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	1/9/2019-1/23/2019*
	FEI NUMBER 3010922197

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

FIRM NAME	STREET ADDRESS
Complete Pharmacy and Medical Solutions, LLC dba Complete Pharmaceutics	5829 NW 158th St
CITY, STATE, ZIP CODE, COUNTRY Miami Lakes, FL 33014-6721	TYPE 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 OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically, your firm failed to perform and document investigations for stability failures for the following drug products:

- Atropine Sulfate 0.4mg/mL (b) (4) syringe, Lot 33226/H: Accelerated testing documented a potency of 108% and room temperature testing documented a potency of 107.8% (specifications (b) (4)) at day 8.
- Epinephrine 0.1mg/mL (b) (4) syringe, Lot 34523/C: Accelerated testing documented a potency of 89.2 % at 31 days and 79.9% at 48 days (specification (b) (4)).
- Succinylcholine Chloride PF (b) (4) 20mg/mL syringe, Lot 32995/C: Accelerated testing documented a potency of 79.7% (specification (b) (4)) at day 63.

OBSERVATION 2

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, your firm does not perform potency testing prior to release for (b) (4) out of (b) (4) sterile drug

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formulations and (b) (4) out of (b) (4) non-sterile drug formulations. Examples include, but are not limited to the following sterile and non-sterile drug products:

- Hydroxocobalamin 1000 mcg/mL injectable, Lot 35710/B, BUD 08/30/19
- Testosterone Cypionate 200 mg/mL injectable, Lot 35031/C, BUD 04/27/19
- HCG 5,000 IU (b) (4) Lot 32410, BUD 03/30/19
- Cholecalciferol 50,000 IU #2476, Lot 32485/B, BUD 04/16/19
- L-asparaginase 10,000 IU, Lot 34417, BUD 03/11/19
- Hydroquinone/Fluocinolone/Tretinoin 4%/0.01%/0.05% cream, Lot 33672, BUD 09/29/18
- HCG ODT (b) (4) 1,000 IU tablet, Lot 36034, BUD 01/08/20
- Tadalafil 20MG/GM (b) (4) (Crème de Menthe) troche, Lot 35966, BUD 06/02/19
- Naltrexone (b) (4) 4.5MG capsule, Lot 35951, BUD 07/01/19
- Progesterone/Pregnenolone/DHEA 260MG/20MG/5MG, Lot 35989, BUD 05/04/19

OBSERVATION 3

Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use.

Specifically, your firm has failed to perform stability testing on (b) (4) out of (b) (4) sterile drug formulas and (b) (4) out of (b) (4) non-sterile drug formulas. Examples include, but are not limited to the following sterile and non-sterile drug products:

- Hydroxocobalamin 1000 mcg/mL injectable, Lot 35710/B, BUD 08/30/19 (330 days)

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- Testosterone Cypionate 200 mg/mL injectable, Lot 35031/C, BUD 04/27/19 (180 days)
- HCG 5,000 IU (b) (4) Lot 32410, BUD 03/30/19 (330 days)
- Cholecalciferol 50,000 IU #2476, Lot 32485/B, BUD 04/16/19 (330 days)
- L-asparaginase 10,000 IU, Lot 34417, BUD 03/11/19 (180 days)
- HCG ODT (b) (4) 1,000 IU tablet, Lot 36034, BUD 01/08/20 (365 days)
- Methionine (b) (4) Lot 33685/B, BUD 04/20/19 (330 days)

OBSERVATION 4

Specific identification tests are not conducted on components that have been accepted based on the supplier's report of analysis.

Specifically, your firm does not perform identity testing on any lot of active drug ingredient used in the production of drug products.

OBSERVATION 5

The results of the examination of the packaged and labeled products were not documented in the batch production or control records.

Specifically, your firm has no evidence that you perform visual inspections of your sterile drug products after labeling and prior to release for distribution. For example, your firm does not document visual inspections of finished, labeled drug products nor does your firm have a procedure describing a visual inspection of finished, labeled drug products prior to release for distribution.

OBSERVATION 6

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Equipment for adequate control over air pressure is not provided when appropriate for the manufacture, processing, packing or holding of a drug product.

Specifically, your firm does not continuously monitor the pressures in your ISO 7 positive pressure and negative pressure clean rooms, ISO 7 ante rooms, and ISO 8 Main Lab.

OBSERVATION 7

Your firm compounds drugs that are essentially a copy of one or more approved drugs within the meaning of sections 503B(a)(5) and 503B(d)(2).

Specifically, you compound drug products that:

a) are identical or nearly identical to an approved drug that is not on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing; or

b) are not identical or nearly identical to an approved drug but contain a bulk drug substance that is also a component of an approved drug, and for which there is no change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

Examples of compounded drug products that are essentially a copy of one or more approved drugs include:

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***DATES OF INSPECTION**

1/09/2019(Wed), 1/10/2019(Thu), 1/11/2019(Fri), 1/14/2019(Mon), 1/16/2019(Wed), 1/22/2019(Tue), 1/23/2019(Wed)

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