

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER U. S. Food and Drug Administration Florida District 555 Winderley Place Suite 200 Maitland, FL 32751 (407) 475-4700 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 1/23/2017- 2/23/2017
	FEI NUMBER 3010922197

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Gregory G. Gaiser, President and Owner

FIRM NAME Complete Pharmacy & Medical Solutions, LLC	STREET ADDRESS 5829 NW 158th Street
CITY, STATE AND ZIP CODE Miami Lakes, FL 33014	TYPE OF ESTABLISHMENT INSPECTED Outsourcing Facility

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:

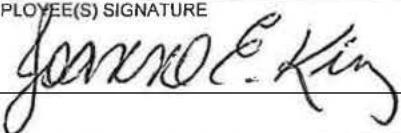
Results of stability testing are not used in determining expiration dates. Specifically, your outsourcing facility lacked analytical and sterility data to support beyond use dates (BUDs) assigned to sterile compounded drug products. You stated your firm's BUDs are based on literature; however, this information is not specific to your firm's operations (for example, container closure data).

Below are your firm's BUDs that are pre-printed in your firm's batch records which are sometimes (b) (4) (as stated in your BUD written procedure):

1. Human chorionic gonadotropin (HCG) 125 IU/ 0.5 ml, 0.5ml syringe - 60 day BUD.
2. HCG lyophilized vials all strengths - 2 year BUD.
3. HCG lyophilized reconstituted vials all strengths - no BUD.
4. Lipo-Blast #(b) (4), 30 ml vial - 3 month BUD.
5. MIC #504, 5 ml vial preserved - 6 month BUD.
6. Ultra Burn #(b) (4), 10 ml vial preserved - 6 month BUD.
7. Testosterone cyp/prop 180 mg /20 mg, 8 ml vial preserved - 6 month BUD.

1 year BUD for the below products with preservative:

1. Cyanocobalamin #(b) (4), 1mg/ml, 30 ml vial.
2. Hydroxycobalamin #(b) (4), 1 mg/ml, 30 ml vial.
3. Lipolean #(b) (4) 30 ml vial.
4. MIC B6 + B12 #(b) (4) 30 ml vial.
5. MIC B12 #(b) (4), 10 ml vial.
6. Lipo-Vite #(b) (4), 30 ml vial.
7. Lipolean #(b) (4) 30 ml vial.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Joanne E. King Investigator	DATE ISSUED 2/23/17
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- 8. Lipo-B #(b) (4), 30 ml vial.
- 9. Super MIC B12 #(b) (4) 30 ml vial.
- 10. MIC #(b) (4), 30 ml vial.
- 11. Lipolean #(b) (4), 30 ml vial

Observation 2

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10) (A) and (B).

A. Specifically, the drug product label with the information required by section 503B(a)(10)(A) is not included on the following product: HCG 125 IU/0.5 ml, 0.5 ml pre-filled syringe.

B. In addition, the following information is not found on your drug product labels:

The statement, "Office Use Only".

Examples of drug products that do not contain this information:

- 1. HCG 11,000 units injectable.
- 2. Cyanocobalamin #(b) (4) 1 mg/ml injectable.
- 3. MIC B6+B12+L carnitine #(b) (4) injectable.
- 4. Hydroxycobalamin #(b) (4) 1 mg/ml injectable.
- 5. Lipolean #(b) (4) injectable.
- 6. Lipo-vite #(b) (4) injectable.
- 7. Lipo-B #(b) (4) injectable.
- 8. Lipo-Blast #(b) (4) injectable.
- 9. BLT 20% - 8% - 6% cream.
- 10. BLT 20% - 12% - 12% cream.
- 11. HCG/methycobalamin/inositol #(b) (4) tablet.
- 12. Vardenafil troche.

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The statement, "This is a compounded drug" and "Not for Resale".

Examples of drug products that do not contain this information:


1. Yohimbine/caffeine 2 mg/50 mg capsule.
2. Yohimbine/caffeine 4 mg/50 mg capsule.
3. Ultra Burn 25/50/1/33/33.3/33.3/2.2/66.6/50/60 capsule.

B. The following information is not found on your drug product container labels:

Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088.

Examples of drug products that do not contain this information:

1. BLT 20% - 8% - 6% cream.
2. Yohimbine/caffeine 4mg/50mg capsules.
3. Yohimbine/caffeine 2mg/50mg capsules.
4. BLT 20% - 12% - 12% cream.
5. HCG/methylcobalamin/inositol (#^(b)(4)) tablet.
6. Vardenafil troche.
7. Ultra Burn 25/50/1/33/33.3/33.3/2.2/66.6/50/60 capsules.

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