

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax: (718) 662-5661	DATE(S) OF INSPECTION 11/13/2018-12/11/2018*
	FEI NUMBER 3006141618

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
John J. Herr, RPh, FIACP, Owner/Pharmacist-In-Charge

FIRM NAME Town and Country Compounding and Consultation Services, LLC	STREET ADDRESS 106 Prospect St Ste 2
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CITY, STATE, ZIP CODE, COUNTRY Ridgewood, NJ 07450-4433	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non Sterile Drug Products.
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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**

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

Specifically, you have the following actionable microbial contamination of the ISO 5 areas:

- ISO Class 5, LFH <sup>(b) (4)</sup> passive air sampling: 1.0 CFU on 6/1/18 15:50;
- ISO Class 5, LFH <sup>(b) (4)</sup> surface sampling: 1.0 CFU on 8/17/18 15:24; and,
- ISO Class 5, LFH <sup>(b) (4)</sup> surface sampling: 1.0 CFU on 8/31/18 13:52.

Products made on these dates include:

- Autologous serum ophthalmics (BUD: 90 days frozen),
- Azithromycin ophthalmic (BUD: 7 days refrigerated or 45 days frozen),
- Droperidol injection (BUD: 3 days refrigerated),
- Fentanyl/Droperidol injection (BUD: 3 days refrigerated),
- Glutathione pre-filled syringe (BUD: 60 days refrigerated),
- Levetiracetam IV bag (BUD: 14 days refrigerated),
- Morphine IV bags (BUD: 3 days refrigerated),
- Morphine injections (BUD: 3 days refrigerated),

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Rachael A Moliver, Investigator	Rachael A Moliver Investigator Signed By Rachael Moliver-S Date Signed 12-11-2018 17:00:58  X _____	DATE ISSUED 12/11/2018

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- Morphine/Clonidine (BUD: 3 days refrigerated),
- Morphine/Bupivacaine/Clonidine injection (BUD: 3 days refrigerated),
- Myer cocktail (BUD: 3 days refrigerated),
- Pilocarpine ophthalmic (BUD: 3 days refrigerated or 45 days frozen),
- Sodium tetradecyl sulfate injection (BUD: 3 days refrigerated or 45 days frozen),
- Tacrolimus ophthalmic (BUD: 3 days refrigerated or 45 days frozen),
- Valproate sodium IV bags (BUD: 14 days refrigerated), and
- Vancomycin ophthalmic (BUD: 14 days refrigerated).

No product impact assessment was conducted and recorded.

**OBSERVATION 2**

Pressure differentials between areas with different air classifications were not monitored prior or during sterile drug production.

Specifically, on 8/13/18 and 8/27/18, daily pressure differentials checks were not performed and recorded in the sterile production suite. Currently, one of your aseptic operators records one pressure differential reading for each magnehelic gauge (b) (4) at a time determined by the same aseptic operator (b) (4)

Products made on these dates include:

- Albumin (human) ophthalmic (BUD: 7 days refrigerated or 90 days frozen),
- Alprostadi/Atropine/Papaverine HCl/Phentolamine mesylate injection (BUD: 3 days refrigerated or 45 days frozen),

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- Alprostadil/Papaverine HCl/Phentolamine mesylate injection (BUD: 3 days refrigerated or 45 days frozen),
- Atropine ophthalmics (BUD: 14 days refrigerated or 45 days frozen),
- Autologous serum ophthalmics (BUD: 90 days frozen),
- Hydromorphone IV bag (BUD: 3 days refrigerated),
- Hydromorphone/Bupivacaine/Clonidine injections (BUD: 3 days refrigerated),
- Baclofen intrathecal syringes (BUD: 3 days refrigerated),
- Morphine intrathecal syringes (BUD: 3 days refrigerated),
- Morphine/Bupivacaine/Clonidine intrathecal syringes (BUD: 3 days refrigerated),
- Methylcobalamin injections (BUD: 3 days refrigerated or 45 days frozen),
- Mitomycin ophthalmic (BUD: 3 days refrigerated or 45 days frozen),
- Myer cocktail (BUD: 3 days refrigerated or 45 days frozen),
- Phenol in cottonseed oil injection (BUD: 3 days refrigerated or 45 days frozen),
- PHMB (polyhexamethylene biguanide) ophthalmic (BUD: 3 days refrigerated or 45 days frozen),
- Procaine HCl injection solution (BUD: 3 days refrigerated or 45 days frozen),
- Riboflavin ophthalmic (BUD: 3 days refrigerated or 45 days frozen),
- Sermorelin injectable (BUD: 3 days refrigerated or 45 days frozen), and
- Sufentanil/Bupivacaine intrathecal (BUD: 3 days refrigerated).

No product impact assessment was conducted and recorded.

**OBSERVATION 3**

Non-microbial contamination was observed in your production area.

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Specifically,

a) On 11/29/18, I observed non-sterile drug products being produced inside (b) (4) of your firm's (b) (4) hoods on top of commercial (b) (4) paper towels, where instruments, equipment, containers and closures are placed to be used in producing non-sterile drug products.

b) On 11/29/18, I observed a (b) (4) graduated cylinder in the cabinet in the general non-sterile production area laying faced down with water droplets in it.

**\*DATES OF INSPECTION**  
11/13/2018(Tue), 11/14/2018(Wed), 11/15/2018(Thu), 11/16/2018(Fri), 11/27/2018(Tue), 11/28/2018(Wed), 11/29/2018(Thu), 12/03/2018(Mon), 12/11/2018(Tue)

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