Professional Arts Pharmacy 4/3/17

Baltimore District Office
6000 Metro Drive, Suite 101
Baltimore, MD 21215
Telephone: (410) 779-5455
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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
WL # 518272

April 3, 2017

Mr. Simeon Georgiou, Owner
Professional Arts Pharmacy
2015 Lord Baltimore Drive
Baltimore, MD 21244-2558

Dear Mr. Georgiou:

From March 2, 2016, to March 23, 2016, U.S. Food and Drug Administration (FDA) investigators conducted an inspection of your facility, Professional Arts Pharmacy, located at 2015 Lord Baltimore Drive, Baltimore, MD 21244-2558. During the inspection, the investigators observed 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 March 23, 2016. FDA acknowledges receipt of your firm's response to the Form FDA 483 dated April 13, 2016. Further, FDA acknowledges your action on April 13, 2015, to cease sterile operations and your action on April 15, 2016, to voluntarily recall all sterile products within expiry.

Based on this inspection, it appears that you are producing drugs that violate the Federal Food, Drug, and Cosmetic Act (FDCA).

A. Violations of the FDCA

Adulterated Drug Products

The FDA investigators noted 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 rendered injurious to health, causing your drug products to be adulterated under section 501(a)(2)(A) of the FDCA. For example, our investigators noted the work areas/countertops of the laminar flow hoods (LFH) are constructed of **(b)(4)**. A technician was observed cleaning the exterior, interior and equipment located inside the LFH using the same non-sterile wipe. In addition, your firm did not sterilize and depyrogenate glassware used in the production of sterile drug products. The Heating, Ventilation and Air Conditioning (HVAC) system feeding air to the HEPA filters is turned off at the end of the workday and on the weekends, and you have no data showing that your cleanroom environment returns to the desired air quality upon restarting the HVAC system. Moreover, your cleanroom is only separated from the general unclassified area via plastic strip curtains and your facility lacks pressure gauges to monitor the pressure differential between these areas. Furthermore, your firm failed to demonstrate, through appropriate studies, that your hoods are able to provide adequate protection of the ISO 5 areas in which sterile products are being produced.

Under section 301(a) of the FDCA [21 U.S.C. § 331(a)], the introduction or delivery for introduction into interstate commerce of any drug that is adulterated is a prohibited act. Further, 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 planned corrective actions, as documented in your April 13, 2016 response to the Form FDA 483 of inspectional observations issued at the close of the inspection, and acknowledge your actions taken on April 13 and 15, 2016, to temporarily suspend the production of sterile products and voluntarily recall all sterile drug products within expiry. Regarding the following insanitary condition observations in the Form FDA 483, the following corrective action appears adequate:

Form FDA 483 Observation 4A – you stated that you upgraded the work areas/countertops to **(b)(4)** and had all pharmacy technicians and pharmacists retrained on the proper cleaning of the cleanroom to produce and maintain aseptic conditions.

Regarding the following insanitary conditions observations in the Form FDA 483, we are unable to fully evaluate the following corrective actions due to lack of adequate supporting documentation:

Form FDA 483 Observation 1 – you stated that "effective immediately after FDA's March 2016 inspection, Professional Arts has changed its prior procedures concerning turning off and on the HEPA filters. The Pharmacy now feeds the HEPA

filters (i.e., keeps them on and running) 24 hours a day." We acknowledge that the air feeding the HEPA filter will run continuously; however, your certification report (184025) dated November 19, 2015, indicates that the gowning room does not have a HEPA filter. We will verify the gowning room certification and differential pressures in the cleanroom areas during our next inspection.

Form FDA 483 Observation 2 – you stated that "Professional Arts immediately instituted a Clean Room Cleaning Competency training program for all pharmacists and technicians that perform sterile compounding at the Pharmacy. The training focuses on appropriate clean room garb and gowning technique." However, you did not specifically address concerns regarding the reuse of hair nets. In addition, you failed to provide documentation of the updated gowning procedures.

Form FDA 483 Observation 3B – you stated that smoke studies will be performed around mid-May 2016 under dynamic conditions, and that you would provide the results to FDA when complete. However, you still have not provided this documentation for our review.

In addition, you did not address certain observations related to insanitary conditions, including Form FDA 483 Observation 4B. Specifically, your firm has not addressed the concerns of our investigators regarding the white or the yellow residue and any corrective actions that the firm has taken to ensure it has been adequately removed.

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, which provides exemptions from certain other requirements of the FDCA.

FDA strongly recommends that if you plan to resume production of sterile drugs, your management immediately undertake a comprehensive assessment of your operations, including facility design, procedures, personnel, processes, materials, and systems before doing so. 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.

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.

If you decide to resume sterile operations, 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, 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 15 days prior to resuming production of any sterile drugs in the future.

Your written notification should refer to Warning Letter Number above (518272). Please address your reply to:

Ernest F. Bizjak, Compliance Officer
FDA Baltimore District Office
U.S. Food and Drug Administration
6000 Metro Drive, Suite 101
Baltimore, MD 21215

If you have questions regarding the contents of this letter, please contact Mr. Bizjak via email at ernest.bizjak@fda.hhs.gov or by phone at 301-796-4081.

Sincerely,
/S/
Evelyn Bonnin
District Director
Baltimore District