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	12/2/2019-12/20/2019* FEI NUMBER 3013341563

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Navid Vahedi, President

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

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

Buildings used in the manufacture, processing, packing or holding of drug products are not maintained in a clean and sanitary condition.

Specifically,

A.

On 12/2/2019, I observed (b) (4) laminar flow bench (b) (4) with yellow staining on the inside of the ISO-5 laminar flow workstation on the HEPA grid. Aseptic filling of drug products occurs in this LFW. The firm could not provide documentation of the last batches of drug product produced in this laminar flow hood.

B. On 12/2/2019, I observed yellow peeling tape on the aseptic worksurface inside of ISO-5 laminar flow wokstations; (b) (4) . The tape was fraying and half of the yellow tape line was off. The line was being used as a line of demarcation for the aseptic operators. On 12/3/19, Methylprednisolone Acetate lot 12022019+53297 was being filled and (b) (4) in (b) (4) .

C. On 12/2/2019, I observed a black plastic tube inside the ISO-5 Laminar flow (b) (4) station acting as a particle counter. The black plastic tubing had double sided tape around the top which was

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frayed. On 12/3/19, Methylprednisolone Acetate lot 12022019+53297 was being filled and (b) (4) in this LFW.

OBSERVATION 2

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

Specifically,

A.

Observed on 12/3/2019, during the aseptic processing of Methylpredinsolone Acetate batch 12022019+53297, technician dispensed (b) (4) from the (b) (4) bag onto the table top of the laminar flow workstation and use (b) (4) each vial (Theoretical yield (b) (4) unit vials). Your firm is not following your standard operating procedure document number 4.71 titled, "Aseptic Processing Requirements and Technique" which reads in section 7.1.10, "Compounding personnel shall not use a gloved hand to touch any product contact surfaces, but should use appropriately sterilized utensils (e.g., forceps), as needed."

B.

Observed on 12/11/2019 in the ISO 5 aseptic filling room, aseptic filling operator performed (b) (4) interventions during the (b) (4) filling of Glutathione batch 12102019+53365 without routinely sanitizing hands. I observed the operator open the cabinet door of the filling machine (ISO 5) and perform interventions at least (b) (4) stopping and starting the machine, dispensing components in the hopper, manipulate capped vials inside the filling machine for approximately a (b) (4) period. Your firm is not following your standard operating procedure document number 4.71 tiled, "Aseptic

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Processing Requirements and Technique" which reads in section 7.1.11, "Compounding personnel shall change sterile gloves on a frequent basis or disinfect them routinely with (b) (4) during prolonged compounding manipulations."

C.

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 solutions. You failed to investigate the root cause for the following media fill failures prior to producing and distributing sterile products. See four examples found below:

1.

Run (b) (4) (b) (4) ml syringe); Summary report (b) (4) RPT notes the following fill runs passed:

Run Number	Result
(b) (4)	Pass
	Pass
	Pass

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However, the "Summary of Validation Discrepancies" reads "there was a failure noted". Media fill number (b) (4) is noted as failed. Your firm failed to investigate the failure per your SOP 4.80, titled, "Validation Protocol for Aseptic Process Simulations". It reads in section 9.1.1.1., "Any positive units, deviations, or discrepancies must be investigated and shown to have no impact on the validation. In addition, your firm could not provide the batch production record for this failed trial run (b) (4)

2.

Run Type (b) (4) (b) (4) ml vial); Summary report (b) (4) RPT notes the following media fill runs passed:

Run Number	Result
(b) (4)	Pass
	Pass
	Pass

The "Summary of Validation Discrepancies" reads "there was a failure noted". The summary report does not list the failure. However, it was found media fill run (b) (4) ((b) (4)) contained the failure. The batch production record for media fill run (b) (4) ((b) (4) reads the media solution was aseptically (b) (4) The solution "turned turbid after (b) (4) and was not filled into the vials". Media fill run (b) (4) was replaced with media fill run (b) (4).

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Your firm failed to investigate the failure per your SOP 4.80, titled, "Validation Protocol for Aseptic Process Simulations". It reads in section 9.1.1.1., "Any positive units, deviations, or discrepancies must be investigated and shown to have no impact on the validation.

3.

Run Type (b) (4) ((b) (4) validation) (b) (4) filling machine Aseptic Processing Simulation ((b) (4) ml vial); Summary report (b) (4) RPT notes the following fill runs passed:

Run Number	Result
(b) (4)	Pass
	Pass
	Pass

The "Summary of Validation Discrepancies" reads "there was a failure noted". The summary report does not list the failure. Your firm failed to investigate the failure per your SOP 4.80, titled, "Validation Protocol for Aseptic Process Simulations". It reads in section 9.1.1.1., "Any positive units, deviations, or discrepancies must be investigated and shown to have no impact on the validation.

4.

Run Type (b) (4) (b) (4) ml vial); Summary report (b) (4) RPT notes the following media fill runs passed:

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Run Number	Result
(b) (4)	Pass
	Pass
	Pass

The "Summary of Validation Discrepancies" reads "there was a failure noted". The summary report does not list the failure. However, it was found media fill run (b) (4) ((b) (4)) contained the failure. The batch production record for media fill run (b) (4) ((b) (4) 3) reads "APS(b) (4) has been cancelled due to turbidity of solution after approximately (b) (4) in room temperature." Media fill run (b) (4) was replaced with media fill run(b) (4)

Your firm failed to investigate the failure per your SOP 4.80, titled, "Validation Protocol for Aseptic Process Simulations". It reads in section 9.1.1.1., "Any positive units, deviations, or discrepancies must be investigated and shown to have no impact on the validation.

Failure to perform investigations into the root cause of media fill sterility failures for media fill runs is a repeat objectionable observation listed on the FDA 483 inspection dated March 2017.

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D.

All media vials from the Aseptic Process Simulation are not being incubated. For example; the Aseptic Processing simulations for the (b) (4) Vial filler Report ID# (b) (4) details Run (b) (4) (lot number (b) (4) yielded (b) (4) (b) (4) ml vials; however only (b) (4) were incubated.

Run (b) (4) lot number (b) (4) yielded (b) (4) only (b) (4) vials were incubated. Run (b) (4) lot number (b) (4) yielded (b) (4) vials only (b) (4) vials incubated. Justification provided in the batch record stated it was due to "space constraints". Therefore, your firm selected every (b) (4) vial to be incubated.

E.

Your firm is not following SOP 3.40 Cleaning and Disinfection in Sterile Compounding Areas, version 4 section 4.3. Quality Unit is responsible for reviewing documentation of the cleaning of the contracted cleaning personnel performing the cleaning of the cleanroom suites and laminar flow workstations. There is no review by signature on the (b) (4) cleaning logs completed by the cleaning contractor for the months of October and November 2019. There is no Check By signature on the (b) (4) and (b) (4) cleaning logs completed by the cleaning contractor for the months of October and November 2019.

OBSERVATION 3

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

A.

Deviation DEV-2018-002 investigation report details a sterility failure for five drug lots. Your firm

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invalidated the initial sterility failure without adequate justification to support the probable root cause of analytical lab error and noted no recall was necessary due to no patients had reported adverse events. Furthermore, the investigation did not identify the organisms which caused the contamination to the genus or species level or perform a gram stain per the OOS.
The following are the drug product batches:
Alprostadil 40mcg/Papaverine 30mg/Phentolamine 2 mg; batch lot 02052018+48999
Alprostadil 60mcg/Papaverine 30mg/Phentolamine 2 mg/Atropine 0.15 mg; batch lot 02192018+49094
Alprostadil 60mcg/Papaverine 30mg/Phentolamine 2 mg/Atropine 0.15 mg; batch lot 01152018+48848
Alprostadil 40mcg/Papaverine 25mg/Phentolamine 0.5 mg/Atropine 0.1 mg; batch lot 02212018+49131
Alprostadil 10mcg/Papaverine 30mg/Phentolamine 1 mg; batch lot 02262018+49157

The batches were quarantined in the (b) (4) however, they were inadvertently distributed and sent to customers due to the label being half applied and fell off. The report stated the customers were contacted and notified the samples were under additional testing (Contract lab testing) however, there is no documentation of customers who were contacted and with whom your personnel spoke with. It was also stated in the investigation report "there is no cause for concern or recall necessary as independent testing revealed them to have been clear of contamination. Furthermore, by the time the mistake release had been discovered, no patient had reported any adverse events" The following lots were released and distributed to patients:

Alprostadil 60mcg/Papaverine 30mg/Phentolamine 2 mg/Atropine 0.15 mg; batch lot 02192018+49094
Alprostadil 40mcg/Papaverine 25mg/Phentolamine 0.5 mg/Atropine 0.1 mg; batch lot 02212018+49131

The following lots were rejected:
Alprostadil 40mcg/Papaverine 30mg/Phentolamine 2 mg; batch lot 02052018+48999
Alprostadil 60mcg/Papaverine 30mg/Phentolamine 2 mg/Atropine 0.15 mg; batch lot 01152018+48848
Alprostadil 40mcg/Papaverine 25mg/Phentolamine 0.5 mg/Atropine 0.1 mg; batch lot 02212018+49131

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OBSERVATION 4

Employees are not given training in the particular operations they perform as part of their function, current good manufacturing practices and written procedures required by current good manufacturing practice regulations.

Specifically,

A.

Quality Control technician (initials (b) (6)) performing the sterility testing and the endotoxin testing for finished drug products has no documented training for conducting the QC sterility and endotoxin tests or general current good manufacturing practice training or current good documentation practice training. Since the QCs technician hire date of (b)(6) the following analysis have been completed by this technician:

(b) (4) finished drug product lots ran using the (b) (4) sterility test method

(b) (4) finished drug product lots using the (b) (4) sterility

(b) (4) samples ran for endotoxin testing of the finished drug products

B.

Process Engineer (b) (6) performing the labeling of Triamcinolone acetate lot 12032019+53303 and the visual inspection on the (b) (4) (b) (4) visual inspection machine has no documented training of reading procedures, 5.40 "Policy on Label Control" and 2.87 "Visual Inspection of Finished Pharmaceuticals".

C. Quality Systems Manager (initials (b) (6) training file contained no documentation for reading of the firm's SOP's: 5.40 "Policy on Label Control" and 2.87 "Visual Inspection of Finished Pharmaceuticals".

OBSERVATION 5

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Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that conform to appropriate standards of identity, strength, quality and purity.

Specifically,

A. Growth Promotion testing of the (b) (4) used in the Aseptic Process Simulations are challenged with only two organisms; Bacillus subtilis and Candida Albicans. The testing of only two organisms does not demonstrate the media can support growth of a wide range of microorganisms. Your firm is not following the Policy on Aseptic Process Simulations as stated in SOP 4.72 section 8.4.8 which states the selection of 5 microorganisms.

B. Your firm has 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, the following drug stock solutions have a shelf life of six months and contain a preservative. You have not verified through antimicrobial effectiveness studies the content of the preservative. In addition, stability studies have not been provided to show the drug product is stable in its container.

Papaverine HCL; lot 10142019+53116, discard after April 11, 2020

Phentolamine Mesylate; lot 10142019+53114, discard after April 11, 2020

This is a repeat objectionable observation from the March 2017 FDA inspection.

C.

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Your firm's manual visual inspection is inadequate and does not ensure your drug product is contamination free prior to distribution.

1. I observed on 12/5/2019 in the cleanroom suite (ISO 7), aseptic fill technician performing visual inspections at a metal table on finished drugs in (b) (4) vials without assistance from light magnification or contrasting white background. I observed the fill technician hold the vial (b) (4) and shake the vial (b) (4) then label the vials. The fill technician conducted visual inspection and labeling on the following drug lots:

Alprostadil 150 mcg/ml lot 12042019+53331

Papaverine HCL/Phentolamine mesylate 60mg/40mg/ml lot 12042019+53329

Alprostadil/Papaverine HCL/Phentolamine mesylate/Atropine 18mcg/1.8mg/0.2mg/0.2mg/ml lot 12042019+53327

Alprostadil/Papaverine HCL/Phentolamine mesylate/Atropine 40mcg/25mg/0.5mg/0.1mg/ml lot 12042019+53325

Alprostadil/Papaverine HCL/Phentolamine mesylate/Atropine 60mcg/30mg/2mg/0.15mg/ml lot 12042019+53323.

2. On 12/5/2019 in the visual inspection room, I observed an employee maneuver Triamcinolone Acetonide (Preservative Free) 2 ml vials lot 12032019+53303 onto the table for labeling and inadvertently drop a vial on the concrete floor. He picked up the vial held it up for approximately one second to the light asked the process engineer if it was ok. The process engineer nodded and the

employee placed it back on the table for labeling. There was no additional examination of the integrity of the glass vial. This visual inspection practice does not adhere to your firm's SOP 2.87, titled, 'Visual Inspection of Finished Drug Products" section 8.5.2 that "if the inspector is uncertain about a potential defect, the unit should be segregated and evaluated more thoroughly by another qualified inspector and/or a Quality Unit representative…"

3. Prior to the (b) (4) visual inspection of Triamcinolone Acetonide (Preservative Free) 2 ml vials lot 12032019+53303, your firm failed to measure the intensity of the light source using a calibrated (b) (4) on the visual inspection machine. SOP 2.87, titled, 'Visual Inspection of Finished Drug Products" section 8.4 requires the measurement to be recorded in the batch production record; however, there is no allotted space in the batch record to record this measurement.

OBSERVATION 6

The quality control unit lacks authority to fully investigate errors that have occurred.

Specifically,

A.

Your firm failed to perform investigations into "Positive" sterility results as outlined in SOP 5.30, titled, Testing of Sterile Preparations section 8.3.1.1. and SOP 5.54, "Investigating an Out of Specification" section 7.1.

1. Triamcinolone Acetonide 40mg/ml (Preservative Free) lot number 08272019+52841 culture result was "Positive" for media bottle (b) (4) utilizing the (b) (4) sterility test method. There was no

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subculture or gram staining performed. There was no out of specification investigation or deviation performed. The lot was distributed to (b) (4) office orders.

2. Levocarnitine 500mg/ml lot number 08212019 +52824 culture result was "Positive" for (b) (4) media bottles (b) (4). A handwritten note on the Accession report reads, "Plating (subculture) was performed on sample & corresponding (b) (4) bottle; Result was negative". However, three culture bottles were shown positive and it is not stated by the handwritten note if all three bottles were subcultured. Furthermore, there is no documentation of the subculturing. There is no "Review By" Signature and date by the Quality Unit on the Sterility Test Report. There was no out of specification investigation or deviation performed. The lot was distributed to (b) (4) office orders.

3. Levocarnitine 500mg/ml lot number 01292019+51387 culture result was Positive for (b) (4) media bottles (b) (4) and (b) (4) Handwritten note on the (b) (4) (b) (4) sterility report for bottle (b) (4) notes a subculture was performed on the inoculated media bottle and results were negative. However, there was no subculture of media bottle (b) (4). There is no documentation of the subculturing. There is no "Review By" Signature and date by the Quality Unit on the Sterility Test Report. There was no out of specification investigation or deviation performed. The lot was distributed to (b) (4) office orders.

4. Methylprednisolone Acetate (Preservative Free) lot number 02272019+51657 culture result was Positive for (b) (4) media bottle (b) (4). There was no out of specification investigation performed or deviation report generated. There is no "Review By" Signature and date by the Quality Unit on the Sterility Test Report. There was no subculture performed. The lot was distributed to (b) (4) office orders. The lot was distributed to (b) (4) office orders.

5. Zinc Chloride 02192019+51574 culture result was Positive. There was no out of specification investigation performed or deviation report generated. There is no "Review By" Signature and date by the Quality Unit on the Sterility Test Report. There was no subculture performed. The lot was distributed to (b) (4) office orders.

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B.

Your firm failed to perform complaint investigations as outlined in SOP 5.51, Handling of Customer Complaints and Adverse Drug Reactions.

1. Complaint number CR 2018-004 dated November 27, 2018 on the complaint log reads a patient had went into the hospital for sepsis after injection of Testosterone cypionate lot number 09182018+50532. The log details a review of the batch record, release testing and if there were other complaints on this lot. The complaint log does not provide information on who the complainant is, if samples were returned or if additional testing was performed on this lot. The complaint investigation is incomplete. Furthermore, your firm failed to submit an adverse event reporting to the FDA as required by section 8.1 in SOP 5.51, Handling of Customer Complaints and Adverse Drug Reactions.

2. Complaint number CR-2018-003 dated May 11, 2018 on the complaint log reads a customer reported sediment in one vial of Methylcobalamin 10mg/ml 03012019+49188. Complaint outcome reads, "Customer was resupplied; sedimenting attributed to poor grade API reagent. There was no complaint investigation performed and no investigation with the API supplier.

3. Complaint number CR-2017-006 dated October 22, 2018 complainant from doctor reported black specs in "beta/beta", no lot number reported on complaint log. Complaint outcome on log reads, "Administrator was coring the vial septa. Not traceable to AXIA" There is no additional complaint information or complaint investigation report regarding the review of batch records, testing records or the manufacturing process.

4. Complaint number CR 2019-002 dated June 3, 2019 does not show a completion date on the complaint log and appears to still be an open complaint. Complaint log reads that Betamethasone Acetate/Betamethasone Sodium Phosphate lot 03132019+51752 is clumping. Upon review of the complaint sample, the sample was drawn into a syringe and clumping was observed. There is no

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complaint investigation into the manufacturing process, testing or formulation. "No" is marked on the log for whether an investigation is required.

OBSERVATION 7

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

Specifically,

A.

Your firm has failed to document the electronic review of pressure differential monitoring to ensure during production that pressure differentials are maintained in the ISO-5, ISO-6, ISO-7 and ISO-8 clean rooms during production. SOP 7.13 titled, "Automated EM" section 9.4 requires Quality Unit to document the EM results.

B.

Your firm has failed to investigate the environmental monitoring action limit observed for active viable air sampled in the ISO 5 filler room, location (b) (4), 1 cfu recovered. Action limit is (b) (4) Your firm did not follow SOP 7.11 titled, Environmental Monitoring which requires as investigation to assess product impact when applicable.

C. Your firm has failed to perform the (b) (4) environmental monitoring in the classified cleanroom areas after November 11, 2019 according to the environmental log book and the Quality Manager. Drug production has continued to be manufactured in these cleanroom suites since November 11, 2019.

OBSERVATION 8

Examination of packaging and labeling materials for suitability and correctness before packaging operations is not documented in the batch production records.

Specifically,

On 12/5/19, I observed the potential for label mix-ups when labeling of small batches were performed in the filling clean room suite conducted on a table with 5 different drug product lots. The aseptic filling operator had just completed (b) (4) a small batch. He then placed 5 small drug batches on the table each batch had approximately (b) (4) filled vials. The lots were:

Alprostadil 150 mcg/ml lot 12042019+53331

Papaverine HCL/Phentolamine mesylate 60mg/40mg/ml lot 12042019+53329

Alprostadil/Papaverine HCL/Phentolamine mesylate/Atropine 18mcg/1.8mg/0.2mg/0.2mg/ml lot 12042019+53327

Alprostadil/Papaverine HCL/Phentolamine mesylate/Atropine 40mcg/25mg/0.5mg/0.1mg/ml lot 12042019+53325

Alprostadil/Papaverine HCL/Phentolamine mesylate/Atropine 60mcg/30mg/2mg/0.15mg/ml lot 12042019+53323

The labels were issued without documentation, batch record or verification of the lot number by Quality Unit. It was stated by the Process Engineer that if the batch record has not been printed then he would just write what he has issued down on a piece of paper. Your firm is not documenting manufacturing activities contemporaneously.

OBSERVATION 9

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	12/2/2019-12/20/2019*
	FEI NUMBER 3013341563

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Navid Vahedi, President	
FIRM NAME Fusion IV Pharmaceuticals, Inc. dba Axia Pharmaceutical	STREET ADDRESS 1990 Westwood Blvd Ste 135
CITY, STATE, ZIP CODE, COUNTRY Los Angeles, CA 90025-4650	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drug Products

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically,
A.

You have not completed method suitability for the (b) (4) sterility testing Method Validation document VAL-16-001 for your drug products tested with this sterility test method. Validation Protocol Deviation Report #2 lists test procedures which did not meet the acceptance criteria. Your Quality Unit has not reviewed and summarized the validation data and signed as Reviewed and Approved by.

B.

You have not completed the method suitability for the endotoxin testing using (b) (4) Assay (b) (4) for all drug products. Currently, only three drug products have completed method suitability.

***DATES OF INSPECTION**
12/02/2019(Mon), 12/03/2019(Tue), 12/04/2019(Wed), 12/05/2019(Thu), 12/06/2019(Fri), 12/09/2019(Mon), 12/10/2019(Tue), 12/11/2019(Wed), 12/12/2019(Thu), 12/13/2019(Fri), 12/16/2019(Mon), 12/17/2019(Tue), 12/18/2019(Wed), 12/19/2019(Thu), 12/20/2019(Fri)

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