DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Los Angeles District Office 19701 Fairchild Irvine, CA 92612 949-608-2900 Industry Information: www.fda.gov/oc/industry	13Mar2017 - 23Mar2017
	FEI NUMBER 3013341563

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Navid (NMI) Vahedi, PharmD., Owner

FIRM NAME	STREET ADDRESS
Fusion IV Pharmaceuticals, Inc. dba Axia Pharmaceutical	1990 Westwood Blvd Ste 135
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Los Angeles, CA 90025-4650	Producer of Sterile Drug Products

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

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

Specifically,

A. You did not perform investigations into the root cause of media fill sterility failures for media fill runs performed in ISO 5 Laminar Flow Workstations (LAFWs) from (b) (4) . Turbidity was observed in the growth promotion media for (b) (4) media fill runs initiated between (b) (4) . Additionally, you failed to investigate the root cause of the following sterility failures observed during media fill validation runs prior to producing and distributing sterile drug products:

(b) (4)

B. You have never performed media fill validation runs on the (b) (4) Stoppering and Capping machine (PennTech automated vial filling machine) located in the ISO 5 filling room. According to "Log of (b) (4) Line Report" printed 20Mar2017, you produced (b) (4) batches of sterile drug products on the PennTech automated vial filling machine between (b) (4)

C. You have not performed a Smoke Pattern Test in your "ISO 5 Filler Room" where the PennTech automated

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vial filling machine is used to (b) (4) of product into vials ranging between (b) (4) (b) (4)

D. During preparation of (b) (4) in the ISO 5 classified workstation # (b) (4) on 13Mar2017, an individual was observed placing (b) (6) arm in the path of unidirectional airflow directly above the (b) (4) portion of a partially filled syringe. The contents of the syringe were being (b) (4) of (b) (4) (b) (4) (Total Parenteral Nutrition) Rx number (b) (6).

E. You failed to perform growth media promotion testing for (b) (4) t growth medium (b) (4) lot numbers: (b) (4), (b) (4), expiration dates: (b) (4) respectively, prior to use. (b) (4) media (b) (4) were used to fill vials during execution of media fill validation batches initiated between (b) (4). For example, positive and negative control experiments for either lot of (b) (4) growth media (b) (4) were not performed prior to use.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically,

A. The following was noted during a review of the Installation and Operational Qualification (IOQ) and Performance Qualification (PQ) for the (b) (4) dated 03May16 and 04May16, respectively. This (b) (4) is used for (b) (4) sterilization of (b) (4) drug products, as well as for sterilization of equipment and utensils used during preparation of sterile drug products.

(b) (4) were not (b) (4) identified during the IOQ.

2) The (b) (4) temperature failed to meet pre-determined criteria of (b) (4) batches for

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"PQ Test Case (b) (4) Verification for (b) (4)

3) The (b) (4) temperature failed to meet pre-determined criteria of (b) (4) batches for "PQ Test Case(b) (4) (b) (4) Verification for Equipment".

4) The (b) (4) temperature failed to meet pre-determined criteria of (b) (4) batches for "PQ Test Case(b) (4): (b) (4) Verification for Vial (b) (4)

The "Performance Qualification Summary Report for the (b) (4) ", Report ID VAL-15-010, was approved by the Director of Quality and Sterile Operations on 01Aug16.

B. The (b) (4), which is used to (b) (4) sterilize (b) (4) injectable drug products at (b) (4), did not meet the required (b) (4) temperature of (b) (4) (b) (4) batches during performance qualification (PQ) of (b) (4) preparations. There was no data to show the (b) (4) was capable of maintaining a (b) (4)

Although the "Performance Qualification Protocol for the (b) (4) (b) (4) " was pre-approved by the QA Manager on 30Jun2016 and executed between 30 Jun2016 and 01Jul2016, the Final Report titled "Performance Qualification Summary Report for the (b) (4) (b) (4) was written and approved on 21Mar17.

C. Records were insufficient regarding incubation of (b) (4) as follows:

1) According to manufacturer's instructions, (b) (4) are required to be at (b) (4) incubator(b) (4) which is used for (b) (4) was never qualified or calibrated, and the temperature at the time of incubation was not recorded.
2) According to manufacturer's instructions, (b) (4) (b) (4) qualification are required to be incubated for (b) (4) Documentation is not available to demonstrate these (b) (4) were incubated for the appropriate timeframe and at the appropriate temperature.

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OBSERVATION 3

Drug product containers and closures were not sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

Specifically,

A. You failed to demonstrate control of endotoxin and bioburden through the (b) (4)
For example:

1) You did not show through validation studies that the (b) (4) process and equipment were capable of reducing endotoxin to an acceptable level.

2) The following was noted regarding (b) (4) (b) (4) performance qualification (PQ) activities, conducted according to protocol VAL 15-025, approved 23Jun16:

a. The PQ records do not include (b) (4) or describe placement of equipment such as (b) (4) (b) (4)

b. The PQ records do not describe the quantity o (b) (4) during performance qualification.

c. The PQ records do not include the (b) (4) incubation dates, times, and temperature. According to the (b) (4) manufacturer's instructions, (b) (4) are required to be incubated (b) (4). The (b) (4) incubator, which is used for (b) (4), was never qualified or calibrated, and the temperature at the time of incubation was not recorded.

B. You did not demonstrate endotoxin reduction during qualification of the (b) (4) (b) (4) For example, you did not use (b) (4) in the qualification runs. According to the Pharmacist in Charge, the firm uses this machine to depyrogenate and sterilize glass vials prior to being filled with (b) (4) drug product.

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OBSERVATION 4

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

You do not perform environmental monitoring (EM) for microbiological contamination of viable air and surfaces at least daily in the five (5) laminar air flow work stations (LAFWs) located in the ISO 7 Filling Room, for lots categorized as "Not a Batch". "Not a Batch" is defined as (b) (4) . In addition, you do not perform EM in the event of multiple "Not a batch" lots produced on the same day in the same LAFWs.

OBSERVATION 5

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically,

A. You have not completed method suitability testing of your (b) (4) sterility test for any of the (b) (4) drug products that are sterility-tested with this method.

B. You have not performed an antimicrobial effectiveness study to verify that the preservative system is effective and protects the product over its shelf life under expected conditions of use.

For example, on 12Jan17, you produced (b) (4) 30 ml Multi-dose vials of Methylcobalamin, 1 mg/ml Injectable, Lot Number 01122017+44269, and assigned a beyond use date (BUD) of 11Jul17; however, you have not verified the preservative would be effective throughout this product's shelf life.

OBSERVATION 6

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

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Specifically,

The Labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A). Specifically, the statement "Office use only" is not on your drug product labels. Labels for the following drug products do not contain this statement:

- Methionine/Inositol/Choline (MIC) Injectable, 25mg/50mg/50mg/mL, 30mL Multi-dose Vial
- Testosterone Cypionate Injectable, 200mg/mL, CIII, 10mL Multi-dose Vial
- Human Chorionic Gonadotropin (Hcg) Injectable, 1000IU/mL, 10mL Multi-dose Vial
- Hyrdoxocobalamin Injectable, 1mg/mL, 30mL Multi-dose Vial
- Methylprednisolone Acetate (PF Injectable Suspension), 80mg/mL, 2mL Single-dose Vial
- Chromium Picolinate Injectable, 200mcg/mL, 30mL Multi-dose Vial
- Methylcobalamin Injectable, 1mg/mL, 30mL Multi-dose Vial
- Ascorbic Acid (Vitamin C) Injectable, 500mg/mL, 30mL Multi-dose Vial
- B-Complex Injectable, B Vitamin Complex, 30mL Multi-dose Vial
- Cyanocobalamin Injectable, 2000mcg/mL, 30mL Multi-dose Vial
- Pyridoxine Hydrochloride Injectable, 100mg/mL, 30mL Multi-dose Vial
- Gluthathione Injectable, 200mg/mL, 30mL Multi-dose Vial
- Triamcinolone Diacetate Injectable Suspension, 40mg/mL, 10mL Multi-dose Vial
- Methylprednisolone Acetate Injectable Suspension, 100mg/mL, 10mL Multi-dose Vial
- Dexamenthasone LA injectable Suspension, 16mg/mL, 10mL Multi-dose Vial

OBSERVATION 7

Strict control is not exercised over labeling issued for use in drug product labeling operations.

Specifically,

You have (b) (4) container labels which include information to facilitate adverse event reporting. However, (b) (4)

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(b) (4) labels possesses both the adverse event reporting number (1-800-FDA-1088) and web address (www.fda.gov/medwatch). Furthermore, there are no records to indicate (b) (4) adverse events reporting label was used to label drug product packaged at your firm.

OBSERVATION 8

Your outsourcing facility did not submit an initial report to FDA identifying products compounded during the previous six months as required by section 503B(b)(2)(A).

*DATES OF INSPECTION
3/13/2017(Mon),3/14/2017(Tue),3/15/2017(Wed),3/16/2017(Thu),3/17/2017(Fri),3/20/2017(Mon),3/21/2017(Tue),3/22/2017(Wed),3/23/2017(Thu)

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