DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	3/1/2022-3/10/2022*
	FEI NUMBER 3014229024

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Robert A. Harris, Director of Business Development/Facility Manager

FIRM NAME	STREET ADDRESS
North American Custom Laboratories, LLC dba FarmaKeio Superior Custom Compounding	1736 N Greenville Ave
CITY, STATE, ZIP CODE, COUNTRY Richardson, TX 75081-1808	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-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 I OBSERVED:

OBSERVATION 1

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

Specifically,

On 3/1/2022, I observed the Pharmacist in Charge use (b) (4) (b) (4) , non-pharmaceutical grade sterile (b) (4) to (b) (4) sterilize a solution of Sermorelin Acetate 1mg/ml, Lot #34585 with a beyond use date of 05/30/2022. In addition, the (b) (4) test conducted on the non-pharmaceutical grade (b) (4) post compounding was inadequate because no (b) (4) was used while performing the test.

On 2/18/2022, a non-pharmaceutical grade (b) (4) was used to (b) (4) a solution of CJC-1295 Acetate/Ipamorelin Acetate Injection Lot #34383 with a beyond use date of 08/17/2022. An inadequate (b) (4) (b) (4) ((b) (4) test was conducted on that (b) (4) also and the drug product were distributed to patients nationwide.

OBSERVATION 2

Materials or supplies were not disinfected prior to entering the aseptic processing areas.

Specifically,

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On 3/1/2021, a plastic tote containing materials and supplies such as but not limited to sterile tubing, sterile (b) (4) sterile vials and sterile rubber stoppers used in the aseptic compounding of Sermorelin Acetate, Lot #34824, BUD 05/30/2022 was not disinfected when placed in the (b) (4) located in the ISO8 non-sterile compounding room nor were they disinfected when introduced into the ISO5 buffer room or the ISO5 LAFH where aseptic operations are conducted.

OBSERVATION 3

Non-sterilized equipment was used in sterile drug production.

Specifically,

a) On 3/1/2022, I observed your Pharmacist in Charge remove non-sterile scissors and a non-sterile hand held (b) (4) from a drawer located in the ISO5 buffer room, wipe the non-sterile equipment with sterile (b) (4) placed them in the ISO5 LAFH and use them in the (b) (4) process of Sermorelin Acetate Injection Lot #34585, BUD 05/30/2022.

b) On 3/1/2022, upon completion of aseptic activities of Sermorelin Acetate 1mg/ml, Lot #34585 with a BUD of 05/30/2022, I observed your Pharmacist in Charge (PIC) clean/disinfect the ISO5 buffer room floor using (b) (4) a non sterile disinfectant. According to your PIC, the floors of the ISO5 buffer room are disinfected using (b) (4) and (b) (4) a non-sterile quaternary based disinfectant on a (b) (4) basis.

OBSERVATION 4

You did not make adequate product evaluation and take remedial action where actionable microbial contamination was found to be present in an area adjacent to the ISO 5 classified aseptic processing area during aseptic production.

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Specifically,

Your firm conducts environmental sampling (air and surface) of your ISO classified areas every (b) (4) . During the most recent environmental sampling conducted on 10/26/2021, there were actionable microbial contamination in your designated ISO5 areas. Microbial isolates were not sent out for speciation to determine appropriate remedial actions and no assessment was conducted to evaluate whether or not sterile drugs product produced during that timeframe were negatively impacted.

OBSERVATION 5

You produced highly potent drugs without providing adequate containment to prevent cross-contamination.

Specifically,

On 3/1/2022, I observed your technician prepare a batch of (b) (4) vegetarian capsules containing Progesterone 200mg, Lot #34585, BUD 08/21/2022 in your negative pressure hazardous room dedicated to the production of non-sterile drug products containing potent and/or potentially hazardous bulk drug substances such as hormones.

There was visible pink residue located on the ceiling wall directly where the vents to of the (b) (4) containment hoods are located, visible pink residue on the exhaust vent and visible pink residue on the broom kept in the dedicated hazardous room. According to the National Director of Business Solutions, (b) (4) . In addition, finished product capsules of Progesterone 200mg, Lot #34585 were observed in plastic container on a stainless table exposed to the environment.

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Your firm's current controls to contain potent and potentially hazardous non-sterile drug products to prevent cross contamination is insufficient. Approximately (b) (4) batches of Progesterone 200mg vegetarian capsules were produced and about (b) (4) prescriptions were dispensed from September 1, 2021 to March 1, 2022.

OBSERVATION 6

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

Specifically,

1. Your firm routinely uses non-pharmaceutical grade components for compounding drug products. A review of the Certificate of Analysis for various components noted that the following non-pharmaceutical grade components were used in processing injectable drug products:

- CJC-1295 Acetate (b) (4), Lot (b) (4) Exp: 06/02/24 was used in CJC-1295 Acetate/Ipamorelin Acetate (b) (4) mg (b) (4) mg/ml (b) (4) ml) Injection, Lot #34383, BUD: 08/17/2022.
- BPC-157 Acetate (b) (4), Lot (b) (4) Exp: 02/23/2023 was used in BPC-157 Acetate (b) (4) mg/ml (b) (4) ml) Injection, Lot #27757, BUD: 12/01/2021
- Sermorelin Acetate (b) (4), Lot (b) (4) Exp: 11/20/2021 was used in Sermorelin Acetat (b) (4) mg/ml (b) (4) ml) Injection, Lot #32963, BUD: 04/12/2022.

2. Your firm uses a commercially available household detergents, (b) (4) Detergent and (b) (4) to clean/sanitize reusable equipment such glass beakers that are routinely used in the

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production of your compounded sterile injectable drug products. You have not established that your cleaning process is adequate to remove detergent residues from your glassware.

OBSERVATION 7

Smoke studies performed under dynamic conditions are inadequate.

Specifically,

Your firm's dynamic smoke studies only demonstrated your sterile technician ability to set sterile tubing in the (b) (4). You failed to conduct smoke studies on the most critical aspect of your aseptic process which is the (b) (4) of the solution, aseptic filling of your vials and aseptic placement of rubber stoppers to ensure that your sterile technician does not alter, impede or block the unidirectional flow of (b) (4) during aseptic processing.

OBSERVATION 8

Failure to conduct media fills that closely simulates aseptic compounding operations under the worst case, most challenging and stressful conditions.

Specifically,

Your Pharmacist in Charge (PIC) media fill conducted on 3/11/2021 consists of a total of (b) (4) test vials which does not represent routine compounding, worse case scenarios, most challenging and/or stressful conditions. For example, your PIC routinely compounds the following sterile drug product quantities:

- Approximately (b) (4) vials of CJC-1295 Acetate/Ipamorelin Acetate (b) (4) mg (b) (4) mg/m (b) (4) ml) Injection, Lot #34383, BUD 08/17/2022 was produced on 2/18/2022.

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- Approximately (b) (4) vials of BPC-157 Acetate (b) (4) mg/ml (b) (4) ml) Injection, Lot #27757, BUD 12/01/2021 was produced on 8/3/2021.
- Approximately (b) (4) vials of Sermorelin Acetate (b) (4) mg/ml (b) (4) ml) Injection, Lot #32963, BUD 04/12/2022 was produced on 1/12/2022.

***DATES OF INSPECTION**

3/01/2022(Tue), 3/02/2022(Wed), 3/03/2022(Thu), 3/04/2022(Fri), 3/08/2022(Tue), 3/10/2022(Thu)

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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."