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	09/15/2015 - 09/30/2015* FEI NUMBER 1000220363

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Jennifer G. Wood, Pharmacist in Charge

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

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

The control systems necessary to prevent contamination or mix-ups are deficient.

Specifically,
On May 8, 2015, your firm manufactured Dexamethasone 24 mg/ml injection solution 24 mg/ml injectable, lot 05082015@1, a sterile product, in a compounding area of your firm under non-sterile conditions.

OBSERVATION 2

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

Specifically,
The Logged Formula Worksheet record for Dexamethasone 24 mg/ml injection solution 24 mg/ml injectable, lot 05082015@1, identifies to compound the product in a laminar flow hood using aseptic technique and to (b)(4)(b)(4)
Your Pharmacist in Charge identified that the product was(b)(4)
as part of the process, however the entire compounding process including the (b)(4)
(b)(4)

OBSERVATION 3

Rejected components are not controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable.

Specifically,
Dexamethasone 24 mg/ml injection solution 24 mg/ml injectable, lot 05082015@1, was compounded on May 8, 2015. Per the Logged Formula Worksheet record, an expired ingredient, (b)(4), expiration date 3/20/2015,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Michael P. Sheehan, Investigator	09/30/2015

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was used in the compounding of the product on 5/8/15. Your records also do not identify a lot number for the expired (b)(4) (b)(4) used. Records identify that the product was also dispensed for use to an individual on 5/8/15.

Betahistine Dihydrochloride 12 mg capsules, lot 06192015@1, was compounded on June 19, 2015. Per the Logged Formula Worksheet record, an expired ingredient, (b)(4) lot (b)(4) expiration date 9/1/14, was used in the compounding of the product on 6/19/15.

Carbomer 0.5% Aqueous Gel, lot 08102015@3, was compounded on August 10, 2015. Per the Logged Formula Worksheet record, an expired ingredient, (b)(4) , expiration date 5/7/15, was used in the compounding of the product on 8/10/15.

OBSERVATION 4

Batch production and control records do not include the specific identification of each batch of component used for each batch of drug product produced.

Specifically,
Your Logged Formula Worksheet record do not always identify the lot number and/or expiration date of ingredients used in the compounding of a product.

For example:

Ketoprofen 10% Ketamine 10% Lindocaine USP 10% Pro Gel, lot 07102015@4, does not identify the lot number of the Ketoprofen USP (b)(4) ingredient used, and does not identify the lot number and expiration date of the (b)(4) (b)(4) ingredient or the (b)(4) used in the compounding process.

Zonisamide 100 mg/ml suspension, lot 07152015@2, does not identify the lot number and expiration date of the Zonisamide 100 mg (b)(4) or the (b)(4) (b)(4) used in the compounding process.

Clobetasol/Menthol/Camphor, lot 09092015@1, does not identify the lot number or expiration date for any of the (b)(4) ingredients used in the compounding process.

*** DATES OF INSPECTION:**
09/15/2015(Tue), 09/16/2015(Wed), 09/17/2015(Thu), 09/30/2015(Wed)

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	Michael P. Sheehan, Investigator	09/30/2015