DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT OFFICE ADDRESS AND PHONE NUMBER			DATE(S) OF INSPECTION		
19701 Fairchild			04/10 - 17/2019		
Irvine, CA 92612			FEI NUMBER		
949-608-2900					
Industry Information: www.fda.gov/oc/industry			3013501947		
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED					
To: Robert D. Quinn, Pharm.D., Pharmacist-In-Charge and Owner					
STREET ADDRESS Valoria Pharmaculand Contact for Reconnective Medicine Inc. 181 Tools Form R.			nd Suite 120		
			Fank Farm Road, Suite 120 FESTABLISHMENT INSPECTED		
San Luis Obispo, CA 93401		Producer of non-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) WE) OBSERVED:					
Observation # 1					
Non-pharmaceutical grade components are used in the formulation of non-sterile drug products.					
Specifically,					
Your firm is using non-pharmaceutical grade (b) (4) (b) (4) to produce the following drug products. • Loperamide HCl Oral 1mg/5mL Suspension Lot # 03182019@23 • 7+DBCGT: Diclofenac, Baclofen, Cyclobenzaprine, Gabapentin, Tetracaine 3%,2%,2%,6%,2% Cream Lot # 04032019@7 • Lidocaine 2%/Mylanta/Diphenhydramine/Nystatin/Prednisolone Liquid Lot # 04082019@28					
In addition, your firm also uses non-pharmaceutical grade (b) (4) (b) (4) to produce (b) (4) (b) (4) (b) (4) (c)					
(b) (4) These lots of (b) (4) (b) (4) were used to produce the following drug					
products.					
 Ketamine Nasal Spray 100 mg/ml Lot # 03182019@35 Dyclonine HCl Solution 1% Lot # 03252019@32 Oxytocin Nasal Spray 40 units/mL Lot # 04012019@35 Itraconazole/EDTA/Gentamycin 2%/0.1%/0.25% Nasal Spray Lot # 04082019@36 Add Continuation Page					
END OVER/OUT	ine T	EMDI OVEE/S) NAME AND TITL	E (Print or Tyne)	DATE ISSUED	
EMPLOYEE(S) SIGNATU	A	EMPLOYEE(S) NAME AND TITL	_ transfer sype)	J. 11 E 1000ED	
SEE REVERSE OF THIS PAGE		Uttaniti Limchumroon, CSC)	04/17/2019	

FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE

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19701 Fairchild Irvine, CA 92612	04/10 - 17/2019				
949-608-2900	FEI NUMBER				
Industry Information: www.fda.gov/oc/industry NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED	3013501947				
TO: Robert D. Quinn, Pharm.D., Pharmacist-In-Charge and Owner FIRM NAME STREET ADDRESS					
Kohana Pharmacy and Center for Regenerative Medicine Inc.	181 Tank Farm Road, Suite 120				
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED				
San Luis Obispo, CA 93401	Producer of non-sterile drug products				
Observation # 2 Hazardous drugs were produced without providing adequate cleaning of work surfaces and/or cleaning of utensils to prevent cross-contamination.					
Specifically,					
Your pharmacy does not have dedicated utensils for hazardous drugs. Dirty utensils (used to produce hazardous drug products) are cleaned with detergent and sanitized with (b) (4) and placed into a drawer comingling with utensils for non-hazardous drugs. Between 01/10/2019 to 04/10/2019, your pharmacy produced approximately different hazardous drugs with					
approximately to patient-specific prescriptions per day and different non-hazardous drugs with approximately to patient-specific prescriptions per day.					
Add Continuation Page					
SEE REVERSE March March	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED			
OF THIS PAGE	Uttaniti Limchumroon, CSO	04/17/2019			