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

April 26, 2018

VIA UPS OVERNIGHT

Allison Vordenbaumen Benz
Executive Director
Texas State Board of Pharmacy
William P. Hobby Building, Suite 3-500
333 Guadalupe
Austin, Texas 78701

Dear Ms. Benz:

The purpose of this letter is to refer to the Texas 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 Texas BOP, Option Care, Inc., located at 9030 Kirby Drive, Houston, Texas 77054 (Community Sterile Compounding License #21253).

FDA inspected the firm from July 25, 2017, to August 2, 2017. Texas BOP was informed of the inspection but did not accompany FDA investigators during the inspection. Because we consider this inspection to be "closed" under 21 CFR 20.64(d)(3), you may request a copy of the Establishment Inspection Report (EIR) that FDA will provide to the firm, which contains additional information about our inspection. If you are a Commissioned Official or if your state agency has entered into a 21 CFR 20.88 information sharing agreement, you may be able to receive a copy of the EIR that includes certain nonpublic information. Alternatively, you may also choose to request a copy of the EIR directly from the firm.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Option Care 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.

U.S. Food & Drug Administration
Office of Pharmaceutical Quality Operations, Division 2
4040 North Central Expressway, Suite 300
Dallas, TX 75204-3158
www.fda.gov

During the inspection, the FDA investigators observed deviations from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Specifically, non-sterile disinfectants were used daily in the cleaning of the plexiglass shields of the ISO 5 laminar air flow work stations and ISO 5 Biological Safety Cabinet.

Option Care, Inc., Houston, Texas, committed to FDA in its responses to the Form FDA 483, dated August 23, 2017, and December 6, 2017, to correct the deviations in the Form FDA 483 and provided documentation in support of those corrective actions. In addition, the deviations identified appear to be readily correctable.

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 before distributing its compounded drugs, as required by section 503A(a) of the Federal Food, Drug and Cosmetic Act, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Texas 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 Mr. John Diehl, Director, Compliance Branch, at 214-253-5288 or via e-mail at John.Diehl@fda.hhs.gov, and/or Thao Ta, Compliance Officer, at 214-253-5217 or via e-mail at Thao.Ta@fda.hhs.gov.

Sincerely,

Mark W. Rivero -S

Digitally signed by Mark W. Rivero -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mark W. Rivero -S, 0.9.2342.19200300.100.1.1=1300060122
Date: 2018.04.25 14:32:42 -05'00'

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