DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

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

Specifically,

(A) The firm's SOP 03HVOS-GEN-011 approved 02/10/2017 titled "Qualification of Vendors" describes the process for qualification/approval of vendors and SOP 03HVOS-039 titled "Analytical Testing Laboratory Qualification Procedure" approved 04/10/17 describes guidelines for selection, evaluation and supplier qualification process for Analytical testing facilities used to test outsourced products for sterility, potency and/or endotoxins.

The Quality Assurance, Director of Supply Chain Management and Director of Laboratory Operations are responsible for ensuring compliance with this SOP.

(i) The firm provided a list of their fourteen (14) vendors that supply different drug components, container closures, testing and monitoring services. Seven (7) vendors are not qualified by the firm. Out of seven, two (2) vendors were qualified in 2013 and one (1) was qualified in 2014. None of the vendors have been re-qualified every (b) (4) required by the vendor qualification SOP’s.

(ii) The vendors that are marked even qualified by the firm lack complete documentation required by the SOP such as form GF-27 “Vendor Qualification Questionnaire” and/or form QF-03 “Outside Lab Quality Audit”.

AMENDMENT 1
In addition, the firm failed to collect licensing, accreditations, FDA registration and other critical information for several vendors.

In 2017, the firm compounded and distributed (b) (4) units of Bevacizumab dosage in syringes and vials that were procured from these vendors and finished product was tested for release by these vendors.

(b) The quality unit fails to follow up on the deficiencies observed during analytical lab qualification audit. The quality does not assure and document that adequate corrective and preventive action are implemented by the vendor; prior to its approval as a qualified analytical service provider. For example,

(b) (4) was audited by Avella Specialty Pharmacy on 10/24/2013. Five items on the audit checklist used to evaluate the qualification status of the laboratory were marked as: N1 = Needs Improvement. (b)(4) was approved as qualified supplier for analytical services without any follow up on any corrective and preventive actions taken on the five items that needed improvement. (b)(4) has been providing analytical services to Avella Specialty Pharmacy since 2013 and has never been re-audited.

**OBSERVATION 2**
Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the equipment to produce aseptic conditions.

Specifically,

The firm used (b) (4) as sporidical agent in the ISO 5 hoods with contact time of (b) (4) .

The direction for use as sporicide on the (b) (4) container label indicates that the surface should (b) (4) of contact time for (b) (4) . The firm did not perform any sporicide qualification studies for selecting (b) (4) .

**OBSERVATION 3**

**AMENDMENT 1**

SEE REVERSE OF THIS PAGE

Sangeeta M Khurana, Investigator-GDUFA
Marijo B Kambere, Investigator
The container labels of your outsourcing facility's drug products are deficient.

Specifically,

The labels of several compounded drug at your outsourcing facility do not include information required per section 503B (a) (10) (A) of FDCA.

A. The statement “This is a compounded drug” is not included:

Examples of labels that do not contain this information include:

(i) Vancomycin Inj 1 mg/0.1 mL 0.2 mL PFS
(ii) Moxifloxacin Inj 150 mcg/0.1 mL 0.2 mL PFS
(iii) Dexamethasone Inj 400 mcg/0.1 mL 0.2 mL PFS
(iv) 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 is not included:

Examples of labels that do not contain this information include:

(i) Iohexol 300 mg/mL 5 mL SDV
(ii) Cyclopentolate HCl/Lidocaine HCl/Phenylephrine HCl/Tropicamide 0.05/1.7/0.5/0.05% Drop 0.5 mL PFS
(iii) Povidone Iodine 5% Drop 5 mL PFS

This is a repeat observation from previous FDA inspection.

AMENDMENT 1
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
John D. Musil, Pharm.D., Founder and Chairman

FIRM NAME
Avella Specialty Pharmacy

STREET ADDRESS
23620 N 20th Dr Ste 12

CITY, STATE, ZIP CODE, COUNTRY
Phoenix, AZ 85085-0621

TYPE ESTABLISHMENT INSPECTED
Outsourcing facility

DATES OF INSPECTION
4/10/2018-4/19/2018

FED NUMBER
3006345305

*DATES OF INSPECTION

AMENDMENT 1

SEE REVERSE OF THIS PAGE

Sangeeta M Khurana, Investigator-GDUFA
Marijo B Kambere, Investigator

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4/19/2018