DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax:(407) 475-4768 Industry Information: www.fda.gov/oc/industry	08/11/2014 - 08/13/2014
	FEI NUMBER 3004962739

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: David R. Upson, R.Ph,, Owner and Pharmacist in Charge

FIRM NAME	STREET ADDRESS
DNA Pharmacy Services Inc dba Palm Beach Compounding	2151 South Alternate A1A Suite 1500
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Jupiter, FL 33477	Producer of 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

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, there is no data to justify the beyond use date of more than 9 months for Testosterone Cypionate Injection 220mg/mL Lot 03/02/2014:1106 that you produced on 03/02/2014 and currently distribute with a BUD of 12/27/2014. The stability data you generated for this product only supports a BUD of 3 months.

OBSERVATION 2

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically, Testosterone Cypionate Injection 220mg/mL Lot 03/02/2014:1106 produced on 03/02/2014 is currently distributed with a BUD of 12/27/2014 (9 months) even though there is no current sterility and endotoxin testing data to demonstrate that this lot is safe, effective, and stable for nine months.

OBSERVATION 3

Equipment and utensils are not maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, during the walkthrough of the laboratory, I observed white residue and scratches inside the (b) (4) (a componenet used as part of the high-torque (b) (4) blender) used to blend (active and inactive pharmaceutical ingredients) before encapsulation. Additionally, materials blended using the (b) (4) blender are not tested to ensure that the high-torque and friction do not negatively affect the finish product quality attributes.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Justine C. Tomasso, Investigator	08/13/2014