



VIA SIGNATURE CONFIRMED DELIVERY

July 19, 2018

Alex J. Adams, PharmD, MPh
Executive Director
Idaho State Board of Pharmacy
PO Box 83720
Boise, ID 83720

Reference: FEI # 3012086997

Dear Dr. Adams:

The purpose of this letter is to refer to the Idaho State Board of Pharmacy (BOP) for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concerns about poor non-sterile practice standards observed during an FDA inspection at a pharmacy licensed by the Idaho BOP, Trone Health Services, Inc. dba Medicap Pharmacy #8362, located at 2790 W. Cherry Lane Suite 100, Meridian, ID 83642 (Retail pharmacy license # 1957RP and Retail Outlet with Controlled Substance Registration license # RP-0002755-CS).

FDA inspected the firm from October 30, 2017, to November 21, 2017. FDA investigators were accompanied by an inspector from the Idaho BOP on November 2, 2017, for one day of observation. A copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at: <https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORAElectronicReadingRoom/UCM587692.pdf>, with any nonpublic information redacted. Because we consider this inspection to be "closed" under 21 CFR 20.64(d)(3), you may request a copy of the Establishment Inspection Report (EIR) that FDA will provide to the firm, which contains additional information about our inspection. If you are a Commissioned Official or if your state agency has entered into a 21 CFR 20.88 information sharing agreement, you may be able to receive a copy of the Form FDA 483 or the EIR that includes certain nonpublic information. Alternatively, you may also choose to request a copy of the EIR directly from the firm.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Trone Health Services, Inc. dba Medicap Pharmacy #8362 and determined, based on this sample, that this firm appears to obtain valid prescriptions for individually-identified patients for the drug products that it compounds and distributes.

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During the inspection, the FDA investigators observed deviations from appropriate non-sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Examples of deviations observed during our inspection include:

1. The use of a non-pharmaceutical grade component (water) to produce drug products.
2. The production of hazardous drugs (hormones) without providing adequate cleaning of work surfaces, equipment and utensils to prevent cross contamination.

Trone Health Services, Inc. dba Medicap Pharmacy #8362 committed to FDA in its responses to the Form FDA 483 dated December 12, 2017, and March 23, 2018, to correct the deviations and provided documentation in support of those corrective actions. In addition, the deviations identified appear to be readily correctable.

After review of the records, FDA does not intend to take further action at this time with regards to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients before distributing its compounded drugs, as required by section 503A(a) of the Federal Food, Drug and Cosmetic Act, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Idaho BOP for follow up to ensure appropriate corrective action is taken. Please notify us if you become aware of any adverse events or product quality concerns associated with drugs made at this facility, or if you observe any practices at this facility that concern you or that could be violations of Federal law.

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact Maria P. Kelly-Doggett, Compliance Officer, at (425) 302-0427, or by email at maria.kelly-doggett@fda.hhs.gov.

Sincerely,

Thomas R. Berry -S

Digitally signed by Thomas R. Berry -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA,
ou=People, 0.9.2342.19200300.100.1.1=1300192872,
cn=Thomas R. Berry -S
Date: 2018.07.19 13:43:59 -0600

CAPT Thomas R. Berry, BSP Pharm, PharmD
Director (Acting), Division of Pharmaceutical Quality Operations IV

SP:mpk

Cc: Trone Health Services, Inc
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2790 W. Cherry Lane Suite 100
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