Temporary Compliance Waiver Notice

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
U.S. Food and Drug Administration 555 Winderley Place Suite 200 Maitland, FL 32751 407-475-4700 Industry Information: www fda.gov/oc/industry	6-26-2017 to 7-20-2017
	FEI NUMBER 3011775721

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Richard Daniel Porter, Pharmacist

FIRM NAME	STREET ADDRESS
Vital Rx, Inc. dba Atlantic Pharmacy and Compounding	1000 E. Atlantic Blvd. # 110
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Pompano Beach, FL 33060	Producer of Sterile and Non-Sterile Drugs

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) (WE) OBSERVED:

Observation 1

You have no assurance that intrathecal drug preparations prepared by your firm, such as the (b) (4) ml of hydromorphone/bupivacaine 10mg/10mg/ml (preservative free) lot 06132017@6, are safe from endotoxins and sterile since you do not perform endotoxin and sterility testing. These preparations are made using non-sterile starting material such as the hydromorphone HCl lot (b) (4) used to prepare the hydromorphone/bupivacaine 10mg/10mg/ml (preservative free) lot 06132017@6.

Observation 2

We observed preparations and reviewed documentation for sterile drug products such as multi-use vials for intravenous infusion therapy that were prepared under the conditions listed below:

Specifically, we observed the following conditions during the sterile drug preparations of magnesium chloride hexahydrate 20 % preservative free lot 06282017@ 8:

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	Joanne E. King -S Digitally signed by Joanne E King -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Joanne E King -S, 0.9.2342.19200300.100.1.1=1300174867 Date: 2017.07.20 12:12:00 -04'00'	Joanne E. King, Investigator	07/20/2017

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1.) Commercially sterilized vials labeled to have been sterilized on 8/31/2015 with no assigned expiration date were used for this and other sterile drug preparations. You have no assurance that these glass vials remain sterile during this time period.

2.) A (b) (4) lot (b) (4) was used to sterilize (b) (4) ml of the magnesium chloride hexahydrate 20 % lot 06282017@ 8. The manufacturer precautions were, "(b) (4) (b) (4) " The label for the (b) (4) stated, "(b) (4) "

3.) The (b) (4) unit integrity (b) (4) was not performed adequately since the (b) (4) to determine if the (b) (4) was functioning at the appropriate pressure as determined by the manufacturer (b) (4) PSI).

4.) The (b) (4) hood located in the ISO 8 clean room used for weighing and mixing bulk drug substances had an air conditioning filter which was not designed for this piece of equipment. We observed this filter falling onto the working surface of this hood prior to use by the pharmacy technician. We also observed that it was held in place using packing tape which was difficult to clean.

5.) The laminar flow hood (ISO 5) (b) (4) air vent through which first air passes had a visible stain.

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Additional examples of sterile drug products for weekly IV infusion therapy over 4 weeks prepared under these conditions include:

1.) Ascorbic acid 500 mg/ml for injection (b) (4) ml multi dose vial lot 06082017@15, BUD 12/5/2017

2.) Vitamin B-complex injectable (b) (4) ml multi dose vial lot 05312017@22, BUD 8/29/2017

3.) Glutathion 200 mg/ml (b) (4) ml multi dose vial lot 06062017@21, BUD 11/3/2017

Observation 3

Your firm failed to perform adequate media fill studies in that they did not closely simulate aseptic operations incorporating as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically, the most recent media fill documentation which demonstrates the ability of your pharmacy technician to prepare sterile drug preparations was performed on 12/20/16 and 1/11/17 did not include the following:

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1.) Dates of media incubation

2.) Temperatures of media incubation

3.) The use of negative controls

Observation 4

Your firm does not perform environmental monitoring for microorganisms. Your are not monitoring your sterile ISO 5 laminar flow hood which is used to produce sterile drug products for intrathecal, ophthalmic, and IV infusion use:

1.) You have not performed viable air particle testing

2.) You do not perform surface testing of the laminar flow hood bench

3.) You do not test gloves or suites worn and used during the preparation of sterile drug products

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Observation 5

You do not have a sporicidal agent for cleaning your ISO 5 laminar flow hood

Observation 6:

Hazardous and highly potent drugs were prepared and handled without providing adequate cleaning of work surfaces and reusable equipment such as spatulas, beakers, and (b) (4) jars to prevent cross-contamination.

Specifically, your operations include the preparation of non-sterile drug products that contain hormones such as progesterone and estriol using reusable equipment that was (b) (4) cleaned using (b) (4) a reusable sponge, (b) (4) detergent, and air drying at room temperature. Working surfaces are wiped down using (b) (4) (b) (4) You do not have documentation do show that these methods are effective in removing and neutralizing these drug residues. Examples of these preparations are as follows:

1.) The progesterone lot 139103 and estriol lot 1608160057 bulk drug substances were used to prepare Rx (b) (6), (b) (7)(C) P150/Biest 1.2/testosterone 1.1cherry red troches lot 07052017@9.

2.) The progesterone lot 139103 bulk drug substance was also used to prepare Rx (b) (6), (b) (7)(C) estradiol/ progesterone/DHEA 1.5mg/40mg/5mg cream.

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