



U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
300 River Place, Suite 5900
Detroit, MI 48207
Telephone: (313) 393-8100
Fax: (313) 393-8139
www.fda.gov

February 23, 2018

Cody C. Wiberg
Executive Director
Minnesota State Board of Pharmacy
2829 University Ave SE, Suite 530
Minneapolis, MN 55414-3251

Dear Dr. Wiberg:

The purpose of this letter is to refer to the Minnesota 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 Minnesota BOP, Heartland I.V. Care, located at 1400 Energy Park Drive, Suite 17, Saint Paul, MN 55108-5272 (Sterile Product Compounding, Home Health Care Pharmacy License 263118).

FDA inspected the firm from July 10, 2017, to July 14, 2017. FDA investigators were accompanied by Minnesota state investigators for four days. 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/OfficeofGlobalRegulatoryOperationandPolicy/ORAElectronicReadingRoom/UCM571293.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 Heartland I.V. Care 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 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:

- The firm did not use a sporicidal agent in the ISO 5 aseptic processing areas.

Heartland I.V. Care committed to correcting the deviation in its July 27, 2017 response to the Form FDA 483. Their response to FDA included a detailed plan of the sporicidal agents to be implemented as well as the frequency and contact times that will be required. In addition, the deviation identified appears 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 Minnesota 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 Brian D. Garthwaite, Ph.D., Compliance Officer, at 612-758-7132, or by email at Brian.Garthwaite@fda.hhs.gov.

Sincerely,

**Nicholas F.
Lyons -S**

Nicholas F. Lyons
Compliance Director
Division of Pharmaceutical Quality Operations III

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

 Digitally signed by Nicholas F. Lyons -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=1300120033,
cn=Nicholas F. Lyons -S
Date: 2018.02.23 12:38:02 -06'00'

CC: Stacey Sekutowski
Regional Pharmacy Manager
Heartland I.V. Care
1400 Energy Park Drive, Suite 17
Saint Paul, MN 55108-5272