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	09/22/2014 - 09/30/2014 FEI NUMBER 1037746

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Rodney NMI Harbin, Sr. , President

FIRM NAME	STREET ADDRESS
Wellness Pharmacy, Inc.	3401 Independence Drive Suite 231
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Birmingham, AL 35209-8326	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 are not established, written, and followed.

Specifically,

a) your firm has not validated the process used in the sterilization of filters used in the sterile filtration of drugs. The autoclave cycle used is based on manufacturer recommendation; however, your firm has not performed any testing to ensure your autoclave sterilizes these filters under your conditions of use. The autoclave cycle is run at 121°C for 20 minutes.

b) your firm has not validated the oven cycle used in the depyrogenation of glassware and utensils used during compounding of drug products intended to be sterile. The oven cycle is run at 250°C for 45 minute; however, your firm has not performed any testing to ensure your equipment is depyrogenated under your conditions of use. Additionally, no time limits have been established for how long depyrogentated equipment can be used past their depyrogenation dates.

c) on 9/23/2014, I observed an operator working in an ISO 5 hood filling PAP +2, lot 140923@40. During set-up for filling, the operator was observed to lean into the vertical flow hood over stoppered, pre-sterilized vials, disrupting air flow.

OBSERVATION 2

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

Specifically, the sporicidal in use at your firm, Sporgon made by Decon, is not appropriate for use over large surface areas. Your firm uses Sporgon for the purpose of sanitizing controlled room surfaces and hoods on a routine basis. Sporgon is designed for soaking and requires a 3 hour contact time.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Samantha J. Bradley, Investigator Patrick C. Dooley, Investigator	09/30/2014

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."

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OBSERVATION 3

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

Specifically, your firm does not perform endotoxin testing on 100% of the products purporting to be endotoxin free. Endotoxin testing is limited to the largest finished volume container of product produced from each bulk batch, which means this only affects stock solutions that were used to fill more than one vial size.

OBSERVATION 4

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically, the personnel working in the ISO 7 area and under ISO 5 hoods are garbed in a hair net, non-sterile mask, sterile gown, dedicated shoes, disinfected safety glasses, and sterile gloves. The non-sterile mask and glasses leave areas of exposed skin of the operator's face. Sterile gowns are re-used throughout the day for a full day; gowns are stored in the ISO 8 ante room when operators leave the ISO 7 area.

OBSERVATION 5

Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable construction to facilitate cleaning, maintenance, and proper operations.

Specifically, the ceiling in the ISO 7 and ISO 8 rooms are not cleanable. Drop-tiles, which appear to be non-porous, are caulked in place causing the tiles to be a uneven. Additionally, metal inlets for HEPA filter maintenance and fire sprinklers protrude from the ceiling in numerous places.

OBSERVATION 6

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

Specifically,

a) surface and air monitoring of the ISO 5 environment are not performed each day sterile drug products are produced. Currently, surface monitoring is performed once every 2 weeks and viable and non-viable air monitoring is performed once every 6 months under static conditions.

b) personnel monitoring is not performed each day sterile drug products are produced. Currently, finger-tip testing is

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performed once every 6 months.

c) smoke studies have not been conducted in all ISO 5 hoods where sterile drug products are produced and they were not performed under dynamic conditions.

d) media used for surface sampling and personnel monitoring is not growth promoted; media used for media fills is not appropriately growth promoted.

e) temperature and relative humidity conditions are not continuously monitored in controlled production rooms or in the freezer and refrigerator which contain media, raw materials, and finished drug products purporting to be sterile.

f) pressure differentials between controlled rooms are not continuously monitored. Currently, your practice is to document these values once per day.

OBSERVATION 7

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

Specifically, potency testing is not performed on every batch of drug product purporting to be sterile. Currently, your firm performs potency testing on every fourth batch of drug product purporting to be sterile.

OBSERVATION 8

Routine calibration of mechanical and electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically, thermometers, hygrometers, and pressure gauges are not routinely calibrated by your firm. These instruments are used for temperature and relative humidity monitoring in controlled rooms, refrigerators holding components and finished products, incubators used for routine environmental monitoring activities, an autoclave used for terminal sterilization of one drug product and one type of filter, and an oven used to depyrogenate glassware and utensils used for compounding. The pressure gauges are used for controlled room monitoring and bubble point testing of filters.

OBSERVATION 9

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

Specifically, stability data is either unavailable or limited for numerous drug products purporting to be sterile. There is no written testing program for on-going stability monitoring. Injectable, preservative free drug products are assigned dates as

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long as 6 months. Some products have data from studies to support their dates, while other expirations are assigned based on literature.

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