**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT OFFICE ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| FDA Florida District<br>555 Winderley Place, Suite 200<br>Maitland, FL 32751<br>(407) 475-4700<br>Industry Information: www.fda.gov/oc/industry | 8/4/2014-8/12/2014 |
| | FEI NUMBER<br>3010922197 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Gregory G. Gaiser, RPh, DPh, President and Owner

| FIRM NAME | STREET ADDRESS |
|---|---|
| Complete Pharmacy & Medical Solutions LLC | 5829 N.W. 158th St. |
| CITY, STATE AND ZIP CODE | TYPE OF ESTABLISHMENT INSPECTED |
| Miami Lakes, FL 33014 | 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:

1. Your firm lacks an adequate control system to ensure all containers and closures such as glass vials and rubber stoppers are properly sterilized and depyrogenated prior to filling sterile injectable drug products. For example,

a. LipoLean/MIC-B Complex (#1899) Injectable, lot # 13879 filled on 5/28/14 failed sterility testing; the batch was re-processed as lot # 13879/A on 6/3/14 by [redacted] (b) (4) and filling it into newly sterilized vials, and it again failed sterility testing resulting in the rejection of the batch. The contamination was identified as Pseudomonas aeruginosa. Your investigation concluded that the glass vials were not properly sterilized due to operator's error but your firm failed to extend the investigation to other potentially affected batches of sterile drug products filled between 5/28/14 and 6/3/14, and did not take adequate corrective and preventive action.

b. Cyanocobalamin injectable, lot # 13800/C , was rejected on 5/29/14 due to particulates in the finished product. The contamination was attributed to inadequate glassware cleaning. However, adequate procedures for glassware cleaning have not been established to remove particulates. For example, a [redacted] (b) (4) is used to wash glass vials prior to sterilization/depyrogenation. Inspection of the [redacted] (b) (4) on 8/12/14 showed multiple particulates and mineral residue on the bottom of the [redacted] (b) (4). Your firm lacked adequate controls and maintenance/cleaning procedures for the [redacted] (b) (4) to prevent cross-contamination of glass vials.

c. Your firm lacked adequate procedures for the washing, sterilization, and depyrogenation of rubber stoppers in that:

i. The stoppers are rinsed with [redacted] (b) (4) obtained from a [redacted] (b) (4) dispenser instead of Water for Injection (WFI). Brown residue was observed on the nozzle of this dispenser.

ii. There is no scientific data to demonstrate that the [redacted] (b) (4) is effective in removing endotoxins. In addition, pharmacy technicians failed to follow SOP 6.002 "Preparation of Rubber Stoppers" in that approximately [redacted] (b) (4), instead of [redacted] (b) (4) as specified in the SOP.

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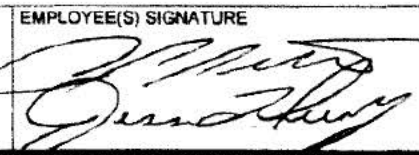
| |  | CDR Ileana Barreto-Pettit, Investigator<br>Jessica L. Pressley, Investigator | 8/12/14 |

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iii. SOP 6.002 does not specify the amount of [redacted] (b) (4) in order to remove oil residue from the stoppers.

iv. The [redacted] (b) (4). specified in SOP 6.002 is not followed in that the [redacted] (b) (4) [redacted] is sometimes used. The [redacted] (b) (4) has not been validated by your firm for the sterilization of rubber stoppers.

2. Your firm lacks an adequate control system for the [redacted] (b) (4) sterilization of Testosterone cypionate injectable in that there are no written procedures describing the [redacted] (b) (4) the [redacted] (b) (4) [redacted] has not been validated, and conduct of the [redacted] (b) (4) is not documented in the Log of Use, Maintenance and Cleaning (LUMAC) of the [redacted] (b) (4). For example, Testosterone Cypionate lot 14196/C was documented in the production record as [redacted] sterilized [redacted] (b) (4) in [redacted] (b) (4) on or about 6/17/14 but there is no documentation in the June LUMAC log of the conduct of the [redacted] (b) (4) used. In addition, your firm lacked calibration records for [redacted] (b) (4) [redacted].

3. Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

a. Specifically, your firm did not perform environmental monitoring of the ISO 5/7/8 controlled areas for a period of 20 days (4/30/14-5/19/14), due to a shortage of media plates in your inventory, which is not in accordance with your firm's standard operating procedure (SOP 8.049), which states EM shall be conducted during aseptic operations. [redacted] (b) (4) batches of sterile drug products were produced during this 20 day period. For example, HCG injectable 125U/0.5mL, Lot # 13570 produced on 4/30/14; MIC #359 injectable, Lot # 13583/B produced on 5/1/14; HCG injectable 125 IU/0.5mL, Lot # 13441-PS2 produced on 5/1/14; HCG injectable 125 IU/0.5mL, Lot # 13570-PS2 produced on 5/7/14; HCG injectable 125U/0.5mL, Lot # 13684 produced on 5/12/14; I.C. B-Complex injectable #634, Lot # 13669/C produced on 5/13/14; MIC B12 (#390) injectable, lot 13604/A produced on 5/15/14; and HCG injectable 5,000 IU per vial, Lot # 13692 produced on 5/15/14.

b. Surface samples are only taken [redacted] (b) (4) of the ISO 5 hoods and ISO 7 clean room and not during or immediately after production.

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c. Fingertip sampling of pharmacy technicians conducting aseptic operations in the ISO 5 hood is performed only for [redacted] (b) (4).

4. Your ISO 5/7/8 classified areas where sterile injectable drug products are produced are not adequately sanitized in that disinfectants are not [redacted] (b) (4) as per SOP 4.001 "Environmental Monitoring & Control Procedures" and the disinfectant solution [redacted] (b) (4) identified as your sporicidal agent has not been shown to have sporicidal activity against all types of bacterial spores.
In addition, during the cleaning operations prior to the conduct of a media fill on 8/7/14 it was observed that a pharmacy technician ripped a sterile non-shedding wipe in half and proceeded to wipe the interior surface of the ISO 5 hood. During the inspection, it was demonstrated that the non-shedding wipes release fibers when ripped in half.

5. The sterility testing by [redacted] (b) (4) which is used to test pre-filled Human Chorionic Gonadotropin (HCG) syringes has not been validated to determine whether the HCG formulation is bacteriostatic or fungistatic. In addition, [redacted] (b) (4), which is not in accordance with your SOP 9.022 "Sterility Testing: [redacted] (b) (4)" which requires [redacted] (b) (4).

6. Your firm does not test finished drug products for preservative content/anti-microbial effectiveness of [redacted] (b) (4)

7. The conduct of endotoxin test by [redacted] (b) (4) is not adequate in that:

a. It has not been validated to ensure substances in product formulations do not interfere with the test. In addition, as per the [redacted] (b) (4) manufacturer's instructions, syringes used to perform this test (as observed on 8/11/14) should be tested for interference due to [redacted] (b) (4).

b. [redacted] (b) (4)

c. During the conduct of endotoxin testing on 8/11/14, it was observed that a dilution factor of [redacted] (b) (4) of the

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test specimen was conducted; however, your SOP 8.090 "[redacted] (b) (4) for Determination of Bacterial Endotoxin" does not specify a dilution factor.

d. Endotoxin testing is only conducted on the non-sterile mix prior to [redacted] (b) (4) and filling of injectable products.

e. The water bath was located on working table that was not stable enough to prevent the vials from being disturbed during [redacted] (b) (4) In addition, the temperature of the water bath was only measured at the beginning of [redacted] (b) (4) and not at the end to ensure temperature was maintained at [redacted] (b) (4)

f. It was observed on 8/11/14 that the pharmacy technician who read the vials at the end of [redacted] (b) (4) shook the vials to determine if a clot was formed instead of gently inverting each vial in one smooth motion.

8. Smoke studies were not conducted for the ISO 5 hoods; they were only conducted in the ISO 7 cleanroom with [redacted] (b) (4) present which is not representative of routine aseptic operations with [redacted] (b) (4) operators. In addition, the smoke studies were not recorded to demonstrate laminar air flow during dynamic conditions.

9. Inspection of finished product vials for particulates is not conducted against a contrasting background.

10. Your firm lacked written procedures for qualifying vendors of non-sterile components used in the production of sterile drug products.

11. Your firm lacks adequate controls for issuing labels, examining issued labels, and reconciliation of used labels to prevent mix-ups. Your firm's Drug Product Labeling Process Standard Operating Procedure (SOP No. 8.006), is deficient in that it does not state that a review of the immediate container labeling should be conducted and compared with the secondary packaging labeling before release of the finished drug product. In addition, your firm's SOP states that the number of labels shall be calculated, but no reconciliation of labels is being conducted.

Your firm has received a total of four (4) complaints related to incorrect labeling between the time period of 6/12-7/1/14. For example, according to Complaint # 7/1/2014-1 received on 7/1/14, two related clinics received incorrect and illegible product labeling for six (6) batches of HCG 125U/0.5mL pre-filled syringes. The

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investigation showed that your firm shipped large quantities of HCG pre-filled syringes in bulk without immediate label containers. Instead your firm only placed secondary "Office Stock" labeling on zip-lock bags containing approximately (b)(4) unlabeled bags of (b)(4) syringes each and supplied the clinic with separate pre-printed labels to affix on each of the bags containing the (b)(4) syringes. The lot numbers on these separate labels did not match the lot numbers on the secondary packaging labeling. Your firm lacked adequate controls to ensure correct labels were applied to immediate and secondary packaging prior to release and distribution of the finished drug product.

12. The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A). Specifically, your firm does not include an immediate container label for your HCG pre-filled syringes 125U/0.5 ml. Secondary labels affixed to the plastic bag containing HCG pre-filled syringes produced by your firm do not include the statement, "This is a compounded drug", the established name of the drug, the date the drug product was compounded, storage and handling instructions, the statement, "Not for Resale", a list of active and inactive ingredients, and the quantity or proportion of each ingredient.

In addition, your firm's labels affixed to all drug products produced by your firm do not include a list of inactive ingredients, identified by established name and the quantity or proportion of each ingredient as required by section 503B(a)(10)(A). Furthermore, the container from which the individual units of the drug are removed for dispensing or administration do not include a list of inactive ingredients, identified by established name and the quantity or proportion of each ingredient as described in section 503B(a)(10)(B)(i).

The container from which the individual units of the drug are removed for dispensing or for administration also does not include the following information to facilitate adverse event reporting: www.fda.gov/medwatch; and 1-800-FDA-1088 as required by section 503B (a)(10)(B)(ii).

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."