



August 17, 2018

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 N Market Blvd N219
Sacramento, CA 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 regard to an inspection of a pharmacy licensed by the California BOP, McGuff Compounding Pharmacy Services, Inc., 2921 W. MacArthur Blvd. Suite 142, Santa Ana, CA 92704-7944 (Retail Pharmacy license #43950, Expiration date 3/1/2019; Sterile Compounding license #99004, Expiration date 3/1/2019).

FDA inspected the firm from May 25, 2017, to June 2, 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 McGuff Compounding Pharmacy Services, Inc., 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 on 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 Jessica Mu, Compliance Officer, at 949-608-4477.

Division of Pharmaceutical Quality Operations IV
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Sincerely,

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

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

SP: jm

Cc: Ronald M. McGuff, President/CEO
McGuff Compounding Pharmacy Services, Inc.
2921 W. MacArthur Blvd. Suite 142
Santa Ana, CA 92704-7944