow hood to prepare components

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for further processing. The pharmacist performed those procedures outside of the ISO 5 conditions while wearing the same gloves and protective apparel that he wore while performing sterile operations inside of the ISO 5 laminar airflow hood. In one instance, I observed the employee to retrieve supplies from a storage area (unclassified storage area) completely outside of the pharmacy's sterile processing then return to the ISO 5 processing laminar airflow hood. Upon returning to the sterile ISO 7 area the pharmacist's apparel came in direct contact with the (b) (4) that separated an unclassified area from the ISO 7 area. The (b) (4) separting the ISO 7 area from the unclassified area was not observed to be cleeaned and sanitized during the inspection. The pharmacist changed his gloves but did not change his protective apparel (apron, foot covering, hair net, sleeve covering, face mask). Later during sterile nuclear pharmaceutical manufacturing, the pharmacist performed quality control testing on finished products in an ISO class 7 section of the pharmacy while wearing the same garb he had on while performing manufacturing operations. After receiving unacceptable results, the pharmacist returned to the area containing the ISO 5 laminar airflow hood to retrieve another sample but did not change his protective apparel (apron, foot covering, hair net, sleeve covering, face mask), prior to retrieving the sample. Also, following the completion of manufacture of the first round of radiopharmaceuticals, the pharmacist began preparation, and then manufactured more sterile radiopharmaceuticals. I did not observe the pharmacist to change his protective apparel during 06/26/2019 operations.

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

Specifically, on 06/26/2019, I observed your firm's employees using (b) (4) and non-sterile (b) (4) (b) (4) within your sterile nuclear pharmacy ISO 5 Classified Laminar Airflow Hoods. Your employees did not allow for enough contact time after the application of (b) (4) prior to applying the non-sterile (b) (4) On 06/27/2019, I observed your procedures to prepare the work surfaces of your ISO 5 (b)(6) in your sterile non-nuclear pharmaceutical operations. You were using (b) (4) disinfectant (non-sterile) on those services. Likewise, your employee did not allow for enough contact time after the application of the (b) (4) (non-sterile) disinfectant prior to applying the non-sterile (b) (4) on the surfaces of the ISO 5 laminar airflow hoods.. A review of the labeling for this product does not support its sporicidal capabilities.

OBSERVATION 6
Your firm's records are deficient in that they do not include complete documentation of all data obtained during

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testing to provide assurances that your product meets release specifications.

Specifically,

A. Your firm's Audit Trails for Kit QC Controls obtained from your firm's (b) (4) Software used in your firm's nuclear pharmacy, shows your pharmacists (b) (6)), changed QC data from a failing result to a passing result twenty-nine (29) times without justification from 07/02/2018-07/02/2019. Examples include, but are not limited to:

1. During this FDA inspection, on 06/27/2019, your pharmacist, (b) (6) changed failing results to passing results. However, the failing results occurred in 2018. According to your Pharmacist-in-Charge, this product has a half-life of 6.02 hours and an expiration time of 12 hours. For example: on 06/27/2019, your audit trail documents the following changes were made:

i. MAG3-Mertiatide Tc99m (b) (4) (LEU), Lot # K-20180907-006, shows a failing result was entered on 09/07/2018. However, on 06/27/2019, the results were modified from 84.567% to 93.724%.

ii. MAG3-Mertiatide Tc99m (b) (4) (LEU), Lot # K-20180719-001, shows a failing result was entered on 07/19/2018. However, on 06/27/2019, the results were modified from 82.928% to 91.119%.

Your firm distributed (b) (4) of these lots to end users. For example, but are not limited to:

Product Name	Lot Number	Original QC Result	Changed QC Result
MAG3-Mertiatide Tc99m (b) (4) (LEU)	K-20180719-001	82.928	91.119
MAG3-Mertiatide Tc99m (b) (4) (LEU)	K-20180720-003	84.536	94.389
MAG3-Mertiatide Tc99m (b) (4) (LEU)	K-20180726-002	83.933	94.411
MAG3-Mertiatide Tc99m (b) (4) (LEU)	K-20180731-003	83.477	96.213
MAG3-Mertiatide Tc99m (b) (4) (LEU)	K-20180806-009	82.273	97.892
MAG3-Mertiatide Tc99m (b) (4) (LEU)	K-20180807-005	83.182	94.761
MAG3-Mertiatide Tc99m (b) (4) (LEU)	K-20180816-004	82.461	92.294
MAG3-Mertiatide Tc99m (b) (4) (LEU)	K-20180817-005	83.084	94.796
MAG3-Mertiatide Tc99m (b) (4) (LEU)	K-20180820-008	87.583	92.442
MAG3-Mertiatide Tc99m (b) (4) (LEU)	K-20180828-002	82.299	96.415
MAG3-Mertiatide Tc99m (b) (4) (LEU)	K-20180829-009	87.181	90.771

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MAG3-Mertiatide Tc99m (b) (4) (LEU)	K-20180830-004	82.589	91.901
MAG3-Mertiatide Tc99m (b) (4) (LEU)	K-20180904-007	88.636	98.486
MAG3-Mertiatide Tc99m (b) (4) (LEU)	K-20180907-006	84.567	93.724
MAG3-Mertiatide Tc99m (b) (4) (LEU)	K-20180910-006	84.711	97.847
MAA-Tc99m (RP) (LEU) (b) (4)	K-20180910-012	74.251	96.652
MAG3-Mertiatide Tc99m (b) (4) (LEU)	K-20181002-011	82.018	97.02
MAG3-Mertiatide Tc99m (b) (4) (LEU)	K-20181003-012	83.75	98.157
MAG3-Mertiatide Tc99m (b) (4) (LEU)	K-20181004-010	87.467	95.748
MAG3-Mertiatide Tc99m (b) (4) (LEU)	K-20181015-008	89.267	91.186
MAG3-Mertiatide Tc99m (b) (4) (LEU)	K-20181016-005	86.141	90.999
MAG3-Mertiatide Tc99m (b) (4) (LEU)	K-20181017-008	88.128	93.656
MAG3-Mertiatide Tc99m (b) (4) (LEU)	K-20181023-004	85.041	92.587
MAG3-Mertiatide Tc99m (b) (4) (LEU)	K-20190204-013	89.359	93.254
MAG3-Mertiatide Tc99m (b) (4) (LEU)	K-20190211-007	83.202	90.056
Sestamibi-Tc99m (b) (4) (LEU)	K-20190429-012	87.969	90.886
Myoview - Tc99m (b) (4) (LEU)	K-20190524-011	83.555	98.047

B. Your firm released failing product to end users. For example, but are not limited to:

Product Name	Finished Product Lot Number	QC Result - % Tagging Failure(Acceptance Criteria = (b) (4))
DTPA-Tc99m (b) (4)	K-20180328-008 5	8.966
DTPA-Tc99m (b) (4)	K-20180517-011	49.022
MAATc99m (b) (4) (LEU)	K-20180913-009	75.817
MAATc99m (b) (4)	K-20180809-007	43.091
Mebrofenin Tc99	K-20181216-001	2.234
Mebrofenin Tc99	K-20181011-009	43.315
MAG3-Mertiatide	K-20181219-010	89.248
MAG3-Mertiatide	K-20181009-003	89.008
MAG3-Mertiatide	K-20181105-006	88.272
MAG3-Mertiatide	K-20180823-013	87.731
MAG3-Mertiatide	K-20181130-006	87.587
MAG3-Mertiatide	K-20181003-010	82.37

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	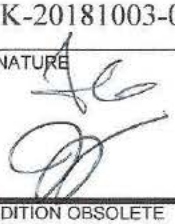	Francis Guidry, Investigator June P. Page, Investigator	07/18/2019

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C. A QC Report obtained from your firm's (b) (4) Software system, dated 01/01/2018-07/01/2019, shows QC testing was not performed on approximately (b) (4) lots produced in your nuclear pharmacy prior to the distribution for the following products:

Product Name
CERETEC-Tc99m (b) (4)
CERETEC-WBC
DMSA-Tc99m(LEU)
DTPA Tc99m (b) (4)
HDP-Tc99m(LEU)
MAA-Tc99m (b) (4)
MAA-Tc99m (b) (4) (LEU)
MAG3-Mertiade
MDP-Tc99m (b) (4)
Mebrofenin Tc99m
Myoview -Tc99m
Neurolite-Tc99m
Octreoscan
Sestamibi
Sulfur Colloid Tc99m
~~Grand Total~~ 6

D. On 06/26/2019, I observed finished products radioactivity/tagging QC testing. This procedure is done by, and results generated from, a standalone computer located in the Nuclear Room (classified as ISO 7). The results were transcribed onto a laminated template (Daily Quality Control Data). The results recorded on the laminated template were then entered into the firm's (b) (4) computerized system. The laminated template was then wiped clean. The result for the MAG3 QC first production run were unacceptable (K-20190626-004). The pharmacist indicated that he understood what went wrong, retrieved another sample, repeated the test, recorded those results on the template, then entered them into the (b) (4) computer system. According to the pharmacist, the initial QC test failure results generated by the analyzer are not maintained. The information documented on the results

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template are likewise not maintained. Questionable QC results for Myoview K-20190626-005 and Sestamibi K-20190626-008 were also observed on the QC data results template.

OBSERVATION 7

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.

Specifically, your firm failed to provide complete documentation including but are not limited to: Certificate of Analysis (COA) for the receipt and approval of Octreoscan Cold Kits and Mertiatide Kits from your firm's suppliers. According to your (b) (4) Software System, Octreoscan Cold Kits were received from two different suppliers: (b) (4) .; and Mertiatide Kits were received from three different suppliers: (b) (4) For example, but are not limited to:

A. On 01/18/2019, your firm received container #5645, consisting of (b) (4) vials of Mag3-Mertiatide Kit, Lot (b) (4), with the vendor listed as (b) (4) and the manufacturer listed as (b) (4) Your firm does not have any documentation supporting this (b) (4) product came from (b) (4). Mag3-Mertiatide Kit, Lot (b) (4), was used in the production of at least (b) (4) lots of MAG3-Mertiatide Tc99m from this facility.

B. On 02/22/2019, your firm received container #5711, consisting of (b) (4) vials of Mag3-Mertiatide Kit, Lot (b) (4), with the vendor listed as (b) (4) and the manufacturer listed as (b) (4) Your firm does not have any documentation supporting this (b) (4) product came from (b) (4). Mag3-Mertiatide Kit, Lot (b) (4) was used in the production of at least (b) (4) lots of MAG3-Mertiatide Tc99m from this facility.

C. Your pharmacist in charge received an email from (b) (4) stating (b) (4) shipped (b) (4) vials of (b) (4) (b) (4) in 2019. However, your firm's Received Container Report, dated 01/01/2019-07/01/2019, documents your firm received (b) (4) vials of Mag3-Mertiatide Kit, Lot (b) (4). Your firm could not provide documentation as to where the additional (b) (4) vials originated. Mag3-Mertiatide Kit, (b) (4), was used in the production of (b) (4) lots of MAG3-Mertiatide Tc99m (b) (4) LEU).

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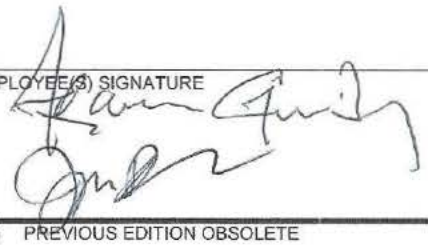
D. Your pharmacist in charge received an email from (b) (4) stating (b) (4) has no records of shipment to your account in 2018. However,

1. On 05/10/2018, your firm received container #5106, consisting of (b) (4) vials of Mag3-Mertiatide Kit, Lot (b) (4) with the vendor and manufacturer listed as (b) (4) . Mag3-Mertiatide Kit, Lot (b) (4) was used in the production of MAG3-Mertiatide Tc99m, Lot #K-20180510-004 and distributed from your facility.
2. On 05/14/2018, your firm received container #5114, consisting of (b) (4) of Mag3-Mertiatide Kit, Lot (b) (4) with the vendor and manufacturer listed as (b) (4) Mag3-Mertiatide Cold Kit, Lot (b) (4) was used in the production of MAG3-Mertiatide Tc99m, Lot #K-20180514-009 and distributed from your facility.
3. On 06/04/2018, your firm received container #5175, consisting of (b) (4) of Octreoscan Cold Kit, Lot (b) (4) , with the vendor and manufacturer listed as (b) (4) . Octreoscan Cold Kit, Lot (b) (4) was used in the production of Octreoscan In111 (b) (4) lot #M-20180604-003 and distributed from your facility.

E. Your firm's 2018 Received Container Report, documents (b) (4) as the manufacturer and (b) (4) as the vendor for the receipt of (b) (4) vials of Mag3-Mertiatide Kit. However, your firm could not provide documentation supporting (b) (4) is the manufacturer of this product. In addition, your firm's 2018 Received Container Report, documents (b) (4) as the vendor and the manufacture field is blank. For example, but are not limited to, on 12/24/2018, (b) (4) vials of Mag 3-Mertiatide Kit (cold kit), lot (b) (4) , were received by your Pharmacist-In-Charge (PIC), for shipping container #5599. This same lot, Mag 3-Mertiatide Kit (cold kit), lot # (b) (4) , was involved with a complaint received for a gall bladder image expressing in a renal scan for MAG3-Mertiatide Tc99m (b) (4) (LEU). According to your PIC, the naming convention for the final product MAG3-Mertiatide Tc99m (b) (4) (LEU), indicates (b) (4) Your firm did not have any supporting documentation verifying (b) (4) this product. Mag 3-Mertiatide Kit (cold kit), lot (b) (4) was used in the production of at least (b) (4) lots for MAG3-Mertiatide Tc99m (b) (4) (LEU).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Francis Guidry, Investigator June P. Page, Investigator	07/18/2019