# Chen Shwezin, Inc. dba Park Compounding Pharmacy 3/15/17

Los Angeles District
19701 Fairchild
Irvine CA 92612-2506
Telephone: 949-608-2900
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**WARNING LETTER**

**UNITED PARCEL SERVICE**
**SIGNATURE REQUIRED**

March 15, 2017

**WL# 20-17**

Dr. Justin Y. Chen, Owner and Pharmacist in Charge
Chen Shwezin, Inc., dba Park Compounding Pharmacy
280 N. Westlake Blvd, Suite 100
Westlake Village, CA 91362-7014

Dear Dr. Chen:

From August 31, 2015, to September 11, 2015, U.S. Food and Drug Administration (FDA) investigators conducted an inspection of your facility, Chen Shwezin Inc., dba Park Compounding Pharmacy, located at 280 N. Westlake Blvd, Suite 100, Westlake Village, CA 91362-7014.

During the inspection, the investigators noted that you were not receiving valid prescriptions for individually-identified patients for a portion of the drug products you were producing. In addition, the investigators observed serious deficiencies in your practices for producing sterile drug products, which put patients at risk. For example, our investigators observed that your **(b)(4)**, where aseptic processing occurred, was located in an unclassified room and had multiple holes and slots that opened directly to the unclassified area. Moreover, your firm exposed the interior of the **(b)(4)** to

unclassified air by removing the front panel of the unit during **(b)(4)** cleaning. Additionally, your firm did not use a sporicidal agent and used non-sterile sanitizers and non-sterile wipes to clean the **(b)(4)**. In addition, the investigators observed a tear in one pair of gloves installed on the **(b)(4)**, as well as multiple stains at various locations within the **(b)(4)**. Furthermore, your firm failed to demonstrate through appropriate studies that your **(b)(4)** is able to provide adequate protection of the aseptic production area in which sterile products are processed. Therefore, your products may be produced in an environment that poses a significant contamination risk. FDA investigators collected environmental samples of multiple locations in your facility. Testing results of these samples identified microbial contamination in multiple locations, including the area where aseptic processing occurred.

FDA issued a Form FDA 483 to your firm on September 11, 2015. Based on this inspection, it appears that you produced drugs that violate the Federal Food, Drug, and Cosmetic Act (FDCA).

**A. Compounded Drugs Under the FDCA**

Section 503A of the FDCA [21 U.S.C. § 353a] describes the conditions under which certain compounded human drug products may qualify for exemptions from three sections of the FDCA: compliance with current good manufacturing practice (CGMP) (section 501(a)(2)(B) of the FDCA) [21 U.S.C. § 351(a)(2)(B)]; labeling with adequate directions for use (section 502(f)(1) of the FDCA) [21 U.S.C. § 352(f)(1)]; and FDA approval prior to marketing (section 505 of the FDCA) [21 U.S.C. § 355]. Receipt of valid prescriptions for individually-identified patients is one of the conditions for the exemptions under section 503A of the FDCA.

During the FDA inspection, the investigators observed that your firm does not receive valid prescriptions for individually-identified patients for a portion of the drug products you produce. Accordingly, the drugs you compound without valid prescriptions for individually identified patients do not qualify for the exemptions in section 503A of the FDCA.

In addition, we remind you that there are other conditions that must be satisfied to qualify for the exemptions in section 503A of the FDCA.[1]

**B. Violations of the FDCA**

The drug products that you manufacture and distribute without valid prescriptions for individually-identified patients are misbranded drugs in violation of section 502(f)(1) of the FDCA.

In addition, drug products that are intended or expected to be sterile were prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth, or whereby they may have been rendered injurious to health. As such, all sterile products you manufacture are adulterated within the meaning of section 501(a)(2)(A) [21 U.S.C. § 351(a)(2)(A)] of the FDCA. Furthermore, because you manufacture and distribute a portion of your drugs without valid prescriptions for individually-identified patients, the manufacture of those drugs is also subject to FDA's CGMP regulations for Finished

Pharmaceuticals, Title 21, *Code of Federal Regulations* (CFR), Parts 210 and 211. FDA investigators observed significant CGMP violations at your facility, causing such drug products to be adulterated within the meaning of section 501(a)(2)(B) of the FDCA.

**Misbranded Drug Products**

You compounded drug products for which you did not obtain valid prescriptions for individually-identified patients. These drug products are intended for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners. Therefore, adequate directions for use cannot be written 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, and they are not exempt from the requirement to have labeling with adequate directions for use, 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) (*see, e.g.*, 21 CFR § 201.115).

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 misbranded.

**Adulterated Drug Products**

FDA investigators observed that drug products 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 may have been rendered injurious to health, causing the drug products to be adulterated under section 501(a)(2)(A) of the FDCA. For example, your **(b)(4)**, where aseptic processing occurred, was located in an unclassified room and had multiple holes and slots that opened directly to the unclassified area. Moreover, your firm exposed the interior of the **(b)(4)** to unclassified air by removing the front panel of the unit during **(b)(4)**cleaning. Additionally, your firm did not use a sporicidal agent and used non-sterile sanitizers and non-sterile wipes to clean the **(b)(4)**. In addition, the investigators observed a tear in one pair of gloves installed on the **(b)(4)**, as well as multiple stains at various locations within the **(b)(4)**. Furthermore, your firm failed to demonstrate through appropriate studies that your **(b)(4)** is able to provide adequate protection of the aseptic production area in which sterile products are processed.

FDA investigators collected environmental samples of multiple locations in your facility. Testing results of these samples identified microbial contamination in multiple locations, including the area where aseptic processing occurred.

The FDA investigators also observed CGMP violations at your facility, causing the drug products for which you have not obtained valid prescriptions for individually-identified patients to be adulterated under section 501(a)(2)(B) of the FDCA. The violations include, for example:

1. Your firm failed to establish an adequate system for maintaining equipment used to control the aseptic conditions (21 CFR 211.42(c)(10)(vi)).

2. Your firm failed to establish an adequate system for cleaning and disinfecting the room and equipment to produce aseptic conditions (21 CFR 211.42(c)(10)(v)).

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

4. 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)).

5. Your firm does not have, for each batch of drug product purporting to be sterile and/or pyrogen-free, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product (21 CFR 211.167(a)).

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

Under section 301(k) of the FDCA, it is a prohibited act 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.

**C. Corrective Actions**

FDA acknowledges that on September 30, 2015, your firm stated its intent to cease sterile drug production and surrender its Sterile Compounding Pharmacy License (SCPL) to the California State Board of Pharmacy, and that on October 6, 2015, your firm voluntarily recalled all sterile drug products within expiry. Further, FDA acknowledges receipt of your letter dated September 20, 2016, in which you state your firm's decision to permanently stop all sterile compounding activities and surrender your SCPL.

If your firm decides to resume processing of sterile drugs in the future at the facility we inspected or another facility, 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 and design. A third party consultant with relevant sterile drug manufacturing expertise could be useful in conducting this comprehensive evaluation.

Please be aware that section 501(a)(2)(A) of the FDCA concerning insanitary conditions applies regardless of whether the drugs are compounded and distributed after receipt of a prescription for an identified individual patient.

In addition, if you resume the manufacture and distribution of drug products without valid prescriptions for individually-identified patients, the manufacture of such drugs would be subject to FDA's drug CGMP regulations (21 CFR Parts 210 and 211), among other requirements, and, before doing so, you should fully implement corrections that meet the minimum requirements of 21 CFR Part 211 in order to provide assurance that the drug products produced by your firm conform to the basic

quality standards regarding safety, identity, strength, quality, and purity. You should also correct the violations of section 502(f)(1) of the FDCA, noted above.

**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.

If you decide to resume processing of sterile drugs, 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.

Within fifteen working days of receipt of this letter, please notify this office in writing if you have taken any specific steps to correct violations, or you may inform us that you do not intend to resume production of sterile drugs. If you intend to resume production of sterile drugs in the future, 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. In addition to taking appropriate corrective actions, you should notify this office fifteen working days prior to resuming production of any sterile drugs in the future.
Your written response should be directed to:

Kelly Sheppard
Director, Compliance Branch
Food & Drug Administration
Los Angeles District Office
19701 Fairchild
Irvine, CA 92612

If you have questions regarding any issues in this letter, please contact Ms. Jessica Mu, Compliance officer, via email at jessica.mu@fda.hhs.gov or by phone at 949-608-4477.

Sincerely,
/S/
CDR Steven E. Porter, Jr.
Director, Los Angeles District

Cc: Virginia Herold, Executive Officer (Via E-mail)
California State Board of Pharmacy
1625 N. Market Boulevard, Suite N-219
Sacramento, CA 95834

[1] For example, section 503A also addresses anticipatory compounding, which includes compounding (not distribution) before receipt of a valid prescription order for an individual patient. We are not addressing anticipatory compounding here.