DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	07/20/2015 - 07/29/2015
	FEI NUMBER 3006345305

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: John D. Musil, Pharm.D., Chairman / Founder

FIRM NAME	STREET ADDRESS
Avella of Deer Valley, Inc. dba Avella	23620 N 20th Dr Ste 12
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Phoenix, AZ 85085-0621	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 the system for monitoring environmental conditions.

Specifically, the firm's monitoring program for ISO 5 hood and ISO 7 clean room used to produce sterile drug products in suite (b)(4) is deficient in that:

A. SOP 03 S-05, version 4, effective date 07/07/15 titled "Environmental Monitoring of the Aseptic Laboratory"

a. section 4 states "in house non-viable particle monitoring shall be done (b) (4) " for ISO 5 hood, ISO 7, and ISO 8 environment instead of daily monitoring.

b. section 7 states "viable air sampling for fungus and bacteria should be performed (b) (4) for all ISO classified rooms" instead of daily monitoring.

c. section 10 states "surface/environmental sampling (b) (4) will be performed in house by personnel (b) (4) in the ISO classified areas" instead of daily monitoring.

B. SOP 03 S-04, version 4, effective date 06/30/15 titled "Monitoring of Aseptic Personnel"

a. section 5 states "(b) (4) fingertip sampling shall be conducted (b) (4) instead of at the (b) (4) (b) (4) .

b. section 4 states "body sampling shall be conducted (b) (4) in the 503A pharmacy" when in actuality the firm monitors (b) (4) .

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Roger F Zabinski, Investigator Sangeeta M. Khurana, Investigator	DATE ISSUED 07/29/2015

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OBSERVATION 2

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

Specifically,

SOP 03 OS-04, version 1, effective date 06/02/2015 titled "Cleaning of the Outsourcing Facility" and SOP 03 S-02, version 5, effective date 06/18/2015 titled "Cleaning of the(b) (4) Pharmacy" fail to include a requirement for cleaning of the chairs used in the aseptic labs. On 7/21/2015 we observed a technician manufacturing sterile drug product in the outsourcing facility while sitting on a chair that is not impervious or easily cleanable, and may not ensure aseptic cleaning. The firm has no other SOP to address the cleaning of these chairs and no cleaning log to show that the chairs are cleaned.

OBSERVATION 3

The labels and containers for some of the drug products you produce do not contain information required by section 503B(a)(10)(A) and 503B(a)(10)(B).
Specifically, the following information is not found on some of your drug product labels:

A. The statement, "This is a compounded drug."
B. Storage and handling instructions.
C. The statement, "Not for resale."
D. The dosage form.
E. A list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.
F. Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088.

Examples of drug product labels and container labels with these deficiencies include the following:

- Magnesium/Soy Protein 60 mg/11.73 mg/mL Sus
- Tacrolimus 1 mg/mL Sus
- Budesonide/Tobramycin 5 mg-80 mg/L Nasal Rinse
- Progesterone 100 mg SR Cap
- Progesterone 400 mg Sup
- Leuprolide Acetate 1 mg/0.2 mL
- Mitomycin 0.02% PF GTT (2 mL)
- Progesterone 50 mg/mL Inj
- Methotrexate 400 mcg/0.1 mL PFS
- Hepa/Lido/NABC 1176.47 U/mL/1.18%/2.47% IRR
- Bevacizumab 1.25 mg/0.05 mL

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- Iohexol 240 mg/mL 5 mL SDV
- Povidone Iodine 5% Drop 5 mL
- Dexamethasone inj. 400 mcg/0.1 mL (0.2 mL PFS)

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