Vital Rx, Inc. dba Atlantic Pharmacy and Compounding 9/26/18

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

September 26, 2018

CMS# 539399

VIA UPS OVERNIGHT

Jeffrey Friedman, Owner
Vital Rx, Inc. dba Atlantic Pharmacy and Compounding
1000 E. Atlantic Blvd., Suite 110
Pompano Beach, Florida 33060-7479

Mr. Friedman:

From June 26, 2017, to July 20, 2017, U.S. Food and Drug Administration (FDA) investigators inspected, Vital Rx, Inc., dba Atlantic Pharmacy and Compounding, located at 1000 E. Atlantic Blvd., Suite 110, Pompano Beach, Florida 33060. At the time of the inspection, this firm was owned by Mr. Serge Francois. This firm and its assets were then purchased by you on August 16, 2017. During the inspection, the investigators noted serious deficiencies in your firm's practices for producing drug products, which put patients at risk.

FDA issued a Form FDA 483 to your firm on July 20, 2017. FDA acknowledges your firm ceased drug production on July 20, 2017, and your firm initiated a voluntary recall of all lots of unexpired compounded injectable drug product on August 17, 2017. Lastly, FDA acknowledges the September 5, 2017, Florida Department of Health order for the emergency restriction of your firm's special sterile compounding permit, which acts to "prohibit the pharmacy from compounding sterile preparations and dispensing any compounded sterile preparations, until a Department inspector confirms through re-inspection that Vital Rx is safe to resume the practice of compounding sterile preparations."

Based on this inspection, it appears that you produced drug products that violate the FDCA.

A. Violations of the Federal Food Drug and Cosmetic Act (FDCA)

Adulterated Drug Products

The FDA investigators noted that drug products 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. Your firm did not use a sporicidal agent to disinfect the laminar flow hood, an area where drug products intended to be sterile were produced.

2. Your firm has no assurance that the endotoxin level of your intrathecal drug products is safe since you do not have any endotoxin data and your firm doesn't perform endotoxin testing for the intrathecal finished drug products.

3. Your firm used non-pharmaceutical grade filters to sterilize drug products. Specifically, the filter manufacturer precautions "Do not use this product for direct patient care applications; it was designed for laboratory use only."

4. Your firm has no assurance that glass vials used for filling injectable drug products are sterile.

5. Your environmental monitoring program is inadequate. For example, there was no viable or surface monitoring of your laminar flow hood where drug products intended to be sterile were produced.

6. Your laminar flow hood horizontal air vent, through which first air passes, had a visible stain.

7. Your firm produced hazardous drugs without providing adequate cleaning of work surfaces and reusable equipment to prevent cross-contamination.

8. The powder containment hood located in the ISO 8 cleanroom used for weighing and mixing bulk drug substances housed an air conditioning filter which was not designed for this piece of equipment. The filter was observed falling onto the work surface of this hood and it was held in place using packing tape, which is a difficult to clean surface.

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

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

FDA did not receive a response from your firm to the Form FDA 483 issued at the close of the inspection on July 20, 2017. As a result, we have not been able to evaluate the adequacy of any corrective actions that you may have taken in response to the Form FDA 483. We acknowledge your voluntary recall of all lots of unexpired compounded injectable drug product due to concern over lack of sterility assurance. In addition, we acknowledge that you

ceased drug production on July 20, 2017. Lastly, FDA acknowledges the September 5, 2017, Florida Department of Health order for the emergency restriction of your firm's special sterile compounding permit.

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.

FDA strongly recommends that if you decide to resume production of sterile drugs, your management first 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 processing 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 the firm complies with all requirements of federal law, including FDA regulations.

If you decide to resume sterile operations, the current owner 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 (15) working days of receipt of this letter, we ask that the current owner please notify this office in writing if you have taken any specific steps to correct the violations cited in this letter, 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, the current owner should 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 violated the FDCA, include the reason and any supporting information for our consideration. In addition to taking appropriate corrective actions, the current owner should notify this office 15 days prior to resuming production of any sterile drugs in the future.

Electronically mail your written response to Mark W. Rivero, Compliance Officer, Office of Pharmaceutical Quality Operations, Division 2, Compliance Branch, at ORAPHARM2_RESPONSES@fda.hhs.gov. Please identify your response with CMS Case # 539399.

If you have questions regarding the contents of this letter, please contact Mr. Rivero at (504) 846-6103.

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

CC:

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