


DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT OFFICE ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION	
19701 Fairchild Irvine, CA 92612 949-608-2900		04/10 - 17/2019	
Industry Information: www.fda.gov/oc/industry		FEI NUMBER	
		3013501947	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED			
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	
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 (b) (4) (b) (4) 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.			
<ul style="list-style-type: none"> • 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)) (b) (4) . These lots of (b) (4) (b) (4) were used to produce the following drug products.			
<ul style="list-style-type: none"> • 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			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
			04/17/2019
		EMPLOYEE(S) NAME AND TITLE (Print or Type)	
		Uttaniti Limchumroon, CSO	

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FOOD AND DRUG ADMINISTRATION**

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CITY, STATE AND ZIP CODE San Luis Obispo, CA 93401	TYPE OF ESTABLISHMENT INSPECTED 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 (b) (4) different hazardous drugs with approximately (b) (4) to (b) (4) patient-specific prescriptions per day and (b) (4) different non-hazardous drugs with approximately (b) (4) to (b) (4) patient-specific prescriptions per day.

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Uttaniti Limchumroon, CSO	DATE ISSUED 04/17/2019
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