

VIA SIGNATURE CONFIRMED DELIVERY

June 7, 2018

Virginia Herold, Executive Officer California State Board of Pharmacy 1625 N Market Blvd N219 Sacramento, California 95834

Dear Ms. Herold:

The purpose of this letter is to notify the California State Board of Pharmacy (BOP) that the U.S. Food and Drug Administration (FDA) does not intend to take further action with regards to an inspection of a pharmacy licensed by the California BOP, Innovative Compounding Pharmacy, located at 820 Wales Drive, Suite 3, Folsom, California 95630-5546 (Retail Pharmacy License #PHY 48417; Sterile Compounding License #LSC 99600).

FDA inspected the firm from July 19, 2017, to July 28, 2017. The California BOP was informed of the inspection but did not accompany the FDA investigator during the inspection. No Form FDA 483 was issued to the firm.

During the inspection, the FDA investigator reviewed a small sample of records for products compounded by Innovative Compounding Pharmacy and determined, based on this sample, that this firm appears to obtain valid prescriptions for individually-identified patients for the drug products that it compounds and distributes, which is consistent with traditional pharmacy practice. After review of the records, FDA does not intend to take further action with regards to the findings of this inspection at this time and believes that the firm's pharmacy practice can be appropriately overseen by the State. Please notify us if you become aware of any adverse events or product quality concerns associated with drugs made at this facility, or if you observe any practices at this facility that concern you or that could be violations of Federal law.

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact Maria P. Kelly-Doggett, Compliance Officer at (425) 302-0427 or via email at Maria.Kelly-Doggett@fda.hhs.gov.

Sincerely,

Steven E. Porter Jr - S Dic : e-US, =0 L/S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19203030.100.1.1=1300433092, cn=Steven E. Porter Jr - S Date: 2018.06.07 14.03:44-0700′

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

SP: mpk

Division of Pharmaceutical Quality Operations IV 19701 Fairchild, Irvine CA 92612-2506 Telephone: 949-608-2900 Fax: 949-608-4417 www.fda.gov