DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410) 779-5455 Fax:(410) 779-5707 Industry Information: www.fda.gov/oc/industry	03/09/2015 - 03/12/2015
	FEI NUMBER 3011402879

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Russell T. Lederhouse, Owner

FIRM NAME	STREET ADDRESS
The Wellness Pharmacy LLC	2228 Papermill Rd Ste E
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Winchester, VA 22601-3681	Sterile Drug Producer

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

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

For example,

No sterile parenteral product produced since 2013 has been tested for sterility or endotoxins.

OBSERVATION 2

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

For example,

1) All sterile parenteral products produced to date have been produced with (b) (4) [redacted]. In addition, there are no further steps to remove endotoxin or microbial contamination from the water before using it to produce sterile drug products, nor has the system been validated to produce water of suitable quality for use in sterile products.

2) Non-sterile patient isolation gowns are used as outer garments and non-sterile latex gloves sprayed with a (b) (4) [redacted] solution are used as the (b) (4) [redacted] in the production of sterile parenteral drugs.

OBSERVATION 3

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

For example,

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1) Only non-sterile (b) (4) and non-sterile (b) (4) wipes are used for disinfection of the (b) (4) and items that enter the (b) (4) used to produce sterile parenteral products.

2) The (b) (4) used to compound sterile parenteral products is located in an unclassified area with the (b) (4), allowing outside unclassified air to enter the critical processing area (b) (4). Additionally, there is no procedure to adequately disinfect (b) (4) before it is used after being stored in this manner.

3) The (b) (4) used to produce sterile parenteral products has multiple objects inside that may impede the laminar air flow, including, but not limited to a large red "sharps" container, an IV bar directly below the HEPA filter, plastic trays of extra syringes and needles, (b) (4), and the jar of non-sterile cleaning wipes used in the (b) (4). All of these items were brought into the (b) (4) using only the non-sterile (b) (4) wipes for disinfection. None of these items appear to be designed for easy disinfection (b) (4)

4) The trash receptacle inside the (b) (4) used to produce sterile parenteral products is full of refuse from the production process. Based on records of the amount of product produced, the trash does not appear to have been emptied for at least several days. In addition, there is no procedure to disinfect the trash or trash bag between production runs and the trash bag is secured inside the (b) (4) with a non-sterile large rubber band.

5) The non-sterile (b) (4) wipes used to disinfect the (b) (4) used to produce sterile parenteral products and items entering the (b) (4) expired in November 2014.

6) There is no environmental monitoring performed during the production of sterile parenteral drugs.

7) Smoke studies for the (b) (4) used in the production of sterile parenteral drugs are not performed under dynamic conditions.

OBSERVATION 4

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

For example,

The (b) (4) used to sterilize larger volumes of parenteral products, such as sterile Cyanocobalamin injections, are labeled "For research use only, not for in-vitro diagnosis or for parenterals." There have been no studies performed to demonstrate that (b) (4) are appropriate for the production of sterile parenterals.

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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."