

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

U.S. Food and Drug Administration
555 Winderley Place Suite 200
Maitland, FL 32751

Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

11/7-9,13-16,20/2017

FEI NUMBER

3013918415

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Veronica Taran, President and Owner

FIRM NAME

Pharmacy Doctors Enterprises dba Zion Clinical Pharmacy

STREET ADDRESS

205 East Hallandale Beach Blvd.

CITY, STATE AND ZIP CODE

Hallandale Beach, FL 33009

TYPE OF ESTABLISHMENT INSPECTED

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:

Highly potent drugs such as buprenorphine HCl and hazardous drugs such as human chorionic gonadotropin (HCG) were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination.

Specifically,

A. Sources of potential cross contamination include the design and location of the equipment washing area where vials, beakers, and utensils are cleaned which is a single basin hand wash sink located in the ISO7 ante-room adjacent to the ISO 7 buffer room door. The buffer room door opens facing the (b) (4) with (b) (4) recirculating air flow.

Add Continuation Page

SEE
REVERSE
OF THIS
PAGE

EMPLOYEE(S) SIGNATURE

Joanne E. King -S

Digital y signed by Joanne E King S
DN: cn=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People
cn=Joanne E King S 0 9 2342 10200300 100 11-1300174867
Date: 2017.11.20 15:35:51 -05'00'

EMPLOYEE(S) NAME AND TITLE (Print or Type)

Joanne E. King, Investigator

DATE ISSUED

11/20/2017

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B. The use of non-sterile hair nets and face covers to prepare sterile drug products in the (b) (4)

C. Sporicidal agents are not used in your facility's cleanrooms and/or ISO 5 area within the (b) (4).

D. The facility is also designed and/or operated in a way that permits poor flow of personnel or materials in that the (b) (4), and non-sterile processing components are all stored in the ISO 7 ante-room. The presence of this equipment and operations of use may increase the presence of dust particles, increase the room humidity as well as elevate the room temperature. Higher particle counts surrounded by moist warm air may increase the rooms bacterial and fungal bio-burden.

These sterile and non-sterile human and animal drug preparations include the following:

- buprenorphine HCL 0.3mg/ml for injection 30 ml multi-dose vial (veterinary drug) lot BUV030526
- tadalafil/arginine 20/300 mg capsules lot TAC201530
- metronidazole 5% ointment lot ABMO
- Z4 dental gel (lidocaine HCl 10%, prilocaine HCl 10%, tetracaine HCL 4%, phenylephrine 2%) lot Z4D003524
- Sermorelin+GHRP2+GHRP6 100/100/200 mcg troches lot SEM620684
- Nifedipine 0.3% lidocaine 1.5% ointment lot ABNFO
- No pain gel lidocaine HCl 0.1g, tetracaine HCL 0.04g, phenylephrine HCl 0.2g, prilocaine 0.1g lot Z4D003525
- HCG (human chorionic gonadotropin) troches 250 IU Lot HCGTR5058

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		Joanne E. King, Investigator	11/20/2017