DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	7/11/2016-7/22/2016* FEI NUMBER 3005247494

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Reggie L. Orchid , Vice-President Operations

FIRM NAME	STREET ADDRESS
Advanced Pharma Inc.	9265 Kirby Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Houston, TX 77054-2520	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

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.

Specifically,

A) Your firm uses non-sterile (b) (4) and Sterile (b) (4) for the sanitization of the interior of the (b) (4) ISO 5 Laminar Air Flow hoods.

The (b) (4) are (b) (4) before use. However, the (b) (4) is not sterilized prior to use.

In addition, your firm has no data to demonstrate that the (b) (4) can be utilized as a sporicidal disinfectant.

B) Your media fill process simulations are not performed under the most stressful or challenging conditions. For example, your media fill for (b) (4) utilized a total of (b) (4) (b) (4). The majority of the (b) (4) the media fill consisted of (b) (4).

On 4/22/16, your firm produced a lot of Phenylephrine 100mcg/ml in Normal Saline in Syringes (lot #4/22/16 1310 830-61(s)) which totaled (b) (4) units.

THIS IS A REPEAT OBSERVATION FROM THE PREVIOUS INSPECTION.

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OBSERVATION 2
Test procedures relative to appropriate laboratory testing for sterility and pyrogens are not written.

Specifically,

A) Your firm does not conduct testing for endotoxin for any epidural drug products. For example,

1. Fentanyl (2mcg/ml) and 0.125% Bupivicaine HCl PF in 150ml Bag, lot #6/27/16 1021 21915P (Expiration date: 9/10/2016) was produced on 6/27/16 and distributed to consignees.

2. Morphine Sulfate PF 1mg/ml in 2ml vial, lot #6/29/16 1045 24142EPF, was produced on 6/29/16 and distributed to consignees.

B) Your firm has not conducted suitability testing for approximately (b)(4) % of the sterile, finished drug products distributed. To date, suitability testing has been performed for various products including the following: Cefazolin, lot #1/21/15 0925 000-6015P (b) (4) and Propofol Emulsion, lot #2/4/5 1442 192-851625 (b) (4) .

OBSERVATION 3
Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically, your firm utilized a contract testing laboratory between 2014-2016 to conduct potency testing on approximately (b)(4) lots of sterile, finished drug products in order to establish Beyond Use Dating (BUD) for the products. (b) (4) of the lots were not distributed.

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However, your firm does not conduct routine potency testing for any sterile, finished drug products released for distribution. Between 12/1/15 and 5/31/16, your firm produced and distributed a total of (b) (4) lots of finished, drug products which were not tested for potency.

Some examples of lots of finished drug products which were not tested for potency include the following:

A. Norepinephrine Bitartrate 8 mg in 5% Dextrose 250 ml Bag , lot #7/1/16 0300 815-25(P) (Distributed to a consignee on 7/12/2016)

B. Phenylephrine HCl (40mcg/ml) in Sterile Water for Injection, 10ml BD Syringe, lot #6/2/16 0904 80461S (Distributed to a consignee on 7/11/2016)

C. Fentanyl Citrate (10mcg/ml) in 0.9% Sodium Chloride 100ml Bag, lot #6/1/16 1800 210-10(P) (Distributed to a consignee on 7/12/2016)

OBSERVATION 4
Procedures describing the calibration of instruments, apparatus, gauges and recording devices are not written or followed.

Specifically, your firm has utilized the (b) (4) since (b) (4) to monitor temperature, relative humidity, and (b) (4) in the controlled areas. The (b) (4) have not been calibrated since installation. To date, written procedures describing the calibration of the (b) (4) have not been established.

OBSERVATION 5
The labels of your outsourcing facility's drug products are deficient.

The following information is not found on some of your drug product labels, as required by section 503B(a)(10)(A):

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1. The dosage form of the product.

Examples of drug product labels that do not contain this information include:

- Magnesium Sulfate 2 gm in NS 50ml
- Ephedrine Sulfate in 0.9% Sodium Chloride 50mg/10ml
- Fentanyl in 0.9% Sodium Chloride 1250mcg/250ml

2. A list of active ingredients and inactive ingredients, identified by the quantity and proportion of each ingredient:

An example of a product and container label which does not contain this information includes the following: "Phenylephrine 100mcg in Sterile Water for Injection (1mg/10ml)"

***DATES OF INSPECTION**
7/11/2016(Mon),7/12/2016(Tue),7/13/2016(Wed),7/14/2016(Thu),7/15/2016(Fri),7/18/2016(Mon),7/22/2016(Fri)

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	Stephen D Brown, Investigator	X Stephen D Brown Investigator Signed By: Stephen D Brown	7/22/2016