

June 8, 2018

Malcom J. Broussard, Executive Director Louisiana State Board of Pharmacy 3388 Brentwood Drive Baton Rouge, Louisiana 70809-1700

Dear Mr. Broussard:

The purpose of this letter is to notify the Louisiana State Board of Pharmacy (BOP) that the U.S. Food and Drug Administration (FDA) does not intend to take further action with regard to an inspection of a pharmacy licensed by the Louisiana BOP, The Wellness Corner located at 17733 Old Jefferson Hwy, Prairieville, LA 70769-3934 (community/independent pharmacy license #PHY.006397-IR; controlled drug substance pharmacy license # CDS.040488-PHY, and durable medical equipment provider license # DME.000511).

FDA inspected the firm from August 10, 2017, to August 16, 2017. Investigators from the Louisiana BOP accompanied 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 The Wellness Corner 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 regard 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 Jose R. Lopez, Compliance Officer at <u>JoseR.Lopez@fda.hhs.gov</u> or (787) 729-8603.

Sincerely,

John W.

Digitally signed by John W. Diehl -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=John W. Diehl -S, 0.9.2342.19200300.100.1.1=2000099727 Date: 2018.06.08 17:02:50 -05'00'

Diehl -S LCDR John W. Diehl, M.S. Director, Compliance Branch Office of Pharmaceutical Quality Operations, Division II