U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
10 Waterview Blvd, 3rd FL
Parsippany, NJ 07054
Telephone: (973) 331-4900
Fax: (973) 331-4969
www.fda.gov

November 15, 2019

VIA UNITED PARCEL SERVICE

Paul W. Thompson
Interim Executive Secretary
New York State Education Department
Office of the Professions
New York State Board of Pharmacy
89 Washington Avenue, 2nd Floor W
Albany, NY 12234-1000

Dear Mr. Thompson:

The purpose of this letter is to refer to the New York State Education Department, Office of the Professions, referred here as New York State Board of Pharmacy [NYS-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 NYS-BOP, Kings Park Slope, Inc., dba Kings Super Pharmacy/Kings Pharmacy, located at 357 Flatbush Avenue, Brooklyn, NY 11238 (pharmacy license # 019339; wholesaler license # 024845).

FDA inspected the firm from August 21, 2018, to September 14, 2018. The NYS-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/123505/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 reviewed a small sample of records for products compounded by Kings Park Slope, 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. Examples of deviations observed during our inspection include:

1. The use of sporicidal agents in the ISO 5 classified aseptic processing area was inadequate.
2. Disinfecting agents and cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.
3. The facility design allowed the influx of poor-quality air into a higher classified area.
4. Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Kings Park Slope, Inc. committed to respond to Inspectional Observations in Form FDA 483 dated October 2, 2018, to correct the deviations cited 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 NYS-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 send your electronic inquiries to orapharm1_responses@fda.hhs.gov.

You may also contact Compliance Officer Juan Jimenez at juan.jimenez@fda.hhs.gov or call 1-518-453-2314 X-1014.

Craig W. Swanson -S

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Date: 2019.11.15 12:50:19 -05'00'

Craig Swanson
Acting Program Division Director/District Director
U.S. Food and Drug Administration
OPQO Division I / New Jersey District

CC:
Mr. Dmitry Vagman,
VP & Pharmacist in Charge
Kings Park Slope, Inc.
dba Kings Super Pharmacy/Kings Pharmacy
357 Flatbush Avenue
Brooklyn, NY 11238