American Specialty Pharmacy 4/4/17

Dallas District Office
4040 N. Central Expressway,
Suite 300
Dallas, Texas 75204

April 4, 2017

2017-DAL-WL-13

WARNING LETTER

UPS OVERNIGHT

Abdul Hameed, Owner
American Specialty Pharmacy, Inc.
13988 Diplomat Drive, Suite 100
Farmers Branch, Texas 75234

Dear Mr. Hameed:

From July 29, 2015, to August 5, 2015, U.S. Food and Drug Administration (FDA) investigators inspected your facility, American Specialty Pharmacy, located at 10 Medical Parkway, Suite 105, Dallas, Texas 75234. During the inspection, the investigators noted serious deficiencies in your practices for producing sterile drug products, which put patients at risk.

FDA issued a FDA-483, Inspectional Observations, to your firm on August 5, 2015. FDA acknowledges receipt of your facility's responses, dated August 20, 2015, and July 13, 2016. Based on this inspection, it appears that you produced 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 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, the investigators observed that poor aseptic practices, including operators not disinfecting their materials and components prior to introducing them into the ISO 5 area from the ISO 7 area. Additionally, expired cleaning agents were used to clean the ISO 5 area. Furthermore, our investigators noted that your firm did not conduct any environmental monitoring within your ISO 5 area since January 2015.

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 responses to the FDA 483. We acknowledge your firm's intention to cease sterile drug production at this facility. You stated that you are "voluntarily closing" the sterile division at 10 Medical Parkway, Dallas, Texas, "with no intentions of resuming sterile drug production." FDA also acknowledges receipt of your electronic communication dated September 7, 2016, in which you stated that the "facility at 10 Medical Pkwy is already closed and we never did any non-sterile drugs compounding at that location."

FDA strongly recommends that if you decide to resume production of sterile drugs, your management immediately first undertake a comprehensive assessment of your 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 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 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, 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 violated 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 the Warning Letter Number above (2017-DAL-WL-13). Please address your reply to John W. Diehl, Compliance Officer, at the address above.

If you have questions regarding the contents of this letter, please contact John Diehl at 214-253-5288.

Sincerely,
/S/
Shari J. Shambaugh
Acting Dallas District Director

CC:

Gay Dodson, RPh, Executive Director
Texas State Board of Pharmacy
William P. Hobby Building
Tower 3, Suite 600
333 Guadalupe Street
Austin, Texas 78701