Greenpark Compounding Pharmacy 10/26/18

Office of Pharmaceutical Quality
Operations, Division II
4040 N. Central Expressway, Suite 300
Dallas, Texas 75204

October 26, 2018

CMS CASE #566233

WARNING LETTER

VIA UPS EXPRESS

Kenneth L. Hughes
Co-Owner and President
Prescription Labs, Inc.
dba Greenpark Compounding Pharmacy
4061-F Bellaire Blvd.
Houston, Texas 77025

Mr. Hughes:

From October 16, 2017, to October 27, 2017, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Prescription Labs, Inc., dba Greenpark Compounding Pharmacy, located at 4061-F Bellaire Blvd., Houston, Texas 77025. The investigator noted serious deficiencies in your practices for producing sterile drug products, which put patients at risk.

FDA issued a Form FDA 483 to your firm on October 27, 2017. FDA acknowledges receipt of your facility's response, dated November 30, 2017. Based on this inspection, it appears that you produced drug products that violate the Federal, Food Drug and Cosmetic Act (FDCA).

A. Violations of the FDCA

Adulterated Drug Products

The FDA investigator noted that drug products 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 [21 U.S.C. § 351(a)(2)(A)]. For example:

1. Personnel were engaged in aseptic processing inside the ISO5 area with partially exposed skin and wearing non-sterile garb.

2. Personnel were observed re-sanitizing gloved hands with non-sterile **(b)(4)** before resuming aseptic processing inside the ISO 5 area.

3. The wipes used for disinfecting the interior of the ISO 5 hood are not sterile.

4. The certification of the ISO 5 classified areas is inadequate because there is no evidence it included non-viable particle counts.

5. Your firm failed to perform smoke studies under dynamic conditions to demonstrate unidirectional airflow within the ISO 5 area. Therefore, your products intended to be sterile are produced in an environment that may not provide adequate protection against the risk of contamination.

6. **(b)(4)** testing of the **(b)(4)** was not routinely performed for products intended to be sterile.

7. The use of **(b)(4)**-minute contact time for the use of **(b)(4)** as a sporicidal agent in the ISO 5 areas is inadequate.

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.

B. Corrective Actions

We have reviewed your firm's response to the Form FDA 483.

Regarding some of the insanitary condition observations in the Form FDA 483, we cannot fully evaluate the adequacy of the following corrective actions described in your response because you did not include sufficient information or supporting documentation:

1. According to your response, you will "conduct a more comprehensive observation of competency assessments: Aseptic Technique." However, you did not provide any details of what the "more comprehensive observation" will entail and who would be conducting these observations. Furthermore, you did not include any timeframe or completion date for these assessments or what actions you intend to take if deviations are identified.

2. According to your response, you will "review with sterile compounding personnel, that sterile **(b)(4)** is the approved sanitizing solution." However, it is unclear how or when you intend to obtain the sterile **(b)(4)** since you did not include a receipt or a Certificate of Analysis (CoA) for the sterile **(b)(4)**. In addition, you did not provide any supporting training documentation for staff pertaining to the use of sterile **(b)(4)** in the aseptic processing areas.

3. According to your response, you will review with compounding personnel "the importance of process documentation for all **(b)(4)** testing." However, you did not provide any supporting training documentation for staff to ensure that they will be documenting and performing the test according to procedure. In addition, you have not provided safeguards to confirm that this process is documented appropriately in the future.

4. According to your response, you will "begin using **(b)(4)** Wipes" with a contact time "determined by the manufacturer." However, you did not provide a receipt, CoA, or the contact time being used for the wipes. Furthermore, you did not provide the expected date the **(b)(4)** wipes would be received or used within the ISO 5 areas or any information regarding the wipes being non-shedding. You also did not provide any personnel training documentation for this changed procedure.

Regarding other observations related to insanitary conditions, some of your corrective actions appear deficient:

1. In your response, you indicated that you comply with the "Texas State Board of Pharmacy and USP <797> requirements, to use lint free wipes in the clean room"; however, the practice of using non-sterile wipes in the ISO 5 hood can increase the potential for contamination to be introduced into the ISO 5 aseptic processing areas.

2. In your response, you indicated that you comply with the "Texas State Board of Pharmacy requirements regarding airflow smoke pattern Test." However, you failed to commit to conducting new certifications or smoke pattern tests under dynamic conditions to show that ISO 5 areas can maintain unidirectional air flow. In response to this letter, please also include the non-viable particle counts as part of the new certifications.

Please be aware that section 501(a)(2)(A) of the FDCA concerning insanitary conditions applies regardless of whether drug products you compound meet the conditions of section 503A of the FDCA.

In addition, our review of the information collected during the inspection revealed the following:

1. You did not appear to use biological indicators (BI) during **(b)(4)** sterilization of finished drug products. Consequently, it is unclear if the sterilization conditions are adequate for inactivating all potential microbial contamination.

2. The **(b)(4)** is classified as an ISO 8, even though it is attached to an ISO 7 **(b)(4)** with an ISO 5 **(b)(4)** used for hazardous drug production. When an ISO 7 **(b)(4)** is negative to the **(b)(4)**, the **(b)(4)** should be classified ISO 7 or better to prevent ingress of lesser quality air.

3. Your media fills were not performed under the most challenging or stressful processing conditions. Therefore, there is a lack of assurance that your firm can aseptically produce drug products within your facility.

FDA strongly recommends that your management undertake a comprehensive assessment of operations, including facility design, procedures, personnel, processes, maintenance, materials, and systems. In particular, this review should assess your aseptic processing

operations. A third-party consultant with relevant sterile drug manufacturing expertise should assist you in conducting this comprehensive evaluation.

C. 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.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that 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 you cannot complete corrective action within 15 working days, state the reason for the delay and the time within which you will complete the correction.

Your written notification should refer to the Warning Letter Number above (**CMS Case #566233**). Please address your reply to John W. Diehl, Director, Compliance Branch, at the FDA address provided on bottom of first page of this letter. Additionally, please submit a signed copy of your response on your firm's letterhead via e-mail to ORAPHARM2_Responses@fda.hhs.gov.

If you have questions regarding the contents of this letter, please contact Rebecca A. Asente, Compliance Officer, via (504) 846-6104 or Rebecca.asente@fda.hhs.gov.

Sincerely,
/S/
Monica R. Maxwell
Program Division Director
Office of Pharmaceutical Quality Operations, Division II

Cc:
Allison Vordenbaumen Benz, Executive Director Texas State Board of Pharmacy
William P. Hobby Building, Suite 3-500 333 Guadalupe Street
Austin, Texas 78701

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