DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Drive BLDG 200, STE 500 Nashville, TN 37217 (615) 366-7801 Industry Information: www.fda.gov/oc/industry	12/12/2017 - 12/14/2017; 12/18/2017; 12/22/2017
	FEI NUMBER 3004578635

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Randal J. Davis, Owner

FIRM NAME	STREET ADDRESS
The Wellness Center Pharmacy, Inc., dba Designer Drugs	7304 Jarnigan Road
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Chattanooga, TN 37421	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:

Non-microbial contamination was observed in your production area.

Specifically, on 12/12/2017, rust-like stains were observed on the clean room (non-hazardous buffer room - ISO 7) floor adjacent to the Laminar Air Flow Hood (ISO 5 area). Additionally, rust-like stains were observed on the seat of a metal stool located in the clean room (non-hazardous buffer room). This stool was used during aseptic processing on 12/12/17.

Observation 2:

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically, your firm's large batch media fill consists of 25 test vials however your firm routinely produces a sterile ophthalmic product (Cataractive 3) with a batch volume of 10 liters which is packaged in 2,000 individual units.

Observation 3:

The ISO 5 classified aseptic processing areas contained dust-collecting overhangs without adequate and frequent cleaning.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Brandon C. Heitmeier, Investigator	12/22/2017

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Specifically, on 12/12/2017, I observed the cleaning of the Laminar Air Flow Hood (ISO 5 area) by your Lab Coordinator prior to aseptic processing. During the cleaning of the hood canopy the plastic cover became dislodged exposing the inner housing of canopy/light fixture. The inner housing of canopy/light fixture and overhang is not included in your firm's cleaning procedures.

Add Continuation Page

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	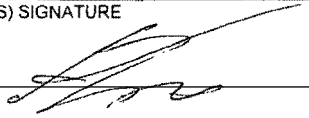	Brandon C. Heitmeier Investigator	12/22/2017