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

July 1, 2019

UPS NEXT DAY
SIGNATURE REQUIRED

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

Dear Mr. 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, Infuscience, Inc., located at 2915 Waters Road, Suite 110, Eagan, MN 55121-1562 (Pharmacy License #262958).

FDA inspected the firm from April 17, 2018, to April 25, 2018. FDA investigators were accompanied by a Minnesota state investigator for 5 days. 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/ucm606504.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 Infuscience, Inc. 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. In the response to the Form FDA 483, dated May 10, 2018, the firm advised FDA that it "compounds and dispenses human medications that comply with Section 503A of the Federal Food, Drug and Cosmetic Act ("Section 503A")."

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:

1. The ISO 5 classified aseptic processing areas had visibly dirty surfaces.

2. Personnel moved quickly in a critical area such that unidirectional airflow is likely to be disrupted.

3. Personnel conducted aseptic manipulations in an area where the movement of "first air" in the ISO 5 area was blocked.

4. Materials or supplies were not disinfected prior to entering the aseptic processing areas.

5. Personnel engaged in aseptic processing were observed with exposed hands.

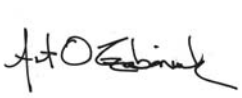
6. ISO 5 classified areas were not certified under dynamic conditions.

Infuscience, Inc. committed to FDA in its written responses to correct the deviations in the Form FDA 483 and provided documentation 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 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 Eric Mueller, Compliance Officer, at 402-331-8536 ext. 101.

Sincerely,



Digitally signed by Art O. Czabaniuk -S
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Date: 2019.07.01 15:40:51 -04'00'

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

cc: Lee R. Boyd
General Manager
Infuscience, Inc.
2915 Waters Road, Suite 110
Eagan, MN 55121-1562