Kings Park Slope Inc 3/27/15

Department of Health and Human Services

Public Health Service
Food and Drug
Administration
New York District
158-15 Liberty Ave.
New York, NY 11433

Telephone: 718-340-7000
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March 27, 2015

WARNING LETTER NO., NYK 2015-28

UNITED PARCEL SERVICE
DELIVERY SIGNATURE REQUESTED

Ronald DelGaudio, President and CEO
Kings Park Slope, Inc. (dba Kings Pharmacy)
357 Flatbush Avenue
Brooklyn, NY 11238

Dear Mr. DelGaudio:

You registered with the U.S. Food and Drug Administration (FDA) as an outsourcing facility under section 503B of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 353b]***[1]*** on December 23, 2013, and again on January 5, 2015. From March 4, 2014, to March 14, 2014, FDA investigators inspected your facility, Kings Park Slope, Inc., dba Kings Pharmacy, located at 357 Flatbush Ave., Brooklyn, NY 11238. During the inspection, the investigators observed serious deficiencies in your practices for producing sterile drug products, which put patients at risk. For example, the investigators observed that operators produced sterile drug products with exposed skin on their faces and wearing non-sterile gowns and non-sterile facemasks. In addition, the investigators observed that operators wore non-sterile gloves in at least one of the ISO 5 areas while producing sterile drug products. Furthermore, the investigators found that your firm failed to demonstrate through appropriate studies that your hoods are able to provide adequate protection of the ISO 5 area in which sterile products are produced. Therefore, your products may be produced in an environment that poses a significant contamination risk. In addition, the investigators observed that you failed to meet the conditions under section 503B of the FDCA necessary for drugs produced by an outsourcing facility to

qualify for exemptions from certain requirements under the FDCA. FDA issued a Form FDA 483 to your facility on March 14, 2014. FDA acknowledges receipt of your facility's response, dated March 25, 2014.

Based on this inspection, it appears your facility is producing drugs that violate the FDCA.

A. Compounded Drugs under the FDCA

The Drug Quality and Security Act (DQSA) was enacted on November 27, 2013. Title I of the DQSA, the Compounding Quality Act (CQA), added a new section 503B to the FDCA. Under section 503B(b), a compounder can register as an outsourcing facility with FDA. Drug products compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility can qualify for exemptions from the drug approval requirements in section 505 of the FDCA [21 U.S.C. § 355(a)], the requirement in section 502(f)(1) of the FDCA [21 U.S.C. § 352(f)(1)] that labeling bear adequate directions for use, and the Drug Supply Chain Security Act requirements in section 582 of the FDCA [21 U.S.C. § 360eee-1] if the conditions in section 503B of the FDCA are met.

An outsourcing facility, which is defined in section 503B(d)(4) of the FDCA [21 U.S.C. § 353b(d)(4)], is a facility at one geographic location or address that — (i) is engaged in the compounding of sterile drugs; (ii) has elected to register as an outsourcing facility; and (iii) complies with all of the requirements of this section. Outsourcing facilities must comply with other provisions of the FDCA, including section 501(a)(2)(B) [21 U.S.C. § 351(a)(2)(B)], regarding current good manufacturing practice (CGMP), and section 501(a)(2)(A) [21 U.S.C. § 351(a)(2)(A)], regarding insanitary conditions. Generally, CGMP requirements for the preparation of drug products are established in Title 21 of the Code of Federal Regulations (CFR) parts 210 and 211.

B. Violations of the FDCA

The investigators noted that drug products that were intended or expected to be sterile were prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or rendered injurious to health, causing them to be adulterated within the meaning of section 501(a)(2)(A) of the FDCA. Furthermore, FDA investigators observed significant CGMP violations at your facility, causing your drug products to be adulterated within the meaning of section 501(a)(2)(B) of the FDCA.

In addition, the FDA investigators also observed that your facility failed to meet the conditions of section 503B. For example, during the inspection, FDA investigators noted:

1. None of your facility's drug products include the following on the labeling: "This is a compounded drug." (Section 503B(a)(10) of the FDCA [21 U.S.C. §353b(a)(10)]).

2. Your facility failed to submit a report to FDA upon initial registration as an outsourcing facility in December 2013, and again in June 2014, identifying the drug

products that you compounded during the previous 6-month period. (Section 503B(b)(2) of the FDCA [21 U.S.C. §353b(b)(2)]).

Because your compounded drug products have not met all of the conditions in section 503B, they are not eligible for the exemptions under section 503B from the FDA approval requirements in section 505, the requirement under section 502(f)(1) that labeling bear adequate directions for use, and the Drug Supply Chain Security Act requirements in section 582 of the FDCA. [2]

Specific violations are described below.

Adulterated Drug Products

FDA investigators noted that drug products compounded in your facility that were intended or expected to be sterile were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health, causing your drug products to be adulterated under section 501(a)(2)(A) of the FDCA. For example, the investigators observed that operators produced sterile drug products with exposed skin on their faces and wearing non-sterile gowns and non-sterile facemasks. In addition, the investigators observed that operators wore non-sterile gloves in at least one of the ISO 5 areas while producing sterile drug products. Furthermore, the investigators found that your firm failed to demonstrate through appropriate studies that your hoods are able to provide adequate protection of the ISO 5 area in which sterile products are produced. Therefore, your products may be produced in an environment that poses a significant contamination risk.

FDA investigators also noted CGMP violations at your facility, causing your drug products to be adulterated within the meaning of section 501(a)(2)(B) of the FDCA. The violations include, for example:

1. Your firm failed to establish and follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile, and that include validation of all aseptic and sterilization processes (21 CFR 211.113(b)).

2. Your firm failed to ensure that manufacturing personnel wear clothing appropriate to protect drug product from contamination (21 CFR 211.28(a)).

3. Your firm failed to establish an adequate system for monitoring environmental conditions in aseptic processing areas (21 CFR 211.42(c)(10)(iv)).

Outsourcing facilities must comply with CGMP requirements under section 501(a)(2)(B) of the FDCA. FDA's regulations regarding CGMP requirements for the preparation of drug products have been established in 21 CFR parts 210 and 211. FDA intends to promulgate more specific CGMP regulations for outsourcing facilities. FDA has issued a draft guidance, *Current Good Manufacturing Practice — Interim Guidance for Human Drug Compounding Outsourcing Facilities under Section 503B of the FD&C Act*. This draft guidance, when finalized, will describe FDA's expectations regarding outsourcing facilities and the CGMP requirements in 21 CFR

parts 210 and 211 until more specific CGMP regulations for outsourcing facilities are promulgated.

It is a prohibited act under section 301(k) of the FDCA [21 U.S.C. § 331(k)] to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being adulterated.

Misbranded Drug Products

You compound drug products that are intended for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners, and adequate directions cannot be written for them so that a layman can use these products safely for their intended uses. Consequently, their labeling fails to bear adequate directions for their intended uses, causing them to be misbranded under section 502(f)(1) of the FDCA , and they are not exempt from the requirements of section 502(f)(1) of the FDCA (*see, e.g.,* 21 CFR § 201.115). It is a prohibited act under section 301(k) of the FDCA to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being misbranded.

Failure to Report Drugs

As noted above, your facility failed to submit a report to FDA upon initial registration as an outsourcing facility in December 2013, and again in June 2014, identifying the drug products that you compounded during the previous 6-month period. (Section 503B(b)(2) of the FDCA [21 U.S.C. §353b(b)(2)]). Outsourcing facilities are required to submit a report "identifying the drugs compounded by such outsourcing facility during the previous 6-month period." 503B(b)(2)(A)(i). It does not matter whether they are compounded pursuant to a patient specific prescription or not. The failure to report drugs by an entity that is registered with FDA in accordance with section 503B(b) is a prohibited act under section 301(ccc)(3) of the FDCA [21 U.S.C. § 331(ccc)(3)].

C. Corrective Actions

In your March 25, 2014, response to the Form FDA 483 you stated that your firm does not currently "provide patient non-specific compounding services," although you intend to do so in the future. You referencedyour purported compliance with USP-NF General Chapter <797> Pharmaceutical Compounding - Sterile Preparations, and you committed to correcting some of the deviations identified on the Form FDA 483 issued on March 14, 2014.

As noted above USP <797> is not the applicable standard for outsourcing facilities. Outsourcing facilities must comply with CGMP requirements under section 501(a)(2)(B) of the FDCA. With regard to correcting the conditions observed at your facility, although several of your proposed corrective actions appear adequate, others are deficient. For example, your written response to FDA's observation regarding personnel clothing is inadequate because it is not clear if your procedures will continue to allow exposed skin and the use of non-sterile facemasks and other gowning items. Furthermore, it is not clear if operators will use sterile gloves in all ISO 5 areas.

FDA strongly recommends that your management immediately undertake a comprehensive assessment of your operations, including facility design, procedures, personnel, processes, materials, and systems. In particular, this review should assess your aseptic processing operations. A third party consultant with relevant sterile drug manufacturing expertise could be useful in conducting this comprehensive evaluation. You should fully implement necessary corrections in order to ensure that the drug products produced by your firm conform to the basic quality standards that ensure safety, identity, strength, quality, and purity.

D. Conclusion

The violations cited in this letter are not intended to be an all-inclusive statement of violations at your facility. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction. FDA intends to re-inspect your facility to verify corrective actions have been completed.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps you have taken to correct violations. Please include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you do not believe that the products discussed above are in violation of the FDCA, include your reasoning and any supporting information for our consideration. If the corrective actions cannot be completed within fifteen working days, state the reason for the delay and the time frame within which the corrections will be completed. Please address your reply to LCDR Frank Verni, Compliance Officer, at the address above.

If you have questions regarding the contents of this letter, please contact LDCR Frank Verni at (718) 662-5702.

Sincerely,
/S/
Ronald Pace
District Director
New York District

cc:
Dmitry Vagman, Vice President

Gennady Levin, RPh.

New York State Education Department
Office of the Professions
State Board of Pharmacy

Attn: Lawrence H. Mokhiber, Executive Secretary
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New York State Department of Health
Attn: Dr. Howard A. Zucker, Acting Commissioner
Corning Tower
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Albany, NY 12237

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[1] *See* Pub. L. No. 113-54, § 102(a), 127 Stat. 587, 587-588 (2013).

[2] See, e.g., section 503B(a)(11) of the FDCA [21 U.S.C. § 353b(a)(11)].