

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

DISTRICT ADDRESS AND PHONE NUMBER 6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax: (303)236-3100	DATE(S) OF INSPECTION 7/1/2019-7/18/2019*
	FEI NUMBER 3013438582

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Christopher F. Zuccarelli, Chief Operating Officer

FIRM NAME Denver Solutions, LLC DBA Leiter's Health	STREET ADDRESS 13796 Compark Blvd
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CITY, STATE, ZIP CODE, COUNTRY Englewood, CO 80112-7145	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility
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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

Aseptic processing areas are deficient in that walls are not smooth and/or hard surfaces that are easily cleanable.

Specifically,

On 7/1/19, I observed cracks and chips on the acrylic view screens of (b) (4) ISO 5 laminar flow hoods located in Room 195, where (b) (4) occurs. The crack in Hood (b) (4) appeared to be 5-inches in length spreading horizontally along the view screen above the sterile compounding work space. A thick and uneven bead of silicone caulk was used to repair the crack on an unknown date – there were no maintenance records for the repair. The crack and uneven caulk surface is not smooth or hard and therefore may be difficult to disinfect and sanitize.

In addition, your ISO 5 cleaning procedure (SOP 4.400 DEN) does not address cleaning the inside of the acrylic view screens and front surfaces, within the ISO 5 laminar air flow space where sterile air contacts and passes as it flows down to the compounding work space. On 7/8/19, I observed the ISO 5 laminar flow hood cleaning process and noted the inside of the front view screen and front surfaces were not cleaned prior to compounding.

The following drugs products were compounded in Hood (b) (4) between 4/15/19 and 7/5/19:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Zachery L Miller, Investigator	X Zachery L Miller Investigator Signed by Zachery L Miller-S3 Date Signed 07-18-2019 15:21:05	DATE ISSUED 7/18/2019

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DOM	PRODUCT DESCRIPTION
4/15/2019	Neostigmine Methylsulfate 1 mg/mL Injection
4/16/2019	Rocuronium Bromide (10 mg/mL) (Injection) 5 mL in 5 mL
4/17/2019	Neostigmine Methylsulfate (1 mg/mL) (Injection) 4 mL in a 5 mL Syringe
4/17/2019	Atropine Sulfate (0.4 mg/ mL) (Injection) 2.5 mL in a 3 mL Syringe
4/18/2019	Succinylcholine Chloride (20 mg/mL) (Injection) 7 mL in a 10 mL Syringe
4/18/2019	Phenylephrine HCl 100 mcg/mL (0.1 mg/mL) in 0.9% Sodium Chloride (Injection) 5mL in a 5mL Syringe
4/22/2019	Succinylcholine Chloride (20 mg/mL) (Injection) 7mL in a 10mL Syringe
4/30/2019	Stability Batch of Tropicamide 1% - PHENYLEphrine HCl 2.5% in Sterile Water for Injection, Ophthalmic Solution, 2 mL in an 11 mL Dropper Bottle
5/1/2019	Phenylephrine HCl 100 mcg/mL (0.1 mg/mL) in 0.9% Sodium Chloride (Injection) 10mL in a 10mL Syringe
5/2/2019	Lidocaine HCl 2% (20 mg/mL) (Injection) PF 3 mL in a 3 mL Syringe
5/6/2019	Neostigmine Methylsulfate (1 mg/mL) (Injection) 5 mL in a 5 mL Syringe
5/13/2019	Midazolam HCl 5 mg/mL (Injection) 30 mL in a 35 mL Syringe
5/16/2019	Aseptic Process/Operator Qualification: Avastin
5/28/2019	Phenylephrine HCl 100 mcg/mL (0.1 mg/mL) in 0.9% Sodium Chloride (Injection) 10mL in a 10mL Syringe
6/17/2019	Glycopyrrolate (0.2mg/mL) (Injection) 3mL in a 3mL Syringe
6/19/2019	Ketamine HCl (10 mg/mL) 5 mL in a 5 mL Syringe
7/9/2019	Ketamine HCl (10 mg/mL) 5 mL in a 5 mL Syringe

ITEM 2

You compound drugs that are essentially a copy of one or more approved drugs within the meaning of sections 503B(a)(5) and 503B(d)(2).

Specifically, you compound drug products that:

- a) are identical or nearly identical to an approved drug that is not on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing; or
- b) are not identical or nearly identical to an approved drug, but contain a bulk drug substance that is also a component of an approved drug, and for which there is no change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Zachery L Miller, Investigator	X Zachery L Miller Investigator Signed By: Zachery L. Miller-G3 Date Signed 07-18-2019 15:21:05	DATE ISSUED 7/18/2019

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Examples of compounded drug products that are essentially a copy of one or more approved drugs include:

- 1) Glycopyrrolate 0.4 mg per 2 mL,
- 2) Neostigmine methylsulfate 4 mg per 4 mL, and
- 3) Succinylcholine chloride 140 mg per 7 mL

***DATES OF INSPECTION**

7/01/2019(Mon), 7/02/2019(Tue), 7/03/2019(Wed), 7/08/2019(Mon), 7/09/2019(Tue), 7/12/2019(Fri), 7/15/2019(Mon), 7/16/2019(Tue), 7/17/2019(Wed), 7/18/2019(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Zachery L Miller, Investigator	Zachery L Miller Investigator Signed By: Zachery L. Miller-03 Date Signed 07-18-2019 15:21:05 _____ X	DATE ISSUED 7/18/2019