		ALTH AND HUMAN SERVICES	
DISTRICT ADDRESS AND PHONE		RUG ADMINISTRATION DATE(S) OF INSPECTION	
19701 Fairchi		08/31/2015 FEI NUMBER	- 09/10/2015*
Irvine, CA 9:	ne, CA 92612) 608-2900 Fax:(949) 608-4417		
Industry Info	rmation: www.fda.gov/oc/inc	3004578527 dustry	
NAME AND TITLE OF INDIVIDUAL	TO WHOM REPORT ISSUED		
TO: David A.	Nicoletti, R.Ph., Presider	STREET ADDRESS	
Prescription Colty, STATE, ZIP CODE, COUNTR	Lab Compounding Pharmacy	6586 E Grant Rd Type establishment inspected	
Tucson, AZ 8	5715-3801	Producer of sterile dru	ıgs
observations, and do r observation, or have it action with the FDA r	bservations made by the FDA representative not represent a final Agency determination rumplemented, or plan to implement, corrective representative(s) during the inspection or subtact FDA at the phone number and address a	egarding your compliance. If you have an re action in response to an observation, you omit this information to FDA at the addres	objection regarding an ou may discuss the objection or
DURING AN INSPEC	TION OF YOUR FIRM I OBSERVED:		
OBSERVATION :	1		
		A CONTRACTOR OF THE CONTRACTOR	
Aseptic processing	areas are deficient regarding the system	for monitoring environmental conditi	ions.
	onmental monitoring (b) (4) (b) (4)	used to prepare sterile products is	not conducted each day that
sterne urugs are pre	opared, I or example.		
(b) (4) by the B. Viable air mon vendor that cer C. Surface monito	rtifies the (b) (4)	and in the surrounding ISO 7 buffer room is performed only (b) (4)	formed every (b) (4) by the
OBSERVATION			
Aseptic processing aseptic conditions.	areas are deficient regarding the system	tor cleaning and disinfecting the root	m and equipment to produce
Specifically, a solu 7 workbench.	ition of(b) (4)	is used to clean the	ISO 5 (b) (4) and the ISO
OBSERVATION	3		
Procedures designe validation of the ste	ed to prevent microbiological contamina erilization process.	tion of drug products purporting to be	sterile do not include
Specifically, oil ba	ased products (b) (4)		(4)
validated and no (b) (4) are placed in the(b) (. The proce 4) (b) (4) product. For	
a. Testostero	one (70/30) Cypion/Enan 200mg/ml, l	ot number 08212015:93@32 was p	
SEE REVERSE OF THIS PAGE	Caryn M. Mcnab, Investiga	tor Caryn McNab	09/10/2015
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE IN	SPECTIONAL OBSERVATIONS	PAGE 1 OF 2 PAGES

Definition Appelled Number Definition			ALTH AND HUMAN SERVICES RUG ADMINISTRATION
Industry Information: www.fda.gov/oc/industry Infor		PHONE NUMBER	DATE(S) OF INSPECTION
State Stat			
Industry Information: www.fda.gov/oc/industry Modes Not Title of Notificial Towns against the second of the (b) (4) TO: David A. Nicoletti, R.Ph., President FREMANCE FPERSCRIPTION Lab Compounding Pharmacy GSRET AGGRESS FPERSCRIPTION Lab Compounding Pharmacy GSRET AGGRESS Froducer of sterile drugs Froducer of sterile drugs product was (b) (4) addition, i. There is no validation study showing that these (b) (4) iii. There is no felb (4) iii. There is no record of the actual time (b) (4) of the (b) (4) during the processing period. b. Testosterone Cypionate 200mg/ml Injection, lot number 08262015:94@75 was prepared on 8/26/15. The product was (b) (4) i. There is no record of the(b) (4) ii. There is no validation study showing that the (b) (4) ii. There is no validation study showing that the (b) (4) ii. There is no validation study showing that the (b) (4) iii. There is no validation study showing that the (b) (4) iii. There is no validation study showing that the (b) (4) iii. There is no validation study showing that the (b) (4) for this process. iii. There is no follow the compound of the comp			
TO: David A. Nicoletti, R.Ph., President STREET ADDRESS			
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EMPLOYEE(S) SIGNATURE

Caryn M. Mcnab, Investigator

Caryn Monab

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