Trone Health Services, Inc. 3/22/17

U.S. FOOD & DRUG ADMINISTRATION

Seattle District Office
22215 26th Avenue SE, Suite 210
Bothell, Washington 98021

March 22, 2017

OVERNIGHT DELIVERY
SIGNATURE REQUIRED

In reply refer to WL SEA 17-08

Devin R. Trone, Pharm.D., President
Trone Health Services, Inc. dba Medicap Pharmacy # 8362
2790 W Cherry Lane, Suite 100
Meridian, Idaho 83642-1102

WARNING LETTER

Dear Dr. Trone:

From June 27, 2016, to July 15, 2016, U.S. Food and Drug Administration (FDA) investigators inspected your facility, Trone Health Services, Inc., dba Medicap Pharmacy # 8362, located at 2790 W Cherry Lane, Suite 100, Meridian, Idaho 83642-1102. During the inspection, the investigators noted serious deficiencies in your practices for producing sterile drug products, which put patients at risk. For example, the investigators noted that your firm had produced drug products intended or expected to be sterile in a non-ISO 5 powder containment hood. Consequently, these drug products were produced in an environment that posed a significant contamination risk.

FDA issued a Form FDA 483 to your firm on July 15, 2016. FDA acknowledges receipt of your firm's response, dated August 3, 2016. FDA also acknowledges the statement you "no longer will be compounding any sterile preparations." Additionally, FDA acknowledges your firm's voluntary recall of Acetylcysteine Ophthalmic 10% Solution (Lot 05092016@19) initiated on July 7, 2016. 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 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 may have been rendered injurious to health, causing your drug products to be adulterated under section 501(a)(2)(A) of the FDCA. For example, the investigators observed that your firm had produced drug products intended or expected to be sterile in a non-ISO 5 powder containment hood. Consequently, these drug products were produced in an environment that posed a significant contamination risk.

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. We acknowledge your statement that your firm has ceased all sterile compounding. We further acknowledge your voluntary recall of Acetylcysteine Ophthalmic 10% solution (Lot 05092016@19) on July 7, 2016.

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, materials, and systems. In particular, this review should assess your aseptic processing operations. A third party consultant with relevant sterile drug processing expertise could be useful in conducting this comprehensive evaluation.

C. Production of Domperidone

We also note that in April 2014 and May 2015 your records indicate that you compounded and distributed domperidone products. Drug products compounded using domperidone are not eligible for the exemptions provided by section 503A of the FDCA. Our review of your records indicates that you have not compounded domperidone products since that time.

Should you compound and distribute drug products that do not meet the conditions of section 503A, the compounding and distribution of such drugs would be subject to the new drug approval requirement, the requirement for the labeling of such drugs to bear adequate directions for use, and the drug CGMP regulations.

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

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 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 (SEA 17-08). Please address your reply to:

Jessica L. Kocian, Compliance Officer
22215 26th Avenue SE, Suite 210
Bothell, WA 98021

If you have questions regarding the contents of this letter, please contact Jessica Kocian at 425-302-0444.

Sincerely,
/S/
Miriam R. Burbach
District Director

More in 2017 (/ICECI/EnforcementActions/WarningLetters/2017/default.htm)