DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11155 Dolfield Boulevard, Suite 117 Owings Mills, MD 21117 (410)779-5455 Fax:(410)779-5707 ORAPHARM1_RESPONSES@fda.hhs.gov	11/7/2022-12/9/2022* FEI NUMBER 3012590153

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Bassem W. Girgis, President

FIRM NAME	STREET ADDRESS
Northern VA Compounders PLLC	23475 Rock Haven Way , Suite 105
CITY, STATE, ZIP CODE, COUNTRY Sterling, VA 20166-4444	TYPE ESTABLISHMENT INSPECTED Producer of 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 WE OBSERVED:

OBSERVATION 1

You produced beta-lactam drugs without providing adequate containment, segregation, cleaning of work surfaces, cleaning of utensils and cleaning of personnel to prevent cross-contamination.

Specifically, you produced beta-lactam drug products in the non-sterile, non-hazardous compounding room (b) (4) of your facility on the same day you produced non-beta lactam drug products. Your records do not indicate if the beta-lactam drugs were contained or segregated from non-beta lactam drug products during production. Your cleaning records indicate that you only cleaned the (b) (4) compounding hoods and work surfaces with (b) (4) and (b) (4) and have not determined that this cleaning method is adequate to prevent cross contamination between the beta-lactam drug products and non-beta-lactam drug products.

- On 08/08/2022, you produced (b) lots of Cephalexin / Prednisone 50/2MG Capsules (Lot #s 08082022@ (b) (4)) in Room (b) (4) on the same day you produced (b) (4) lots of non-beta-lactam drug products. Cephalexin / Prednisone 50/2MG Capsules were produced by (b) (4) Cephalexin and emptying the contents into a mortar and pestle, (b) (4) Cephalexin (b) (4) . Your production records do not indicate in which hood the Cephalexin / Prednisone 50/2MG capsules were produced and if non-beta-lactam drug products were produced in the same hood as the Cephalexin / Prednisone 50/2MG Capsules. Your cleaning records do not indicate the type of cleaning performed after producing the (b) (4) lots of Cephalexin / Prednisone 50/2MG Capsules to ensure work surfaces and personnel were properly cleaned to prevent cross contamination of the non-beta-lactam drug products produced on the same day.

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	Jonathan G Matrisciano, Investigator Daniel J Min, Investigator	X Jonathan G Matrisciano Investigator Signed By: Jonathan G. Matrisciano -S Date Signed: 12-09-2022 18:01:53	12/9/2022

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- On 09/09/2022, you produced (b) (4) of Amoxicillin 100MG/ML Suspension (Lot # 09092022@(b) (4) in Room (b) (4) on the same day you produced (b) (4) lots of non-beta-lactam drug products. Amoxicillin 100MG/ML Suspension was produced by (b) (4) Amoxicillin and emptying the contents into a mortar and pestle, (b) (4) Amoxicillin (b) (4) Your production records do not indicate in which hood the Amoxicillin 100MG/ML Suspension was produced and if non-beta-lactam drug products were produced in the same hood as the Amoxicillin 100MG/ML Suspension. Your cleaning records do not indicate the type of cleaning performed after producing the (b) (4) of Amoxicillin 100MG/ML Suspension to ensure work surfaces and personnel were properly cleaned to prevent cross contamination of the non-beta-lactam drug products produced on the same day.

- On 09/19/2022, you produced (b) (4) of Amoxicillin 100MG/ML Suspension (Lot # 09192022@(b) (4)) in Room (b) (4) on the same day you produced (b) (4) lots of non-beta-lactam drug products. Amoxicillin 100MG/ML Suspension was produced by (b) (4) Amoxicillin and emptying the contents into a mortar and pestle, (b) (4) Amoxicillin (b) (4) . Your production records do not indicate in which hood the Amoxicillin 100MG/ML Suspension was produced and if non-beta-lactam drug products were produced in the same hood as the Amoxicillin 100MG/ML Suspension. Your cleaning records do not indicate the type of cleaning performed after producing the (b) (4) of Amoxicillin 100MG/ML Suspension to ensure work surfaces and personnel were properly cleaned to prevent cross contamination of the non-beta-lactam drug products produced on the same day.

- On 09/21/2022, you produced (b) (4) of Cephalexin / Prednisone 50/2MG Capsules (Lot # 09212022@(b) (4)) in Room (b) (4) on the same day you produced (b) (4) lots of non-beta-lactam drug products. Cephalexin / Prednisone 50/2MG Capsules were produced by (b) (4) Cephalexin and emptying the contents into a mortar and pestle, (b) (4) Cephalexin (b) (4) . Your

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production records do not indicate in which hood the Cephalexin / Prednisone 50/2MG capsules were produced and if non-beta-lactam drug products were produced in the same hood as the Cephalexin / Prednisone 50/2MG Capsules. Your cleaning records do not indicate the type of cleaning performed after producing the (b) (4) of Cephalexin / Prednisone 50/2MG Capsules to ensure work surfaces and personnel were properly cleaned to prevent cross contamination of the non-beta-lactam drug products produced on the same day.

- On 11/02/2022, you produced (b) (4) of Cephalexin / Prednisone 50/2MG Capsules (Lot # 11022022@(b) (4)) in Room (b) (4) on the same day you produced (b) (4) lots of non-beta-lactam drug products. Cephalexin / Prednisone 50/2MG Capsules were produced by (b) (4) Cephalexin and emptying the contents into a mortar and pestle, (b) (4) Cephalexin (b) (4). Your production records do not indicate in which hood the Cephalexin / Prednisone 50/2MG capsules were produced and if non-beta-lactam drug products were produced in the same hood as the Cephalexin / Prednisone 50/2MG Capsules. Your cleaning records do not indicate the type of cleaning performed after producing the (b) (4) of Cephalexin / Prednisone 50/2MG Capsules to ensure work surfaces and personnel were properly cleaned to prevent cross contamination of the non-beta-lactam drug products produced on the same day.

OBSERVATION 2

The (b) (4) intended to render final product sterile was not pharmaceutical grade.

Specifically, you use (b) (4) sterile (b) (4), Catalogue Number (b) (4), to (b) (4) your drug products. The information you provided does not show that the (b) (4), Catalogue Number (b) (4), is a pharmaceutical grade (b) (4). A review of the information available on the manufacture's website shows the (b) (4) is for "research use only." On 10/24/2022, you used a (b) (4) to (b) (4) Hyaluronic Acid Sodium Salt/Lidocaine HCL 11MG/10MG/ML

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Injectable, Lot # 10242022@(b)(4).

OBSERVATION 3

You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically,

- You use non-pharmaceutical grade (b)(4) as an ingredient in the production of non-sterile drug products and cleaning of utensils and glassware utilized in non-sterile drug production.
- You do not perform analytical or microbiological testing of this (b)(4) generated through your (b)(4). This (b)(4) is used in the production of non-sterile drug products.

OBSERVATION 4

The ISO 5 classified aseptic processing areas had difficult to clean, particle-generating and visibly dirty equipment or surface.

Specifically, during the inspection the following deficiencies were observed in the sterile compounding areas of the firm's compounding suite.

- On 11/11/2022, two fluorescent lights fixtures were observed mounted on the rear, (b)(4) surface inside the ISO 5 (b)(4) LFH located in the non-hazardous, ISO 7 Buffer Room (b)(4) which have hard to clean surfaces. The bottom fluorescent light fixture mounted inside the ISO 5 (b)(4) LFH was observed to have an unknown black substance on the bottom front face of the light fixture.
- During production operations on 11/07/2022 and 11/08/2022, a white "adhesive substance" was observed on the plexiglass sash of the ISO 5 (b)(4) LFH located in the non-hazardous, ISO 7 Buffer Room (b)(4)
- During production operations on 11/07/2022, the compounding operator was observed filling

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vials of drug product inside the ISO 5 (b)(4) LFH located in the non-hazardous, ISO 7 Buffer Room (b) (4) using white and blue plastic trays with difficult to clean surfaces. The blue trays were also observed to have an unknown white substance on their surface, and unknown white fibers attached to them.

- On 11/11/2022, what appeared to be broken, white pieces of "plastic" were observed attached on the inside surface of the upper and lower sections on the plexiglass sash of the ISO 5 (b)(4) LFH located in the non-hazardous, ISO 7 Buffer Room (b) (4). The piece of white "plastic" on the lower section of the plexiglass sash had unknown fibers attached to it.
- On 11/11/2022, two florescent light sockets were observed mounted by the rear, (b) (4) surface inside the ISO 5 BSC located in the hazardous, ISO 7 Buffer Room (b) (4) which have hard to clean surfaces. An unknown white substance was also observed above the LED display inside this hood.

OBSERVATION 5

You produced hazardous drugs without providing adequate cleaning of work surfaces to prevent cross-contamination.

Specifically, on 11/14/2022, visible white residue was observed in the (b)(4) (b) (4) Biological Safety Cabinets located in the unclassified hazardous, non-sterile room (b) (4), immediately after you performed (b) (4) cleaning of the room and equipment. White residue was observed inside each hood at the corners where the (b) (4) interior surfaces meet the (b) (4) work surface. A layer of dust and a white powdery substance was observed in the air exhaust space inside the top section of each compounding hood and on each (b) (4) located inside the air exhaust space. A white powdery substance was also observed along the surfaces located outside each compounding hood, with a higher concentration observed outside holes in the (b) (4) sides of each hood.

OBSERVATION 6

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Non-microbial contamination was observed in your production area.

Specifically,

- On 11/11/2022, during a walk-through of the sterile compounding rooms, chipping paint was observed above the doorknob on the door face located inside the hazardous, ISO 7 Anteroom (b) (4).
- On 11/10/2022, during the production of (b) (4) Topical (Lipoderm EQ) 23%/6%/4% Cream lot 11102022@(b)(4) in the non-sterile, non-hazardous compounding room (b) (4), we observed the Pharmacy Technician use the ointment mill located in room (b) (4) that had paint chipping adjacent to the rollers, which are product contact surfaces.
- On 11/15/2022, during the production of Estradiol 1mg/gm (0.1%) cream lot 11152022@(b)(4) in the non-sterile, hazardous room (b) (4), we observed the Pharmacy Technician use the ointment mill located in room (b) (4) that had paint chipping adjacent to the rollers, which are product contact surfaces.

OBSERVATION 7

Personnel conducted aseptic manipulations and placed equipment/supplies in an area that blocked the movement of first pass air around an open unit, either before or after it was filled with sterile product.

Specifically, on 11/07/2022, a Pharmacy Technician was observed producing Trimix Original (PG/PAP/PT), Lot # 11072022@(b)(4) in the ISO 5 (b)(4) LFH located in the non-hazardous, ISO 7 Buffer Room (b) (4) During production, the operator was observed filling vials with drug product using a (b) (4) syringe. During filling, the operator placed her hand directly above a tray of empty and filled sterile vials which blocked first pass air from the HEPA filter above the open vials.

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OBSERVATION 8

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

Specifically, on 11/08/2022, a Pharmacy Technician was observed performing gowning in the non-hazardous, ISO 7 Anteroom (b) (4). While donning gowning materials, the technician was observed using the thumb of her sterile gloved hands to push the sleeves of her sterile gown under the cuff of the sterile glove on the opposite hand. This was done when she donned sterile gloves before performing (b) (4) cleaning in the non-hazardous ISO 7 Anteroom (b) (4) and ISO 7 Buffer Room (b) (4) and when she changed her gloves immediately prior to performing production operations in the non-hazardous, ISO 7 Anteroom (b) (4) and non-hazardous, ISO 7 Buffer Room (b) (4).

OBSERVATION 9

You had inadequate HEPA filter coverage and airflow over the area to which sterile product was exposed.

Specifically, you conducted air pattern analyses (smoke studies) in December 2021 and June 2022 for the ISO 5 Biological Safety Cabinet (BSC) used to produce hazardous, sterile drug products and the ISO 5 (b) (4) Laminar Flow Hood ((b) (4) LFH) used to produce non-hazardous, sterile drug products. The smoke studies performed were deficient:

- The 12/2021 and 06/2022 studies for the BSC and (b) (4) LFH did not include the transfer of all starting components and materials into the ISO 5 classified areas and failed to include all manipulations and transfers performed by the operator during production. In addition, the smokes studies performed in the BSC and (b) (4) LFH failed to simulate the most complex products produced in the BSC or (b) (4) LFH which the firm identified as Bimix Intracavernosal Injection Solution, Trimix Intracavernosal Injection Solution, Quadmix Intracavernosal Injection Solution, and Atropine Ophthalmic Solution.
- The equipment used during the 12/2021 studies did not produce enough smoke so the airflow

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within the BSC and (b) (4) LFH could be adequately visualized.

***DATES OF INSPECTION**

11/07/2022(Mon), 11/08/2022(Tue), 11/09/2022(Wed), 11/10/2022(Thu), 11/11/2022(Fri), 11/14/2022(Mon), 11/15/2022(Tue), 11/16/2022(Wed), 11/17/2022(Thu), 11/18/2022(Fri), 11/28/2022(Mon), 11/29/2022(Tue), 11/30/2022(Wed), 12/01/2022(Thu), 12/02/2022(Fri), 12/09/2022(Fri)

X Daniel J Min
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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."