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

VIA EMAIL CONFIRMED DELIVERY

July 20, 2020

Anne Sodergren
Executive Director
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Dear Ms. Sodergren:

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 practices observed during an FDA inspection at a pharmacy licensed by the California BOP, Chen Shwezin, Inc. dba Park Compounding Pharmacy, located at 4333 Park Terrace Drive, Suite 160, Westlake Village, CA 91361 (PHY 54304).

FDA inspected the firm from March 26, 2018, to April 3, 2018. 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/media/112689/download, 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 observed deviations from the appropriate practice standards that, if not corrected, could lead to the contamination of drugs, potentially putting patients at risk. Examples of deviations observed during our inspection include:

1. Production of hazardous drugs without providing adequate cleaning of work surfaces and cleaning of utensils to prevent cross-contamination. Specifically, the firm's updated cleaning procedure does not state how the deactivating agent will be applied. If applied by aerosol spray, hazardous drug residue could be spread

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by aerosolization.

Park Compounding Pharmacy committed to FDA in its response to the Form FDA 483, received April 17, 2018, 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. 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 Andrew Haack, Compliance Officer, at 206-340-8212 or by email at Andrew.Haack@fda.hhs.gov.

Sincerely,

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

SP: ah

Cc: Justin Y. Chen
Owner
Chen Shwezin, Inc. dba Park Compounding Pharmacy
4333 Park Terrance Drive Suite 160
Westlake Village, CA 91361