

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

555 Winderley Place, Suite 200
Maitland, Florida 32751

DATE(S) OF INSPECTION

05/15/17-05/17/17, 05/23/17

FEI NUMBER

3004962739

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

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

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

FIRM NAME

DNA Pharmacy Services dba Palm Beach Compounding

STREET ADDRESS

2151 South Alternate Drive A1A, Suite 1500

CITY, STATE AND ZIP CODE

Jupiter, Florida 33477

TYPE OF ESTABLISHMENT INSPECTED

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) (WE) OBSERVED:

Observation 1:

Hazardous drugs were produced without providing adequate cleaning of utensils and work surfaces to prevent cross-contamination.

Specifically, I observed the (b) (4) used to (b) (4), was stored in alcohol between use rather than cleaned (detergent and sanitized). You do not have documentation to support the cleaning practices and maintenance of the (b) (4).

Also, your operations include the preparation of non-sterile drug products that contain hormones, such as testosterone and progesterone, using reusable equipment that was cleaned with a (b) (4) with (b) (4) detergent or (b) (4) with (b) (4) (b) (4) soap. Working surfaces are wiped down using (b) (4). You do not have documentation to show that these methods are effective in removing and neutralizing these drug residues. Examples of these preparations include:

A. Testosterone (b) (4), lot (b) (4), drug substance was used to prepare "Test/DHEA/Prog/Anastrozole" troche butterscotch 110/10/5/0.5mg, lot 04/21/2017:0308.

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EMPLOYEE(S) SIGNATURE

Jennifer Lalama -S

Digitally signed by Jennifer Lalama -S
DN: cn=US, ou=U.S. Government, ou=HHS, ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=2000548371, cn=Jennifer Lalama -S
Date: 2017.05.23 14:24:42 -0400

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

Jennifer Lalama, Investigator

DATE ISSUED

05/23/2017

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B. Estriol, estradiol, progesterone, testosterone (lots (b) (4), and (b) (4) respectively) drug substances were used to prepare "Bi-est/prog/test" troche butterscotch 2.5/50/1.5mg, lot 05/15/2017:0251.

This is a repeat observation from Form FDA-483, dated 08/13/14.

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Jennifer Lalama, Investigator

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