U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
300 River Place, Suite 5900
Detroit, MI 48207
Telephone: (313) 393-8100
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March 28, 2019

UPS NEXT DAY
SIGNATURE REQUIRED

Steven W. Schierholt, Esq.
Executive Director
Ohio State Board of Pharmacy
77 S High Street, Room 1702
Columbus, OH 43215-6126

Dear Mr. Schierholt:

The purpose of this letter is to bring to the attention of the Ohio Board of Pharmacy (BOP), the U.S. Food and Drug Administration's (FDA) concern about poor sterile practices observed during an FDA inspection at a pharmacy licensed by the Ohio BOP, Infusion Partners, LLC located at 4137 Boardman Canfield Road, Suite L104, Canfield, OH 44406-8087. The inspection occurred between January 22, 2018 and January 26, 2018. FDA investigators were accompanied by an Ohio BOP Compliance Specialist on the first day of the inspection. Attached is a redacted copy of the Form FDA 483 that documents our investigators' observations from the inspection, and a redacted copy of the warning letter issued based on observations made during the inspection.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Infusion Partners, LLC and observed, based on this sample, that this firm appears to obtain valid prescriptions for individually-identified patients for the drug products that it compounds for administration to individual patients.

Drug products compounded in accordance with the conditions in section 503A of the Food Drug and Cosmetic Act (FDCA) [21 U.S.C. § 353a] are exempt from section 501(a)(2)(B) (concerning current good manufacturing practices (CGMP)), section 502(f)(1) (concerning labeling with adequate directions for use), and section 505 (concerning premarket approval)) [21 U.S.C. §§ 351(a)(2)(B), 352(f)(1), and 355]. Among other things, to be eligible for the 503A exemptions, the drug product must be compounded for an identified individual patient based on the receipt of a valid prescription. However, even if they qualify for the exemptions under section 503A, such compounded drug products remain subject to all other applicable provisions of the FDCA, including the requirement that the drug products not be prepared, packed, or held under insanitary conditions (section 501(a)(2)(A)).

During the inspection, the FDA investigators observed deficiencies in the firm's practices for producing sterile products that put patients at risk. The warning letter FDA sent to Infusion Partners, LLC identifies conditions observed during the inspection that appear to violate the FDCA, including the

prohibition on insanitary conditions. Due to the nature of the violations, FDA intends to follow up with the firm regarding correction of the insanitary conditions.

In addition, we ask that you 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, via email at eric.mueller@fda.hhs.gov or by phone at 402-331-8536 ext. 101.

Sincerely,

Digitally signed by Art O. Czabaniuk -S
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Date: 2019.03.28 10:17:04 -04'00'

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