U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations IV
19701 Fairchild Road
Los Angeles, California 92612
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VIA UNITED PARCEL SERVICE

September 26, 2017

Virginia Herold
Executive Director
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 the sterile practices observed during an FDA inspection at a pharmacy licensed by the California BOP, Hartley Medical Center Pharmacy, Inc., located at 113 W. Victoria Street, Long Beach, CA 90805-2162 (Sterile Compounding License #99011).

FDA inspected the firm from March 20, 2017, to March 24, 2017. California BOP was informed of the inspection, but did not accompany the FDA investigator during the inspection. A copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM553468.pdf, with any nonpublic information redacted. 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 Form FDA 483 or 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 investigator reviewed a small sample of records for products compounded by Hartley Medical Center Pharmacy, 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.

During the inspection, the FDA investigator observed deviations from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Specifically, the firm transferred a repeater pump from the anteroom to

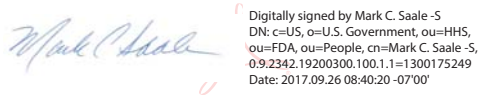
the ISO 6 classified cleanroom without disinfecting the pump.

Hartley Medical Center Pharmacy, Inc. committed to FDA in its response to the Form FDA 483, dated March 31, 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 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 Mariza M. Jafary, Compliance Officer, at 949-608-2977, or by email at Mariza.Jafary@fda.hhs.gov.

Sincerely,



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

SP:mj

Cc: William Stuart, Owner/President
Hartley Medical Center Pharmacy, Incorporated
113 W. Victoria St
Long Beach, CA 90805-2162