DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Southwest Region
Kansas City District
8050 Marshall Drive
Suite 205
Lenexa, Kansas 66214-1524
913-495-5100

May 9, 2016

Kathie Lueke, Program Manager
Nebraska Department of Health & Human Services
Division of Public Health
301 Centennial Mall South
Lincoln, NE 68509

Dear Ms. Lueke:

The purpose of this letter is to refer to the Nebraska 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 Nebraska BOP, Nebraska Methodist Hospital Pharmacy, located at 8303 Dodge Street, Omaha, NE 68114-4108 (Community Pharmacy License #2527).

FDA inspected the firm from December 8, 2015, to December 18, 2015. The FDA investigator was accompanied by a Nebraska state investigator for three days. A redacted copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm485859.pdf

During the inspection, the FDA investigator reviewed a small sample of records for products compounded by Nebraska Methodist Hospital Pharmacy 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 dispenses.

During the inspection, the FDA investigator observed deviations from appropriate aseptic practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. For example, the firm's smoke studies, performed on (b) (4) (b) (4) do not include an evaluation of the (b) (4) ISO 5 Laminar Flow Hoods utilized in the aseptic production of sterile human drug products. In addition, the smoke studies, also performed on (b) (4), of (b) (4) Laminar Flow Hood do not include an evaluation of unidirectional flow of the entire HEPA grid located inside the cabinet.

Nebraska Methodist Hospital Pharmacy committed to correct the deviations in its December 29, 2015, response to the Form FDA 483. In addition, the deviations identified appear to be readily correctable. The firm committed to (b) (4)

After review of the record, at this time FDA does not intend to take further action with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients, consistent with traditional pharmacy practice, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Nebraska 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 Danial Hutchison, Compliance Officer, at 913-495-5154, or by email at Danial.Hutchinson@fda.hhs.gov

Sincerely,

For: Cheryl A. Bigham
District Director
U.S. Food and Drug Administration
Kansas City District Office