U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
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Detroit, MI 48207
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May 1, 2018

UPS NEXT DAY
SIGNATURE REQUIRED

Cheryl Wykoff Pezon
Michigan State Board of Pharmacy
Bureau of Professional Licensing/Licensing Division
611 W Ottawa, 3rd Floor,
PO Box 30670
Lansing, MI 48909-8170

Dear Ms. Pezon:

The purpose of this letter is to refer to the Michigan State Board of Pharmacy (BOP) for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concerns about poor sterile practices observed during an FDA inspection at a pharmacy licensed by the Michigan BOP, Tri-Med, Inc. dba Advanced Care Infusion-Shelby, located at 39011 Harper Avenue, Clinton Township, MI 48036 (pharmacy license #5301006991).

FDA inspected the firm from June 26, 2017, to July 11, 2017. FDA investigators were accompanied by Michigan state investigators for one day. A copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm572410.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), 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.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Tri-Med, Inc. dba Advanced Care Infusion-Shelby 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.

During the inspection, the FDA investigators observed deviations from appropriate aseptic 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. Disinfecting agents and cleaning wipes used in the aseptic processing areas are not sterile.

2. Equipment, materials, and /or supplies are not disinfected prior to entering the aseptic processing areas.

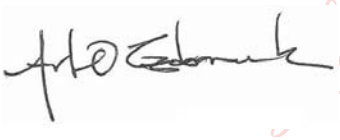
3. Pressure differentials are not adequately monitored between classified and unclassified areas to ensure proper airflow during aseptic processing.

Tri-Med dba Advanced Care Infusion committed to FDA in its response to the Form FDA 483 received July 25, 2017, to correct the deviations in the Form FDA 483. The agency requested additional information on October 12, 2017, for which Tri-Med dba Advanced Care Infusion provided documentation on October 18, 2017, in support of those corrective actions. In addition, the deviations identified appear to be readily correctable.

After review of the record, FDA does not intend to take further action at this time with regard 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 Michigan State 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 Tina M. Pawlowski Compliance Officer, at (313) 393-8217, or by email at tina.pawlowski@fda.hhs.gov.

Sincerely,



Digitally signed by Art O. Czabaniuk -S
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Date: 2018.05.01 10:33:19 -04'00'

Art O. Czabaniuk
Program Division Director
Division of Pharmaceutical Quality Operations III

Cc:

Dr. William C. Drake, PharmD, President
Tri-Med, Inc. dba Advanced Care Infusion-Shelby
39011 Harper Avenue
Clinton Township, MI 48036