

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612 949-608-2900 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 04/10 - 17/2019 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 Kohana Pharmacy and Center for Regenerative Medicine Inc.	STREET ADDRESS 181 Tank Farm Road, Suite 120
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.

Add Continuation Page

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