

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 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	DATE(S) OF INSPECTION 10/14/2014 - 10/22/2014*
	FEI NUMBER 1051570

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Mark F. Binkley, Co-owner

FIRM NAME Green Hills Health and Wellness Pharmacy Inc	STREET ADDRESS 329 21st Ave N Suite 3
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CITY, STATE, ZIP CODE, COUNTRY Nashville, TN 37203-1839	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drug Products
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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.

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, and filtration performed under ISO 5 classified areas. Additionally, media fills do not include a challenge of worst case conditions including but not limited to: duration of aseptic processing and represented batch size.

b) A review of your firm's records noted that a media fill was last performed on 05/07/2014. This media fill was the initial personnel qualification for your technician with initials "NS" however there were no repeat media fill runs to qualify the technician.

OBSERVATION 2

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


Specifically,

The cleaning and disinfecting agents PeridoxRTU and AccelTB used to clean the ISO 5 areas are not sterile.

OBSERVATION 3

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

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Brandon C. Heitmeier, Investigator Justin N. Henson, Investigator	DATE ISSUED 10/22/2014
		

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- a) Surface, air, and personnel monitoring of the ISO 5 areas is not performed for each day sterile drug products are produced. Currently, surface, viable air, and personnel monitoring is only performed every two weeks.
- b) Non-viable air monitoring of the ISO 5 areas is not performed for each day sterile drug products are produced. Currently, non-viable air is only monitored during certification of laminar airflow hoods and biological safety cabinets every 6 months.
- c) Disinfectant neutralizers are not used to assure microbial contamination can be detected in environmental monitoring samples.
- d) Raw data for dynamic smoke studies performed in the laminar air flow hoods and biological safety cabinet was not documented and retained.

OBSERVATION 4

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

Specifically,

Air pressure in classified areas is not continuously monitored during production of sterile drug products. Currently, pressure differentials for ISO 5, ISO 7, and ISO 8 areas are only checked once a day.

OBSERVATION 5

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,

- a) Potency testing is not performed on every lot of sterile drug products produced by your firm. According to your firm's procedure, 6.10 Total Quality Management, potency testing on finished drugs products is not required for every lot.
- b) Sterility and endotoxin testing is not required on every lot of sterile drug products produced by your firm according to your firm's procedure, 6.10 Total Quality Management. This procedure states that sterility and endotoxin testing is only required for sterile preparations with a lot size of 25 or more or preparations which have been exposed to temperatures of 2-8C for 12 hours or 6 hours at warmer temperatures.
- c) Sterile drug product lots produced by your firm and sampled for laboratory testing are sometimes released and distributed before receiving laboratory conformation of potency, sterility, and endotoxin tests meeting final specifications.

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OBSERVATION 6

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

Specifically,

Your firm assigns Beyond Use Dates (BUDs) of up to 90 days for preservative free sterile drug products and up to 180 days for preservative containing sterile drug products. Stability studies have not been performed to support these BUDs. Additionally, no studies have been performed for the antimicrobial effectiveness of preservatives over the labeled shelf life.

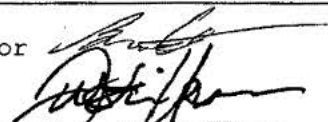
OBSERVATION 7

Equipment and utensils are not maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

Hold time studies have not been performed on equipment that has been autoclaved and depyrogenated and stored for future use. Currently, bulk process equipment and containers used in the production of sterile drugs are given a 90 day expiration, but no studies have been performed to support these hold times.

*** DATES OF INSPECTION:**
10/14/2014(Tue), 10/15/2014(Wed), 10/16/2014(Thu), 10/21/2014(Tue), 10/22/2014(Wed)

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."