DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	4/10/2018-4/19/2018* FEI NUMBER 3006345305

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

FIRM NAME	STREET ADDRESS
Avella Specialty Pharma	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

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 4/10/17 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".

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Sangeeta M Khurana, Investigator-GDUFA Marijo B Kambere, Investigator Sangeeta M Khurana Investigator-GDUFA Signed By: Sangeeta M. Khurana S X Date Signed: 04/19/2018 10:08:27	4/19/2018

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CITY, STATE, ZIP CODE, COUNTRY Phoenix, AZ 85085-0621	TYPE ESTABLISHMENT INSPECTED Outsourcing facility

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 sporicidal 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). The firm did not perform any sporicide qualification studies for selecting (b) (4) of contact time for (b) (4).

OBSERVATION 3

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	Sangeeta M Khurana, Investigator-GDUFA Marijo B Kambere, Investigator	X Sangeeta M Khurana Investigator-GDUFA Signed By: Sangeeta M Khurana S Date Signed: 04-19-2018 10:05:27 EDT	4/19/2018

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CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Phoenix, AZ 85085-0621	Outsourcing facility

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.

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***DATES OF INSPECTION**

4/10/2018(Tue), 4/11/2018(Wed), 4/12/2018(Thu), 4/13/2018(Fri), 4/16/2018(Mon), 4/17/2018(Tue), 4/18/2018(Wed), 4/19/2018(Thu)

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