DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax:(615) 366-7802 Industry Information: www.fda.gov/oc/industry	05/18/2015 - 05/28/2015* FEI NUMBER 3004578635

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Randal J. Davis, President and Owner

FIRM NAME	STREET ADDRESS
The Wellness Center Pharmacy, Inc., dba Designer Drugs	7304 Jarnigan Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Chattanooga, TN 37421	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

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

Specifically,

a) Media fills performed for injectable drug products do not simulate the entire production process including but not limited to: all process steps and manipulations, aseptic filling without terminal filtration, and all container/closure systems used for drug products. Additionally, media fills do not include a challenge of worst case conditions including but not limited to: duration of aseptic processing and representative batch size.

b) Integrity testing specifications set by your firm for the Supor 25 and 32 mm syringe filters (0.22 µm) have not been verified by the manufacturer or otherwise validated. These filters are used as sterilizing filters in production of injectable drug products.

c) Sterilization cycles using the Tuttnauer Tabletop Autoclave Model 2340 have not been validated for terminally sterilized finished drug products. Temperature mapping, heat penetration, and loading configurations have not been evaluated to ensure sterilization of finished drug products, equipment, and containers/closures.

d) Sterilization cycles using the All American Model 75X Electric Pressure Steam Sterilizer (serial number 0001199) have not been validated for terminally sterilized finished drug products. Temperature mapping, heat penetration, and loading configurations have not been evaluated to ensure sterilization of finished drug products, equipment, and container/closures. Additionally, the 75X steam sterilizer has not been qualified and no calibration/verification has been performed for the temperature and pressure instruments.

e) Sterilization and depyrogenation cycles using the Yamato DK-43 dry heat oven have not been validated for sterilization and depyrogenation of containers, equipment, and powders used in drug products. Temperature mapping, heat penetration, and loading configurations have not been evaluated to ensure sterilization and depyrogenation of containers, closures, equipment, and drug components. Endotoxin challenges have only been performed for one cycle (glassware cycle), however your firm uses another cycle for powders which has not been challenged. Powders intended to be sterilized in this dry heat oven are then mixed into final injectable drug products without further sterilization. Additionally, the dry heat oven has not

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been qualified and no calibration/verification has been performed for the temperature and pressure instruments.

OBSERVATION 2

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

Specifically, polypropylene isolation barrier gowns, earloop masks, and bouffant caps used for aseptic processing in the Laminar Air Flow Hood (LAFH) (ISO 5 area) are not sterile. Additionally, gowning used for processing in the ISO 5 area does not provide for adequate coverage of the operator. The gowning does not cover the operator's skin on the face and neck and it does not completely cover the operator's clothing. Portions of the operator's backside and lower legs are left uncovered by the isolation barrier gown.

OBSERVATION 3

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

Specifically,

a) Sodium Hypochlorite 0.1% solution used to clean the LAFH (ISO 5 area) is not sterile. Additionally, the ISO 5 area is not periodically cleaned with a sporicide that has been demonstrated to be effective.

b) Blue Shop Towels used for cleaning the LAFH (ISO 5 area) are not sterile.

OBSERVATION 4

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

Specifically,

a) Environmental monitoring of the LAFH (ISO 5 area) including surface, air, and personnel is not performed each day drug products are produced using the LAFH. Currently, surface and personnel monitoring is only performed every two weeks. Also, surface samples taken from the LAFH on 05/18/2015 were taken prior to production immediately after cleaning instead of after production activities. Additionally, non-viable particulate monitoring is only performed every six months during the certification of the LAFH and clean room.

b) The last qualification of the LAFH (Baker model EG-4252 and serial number E-42081) on 01/26/2015 did not include passive viable air sampling. It has been more than 6 months since passive viable air sampling in LAFH has been performed.

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c) Raw data for dynamic smoke studies performed in the LAFH (ISO 5 area) were not documented and retained.

OBSERVATION 5

Equipment for adequate control over air pressure and micro-organisms is not provided when appropriate for the manufacture, processing, packing or holding of a drug product.

Specifically,

The LAFH (ISO 5 area) is not equipped with an air pressure gauge for monitoring pressure differentials. Also, air pressure differentials of the Buffer (IV) Room (ISO 7 area) and the Anteroom (ISO 8 area) are not continuously monitored during production of drug products. Currently, pressure differentials are only checked once a day. Additionally, the pressure reading of the Buffer (IV) Room was observed to be 0.03 inches of water immediately after the sterile filtration of Tri-Mix Lot # 05182015@15. Your firm's pressure differential specification is 0.05 inches of water or greater.

OBSERVATION 6

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

Specifically,

a) The sterile prep area where drug components are weighed, dispensed, and mixed prior to aseptic mixing and filtration is not environmentally controlled. There are no physical barriers to separate the area from the non-sterile prep areas. The air system for the sterile prep area is shared with the rest of the facility and is not appropriately filtered. The ceiling and floors in the sterile prep area are not constructed of readily cleanable materials. Additionally, access to the sterile prep area is not restricted. The area is equipped with a door which opens directly to the retail lobby and entry through this door is not restricted.

b) Hormone Replacement Pellets are prepared in a room, prior to terminal sterilization, which is not environmentally controlled. The air system for the sterile prep area is shared with the rest of the facility and is not appropriately filtered. The ceiling and floors in the sterile prep area are not constructed of readily cleanable materials. The room is equipped with a door which opens directly to a common hallway and entry through this door is not restricted.

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OBSERVATION 7

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design and suitably located to facilitate operations for its cleaning and maintenance.

Specifically,

a) An office phone with handset is mounted to the wall in the Buffer (IV) Room (ISO 7 area).

b) A chair located in the Buffer (IV) Room used by technicians during aseptic operations in the LAFH (ISO 5 area) is not constructed of materials that can be readily sanitized.

c) There is no line of demarcation in the anteroom to separate the clean side from the dirty side. The anteroom is used for hand washing and gowning prior to entering the Buffer (IV) Room (ISO 7).

OBSERVATION 8

The calibration of instruments, apparatus, and gauges is not done at suitable intervals .

Specifically,

a) The Millipore pressure gauge identified as "Jan 2010 8978 8920" used to perform post filtration integrity testing of all sterilizing filters has not been calibrated.

b) Thermometers used in the QL 140E and Boekel model 13200 incubators have not been calibrated. The QL 140E and Boekel model 13200 incubators are used for the incubation of environmental samples and finished drug product sterility and endotoxin samples.

OBSERVATION 9

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

Specifically,

Sterility testing per your firm's procedure "9.110 Sterile Compounding Finished Preparation Testing" is only required on lots consisting of 25 or more units that are exposed longer than 12 hours at temperatures of 2-8 degrees Celsius and longer than six hours at warmer temperatures. Additionally, endotoxin testing is not performed on Hormone Replacement Pellets.

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OBSERVATION 10

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,

Potency testing is not performed on every lot of sterile drug product produced by your firm. Potency testing is at the discretion of the Pharmacist-in-charge according to your firm's procedure "9.110 Sterile Compounding Finished Preparation Testing."

OBSERVATION 11

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

Specifically,

Stability testing performed to extend Beyond Use Dates (BUDs) of sterile drug products up to 270 days did not include sterility testing over the beyond use period. Also, stability studies for preservative containing sterile products did not include testing of the antimicrobial effectiveness of the preservatives over the beyond use period.

OBSERVATION 12

Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.

Specifically,

Temperatures of the QL 140E and Boekel model 13200 incubators are not continuously monitored or documented during incubation of environmental samples and finished drug product sterility and endotoxin samples.

OBSERVATION 13

Each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality.

Specifically, compressed nitrogen used as a blanket/overlay gas in sterile filtered drug products is industrial grade nitorgen. No testing or certificate of analysis in lieu of testing was obtained prior to the use of this industrial grade nitrogen gas in sterile drug production.

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*** DATES OF INSPECTION:**
05/18/2015(Mon), 05/19/2015(Tue), 05/20/2015(Wed), 05/22/2015(Fri), 05/28/2015(Thu)

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