	EALTH AND HUMAN SERVICES BRUG ADJUMSTRATION	*	
District office Address and Phone Number Los Angeles District Office 19701 Fairchild Icvine, CA 92612 949-608-2960 Industry Information: www.fda.gov/oc/inclustry		DATE(S) OF INSPECTION 13 Mar 2017 - 23 Mar 2017 FEI NUMBER 3013341563	
TO: Navid (NMI) Vahedi, PharmD., Owner	STRUCT ANDRESS		
INAME STREET ADDRESS Ion IV Plearmaceuticals, Inc. dba Axia Pharmaceutical 1990 Westwood B		15	
CITY, STATE AND ZIP COUR	TYPE OF ESTABLISHMENT INSPEC		
CITY, STATE AND ZIP CODE LOS Angeles, CA 90025-4650 Producer of Sterilo Di		ON THE LINE OF THE LOCK OF	
objection or action with the Foa Representative(s) ouring the you have any questions, please contact foa at the phone number ouring an inspection of your firm (have) observed: DURING AN INSPECTION OF YOUR FIRM WE OBSERVATION I Procedures designed to prevent microbiological contact established. Specifically, A. You did not perform investigations into the root can be performed in ISO 5 Laminar Flow Workstations (LAF) was observed in the growth promotion media for (b) (4) (b) (4) Additionally, you failed to investigate the nedia fill validation runs prior to producing and distributed to investigate the nedia fill validation runs prior to producing and distributed to investigate the nedia fill validation runs prior to producing and distributed to investigate the nedia fill validation runs prior to producing and distributed to investigate the nedia fill validation runs prior to producing and distributed to investigate the nedia fill validation runs prior to producing and distributed to investigate the nedia fill validation runs prior to producing and distributed to investigate the nedia fill validation runs prior to producing and distributed to investigate the nedia fill validation runs prior to producing and distributed to investigate the nedia fill validation runs prior to producing and distributed to investigate the nedia fill validation runs prior to producing the nedia	RAND ADDRESS ABOVE. BSERVED: mination of drug products purely the second media fill sterility fails (Ws) from (b) (4) media fill runs initiated be root cause of the following steeps.	uporting to be sterile are not ures for media fill runs Turbidity steveen (b) (4)	
You have never performed media fill validation runs archine (PennTech automated vial filling machine) local (4) Report" printed 20lvfar2017, you produce the content automated vial filling machine between	eated in the ISO 5 filling roo		
. You have not performed a Smoke Pattern Test in yo	ALL STRONG PARKET PRACTICAL STRUCTURES AND	re the PennTech automated	
EMPLOYEE(8) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or	Type) DATE ISSUED	
OF THIS This Print CO'nd.	Linda F. Murphy, CSO Tulchun Qin, CSO	03/23/2017	
1001	Marcellinus Dondonoo, 60 C50	43.44	
RM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE IN	2. 03/2	5(1)	

	*			AND HUMAN SERVICE	ces	
DISTRICT OFFICE ADDRESS AND PHONE NUMBER Los Angeles District Office 19701 Fairchild		OATE(S) OF INSPECTION 13M/sr2017 - 23M/sr2017				
					Irvine, CA 92612 949-608-2900 Industry Information: www.fda.gov/ec/industry	
lodust						
	D TITLE OF INDIVIDUAL TO WAS					
TO: N	avid (NMT) Vahedi, Pharm ve	ii)., Civiner	Ts	TREET ADDRESS		
	fusion IV Pharmaceuticals, Inc. dba Axia Pharmaceutical 1990 Westwood Bi		vd Ste 135			
			FE OF FRYABLISHMEN	ENT INSPECTED .		
Los An	gelcs, CA 90025-4650	-		Producer of Sterile Drug Products		
vial fil (b) (4	ling machine is used to)	• (b) (4)	of produ	ct into vials rang	ing between (b) (4)
individ of a pa (b) (4) _{[T}	ing preparation of (b) wat was observed place tially filled syringe. Total Parenteral Nutriti	ing ⁶⁾⁽⁶⁾ arm in the The contents of th on) Rx number ^(b)	e path of unions e syringe we (6)	frectional airtlow re being (b) (4)	directly above t	n 13Mar2017, an he (b) (4) portion of(b) (4)
E. You	failed to perform grow		tion testing f	or(b) (4)		rowth medium
	(b) (4) (ively, prior to use.(b)		lot num	bers: (b) (4) (b)	(4) expiration da4) were used to:	
executi	on of media fill valida e control experiments	tion batches initia for either lot of	ted between (b) (4	(b) (4)	. For a	example, positive and were not performed
		1				
rocedu	VATION 2 ares designed to prevent adequate validation of			ion of drug produ	ets purporting to	be sterile do not
pecific	ally	(*				
beene	eset'y',				H 4	
erform 4May l	following was noted d ance Qualification (Po 6, respectively. This tion of equipment and	Q) for the (b) (4 (b) (4) is used utensils used duri) for(b) (4) ing preparati	(b) (4) sterilization of (l	dated 0 o) (4) drug prod	3May16 and
)	(b) (4)	were not (K	0) (4)	identified dori	ng the IOQ.	
) The	(b) (4) temperature	failed to meet pre	-determined	criteria of	(b) (4)	patches for
- 40,0	EMPLOYEE(S) SIGNATU	IRE	EMPLO	YEE(S) HALRE AND TITLE	(Print or Typa)	DATE ISSUED
REVENS OF THI PAGE	5 0		Taich	P. Murphy, CSO m'Qin, CSO Hines Dordenou, GO	080	03/23/2017

INSPECTIONAL OBSERVATIONS

Page 2 of 7

FORM FDA 483 (9/08) PREVIOUS EDITION COSOLETS

		DEPARTMENT OF H	drug administration		
DISTRICT OFFICE ADDRESS	The first of the second of	ies		DATE(8) OF INSPECTION	Ψ
Los Angeles District Office 19701 Fairchild Irvine, CA 92612 949-608-2900			13Mar2017 - 23Ma	r2017	
		D	FEI NUMBER		
			3013341563		
Industry Information: w NAME AND TITLE OPINDON					
TO: Navid (NMI) Val					×
FIRM NAME	The state of the s	11114	STREET ADDRESS		
Pusion IV Pharmacouticals, Inc. dba Axia Pharmacoutical		1990 Westwood Blvd Ste 135			
		TYPE OF ESTABLISHMENT INSPECTED			
Los Angeles, CA 9002	\$-4 650		Producer of Sterile	Drug Products	
"PQ Test Case (b) (4)	(b) (4)	Verification for	(b) (4)		
3) The (b) (4) fee	mnerature faile	ed to meet pre-deter	mined criteria of	(b) (4)	batches fo
PQ Test Case 2 :		Verification for E		(2) (1)	Outones in
	() ()				
i) The minimum ter	mperature faile	d to meet pre-deten	mined criteria of	(b) (4)	batches fo
PQ Test Case (b) (4)	(b) (4)	Verification for V	詞 (b) (4)		
20 10 10 10 10 10 10 10 10 10 10 10 10 10	10 SOVII - 51 O48		/1- \ / 4 \		
		unmary Report for	the (b) (4)	,	, Report ID
				2 0.73 10 0.741	- No. 10 10 10 10 10 10 10 10 10 10 10 10 10
77U15-010, Was a	bbtoned by the	Director of Quality	and Sterile Operati	ions on 01 Aug16.	Part della ■diction della receive
	190	\		(1-) (4)	intertable drug
B. The(b) (4)	(b) (4) (b) (4) which	th is used to (b) (4)	sterilize(b) (4)	injectable drug
B. The (b) (4) roducts at (b)	(b) (4) (b	(4) which are the requirements	th is used to (b) (4) fred (b) (4) femb	sterilize(b) (4) erature of (b) (4)	(b) (4)
B. The (b) (4) roducts at (b) (4)	(b) (4) (b) (4) (d) (d) (d) (d) (d) (d) (d) (d)	(4) which are the requestration of the transfer which we have the requestration of the transfer which we have the requestration of the transfer which we have the requestration of the requestration o	th is used to (b) (4) red (b) (4) temp ation (PQ) of (b) (4	sterilize(b) (4) crature of (b) (4)) preparations. The	(b) (4)
B. The (b) (4) broducts at (b) c) (4) base (b) (4) was c	(b) (4) (b) (4) (b) (4) d) tches during peraphe of main	(4) which do not meet the requestremance qualificates the state of the	th is used to (b) (4) lred (b) (4) femo ation (PQ) of (b) (4 (b) (4	sterilize(b) (4) crature of (b) (4)) preparations. The	(b) (4)
B. The (b) (4) broducts at (b) c) (4) base how the (b) (4) was constituting the Performance (b)	(b) (4) (b) (4) (b) (4) d) tches during posapable of main	(4) which do not meet the requestrormance qualification protocol for	th is used to (b) (4) led (b) (4) temp ation (PQ) of (b) (4 (b) (4) the (b) (4)	sterilize (b) (4) crature of (b) (4)) preparations. The (b) (4) (b) (4)	(b) (4) The was no data The was pro-
B. The (b) (4) broducts at (b) c) (4) bas chow the (b) (4) was continued by the QA	(b) (4) (b) (4) (b) (ches during posapable of main mance Qualific Manager on 3)	(4) which do not meet the requestionment qualification protocol for Oun2016 and execution (4)	th is used to (b) (4) tred (b) (4) femonstion (PQ) of (b) (4) (b) (4) the (b) (4)	sterilize (b) (4) crature of (b) (4)) preparations. The (b) (4) (b) (4) (2016 and 01Jul2016,	(b) (4) was no data was pro- the Final Repo
B. The (b) (4) broducts at (b) c) (4) base (b) (4) was c lithough the "Performance of the distance of the	(b) (4) (b) (4) (b) (4) (d) (d) (d) (d) (d) (d) (d) (d) (d) (d	(4) which do not meet the requestrormance qualification protocol for	th is used to (b) (4) tred (b) (4) femonstion (PQ) of (b) (4) (b) (4) the (b) (4)	sterilize (b) (4) crature of (b) (4)) preparations. The (b) (4) (b) (4)	(b) (4) was no data was pre- the Final Repo
B. The (b) (4) broducts at (b) c) (4) bas chow the (b) (4) was continued by the QA	(b) (4) (b) (4) (b) (4) (d) (d) (d) (d) (d) (d) (d) (d) (d) (d	(4) which do not meet the requestionment qualification protocol for Oun2016 and execution (4)	th is used to (b) (4) tred (b) (4) femonstion (PQ) of (b) (4) (b) (4) the (b) (4)	sterilize (b) (4) crature of (b) (4)) preparations. The (b) (4) (b) (4) (2016 and 01Jul2016,	(b) (4) was no data was pro- the Final Repo
B. The (b) (4) broducts at (b) c) (4) base (b) (4) was c dthough the "Performance of the dapproved on 21)	(b) (4) (b) (ches during postepable of main mance Qualification Start 7.	d not meet the requestformance qualification protocol for OJun2016 and execution Report for Summary Report for	th is used to (b) (4) Ired (b) (4) temp ation (PQ) of (b) (4) (b) (4) the (b) (4) the (b) (4)	sterilize (b) (4) crature of (b) (4)) preparations. The (b) (4) (b) (4) (c) (4) (b) (4) (d) (d) (d) (d)	(b) (4) was no data was pro- the Final Repo
B. The (b) (4) broducts at (b) c) (4) base (b) (4) was c lithough the "Performance of the distance of the	(b) (4) (b) (ches during postepable of main mance Qualification Start 7.	d not meet the requestformance qualification protocol for OJun2016 and execution Report for Summary Report for	th is used to (b) (4) tred (b) (4) femonstion (PQ) of (b) (4) (b) (4) the (b) (4)	sterilize (b) (4) crature of (b) (4)) preparations. The (b) (4) (b) (4) (2016 and 01Jul2016,	(b) (4) The was no data The was pro- The Final Report
B. The (b) (4) broducts at (b) c) (4) base (b) (4) was c dthough the "Performance of the dapproved on 21)	(b) (4) (b) (ches during posterior during posterior during posterior during posterior during posterior during duri	d not meet the requestformance qualification Protocol for OJun2016 and exection many Report for the incubation of	th is used to (b) (4) Ired (b) (4) temp ation (PQ) of (b) (4) (b) (4) the (b) (4) the (b) (4) (b) (4)	sterilize (b) (4) crature of (b) (4)) preparations. The (b) (4) (b) (4) (c) (4) (b) (4) (d) (d) (d) (d)	(b) (4) The was no data The was pre- The Final Report Was writte
B. The (b) (4) broducts at (b) c) (4) base (b) (4) was c lithough the "Performance of the dispersived on 21) Records were insulated.	(b) (4) (b) (ches during posterior during posterior during posterior during posterior during posterior during duri	d (4) which do not meet the requestion meet the requestion and interesting a second for OJun 2016 and execution and execution are Report for the second for	th is used to (b) (4) Ired (b) (4) temp ation (PQ) of (b) (4) (b) (4) the (b) (4) the (b) (4) (b) (4)	sterilize (b) (4) erature of (b) (4)) preparations. The (b) (4) (b) (4) (c) (4) (b) (4) (d) (d) (d) (d) (e) (e) (e) (e) (e) (f) (f) (f) (f) (f) (g) (f) (f) (f) (f)	(b) (4) The was no data The Was pre- The Pinal Report Was writte
B. The (b) (4) roducts at (b) roducts at (b) roducts at (b) roducts at (b) products at (b) particles (b) (4) was conditionally the "Performance and approved on 21) Records were insurance for the conditionally to manage and approved to be at as never qualified of	(b) (4) (b) (c) (d) (d) (d) (d) (d) (d) (d) (d) (d) (e) (e) (e) (e) (f) (f) (f) (f) (f) (f) (f) (f) (f) (f	d not meet the requestion and included and meet the requestion of the control of	th is used to (b) (4) led (b) (4) femo ation (PQ) of (b) (4) (b) (4) the (b) (4) the (b) (4) (b) (4) (b) (4) (b) (4)	sterilize (b) (4) crature of (b) (4) crature of (b) (4)) preparations. The (b) (4) (b) (4) (2016 and 01Jul2016, (b) (4) (b) (4) as follows: (c) (4) s used for (lation was not recorded	(b) (4) " was pre- the Final Repo was writte
B. The (b) (4) roducts at (b) roducts at (b)	(b) (4) (b) (4) d) (ches during perapable of main (mance Qualification Section 17. (b) (corealibrated, and ufacturer's instituted)	d not meet the requestion meet the requestion meet the requestion and including a lication Protocol for OJun 2016 and execution of tructions. 4) include the temperature and the temperature are rections.	th is used to (b) (4) led (b) (4) femp ation (PQ) of (b) (4 (b) (4) the (b) (4) the (b) (4) (b) (4) (b) (4) (b) (4) (b) (4)	sterilize (b) (4) erature of (b) (4)) preparations. The (b) (4) (b) (4) (2016 and 01Jul2016, (b) (4) (b) (4) as follows: (b) (4) as follows: (c) (4) as for (lation was not recorded (4) (d) (d)	(b) (4) " was no data " was pre- the Final Repo was writte b) (4) f. Teation are
B. The (b) (4) roducts at (b) bat how the (b) (4) was c lithough the "Performance of the distribution of the condition of the	(b) (4) (b) (4) (d) (ches during posterior mance Qualification Sector regard ufacturer's instituted for	to (4) which do not meet the requestion mane qualificantaining a security of the control of the control of the control of the temperature of the control of (b) (4) (b) (4)	th is used to (b) (4) lend (b) (4) femons (PQ) of (b) (4) (b) (4) the (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) (b) (b) (b) (b) (b) Document	sterilize (b) (4) crature of (b) (4) crature of (b) (4)) preparations. The (b) (4) (b) (4) (2016 and 01Jul2016, (b) (4) (b) (4) as follows: (a) (4) sused for (a) stion was not recorded (4) qualification is not available	(b) (4) " was no data " was prothe Final Report was writh (b) (4) It. To demonstrate
B. The (b) (4) roducts at (b) roducts at (b)	(b) (4) (b) (4) (d) (ches during posterior mance Qualification Sector regard ufacturer's instituted for	to (4) which do not meet the requestion mane qualificantaining a security of the control of the control of the control of the temperature of the control of (b) (4) (b) (4)	th is used to (b) (4) lend (b) (4) femons (PQ) of (b) (4) (b) (4) the (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) (b) (b) (b) (b) (b) Document	sterilize (b) (4) erature of (b) (4)) preparations. The (b) (4) (b) (4) (2016 and 01Jul2016, (b) (4) (b) (4) as follows: (b) (4) as follows: (c) (4) as for (lation was not recorded (4) (d) (d)	(b) (4) " was no data " was prothe Final Report was writh (b) (4) It. To demonstrate
B. The (b) (4) roducts at (b) bat how the (b) (4) was c lithough the "Performance of the distribution of the condition of the	(b) (4) (b) (4) (d) (ches during posterior mance Qualification Sector regard ufacturer's instituted for	to (4) which do not meet the requestion mane qualificantaining a security of the control of the control of the control of the temperature of the control of (b) (4) (b) (4)	th is used to (b) (4) lend (b) (4) femons (PQ) of (b) (4) (b) (4) the (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) (b) (b) (b) (b) (b) Document	sterilize (b) (4) crature of (b) (4) crature of (b) (4)) preparations. The (b) (4) (b) (4) (2016 and 01Jul2016, (b) (4) (b) (4) as follows: (a) (4) sused for (a) stion was not recorded (4) qualification is not available	(b) (4) " was no data " was prothe Final Report was writte b) (4) f. Teation are to demonstrate
B. The (b) (4) roducts at (b) bather how the (b) (4) was c atthough the "Performance to red approved on 21) atther "Performance to red approved on 21) attention to be atther approved to be incubated to	(b) (4) (b) (4) (d) (c) (4) (d)	to (4) which do not meet the requestion mane qualificantaining a security of the control of the control of the control of the temperature of the control of (b) (4) (b) (4)	th is used to (b) (4) lend (b) (4) femons (PQ) of (b) (4) (b) (4) the (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) (b) (b) (b) (b) (b) Document	sterilize (b) (4) crature of (b) (4) crature of (b) (4)) preparations. The (b) (4) (b) (4) (2016 and 01Jul2016, (b) (4) (b) (4) as follows: (a) (4) sused for (a) stion was not recorded (4) qualification is not available	(b) (4) " was prothe Final Report was writte a b) (4) cation are to demonstrate
B. The (b) (4) roducts at (b) batter though the "Performance of the approved by the QA tied "Performance of the approved on 21) Records were insufficient to the at as never qualified of According to manual quired to be incubated as (b) (4)	(b) (4) (b) (c) (4) (d)	d not meet the requestion and the temperature of the temperature of the tructions (b) (4) (b) (4) ere incubated for the	th is used to (b) (4) lend (b) (4) femons (PQ) of (b) (4) (b) (4) the (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) (b) (b) (b) (b) (b) Document	sterilize (b) (4) crature of (b) (4)) preparations. The (b) (4) (b) (4) (co) (4) (b) (4) (co) (4) (b) (4) as follows: (co) (4)	(b) (4) The was no data to the Final Report was written b) (4) f. The to demonstrate
B. The (b) (4) roducts at (b) bather how the (b) (4) was conditionally the Performance of the perf	(b) (4) (b) (c) (4) (d)	d not meet the requestion and the temperature of the temperature of the tructions (b) (4) (b) (4) ere incubated for the	th is used to (b) (4) lred (b) (4) femp ation (PQ) of (b) (4 (b) (4) the (b) (4) the (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) (b) (b) (c) (c) (b) (d) (b) (c) (c) (d) (d) (d) (d) (d) (d	sterilize (b) (4) crature of (b) (4)) preparations. The (b) (4) (b) (4) (co) (4) (b) (4) (co) (4) (b) (4) as follows: (co) (4)	(b) (4) The was no data to the Final Report was written as we with the total and the total and the temperature to demonstrate temperature.
The (b) (4) roducts at (b) products at (b) the (b) (4) was c Ithough the "Performance of the proved by the QA tied "Performance of the approved on 21) Records were insufficient to be at as never qualified of According to manual quired to be incubated to be incubat	(b) (4) (b) (c) (4) (d)	d not meet the requestion and the temperature of the temperature of the tructions (b) (4) (b) (4) ere incubated for the	th is used to (b) (4) lred (b) (4) femp ation (PQ) of (b) (4 (b) (4) the (b) (4) the (b) (4) (b) (4) (b) (4) (b) (4) (b) (b) Document appropriate time from the companies time from the companies time from the companies appropriate time fr	sterilize (b) (4) crature of (b) (4)) preparations. The (b) (4) (b) (4) (2016 and 01Jul2016, (b) (4) (b) (4) as follows: (b) (4) as follows: (c) (4) as follows: (d) attion was not recorded (4) attion is not available ame and at the approp	(b) (4) " was pre- the Final Report was writte b) (4) f. Teation are to demonstrate

	IEALTH AND HUMAN SERVICES DRUG ADMINISTRATION	*
DISTRICT OFFICE ADDRESS AND PHONE NUMBER Los Angeles District Office 19701 Fairchild Irvine, CA 92612 949-608-2900	DATE(S) OF INCENTION OF INCENTI	
Industry Information: www.tdz.gov/oc/uxdustry NAME AND TITLE OF INDMOUAL TO WHOM REPORT IS ISSUED	3013,341,03	
TO: Navid (NMI) Vahedi, PhannD., Owner	7	
From NAME Pusion IV Pharmaceuticula, Inc. dba Axia Pharmaceutical	STREET ADDRESS 1990 Westwood Blvd Ste 135	0
CITY, STATE AND ZIP GODE	TYPE OF ESTABLISHMENT INSPECTED	
Los Angeles, CA 90025-1650	Producer of Sterlle Drug Products	
that they are suitable for their intended use. Specifically, A. You failed to demonstrate control of endotoxin and For example: 1) You did not show through validation studies that the reducing endotoxin to an acceptable level.		(b) (4) ment were capable of
2) The following was noted regarding (b) (4) qualification (PQ) activities, conducted according to p	(b) (4)	performance
a. The PQ records do not include (b) (4)	or describe placement of equ	8
o. The PQ records do not describe the quantity of qualification.	(b) (4) during p	erformance
According to the manufacturer's instructions, (b) (4) b) (4) incubator, which is used for (b) (emperature at the time of incubation was not recorded	4) was never qualified or c	b) (4) The
1. You did not demonstrate endotoxin reduction durin (b) (4) For example, you did not use	The state of the s	4) lification runs.
ceording to the Pharmacist in Charge, the firm uses t	his machine to depyrogenate and ster	ilize glass vials prior
eing filled with (b) (4) drug product.		
SEE SEEST! CO THIS PAGE CO	EMPLOYEE(S) NAME AND TITLE (Prior of Typo) Linda F. Murphy, CSO Taichua Qin, CSO Marcellinus Dordando, E& CSO	03/23/2017
RM FDA 483 (9/08) PREVIOUS BOITION COBOLETE IN	Du 03/23/17	
RM FDA 483 (W66) PREVIOUS EDITION COROLLEGE IN	ISPECTIONAL OBSERVATIONS	Page 4 of 7

Page 4 of 7

		OF HEALTH AND HUMAN SER! AND DRUG ADMINISTRATION "	VICES		
Committee of the Commit	ACE ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECT	NON .	
	Los Angeles District Office 19701 Pairchild Irvine, CA 92612 949-608-2900 Industry Information: www.tita.gov/oc/industry		13Mar2017 - 23h	Mar2017	
Irvine, CA			FEI NUMBER 3013341563		
M. AND THE STREET					
	LE CR INDIVIDUAL TO WHOM REPORT IS ISSUED				
TO: Navid	(NMI) Vahedi, PharmD., Owner		X		
FIRM HAME		STREET ADDRESS			
	harmaceuticals, Inc. dbs Axia Pharmaceutical	1990 Westwood B			
CITY. STATE A	nd zip code s, СА 90025-4650	Producer of Sterile	*		
		A FORDING OF THE STATE	Ding Finding		
OBSERVA	ATION 4 occasing areas are deficient regarding th	sa escutam for monitoring	e an willow mantal and	aditions	
wachite bi	ocessing areas are denoted regarding in	io system for monthierif	cityitoiinenan coi	ruanona,	
Specifical	v				
promotive	J's		*	X	
The state of the s					
Each batch aboratory	of drug product required to be free of o testing.	bjectionable microorga	nisms is not tested t	through appropriate	
Each batch aboratory Specifically	of drug product required to be free of o testing.			through appropriate	
Each batch aboratory Specifically A. You hav	of drug product required to be free of o testing. y, ye not completed method suitability testi	ing of your	(b) (4)		
Each batch laboratory Specifically A. You hav	of drug product required to be free of o testing.	ing of your	(b) (4)		
Specifically A. You havest for any B. You have and protects for example	of drug product required to be free of o testing. y, ye not completed method suitability testi	ing of your y-tested with this methodiveness study to verify to pected conditions of use of Multi-dose vials of M	(b) (4) hat the preservative cthylcobalamin, 1	steritit e system is effective mg/ml Injectable,	
Each batch aboratory Specifically A. You havest for any B. You have and protects for example of Numbe	of drug product required to be free of of testing. y, we not completed method suitability testif of the of the product an antimicrobial effection of the product over its shelf life under expense, on 12Jan17, you produced (b) (4)30 m	ing of your y-tested with this methodiveness study to verify to pected conditions of use of Multi-dose vials of Mond use date (BUD) of 1	(b) (4) hat the preservative cthylcobalamin, 1	steriti e system is effective mg/ml Injectable,	
Each batch aboratory Specifically A. You havest for any B. You have ad protects or example of Numbe	of drug product required to be free of of testing. Ye not completed method suitability testif of the of drug products that are sterility to not performed an antimicrobial effection of the product over its shelf life under experience on 12Jan17, you produced (b) (4)30 mm of 1122017+44269, and assigned a beyon	ing of your y-tested with this methodiveness study to verify to pected conditions of use of Multi-dose vials of Mond use date (BUD) of 1	(b) (4) hat the preservative cthylcobalamin, 1	steriti e system is effective mg/ml Injectable,	
Each batch aboratory Specifically A. You havest for any B. You have ad protects or example of Numbe	of drug product required to be free of of testing. Ye not completed method suitability testif of the of drug products that are sterility to not performed an antimicrobial effection of the product over its shelf life under experience on 12Jan17, you produced (b) (4)30 mm of 1122017+44269, and assigned a beyon	ing of your y-tested with this methodiveness study to verify to pected conditions of use of Multi-dose vials of Mond use date (BUD) of 1	(b) (4) hat the preservative cthylcobalamin, 1	steriti e system is effective mg/ml Injectable,	
Each batch aboratory Specifically A. You have st for any B. You have not protects for example of Numbers preserved	of drug product required to be free of of testing. Ye not completed method suitability testif of the of the of drug products that are sterility to the product over its shelf life under experience on 12Jan17, you produced (b) (4)30 mm of 1122017+44269, and assigned a beyon tive would be effective throughout this	ing of your y-tested with this methodiveness study to verify to pected conditions of use of Multi-dose vials of Mond use date (BUD) of 1	(b) (4) hat the preservative cthylcobalamin, 1	steriti e system is effective mg/ml Injectable,	
Each batch aboratory Specifically A. You have est for any B. You have not protects for example of Number no preserve	of drug product required to be free of of testing. Ye not completed method suitability testif of the of the of drug products that are sterility to the product over its shelf life under experience on 12Jan17, you produced (b) (4)30 mm of 1122017+44269, and assigned a beyon tive would be effective throughout this	ing of your y-tested with this methodiveness study to verify to pected conditions of use of Multi-dose vials of Mondiuse date (BUD) of I product's shelf life.	(b) (4) hat the preservative cthylcobalamin, 1	steritit e system is effective mg/ml Injectable,	
Each batch aboratory Specifically A. You have the for any and protects for example of Number he preserved.	of drug product required to be free of of testing. Ye not completed method suitability testif of the of the products that are sterility to an antimicrobial effect is the product over its shelf life under experience, on 12Jan17, you produced (b) (4)30 mm of 1122017+44269, and assigned a beyon tive would be effective throughout this of your outsourcing facility's drug product of your outsourcing facility's drug product.	ing of your y-tested with this methodiveness study to verify to pected conditions of use of Multi-dose vials of Mondiuse date (BUD) of I product's shelf life.	(b) (4) hat the preservative cthylcobalamin, 1 1Jul 17; however, 3	steritit e system is effective mg/ml Injectable,	
Each batch aboratory Specifically A. You have the for any and protects for example to Number to preserve the labels of the lab	of drug product required to be free of of testing. Ye not completed method suitability testing of the product over its shelf life under expect on 12Jan 17, you produced (b) (4)30 mm of 122017+44269, and assigned a beyon tive would be effective throughout this of your outsourcing facility's drug produced outsourcing facility's drug produced outsourcing facility's drug produced outsourcing facility is drug facility in the facility is drug facility in the facility is drug facility in the facility in the facility is drug facility in the facility in the facility is drug facility in the facility in the facility is drug facility in the facility in the facility is drug facility in the facility in the facility in the facility in	ing of your y-tested with this methodiveness study to verify to pected conditions of use of Multi-dose vials of Mond use date (BUD) of I product's shelf life.	(b) (4) hat the preservative cthylcobalamin, 1 1Jul 17; however, 3	steritit e system is effective mg/ml Injectable, you have not verified	
Each batch aboratory Specifically A. You have the for any and protects for example to Numbe the preserve the labels of the label	of drug product required to be free of of testing. Ye not completed method suitability testif of the of the products that are sterility to an antimicrobial effect is the product over its shelf life under experience, on 12Jan17, you produced (b) (4)30 mm of 1122017+44269, and assigned a beyon tive would be effective throughout this of your outsourcing facility's drug product of your outsourcing facility's drug product.	ing of your y-tested with this method iveness study to verify to pected conditions of use it Multi-dose vials of M and use date (BUD) of I product's shelf life. temployee(s) mane and to Linda F. Muphy, CSO Tuichun Qia, CSO	(b) (4) hat the preservative thylcobalamin, 1 hall7; however, 5	steritit e system is effective mg/ml Injectable, you have not verified	
Each batch aboratory Specifically A. You have the for any B. You have the protects or example to preserve the labels of the labe	of drug product required to be free of of testing. Ye not completed method suitability testing of the product over its shelf life under expect on 12Jan 17, you produced (b) (4)30 mm of 122017+44269, and assigned a beyon tive would be effective throughout this of your outsourcing facility's drug produced outsourcing facility's drug produced outsourcing facility's drug produced outsourcing facility is drug facility in the facility is drug facility in the facility is drug facility in the facility in the facility is drug facility in the facility in the facility is drug facility in the facility in the facility is drug facility in the facility in the facility is drug facility in the facility in the facility in the facility in	ing of your y-tested with this method iveness study to verify to pected conditions of use it Multi-dose vials of M and use date (BUD) of 1 product's shelf life. the conditions of the conditions of the condition of the condition of the conditions	(b) (4) hat the preservative thylcobalamin, 1 hall7; however, 5	steritit e system is effective mg/ml Injectable, you have not verified	

Page 5 of 7

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

OISTRICT OFFICE ADDRESS AND PHONE HUMBER
Los Angeles District Office
19701 Fairchild
Irvine, CA 92612
949-608-2900

DATE(6) OF INSPECTION 13Mar2017 - 23Mai/2017

FEI HUMBER

Industry Information: www.kla.gov/oc/industry

3013341563

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

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

FIRM NAME

STREET ADDRESS

Fusion IV Pharmacouticals, Inc. dba Axia Pharmacoutical

1990 Westwood Blvd Ste 135

CITY, STATE AND ZIP CODE

TYPE OF ESTABLISHMENT INSPECTED

Los Angeles, CA 90025-4650

Producer of Sterile Drug Products

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:

- Methiordne/Inositol/Choline (MIC) Injectable, 25mg/50mg/50mg/mL, 30mL Multi-dose Vial
- Testosterone Cyplonate Injectable, 200mg/mL, CIII, 10mL Multi-dose Vial
- · Human Chorionic Gonadotropia (Ficg) Injectable, 10001U/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, 200mog/mL, 30mL Multi-dose Vial
- · Methylcobalamin Injectable, Img/mL, 30mL Multi-dosc Vial
- · Ascorbic Acid (Vitamin C) Injectable, 500mg/inf., 30ml, Multi-dose Vial
- * B-Complex Injectable, B Vitamin Complex, 30mL Multi-dose Vial
- Cyanocobalamin Injectable, 2000nwg/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
- · Dexamenthesone 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)

SEE REVERSE OF THIS PAGE EMPLOYEE(S) SIGNATURE
TO

EMPLOYEE(S) NAME AND TITLE (Print or 1966)

CATE ISSUED

Lieda F. Murphy, CSO Talehun Qin, CSO

Mircellinus Dordanoo, co CSO

03/23/2017

FORM FOA 483 (9/08) PREVIOUS EDITION OBSCLETE

INSPECTIONAL OBSERVATIONS

Page 6 of 7

	F HEALTH AND HUMAN SERVICES NO DRUG ADMINISTRATION		
DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF	INSPECTION	
Los Angeles District Office 19701 Fulrehild	13Mar20	13Mar2017 - 23Mar2017	
Irvine, CA 92612	FELNUMOGA		
949-608-2900	30133415	63	
Industry Information: www.fda.gov/oc/Industry NAME AND TITLE OF INCIVIDUAL TO WHOM REPORT IS ISSUED		*	
TO: Navid (NMI) Valiedi, PhamiD., Owner	e e e e e e e e e e e e e e e e e e e		
FIRM NAME	STREET ADDRESS		
Fusion IV Pharmaceuticuls, Inc. dba Axia Pharmaceutical	1990 Westwood Blvd Ste 135	ed Ste 135	
GITY, BYAYE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED		
Los Angeles, CA 90025-4650	Producer of Sterile Drug Products		
fda.gov/medwatch). Furthermore, there are no reco was used to label drug product packaged at your fi		lverse events reporting lab	
OBSERVATION 8			
Your outsourcing facility did not submit an initial			
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/Eri\ 3/20	2017(Mon) 3(3) L(2012	
(Tue) ,3/22/2017(Wed),3/23/2017(Thu)	21 2 4 2 2 2 3 4 2 1 1 4 2 3 2 1 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	31MARG	
719Amis			
		*	
N.		3	
		,	
EMPLOAPERA ALAUTE INC	Stern shortest	1	
SEE EMPLOYEE(S) SIGNATURE	EMPLOYEE(G) HALLE AND TITLE (PAN or Type)	DATE ISSUED	
REVERSE Y J INVY	Linda F. Murphy, CSO		
	Teichus Qis, CSO	03/23/2017	
PAGE OWNER had had		03/23/2017	

Page 7 of 7