DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6751 Steger Drive Cincinnati, OH 45237-3097 (513) 679-2700 Fax:(513) 679-2772 Industry Information: www.fda.gov/oc/industry	09/08/2014 - 09/24/2014* FEI NUMBER 1000220363

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: E. Pat Vann, President

FIRM NAME	STREET ADDRESS
Vann Healthcare Services Inc	1220 N Race St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Glasgow, KY 42141-3462	Producer of sterile drugs

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

Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.

Specifically, The gown worn by the operator performing aseptic manipulations on Sept. 10, 2014 in the ISO 5 laminar flow hood was not sterile and it did not grip and cover the wrists and the V-neck gown did not cover the operator's upper chest.

OBSERVATION 2

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

Specifically,

a. The [redacted] (b) (4) sterilization process for Lidocaine 4% injectable and the [redacted] (b) (4) sterilization process for Hydroxyprogesterone caproate injection have not been validated.
b. The [redacted] (b) (4) for the [redacted] (b) (4) stoppers used for Hydroxyprogesterone caproate injection 250 mg/ml has not been validated.
c. Media fills have not been conducted to validate the aseptic processes performed in the ISO 5 laminar flow hood.
d. [redacted] (b) (4) testing, such as a [redacted] (b) (4) test, is not performed for products sterilized by [redacted] (b) (4).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Kathleen Dant Culver, Investigator/Drug Preapproval Manager Kathleen Dant Culver	09/24/2014

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OBSERVATION 3

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically, There is no sterility or endotoxin test data for:
a. Lidocaine 4% injectable with a 60 day beyond use period at refrigerated storage.
b. Epinephrine 1:1000 injection with a 30 day beyond use period at room temperature storage.
c. Hydroxyprogesterone caproate injection, 250 mg/ml, with a 90 day beyond use period at room temperature storage.

OBSERVATION 4

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, There is no potency test data to support the beyond use dating periods assigned for:
a. Lidocaine 4% injectable with a 60 day beyond use period at refrigerated storage.
b. Epinephrine 1:1000 injection with a 30 day beyond use period at room temperature storage.
c. Hydroxyprogesterone caproate injection, 250 mg/ml, with a 90 day beyond use period at room temperature storage. There is also no test data to support antimicrobial effectiveness throughout the labeled beyond use period for this product.

OBSERVATION 5

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

Specifically,

a. There are no smoke studies conducted under dynamic conditions in the ISO 5 laminar flow hood where aseptic operations are performed to verify there is no obstruction or alteration of the HEPA-filtered air.
b. There is no continuous monitoring of differential air pressure between the ISO 5 laminar flow hood where aseptic operations are performed and the adjacent areas during production.

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OBSERVATION 6

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

Specifically, There is no monitoring of viable particles, non-viable particles, work surfaces or personnel in the ISO 5 laminar flow hood where aseptic operations are performed.

OBSERVATION 7

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room to produce aseptic conditions.

Specifically, Sporicidal disinfectants are not used to clean/disinfect the ISO 5 laminar flow hood.

*** DATES OF INSPECTION:**
09/08/2014(Mon), 09/09/2014(Tue), 09/10/2014(Wed), 09/11/2014(Thu), 09/12/2014(Fri), 09/23/2014(Tue), 09/24/2014(Wed)

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9/24/14

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