



VIA SIGNATURE CONFIRMED DELIVERY

November 22, 2019

Robert Quinn, PharmD, FAAO, ABAHP
Co-Founder and President
Kohana Pharmacy and Center for Regenerative Medicine
181 Tank Farm Road, Suite 120
San Luis Obispo, CA 93401

Dear Dr. Quinn:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted April 10-17, 2019, at your facility, Kohana Pharmacy and Center for Regenerative Medicine, Inc., located at 181 Tank Farm Road, Suite 120, San Luis Obispo, CA 93401-7082, by the U.S. Food and Drug Administration (FDA). In addition, we are enclosing the letter sent to the California State Board of Pharmacy for follow up.

When the Agency considers an inspection to be "closed" under 21 C.F.R. 20.64(d)(3), it will release a copy of the EIR to the inspected establishment.

The Agency continually works to make its regulatory process and activities more transparent for regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 C.F.R. Part 20. This, however, does not preclude you from requesting and possibly obtaining any additional information under FOIA.

If there is any question about the released information, please contact Maria Kelly-Doggett, Compliance Officer, at 425-306-0427.

Sincerely,

A handwritten signature in black ink, appearing to read "Steven Porter".

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV

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