

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION									
DISTRICT ADDRESS AND PHONE NUMBER 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969		DATE(S) OF INSPECTION 7/19/2016-8/22/2016* FEI NUMBER 3006141618							
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED John J. Herr, Owner									
FIRM NAME Town and Country Compounding and Consultation Services, LLC		STREET ADDRESS 106 Prospect St #2							
CITY, STATE, ZIP CODE, COUNTRY Ridgewood, NJ 07450-4433		TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drugs							
<p>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.</p>									
<p>DURING AN INSPECTION OF YOUR FIRM WE OBSERVED: OBSERVATION 1 Drug products failing to meet established specifications are not rejected.</p> <p>Specifically,</p> <p>A. From 7/22/2016 through 7/28/2016, twelve (12) vials of Sermorelin/GHRP-6 6mg/3mg Lot # 07172016@1 were dispensed to multiple patients without final review and approval of the Logged Formula Worksheet and finished product testing results. Testing confirmed a sterility failure; however twelve (12) vials of Sermorelin/GHRP-6 6mg/3mg Lot # 07172016@1 had already been delivered to multiple patients.</p> <p>B. For at least three products which your firm has tested, including HCG 1000 Units/vial (Lyophilized) Lot # 05272016@17, Glutathione (PF) 200mg/mL injectable Lot # 120414AS, and Atropine 0.02% ophthalmic Lot # 063015DS, the testing for these lots resulted in potency values outside of specification: 74.3% (spec: (b) (4)), 82.86% at (b) (4) (b) (4) and 91.70% at (b) (4) (spec (b) (4)) respectively. HCG 1000 Units/vial (Lyophilized) Lot # 05272016@17 was dispensed to patients. Your firm was unable to confirm whether Glutathione (PF) 200mg/mL injectable Lot # 120414AS had been dispensed; however your firm has produced this same formulation since and has dispensed it as Lot # 03292016@13 without ensuring that the potency is within specifications for the Beyond Use Dating of 30 days. Atropine 0.02% ophthalmic Lot # 063015DS was not dispensed; however your firm has produced this formulation since and has dispensed it as Lot # 04252016@19 without ensuring that the potency is within specifications for the Beyond Use Dating.</p>									
SEE REVERSE OF THIS PAGE		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="2" style="padding: 5px;">EMPLOYEE(S) SIGNATURE Liatte Krueger, Investigator Nancy F Scheraga, Investigator</td> <td style="padding: 5px; text-align: right;">DATE ISSUED 8/22/2016</td> </tr> <tr> <td colspan="2" style="padding: 5px; vertical-align: bottom;"> <div style="text-align: right;"> <input checked="" type="checkbox"/> Liatte Krueger <small>Liatte Krueger Investigator Signed by: Liatte Krueger -5</small> </div> </td> <td style="padding: 5px;"></td> </tr> </table>		EMPLOYEE(S) SIGNATURE Liatte Krueger, Investigator Nancy F Scheraga, Investigator		DATE ISSUED 8/22/2016	<div style="text-align: right;"> <input checked="" type="checkbox"/> Liatte Krueger <small>Liatte Krueger Investigator Signed by: Liatte Krueger -5</small> </div>		
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<div style="display: flex; justify-content: space-between; font-size: small;"> FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 1 OF 6 PAGES </div>									

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OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not written and followed.

Specifically,

- A. The following poor aseptic practices were observed, which contradict your procedure *SOP 1.40 Compounding Area Requirements (Sterile) (Version 2.0)*:
- i. Incomplete sanitization of supplies such as (b) (4) syringes, (b) (4) and vials (b) (4) the ISO 6 and ISO 7 rooms
 - ii. No disinfection of supplies entering the ISO 5 laminar air hood from the (b) (4)
- B. Your firm has no procedures for (b) (4) qualification of your ISO-5 hood and has not demonstrated uni-directional airflow under 'in situ' or 'dynamic' conditions.

OBSERVATION 3

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

- A. Plastic flaps functioning as separations between ISO 6 and ISO 7 areas and ISO 8 gowning room and ISO 7 area were not observed to be cleaned. Personnel can move into higher-classified areas from lower-classified areas with non-sterile gowns which are reused throughout a single day.
- B. Your firm uses a non-sterile cleaner, with unknown active ingredient, and cleaning wipes to clean the surfaces of the ISO 5 hood as well as the walls and ceiling of the ISO 6 area.

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C. There is no assurance that any cleaning agents used in ISO 5 and ISO 6 areas contain a sporicidal.

OBSERVATION 4

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

Specifically,

- A. Endotoxin testing is not performed on all sterile parenterals made from non-sterile (b) (4). For example, Morphine-Clonidine-Baclofen Intrathecal Lot # 07202016@20 was prepared on 7/20/2016 from non-sterile (b) (4) and was not tested for endotoxin.
- B. There is no formal test method for sterility testing for all products, except for lyophilized products which include HCG and Sermorelin-GHRP-6 (all formulations). The executed method has not been defined to be a compendial method or a method which has been shown to be equivalent or better than the compendial method. Additionally, the (b) (4) Media, which are used for sterility testing cannot support the growth of yeast and molds at (b) (4) which is the temperature in which your firm intends to incubate them at.

In addition, incubators, used for incubation of growth media (b) (4), have not been qualified and the thermometers not calibrated since their installation on an unknown date. On 7/19/2016, the incubator which your firm requires to be operating between (b) (4) was observed to be at 28C while (b) (4) growth media (b) (4) were incubated. 28C is outside of the (b) (4) testing requirement for (b) (4) to support microbial growth.

OBSERVATION 5

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Equipment and utensils are not maintained at appropriate intervals to prevent malfunctions that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

- A. The (b) (4) used for depyrogenating glassware has not been qualified and its thermometer not calibrated since installation of an unknown date. It is routinely used for depyrogenating glassware such as (b) (4) and (b) (4) which are used during production of sterile products, including intrathecal such as Morphine-Clonidine-Baclofen Lot # 07202016@20 which was not tested for endotoxin before dispensing.

Additionally, the (b) (4) has not been (b) (4) and pyrogen testing has not been conducted to validate the (b) (4) depyrogenation (b) (4).

- B. The (b) (4) (b) (4) used for (b) (4) vials and rubber stoppers (b) (4) of sterile drug products, Sermorelin/GHRP-6 and HCG, has not been qualified and its thermometer not calibrated since installation of an unknown date. It is routinely used for sterilizing final containers/closures which are used (b) (4).

Additionally, the program used for (b) (4) these vials and rubber stoppers has not been validated. The location in which the (b) (4) to ensure that it is (b) (4) to sterilize. Since April 2016, your firm has made a total of (b) (4) lots of HCG (1000 units, 5000 units, 6000 units) and (b) (4) lots of Sermorelin/GHRP-6 (3mg-3mg and 6mg-3mg) which have been dispensed to patients.

OBSERVATION 6

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include validation of the sterilization process.

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<p>Specifically,</p> <p>Media fill simulations are not representative of the actual production of aseptically filled sterile products. For example, the production of HCG 6000 units involves (b) (4)</p> <p>(b) (4) and (b) (4)</p> <p>(b) (4) The media fill simulation is limited to (b) (4)</p> <p>However, the media fill simulation on (b) (4) was limited to (b) (4)</p> <p>The media fill simulation was not representative of the most challenging and stressful situation due to the use of different vial size, number of vials filled, time spent producing, and the lack of equivalent aseptic manipulations involved in the lyophilization process.</p>							
<p>OBSERVATION 7</p> <p>Separate or defined areas to prevent contamination or mix-ups are deficient regarding the manufacturing and processing operations.</p> <p>Specifically, with the current design of your aseptic compounding area, your firm produces high risk sterile products using hazardous active ingredients and non-hazardous sterile products in the same positive pressure sterile compounding area as well as in the same ISO 5 hood. The design of your aseptic compounding area does not allow for physical separation from other preparation areas.</p> <p>Additionally, your firm has no procedures for providing adequate containment, segregation, and cleaning of work surfaces, utensils and personnel to prevent cross-contamination between beta-lactams, hazardous, and highly potent drugs that they can (b) (4) for aseptic (b) (4) Your firm has produced Penicillin G and the cytotoxic drug, Anastrozole, and has no formal documentation of the cleaning performed after each was made. On 4/25/2016, your firm produced Penicillin G 10000 units/mL injectable (b) (4) however has no</p>							
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documentation of cleaning and other control systems implemented (b) (4) to ensure that this product did not carry over into other prescriptions produced that day and the next such as: Fentanyl Lot # 04252016@32, Prednisolone 1% PF ophthalmic 1% Lot # 04252016@14, and Alprostadi/Atropine/Papaverine Lot # 04262016@39.

***DATES OF INSPECTION**

7/19/2016(Tue), 7/20/2016(Wed), 7/21/2016(Thu), 7/22/2016(Fri), 7/26/2016(Tue), 7/27/2016(Wed), 7/29/2016(Fri), 8/12/2016(Fri), 8/22/2016(Mon)

8/22/2016

X Nancy F Scheraga

Nancy F Scheraga
Investigator
Signed by: Nancy Scheraga -S

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