DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	2/4/2019-2/8/2019
	FEI NUMBER 3004570352

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Brad M. Cherson, Owner and PIC

FIRM NAME	STREET ADDRESS
Pavilion Compounding Pharmacy	3200 Downwood Cir Nw Ste 210
CITY, STATE, ZIP CODE, COUNTRY Atlanta, GA 30327-1611	TYPE 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 OBSERVED:

OBSERVATION 1

You produced hazardous drugs without providing adequate containment, segregation and cleaning of personnel to prevent cross-contamination.

Specifically, hormone and non-hormone containing drugs are prepared in your negative pressure, non-sterile room without any gowning controls or cleaning procedures in place to prevent cross-contamination between batches. On 02/04/2019, I observed the production of Testosterone LD Topical 8mg/mL Cream (lot 02042019@22) and BIEST (80:20)/Prog LD Topical 3/30mg/GM Cream (lot 02042019@23) in the same area as non-hazardous Bleach-Ease (Nourivan) 8% Cream (lot 02042019@1).

OBSERVATION 2

Unsealed, loose ceiling tiles were observed in your cleanroom.

Specifically, a gap was observed in the ceiling of the ISO 7 ante room around the HEPA filter.

OBSERVATION 3

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Jennifer L Huntington, Investigator

X Jennifer L Huntington
Investigator
Signed By: Jennifer L. Huntington
Date Signed: 02-08-2019 12:49:43

DATE ISSUED
2/8/2019

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	2/4/2019-2/8/2019
	FEI NUMBER 3004570352

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Brad M. Cherson, Owner and PIC	
FIRM NAME Pavilion Compounding Pharmacy	STREET ADDRESS 3200 Downwood Cir Nw Ste 210
CITY, STATE, ZIP CODE, COUNTRY Atlanta, GA 30327-1611	TYPE ESTABLISHMENT INSPECTED Producer of sterile and non-sterile drugs

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

Specifically, your firm does not perform potency testing prior to release for non-sterile drug formulations. Examples include, but are not limited to the following non-sterile drug products:

- Canthardin Plus Topical 1% Liquid, Lot 01032019@75
- Phenylephrine HCL/Lidocaine HCL Nasal 1%/4% Solution, Lot 11282018@32
- Phenylephrine 1% Solution, Lot 05092018@45

OBSERVATION 4

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically, your firm's formula worksheets do not include the following information for non-sterile drug products:

- Identity of major equipment used
- Laboratory results
- Inspection of packaging and labeling
- A statement of actual yield
- Specimens of labeling

Example include, but are not limited to the following:

- Canthardin Plus Topical 1% Liquid, Lot 01032019@75
- Phenylephrine HCL/Lidocaine HCL Nasal 1%/4% Solution, Lot 11282018@32
- Phenylephrine 1% Solution, Lot 05092018@45

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jennifer L Huntington, Investigator	X Jennifer L Huntington Investigator Signed By Jennifer L. Huntington -S Date Signed 02-08-2019 12 49 43	2/8/2019

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	2/4/2019-2/8/2019
	FEI NUMBER 3004570352

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Brad M. Cherson, Owner and PIC	
FIRM NAME Pavilion Compounding Pharmacy	STREET ADDRESS 3200 Downwood Cir Nw Ste 210
CITY, STATE, ZIP CODE, COUNTRY Atlanta, GA 30327-1611	TYPE ESTABLISHMENT INSPECTED Producer of sterile and non-sterile drugs

OBSERVATION 5

Procedures designed to prevent insanitary conditions are not established or followed.

Specifically,

A) Media fills are not representative of all routine aseptic operations. For example, media fills are not performed for vial filling operations. For example, your firm produced Glutathione Solution 200mg/mL Injectable, Lot 01292019@18 which was produced in a vial.

B) There is no documentation or evidence to show that smoke studies are performed under dynamic conditions in your hazardous and non-hazardous ISO 5 glove boxes.

C) Your firm does not perform endotoxin testing for each lot of intrathecal drug product prepared. For example, your firm produced Morphine Sulfate (PF) 20mg/mL Injectable, Lot 01312019@1 for intrathecal use however there was no endotoxin testing performed prior to release for use.

D) Your firm has no evidence that filter integrity testing on filters were performed when dispensing finished drug products from stock solutions. For example, your firm produced Vitamin B Complex 100 Injectable, Lot 10292018@10, BUD 12/13/18 in a bulk syringe which was then frozen. The drug product was thawed for the filling of (b) (6) on 11/05/18, refrozen, and thawed again on 11/13/18 for the filling of (b) (6) There are no formula worksheets documenting the filling, filtration, and filter integrity testing of (b) (6) and (b) (6)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jennifer L Huntington, Investigator	X Jennifer L Huntington Investigator Signed By Jennifer L. Huntington -S Date Signed 02-08-2019 12:49:43	2/8/2019

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	2/4/2019-2/8/2019
	FEI NUMBER 3004570352

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Brad M. Cherson, Owner and PIC

FIRM NAME	STREET ADDRESS
Pavilion Compounding Pharmacy	3200 Downwood Cir Nw Ste 210
CITY, STATE, ZIP CODE, COUNTRY Atlanta, GA 30327-1611	TYPE ESTABLISHMENT INSPECTED Producer of sterile and non-sterile drugs

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Jennifer L Huntington, Investigator

X Jennifer L Huntington
Investigator
Signed By Jennifer L. Huntington -S
Date Signed 02-08-2019 12 49 43

DATE ISSUED
2/8/2019