DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	2/12/2018-2/23/2018* FEI NUMBER 3013438582

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Christopher F. Zuccarelli, COO

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

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

Drug products failing to meet established quality control criteria are not rejected.

Specifically, on 02/14/18, I observed an unidentified black material imbedded into the wall of two filled syringes from Phenylephrine HCl injection, 100 mcg/mL, lot 1730021. The firm's approved visual inspection process failed to detect the defects. One syringe was in the released inventory and the other was a reserve sample.

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

2A) On 02/14/18, I observed the QC Supervisor did not perform surface sampling of all equipment I observed used during production on 02/13/18. The QC supervisor failed to follow the approved sampling procedure and the procedure did not include adequate instructions. Further questioning revealed the following:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Nicholas L Hunt, Investigator	X Nicholas L Hunt Investigator Signed By Nicholas L Hunt -S Date Signed 02-23-2018 13 37 49	2/23/2018

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-- The QC Supervisor confirmed the material cart I observed used to hold components prior to introduction into the ISO 5 hood does not get sampled. The material cart was moved throughout ISO 7 Room (b) (4) as needed during production.

-- The QC Supervisor confirmed one of two tables in the middle of the room, which was used extensively throughout production, does not get sampled. I observed the table used to stage materials, write in logbooks, and other functions during production.

-- The QC Supervisor confirmed there was no way to ensure all equipment in the ISO 7 room was sampled when there are multiple units, per the approved surface sampling procedure. Support equipment such as chairs, production carts, material carts, and tables lacked unique identification markings.

2B) The firm had inadequate justification for their non-viable air monitoring procedures inside the ISO 5 areas. The firm's approved environmental monitoring procedure and building management system parameters do not require an investigation until (b) (4) readings above the action limit for non-viable air. (b) (4) readings correspond to a (b) (4) time interval.

OBSERVATION 3

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

Specifically, on 12/06/17, production personnel failed to perform the (b) (4) clean process for ISO 7 Rooms (b) (4) and (b) (4) after an extended loss of differential pressure. The walls, doors/ door frames, windows/ window frames, ceilings, and light fixtures were not disinfected per the approved procedure. Room (b) (4) is the (b) (4) where the ISO 5 hoods are located for aseptic processing operations. Operators moved materials through the improperly cleaned Room (b) (4) into Room (b) (4) to produce Phenylephrine HCl injection, 100 mcg/mL, lot 1730020 on 12/06/17.

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OBSERVATION 4

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically, Operator (b) (6) performed aseptic filling for finished product lots 1730020, 1730021, 1830003, 1830015, 1830018, and 1830020 before he completed his gowning qualification on 02/13/18. No deviation was initiated per the approved procedure, and there was no assessment of the potential impact to the finished product lots.

*DATES OF INSPECTION

2/12/2018(Mon), 2/13/2018(Tue), 2/14/2018(Wed), 2/15/2018(Thu), 2/16/2018(Fri), 2/21/2018(Wed), 2/22/2018(Thu), 2/23/2018(Fri)

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