FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

UNITED PARCEL SERVICE
SIGNATURE REQUIRED

April 5, 2017

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

Dear Ms. Herold:

The purpose of this letter is to refer to the California State Board of Pharmacy (BOP) for appropriate follow-up, the U.S. Food and Drug Administration's (FDA) concerns about poor sterile practices observed during an FDA inspection at a pharmacy licensed by the California BOP, Professional Partners Inc., dba Westcliff Compounding Pharmacy, located at 1901 Westcliff Dr., Suite 3A Newport Beach, CA 92660 (Retail Pharmacy Permit, License #PHY50599; Sterile Compounding License, License #LSC 100822).

FDA inspected the firm from April 20, 2016, to May 9, 2016. An FDA investigator was accompanied by a California state investigator for one day. A redacted copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm505044.pdf . The Form FDA 483 lists deviations from appropriate sterile practices that, if not corrected, could lead to contamination of drugs potentially putting patients at risk. FDA received Westcliff Compounding Pharmacy's response to the Form FDA 483 on June 1, 2016.

During the inspection, the FDA investigator reviewed a small sample of records for products compounded by Westcliff 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.

Also during the inspection, FDA investigators observed non-sterile disinfectant wipes being used to clean the laminar air flow hood where sterile products are prepared. This deviation was not included in the Form FDA 483 issued at the conclusion of the inspection; rather, it was identified during FDA's post-inspectional review of the documentation collected during the inspection. This deviation appears to be readily correctible, but Westcliff Compounding Pharmacy has not yet committed to correct it, so follow-up as to this observation would be appropriate.

U.S. Food and Drug Administration
Los Angeles District
19701 Fairchild Road
Los Angeles, CA 92612
www.fda.gov

After review of the record, FDA does not intend to take further action at this time with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the California State BOP for follow-up to ensure appropriate corrective action is taken. 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, or by email at Jessica.Mu@fda.hhs.gov .

Sincerely,

Kelly D. Sheppard -S

Digitally signed by Kelly D. Sheppard -S
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Date: 2017.04.05 15:17:58 -07'00'

CDR Steven E. Porter, Jr.
Director, Los Angeles District

Kelly D. Sheppard
Acting District Director
signing for Steven Porter

SP: jm