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 Industry Information: www.fda.gov/oc/industry	06/24/2014 - 07/14/2014* FEI NUMBER 1000511010

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: 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 cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

You have failed to document cleaning of your "Clean Room", including the cleaning of your IV hood (b) and IV hood (b) where you produce sterile drug products. (Sterile, non-shedding wipes and sterile (b) (4) are used).

Specifically, "Compounded Sterile Products, Intravenous Products Compounding, effective 1/1990", states, in part, "The laminar flow hood shall be cleaned at the (b) (4) and (b) (4) during the day with (b) (4) The IV Technician will document cleaning by signing the log next to the hood." Additionally, you have failed to conduct and document cleaning with a sporicidal agent.

Your records documenting cleaning of the IV hoods, bins, cart and shelving are deficient for the months of (at a minimum) April, May and June of 2014. Records indicate this cleaning of the IV hoods (b) and (b) is not documented on a (b) (4) basis. Additionally, the form requires (b) (4) cleaning of Bins, Cart and Shelving. This is not documented as required for the months of April, May and June of 2014.

OBSERVATION 2

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

You have failed to conduct and document Environmental Monitoring in your IV rooms (where sterile drug products are produced)

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	Eric M. Mueller, Investigator Eric Mueller	07/14/2014

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Specifically,

Environmental Monitoring is not conducted daily in areas where sterile drug products are produced.

Additionally, Your procedure for conducting surface sampling states Environmental Monitoring (EM) will be conducted on a (b) (4) basis to monitor microbial bioburden of work surfaces to analyze for trends for improvement. (areas to test include: the IV room laminar hoods, chemo hoods, counters used for checking IVs and pass-through cabinets and or window plates).

Your records (June 2013 to June 2014) indicate this required (b) (4) EM sampling was not completed in entirety for the months of 7/13, 8/13, 9/13, 2/14, 5/14 and 6/14. Additionally, raw data results for surface sampling are not kept by your facility and could not be verified.

Lastly, Procedures and records do not exist for the environmental monitoring of your ISO 5 areas (within your facility) and personnel monitoring of your operators on a daily basis covering all shifts.

OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written, and followed.

Specifically,

Smoke studies are not conducted or documented by your site to verify airflow patterns in the areas where you produce sterile drug products. This failure includes airflow studies are not conducted and documented under static or dynamic conditions.

OBSERVATION 4

Clothing of personnel engaged in the manufacturing, processing, packing, and holding of drug products is not appropriate for the duties they perform.

Specifically,

Personnel producing sterile drug products are not gowned with sterile gowning (for example, non-sterile gowns, masks

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and hair nets are used in the areas where you produce sterile drug products).

Additionally. your personnel have exposed skin around the eyes, head and neck area in your ISO 5 laminar airflow hoods area while producing sterile drug products.

OBSERVATION 5

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Specifically,

You have failed to document a 100% visual check prior to distribution of your sterile finished drug products.

OBSERVATION 6

Test procedures relative to appropriate laboratory testing for sterility and pyrogens are not written and followed.

Specifically,

Specifically, sampling and testing of sterile finished drug products (for sterility/endotoxin) is not conducted by your site prior to release for use.

Lastly, the potency of your sterile drug products is not supported by data for the shelf life claimed. No data exists supporting the shelf life of your sterile drug products produced at this site.

*** DATES OF INSPECTION:**
06/24/2014(Tue), 06/25/2014(Wed), 06/26/2014(Thu), 06/27/2014(Fri), 07/03/2014(Thu), 07/09/2014(Wed), 07/14/2014(Mon)

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	Eric M. Mueller, Investigator E. Mueller	07/14/2014