DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax:(407) 475-4768 Industry Information: www.fda.gov/oc/industry	07/14/2014 - 07/28/2014* FEI NUMBER 3004596923

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: N. Lois Adams, CRPh, MBA, President/CEO

FIRM NAME	STREET ADDRESS
HHCS Pharmacy, Inc. dba Freedom Pharmacy	3901 E. Colonial Dr.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Orlando, FL 32803-4602	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 WE OBSERVED:

OBSERVATION 1

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

a) Your firm stated that you can use the (b)(4) System or the (b)(4) System for the (b)(4) of sterile inhalation drug products produced from non-sterile powder components. However, there is no documentation that these syringe or dispensing systems contain a (b)(4) for the sterilization of liquid drug products. It was stated that the sterile inhalation drug product Vancomycin 200mg/Betamethasone 0.5mg/Tobramycin 125mg, 3ml syringes lot# 060914CE was produced on 6/9/2014 by using one of these devices not intended for sterilization.

b) Your firm stated that (b)(4) is not conducted after producing a sterile drug from non-sterile components when using the (b)(4).

c) You stated your firm has no written procedures for process validation using media fill testing, nor are you following your firm's guidance document that states "validate current pharmacists and technicians who manipulate sterile IV admixtures and validate each newly hired staff member before they begin performing any manipulation requiring impeccable aseptic technique". For high risk compounding the guidance states, (b)(4) for high-risk level tests, or whenever unacceptable technique is observed.

- Your firm produced a high risk inhalation drug product Vancomycin 200mg/Betamethasone 0.5mg/Tobramycin 125mg, 3ml syringes lot# 060914CE on 6/9/2014, from non-sterile components (powders).

The most recent documentation your firm was able to provide was a media fill record dated

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9/3/2010 for a Pharmacy Technician whom is currently performing sterile compounding. There are no records of a media fill conducted by the other (b) (4) Pharmacy Technicians currently performing sterile production.

OBSERVATION 2

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically,
a) On 07/16/14, rust was observed on one (1) HEPA filter ceiling screen within your firm's ISO 7 cleanroom which may increase the risk of particulate contamination to the airflow from the HEPA filter.

b) There is a kitchen grade sink with an open drain located in the anteroom immediately adjacent to the pass-through box which your firm uses to transport drug products, excipients and supplies sprayed with (b) (4) into the classified area (ISO 5 hood) for the production of sterile products.

c) There is no line of demarcation or designated gowning area immediately adjacent to the cleanroom ISO 7 area, no "clean" or "dirty" side and no specific instruction for employees to reduce the potential ingress of contaminants into the cleanroom environment.

d) The ceiling in both the cleanroom and anteroom were not sealed. Three (3) ceiling tiles in the anteroom (ISO 8) were observed to be cracked and water damaged. One (1) ceiling tile within the anteroom was observed to be porous.

OBSERVATION 3

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

Specifically,

a) Surface and air monitoring of the ISO 5 classified laminar airflow workstations (LAFW) is not

conducted when sterile drug products are produced.

b) Personnel monitoring, including fingertip sampling and sampling of the gown for operators involved in sterile operations of injectable and inhalation drug products in the ISO 5 LAFW is not conducted when sterile drug products are produced.

c) Your firm does not monitor the differential pressure, temperature or humidity in your ISO 7 and ISO 8 classified areas.

d) Your firm lacks a magnehelic pressure gauge between the anteroom and un-classified areas; therefore your firm cannot ensure the differential pressure is maintained adequately to prevent the likelihood of contamination of your sterile products. Your firm has a magnehelic gauge located in the ISO 7 cleanroom which measures differential pressure, but your firm could not provide any documentation that the gauge has been calibrated.

e) You stated that your firm experienced a power outage on July 14th, 2014 at approximately 2:00 pm and lasted approximately two (2) hours. On July 16, 2014 we observed that the ISO 5 hoods were turned off. Your firm was unable to provide a procedure for cleaning and sanitizing of the cleanroom environment prior to initiating sterile production to ensure that the environment remains adequate for use.

f) Your firm did not have environmental media plates in your inventory and you stated that you perform (b) (4) environmental monitoring when you have the plates to do so. Your firm's "(b) (4) Culture Testing" logs dated January 2014 through July 2014 indicate the following:

- Your firm conducted environmental monitoring for only one week of each month: January 2014 (Week 3, 1/13-1/17), February 2014 (Week 2, 2/10-2/14), March 2014 (Week 2, 3/10-3/14) and April 2014 (Week 3, 4/14-4/18) and not on the days in which sterile production was performed.

Your firm produced the sterile injectable product Cefepime HCL on 2/17/2014, however your "(b) (4) Culture Testing log" indicates environmental monitoring was only conducted the second week of February (2/10-2/14). This product is preservative free.

Your firm produced the sterile injectable product Amikacin 1,000mg/4 ml vial on or about 4/2/2014,

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however your firm's "(b)(4) Culture Testing log" indicates environmental monitoring was only conducted the third week of April (4/14-4/18). This product is preservative free.
Your firm's guidance document titled "Pharmacy IV Admixture QA Procedures", "A guide to monitoring of work area environmental conditions, validation of aseptic technique, and sterility and pyrogen testing" dated 03/05, which is currently not being used has not been implemented or followed as evidenced by:
You stated your firm has no written procedures for environmental monitoring, nor are you following the recommendations of at least (b)(4) in areas used to compound high-risk preparations as stated in your guidance document. For example:
Your firm produced Gentamycin lot# 012714CA, 7.2mg/15ml on 1/27/2014, and Amikacin lot# 013114CA, 250mg/4ml on 1/31/2014.
Your "(b)(4) CULTURE Testing" log for January 2014 indicates your firm performed environmental monitoring only on (Week 3, 1/13-1/17) of the month.

g) You stated that you have not established specifications for viable organisms in your classified areas, your "(b)(4) Culture Testing Log" indicates "p" for pass, there are no failing results indicated on your logs from January 2014 to present and there is no indication that any bacterial colonies have ever been present on the plates. Your Pharmacy Technician stated that he "wipes" down the surfaces with (b)(4) prior to sampling.

OBSERVATION 4

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

Specifically,

Technicians are not qualified for proper gowning.

- Operators performing aseptic operations in the ISO 5 hoods are wearing non-sterile gowns. In addition, the operators are not wearing appropriate sterile sleeve protectors.

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OBSERVATION 5

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically,

Your firm has not conducted smoke studies under static and dynamic conditions within the ISO 5 laminar air flow hoods to ensure that the presence of operators and equipment do not impede the laminar airflow from the HEPA filters.

OBSERVATION 6

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

Specifically,
a) According to the June 2014 qualification report it revealed that there was one viable bacterial count above the action level in the Class 5 hood located to the left when looking into the cleanroom. The following organism was found from a surface sample plate (b)(4)), identified as coagulase negative Staphylococcus, a human contaminant. Your firm appears to have taken no corrective action in increasing environmental disinfection to every (b)(4) hood cleaning with (b)(4) during active sterile compounding hours as it is not reflected on the Sterile Room Cleaning Log for June 2014. Also a thorough investigation regarding this finding was never conducted as stated in your firm's SOP for "Cleaning of IV Hood & Work Surfaces" Section 3 a-c.

b)Your firm's SOP for "Cleaning of IV Hood & Work Surfaces", dated 05/94, Section 1 g. states that floors in the buffer area as well as the anteroom area, should be mopped (b)(4), but according to your firm's Sterile Room Cleaning Log for the month of May 2014 your firm did not perform a routine (b)(4) cleaning (clean hood, clean counters, mop floors, remove sticky pad layer, remove garbage, restock supplies, etc.) on May 6, 2014, the same day(b)(4) doses of Gentamycin 7.2mg/15ml (for inhalation use), Lot # 050614CB were produced. A routine (b)(4) cleaning was also not performed on

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May 7, 2014.

c) The suitability, efficacy, and limitations of disinfecting agents and procedures have not been assessed to ensure potential contaminants are adequately removed from surfaces in the ISO 5, 7 & 8 classified areas. For example,

1) Your firm uses (b) (4) as your sanitization agent on the floors of the cleanroom and anteroom. Your firm stated that you pour the (b) (4) directly on the floor; there is no indication that the (b) (4) is adequately diluted to ensure adequate sanitization.

2) Routine cleaning procedures of the ISO 5 classified laminar airflow workstation (LAFW) do not include the use of a qualified sporicidal cleaning agent at established frequencies. Your firm does not use a sporicidal agent for cleaning of your classified areas.

3) The (b) (4) antibacterial cleaner is used to mop the floors in the ISO 7 & 8 rooms. In addition, there was no assurance that the " (b) (4) mop pads are non-shedding.

d) Non-sterile wipes are used to wipe the interior surfaces of the (b) (4) ISO 5 hoods. In addition, the non-sterile wipes have not been demonstrated to be non-shedding. An open package of the non-sterile wipes was observed being stored on top of (b) (4) ISO 5 hood within the cleanroom.

e) Your firm's SOP for "Cleaning of IV Hood & Work Surfaces" Section 1 i. states no shipping or other external cartons may be taken into either the buffer or anteroom areas, but on July 16, 2014 a cardboard box containing non-sterile gowns was observed on the countertop of the anteroom (ISO 8).

OBSERVATION 7

Each batch of drug product purporting to be sterile is not laboratory tested to determine conformance to such requirements.

Specifically,

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Your firm has not tested any batch derived from non-sterile drug components for sterility to ensure the products meet the requirements of sterility assurance. For example, your firm produced from non-sterile drug components the sterile inhalation product Vancomycin 200 mg/Betamethasone 0.5 mg/Tobramycin 125 mg per 3 ml syringe lot # 060914CE on 6/9/14, exp: 7/24/14.

OBSERVATION 8

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

Specifically,

The inhalation drug product derived from non-sterile drug components such as Vancomycin 200 mg/Betamethasone 0.5 mg/Tobramycin 125 mg per 3 ml syringe lot # 060914CE on 6/9/14, exp: 7/24/14 was not tested for potency prior to release.

*** DATES OF INSPECTION:**
07/14/2014(Mon), 07/16/2014(Wed), 07/23/2014(Wed), 07/28/2014(Mon)

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