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	4/9/2018-4/20/2018* FEI NUMBER 3012890460

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
John D. Musil, Founder and Chairman of the Board

FIRM NAME	STREET ADDRESS
Avella of Deer Valley, Inc. Store 38	24416 N 19th Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Phoenix, AZ 85085-1887	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 WE OBSERVED:

OBSERVATION 1

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically,

Appropriate alarms were not set to notify your firm of potential non-viable particle excursions within ISO 5 classified laminar flow hoods and biological safety cabinets. Per your SOP 03HVOS-014, "Environmental Monitoring of the Aseptic Laboratory," ISO 5 classified areas should not exceed (b) (4) non-viable particles per (b) (4) size and (b) (4) non-viable particles per (b) (4) size. However, laminar flow hoods (b) (4) and biological safety cabinets (b) (4) were found with action level alarms set at either (b) (4) non-viable particles per (b) (4)

OBSERVATION 2

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

A. Your production technicians are not visually inspecting your sterile products during packaging

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	Rumany C Penn, Investigator Nayan J Patel, Investigator	X Rumany C Penn Investigator Signed By: 2001149060 Date Signed: 04-20-2018 06:49:34	4/20/2018

and labeling operations as required by your SOP 03HVOS-037 "Testing and Release Criteria for Compounded Sterile Products". On 04/10-11/2018, we observed your production of the following products and noted that your technicians did not perform visual inspection:

a. Magnesium Sulfate 2 g in 50 ml D5W lot 138-20181004@(b) (4) bags
b. Phenylephrine 25 mg in 250 ml NS lot 138-20180504@(b) (4) bags
c. Vancomycin 1.5 g in 500 ml NS lot 138-20180504@(b) (4) bags

B. Since your initial certification of compounding suites on 11/02/2016, your firm has not performed HEPA leak testing on HEPA filters used to maintain an ISO 7 classified environment. You firm's SOP's do not define appropriate requirements for recertification.

C. Your SOP 03HVOS-GEN-011, "Qualification of Vendors" states that "the vendor must be formally reassessed no later that [sic] (b) (4) after their current approval date" but the following vendors and associated materials have not been reassessed within (b) (4) :

a. (b) (4) ; growth media (b) (4)); Last assessed December 2014
b. (b) (4) ; vials used for Iohexol product; No assessment on record

OBSERVATION 3

Drug products are not stored under appropriate conditions of temperature and humidity so that their identity, strength, quality, and purity are not affected.

Specifically,

in the warehouse RCP 4/20/18 NSP 04/20/2018

Your firm did not begin temperature and humidity monitoring until February 09, 2018; however, finished drug products and raw materials have been stored in the warehouse since April of 2017. In addition, your firm cannot provide scientific justification for placement of the single temperature/humidity probe in your warehouse used to store both raw materials and finished sterile drugs.

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CITY, STATE, ZIP CODE, COUNTRY Phoenix, AZ 85085-1887	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

OBSERVATION 4

The labels of your outsourcing facility's drug products are deficient.

Specifically,

The labels of some of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A):

A. The statement "This is a compounded drug." Examples of labels that do not contain this information include:
   a. Vancomycin Inj 1 mg/0.1 mL 0.2 mL PFS
   b. Cyclopentolate HCl/Lidocaine HCl/Phenylephrine HCl/Tropicamide 0.05/1.7/0.5/0.05% 0.5 mL PFS

B. The dosage form of the drug. Examples of labels that do not contain this information include:
   a. Magnesium Sulfate 2 gm in 0.9% Sodium Chloride 50 mL
   b. Phenylephrine 20 mg in 0.9% Sodium Chloride 250 mL
   c. Vancomycin 1.5 gm in 0.9% Sodium Chloride 250 mL
   d. Heparin 10,000 units in 0.9% Sodium Chloride 1000 mL
   e. Cyclopentolate HCl/Lidocaine HCl/Phenylephrine HCl/Tropicamide 0.05/1.7/0.5/0.05% 0.5 mL PFS
   f. Povidone Iodine 5% Drop 2 mL PFS
   g. Povidone Iodine 5% Drop 5 mL
   h. Calcium Gluconate 1 gm in 0.9% Sodium Chloride 50 mL
   i. Oxytocin 30 units in 0.9% Sodium Chloride 500 mL

C. Subject to paragraph (B)(i), a list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient. Examples of labels that do not contain this information include

Prior to February 14, 2019

By 4/20/2018 NP 04/20/2018

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	Rumany C Penn, Investigator Nayan J Patel, Investigator	X Rumany C Penn Investigator Signed By: 2001148009 Date Signed: 04-20-2018 08:49:34	4/20/2018

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d. Heparin 10,000 units in 0.9% Sodium Chloride 1000 mL
e. Cyclopentolate HCl/Lidocaine HCl/Phenylephrine HCl/Tropicamide 0.05/1.7/0.5/0.05% 0.5 mL PFS
f. Calcium Gluconate 1 gm in 0.9% Sodium Chloride 50 mL
g. Oxytocin 30 units in 0.9% Sodium Chloride 500 mL

***DATES OF INSPECTION**

4/09/2018(Mon), 4/10/2018(Tue), 4/11/2018(Wed), 4/12/2018(Thu), 4/13/2018(Fri), 4/18/2018(Wed), 4/19/2018(Thu), 4/20/2018(Fri)

X Nayan J Patel
Investigator
Signed By: 2001658919
Date Signed: 04-20-2018 08:50:51

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