DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	12/8/2015-12/18/2015* FEI NUMBER 1000511010

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Firouzan Massoomi , Pharmacy Operations Coordinator

FIRM NAME	STREET ADDRESS
Nebraska Methodist Hospital	8303 Dodge St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Omaha, NE 68114-4108	Producer of Sterile Drug Products

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

Environmental monitoring (viable/non-viable air, surface, and personnel) is not conducted daily during production in areas where sterile drug products are produced. Currently, you conduct fingertip sampling (b) (4) surface microbiological sampling (b) (4), and non-viable/viable air sampling every (b) (4). Sterile drug production occurs (b) (4)% of workdays throughout the year at this site.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically,

a) The smoke studies performed on (b) (4) and (b) (4) do not include an evaluation of (b) (4) ISO 5 laminar flow hoods identified as (b) (4). These (b) (4) ISO 5 laminar flow hoods were identified by management as the primary hoods utilized in bulk production of sterile injectable human drugs such as Phenylephrine 80 mcg/2 mL of normal saline and Hydromorphone 0.2 mg/mL, 30 mL PCA.

Furthermore,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Joseph R Lambert, Investigator 12/18/2015 X Joseph R Lambert Joseph R Lambert Investigator Signed by: Joseph R. Lambert -S	12/18/2015

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The current smoke studies (which were performed on (b) (4) and (b) (4) on ISO 5 laminar flow hood (b) (4)) do not include an evaluation of unidirectional flow of the entire HEPA grid inside the cabinet of the ISO 5 laminar flow hood.

b) The "worst case scenario", in regards to media fills, for production of sterile injectable human drugs has not been established to assure larger batched sterile drug products produced in your ISO 5 laminar flow hoods are sterile. Your current procedure for "high-risk" media fill includes the (b) (4) (b) (4) (b) (4) (b) (4) This is in contrast to the (b) (4) of a typical batch of (b) (4) -2 mL syringes of sterile injectable Phenylephrine 80 mcg/Normal Saline 0.9% 2 mL.

OBSERVATION 3

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically,
The ISO 5 laminar flow hood (identified as (b) (4)), which is utilized for production of batches of sterile drug products, had an approximately 1 inch by 5 inch rectangle filled with what appeared to be clear silicon caulking in the center of the metal grid which protects the laminar flow hood HEPA filter. This occlusion, appearing to be clear silicone caulking, in the metal grid of the laminar flow hood has not been evaluated to ensure unidirectional air flow is not affected.

OBSERVATION 4

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components conform to appropriate standards of identity, strength, quality and purity.

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Specifically,

The certificates of analysis for (b) (4), which are utilized for environmental surface sampling and personnel monitoring in the clean room, are not reviewed prior to use in your environmental sampling plan.

***DATES OF INSPECTION**

12/08/2015(Tue),12/09/2015(Wed),12/10/2015(Thu),12/16/2015(Wed),12/18/2015(Fri)

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."