DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FLA-DO 555 Winderly Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Industry Information: www.fda.gov/oc/industry	8/22-26, 29, 31/2016
	FEI NUMBER 3005630265

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Christopher M. Schulte, Owner

FIRM NAME	STREET ADDRESS
Pensacola Apothecary, Inc. DBA Everwell Specialty Pharmacy	6506 N. Davis Highway
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Pensacola, FL 32504	Producer of Sterile and Non-sterile Drug Products

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:

Sterile Drug Production

OBSERVATION 1

Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

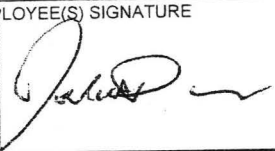
Specifically, the gowns worn during aseptic production are stored on a shelf next to the sink in the anteroom where they can be splashed with water during handwashing.

OBSERVATION 2

Equipment, materials, and/or supplies are not disinfected prior to entering the aseptic processing areas.

Specifically, General Aseptic Technique SOP 5.2.1 states that work surfaces of the aseptic production area shall be cleaned prior to use. While observing the production of Methylcobalamin Lot 08242016@18 it was noted that the inside surface of the ISO5 unit was not sanitized prior to production.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Joshua P. Wireman, Investigator	08/31/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FLA-DO 555 Winderly Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Industry Information: www.fda.gov/oc/industry	8/22-26, 29, 31/2016
	FEI NUMBER 3005630265

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Christopher M. Schulte, Owner

FIRM NAME	STREET ADDRESS
Pensacola Apothecary, Inc. DBA Everwell Specialty Pharmacy	6506 N. Davis Highway
CITY, STATE AND ZIP CODE Pensacola, FL 32504	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and Non-sterile Drug Products

Non-Sterile Drug Production

OBSERVATION 3

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

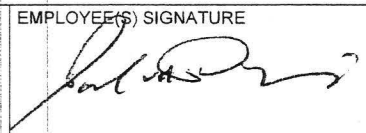
Specifically, finished non-sterile products are not tested for potency and unacceptable microorganisms. For example Benzocaine/Lidocaine/Tetracaine 20%-8%-4% Lipoderm Cream Lot #06102016@12 was not tested for potency and unacceptable microorganisms.

OBSERVATION 4

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically, mixing instructions do not include duration of mixing to assure the replication of the process. For example, the logged formula worksheet instructions for T4-T3 (Dye-Free Veggie Cap) 85 MCG - 15 MCG Capsule Lot 08182016@10 state to mix all powders with agitation in the Turbula however the mixing time is not included in the instructions

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Joshua P. Wireman, Investigator	08/31/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FLA-DO 555 Winderly Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Industry Information: www.fda.gov/oc/industry	8/22-26, 29, 31/2016
	FEI NUMBER 3005630265

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Christopher M. Schulte, Owner

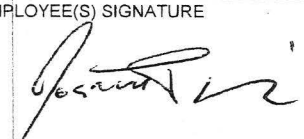
FIRM NAME	STREET ADDRESS
Pensacola Apothecary, Inc. DBA Everwell Specialty Pharmacy	6506 N. Davis Highway
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Pensacola, FL 32504	Producer of Sterile and Non-sterile Drug Products

OBSERVATION 5

Written procedures are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically, the Cleaning And Maintenance of the Non-Sterile Compounding Area SOP 4.15.1 has not been validated to assure removal of residual product and sanitizing agents and prevent crossover between batches.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Joshua P. Wireman, Investigator	08/31/2016