DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313) 393-8139 Industry Information: www.fda.gov/oc/industry	07/01/2013 - 07/19/2013* FEI NUMBER 3009641885

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Wisam (NMI) Alawieh, President/CEO

FIRM NAME	STREET ADDRESS
Beacon Hill Medical Pharmacy, P.C.	18161 W 13 Mile Rd Suite A1
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Southfield, MI 48076-1113	Producer of Drug Products

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 WE OBSERVED:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written, and followed.

Specifically,

i. Adequate validation of aseptic processing operations, specifically, process simulations (media fills), have not been performed under worst case conditions to assure that sterile processing techniques are adequate to ensure the sterility of drug products. Currently, each operator involved in aseptic processing mus[redacted (b) (4)] perform a "Personal Aseptic Technique Test", in which sterile media is transferred from a vial to a bag containing sterile media. This process does not include, for example, use of a representative container closure system, worst case lot sizes or vial sizes, the process of stoppering filled vials, lyophilization, or equipment used in normal aseptic processing such as beakers, sterile filters and syringes. For example, the "Personal Aseptic Technique Test" was not representative of 4,000 mL of Dual Testosterone 200 mg/mL lot 06282013@10 (formulated on 6/28/13) part of which was [redacted (b) (4)] into 2 mL vials after 7/1/13, and 10,000 mL of Ascorbic Acid 500 mg/mL lot 04052013@2, part of which was [redacted (b) (4)] into 50 mL vials.

ii. In situ air pattern analysis has not been performed in the aseptic processing [redacted (b) (4)], where sterile drug products are processed (filling, stoppering, lyophilization), to demonstrate unidirectional airflow over the product during static or dynamic conditions.

iii. The following aseptic practices were observed:
   a. Sterile instruments/tools are not used to handle sterilized materials. For example, [redacted (b) (4)] gloves were used to handle vials and manually place stoppers into vials on 7/2/13 during aseptic processing of ten vials of HCG lot 06242013@21 and six vials of Testosterone Cypionate lot 07012013@5.
   b. Disruption of unidirectional air flow above open vials containing drug product. For example, on 7/1/13 during stoppering of Sermorelin Acetate lot 06082013@3 lyophilized vials, [redacted (b) (4)] gloves and other items such as the stopper bag were observed to be held and manipulated directly above open vials containing product.
   c. Adequate protection is not provided to vials exiting the aseptic processing [redacted (b) (4)] into an unclassified environment prior to further manipulation. On 7/2/13, ten vials of HCG lot 06242013@21 with non-secured

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SEE REVERSE OF THIS PAGE	Jeffrey D. Meng, Investigator Sarah M. Napier, Investigator Sheryl A. Duquet, Microbiology Supervisor	07/19/2013

stoppers were observed to be placed on a tabletop in an unclassified laboratory environment. These vials were later moved to a freezer for storage prior to lyophilization.

iv. [redacted] (b) (4), used to [redacted] (b) (4) non-sterile bulk drug product into finished product vials, have not been evaluated for use in that:
   a. Quantitative testing to ensure the integrity of the [redacted] (b) (4) is not performed subsequent to filling operations. As stated by personnel, though not documented, a qualitative/tactile test is performed on such prior to [redacted] (b) (4).
   b. The bioburden of non-sterile drug products has not been evaluated to determine whether the sterilizing process [redacted] (b) (4) is adequate to remove the microbiological load.

v. Environmental monitoring is not performed during sterile filling activities to evaluate the quality of the aseptic processing environment and assess whether aseptic conditions are maintained. The environmental monitoring program is deficient in that:
   a. Viable passive air monitoring is performed inside the aseptic processing [redacted] (b) (4) every [redacted] (b) (4) (performed on a [redacted] (b) (4) basis prior to April 2013) during static conditions. Active viable air monitoring is not performed at any time.
   b. Viable surface monitoring is not always representative of worst case conditions in the aseptic processing [redacted] (b) (4), as such monitoring can be performed at any time including immediately after cleaning. Viable surface monitoring is performed every [redacted] (b) (4).
   b. Media test kits used for environmental monitoring are not qualified for use, specifically, growth promotion studies are not conducted.
   c. Non-viable particulate monitoring is not performed during each production shift, rather, it is performed by a contracted firm every [redacted] (b) (4) during static conditions.
   d. No data was provided to support that the incubator used to incubate environmental monitoring samples has been qualified for its intended use. [redacted] (b) (4) Directions for Use states, [redacted] (b) (4) [redacted]. The incubator temperature is set to [redacted] (b) (4), however the thermometer used to monitor this temperature has not been calibrated and temperature mapping of the incubator has not been performed.

vi. SOP 9.039.1, *Visual Inspection of a Finished Preparation*, states "All finished preparations from the clean room, pellet room, and cream/capsule hood will be visually examined before they leave the compounding pharmacy"... "For parenterals, hold the preparation up to the light source within the room and visually examine for particulate matter". Documentation of such was not provided for any lots of sterile injectable products, and additionally, a visual examination was not performed after filling and prior to labeling of six vials of Testosterone Cypionate lot 07012013@5 on 7/2/13 or two vials of Magnesium Chloride lot 07032013@7 on 7/3/13.

vii. Process controls are not designed to minimize bioburden and endotoxin in bulk formulated product, and [redacted] (b) (4) bioburden limits have not been established for such. Sterile drug products are comprised of non-sterile components processed in an unclassified room prior to sterilization, for example, processing of Magnesium Chloride lot 0703201327 prior to [redacted] (b) (4) in the aseptic processing [redacted] (b) (4), and processing of Testosterone 50

mg pellets lot 07022013@3 prior to (b) (4) sterilization in (b) (4). Additionally, protective apparel is not worn as necessary to prevent the contamination of drug products. For example, while formulating product to be (b) (4), wrists are exposed and beard nets are not worn when warranted.

OBSERVATION 2

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

Specifically,

i. Documentation was not provided to support that the integrity of HEPA filters, located in the aseptic processing (b) (4), is maintained to ensure aseptic conditions. Documentation provided indicates that testing of such is performed every (b) (4), however, includes only the use of an isokinetic probe measuring particle counts at [redacted] points under the HEPA air outlet, without introducing a challenge of particles of known size upstream of the filter. The velocity of the HEPA filtered air entering the aseptic processing (b) (4) and uniformity of such has not been evaluated.

ii. The integrity of the aseptic processing (b) (4) is not adequately tested or monitored. SOP 6.014.2, *Germfree* - (b) (4), states "Inspect, visually, the (b) (4) for any tears, punctures or defects before turning on the Germfree (b) (4)" and "The (b) (4) should be inspected (b) (4) by the operator". Documentation of such was not provided and the performance of such was not observed.

iii. The inside surfaces of the aseptic processing (b) (4) are cleaned with (b) (4) These cleaning agents are prepared in an unclassified area, are not labeled sterile, and have not been validated under conditions of use to be sporicidal or able to ensure adequate decontamination of equipment surfaces. Additionally, the frequency of cleaning is not specified in SOP 6.014.2, *Germfree* - (b) (4) HCG lot 06242013@21 and Testosterone Cypionate lot 07012013@5 were (b) (4) into finished product vials within the aseptic processing (b) (4) after cleaning of such occurred as previously described.

OBSERVATION 3

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically,

i. No data was provided to support that the (b) (4) (ID # 9 and 10) and the (b) (4) used to (b) (4) sterilize drug products are adequately qualified and validated. Documentation provided did not address temperature mapping of the (b) (4) calibration of temperature sensors, load configuration evaluations, and validation of (b) (4) using appropriate biological indicators. Examples of drug products (b) (4) sterilized

in these [(b) (4)] include:

a. Testosterone and Estradiol pellets formulated and pressed in an unclassified environment and placed individually into glass vials prior to sterilization. For example, Testosterone 100 mg pellet lot 04042013@18.
b. Injectable suspension products, for example, Methylprednisolone Acetate 40 mg/mL vials lot 03192013@22.

ii. No data was provided to support that the lyophilizer is qualified and the lyophilization cycles used to lyophilize drug products are adequately validated. After [(b) (4)] in the [(b) (4)], vials are hand stoppered, removed from the [(b) (4)], and placed in an unclassified freezer. Once frozen, the vials are moved back to the [(b) (4)], unstoppered, placed within the lyophilizer unit and vacuum is drawn for [(b) (4)]. There is no temperature control or monitoring of the lyophilization chamber. Observation on 7/1/13 of the lyophilized product Sermorelin Acetate 10 mg lot 06082013@3 noted several vials with what appeared to be incomplete sublimation of the liquid.

OBSERVATION 4

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

Specifically,

i. Sterility testing is not performed on each batch of implantable or injectable drug products purporting to be sterile. For implantable pellet products, only 7 lots have been tested for sterility since 6/1/12. Approximately [(b)] lots of pellet products were produced in 4/2013 alone. Pertaining to injectable drug products for example, out of approximately 70 injectable drug product lots produced in 4/2013, approximately 30 were tested for sterility. For example, no sterility testing was performed for:
   a. Testosterone 100 mg implantable pellet lot 04042013@18 (total lot size [(b)] pellets, sublot size for sterilization typically [(b)] pellets).
   b. Ascorbic Acid 500 mg/mL injectable lot 04052013@2 (lot size [(b) (4)] mL).

ii. Sterility testing performed in-house by your firm (e.g. Cyanocobalamin 1000 mcg/mL lot 03122013@21 with lot size [(b) (4)] mL tested for sterility on 3/15/13 as sample # 313) is inadequate or is not scientifically sound in that:
   a. SOP 9.050, *General Sterility Testing Procedures of Sterile Compounds*, states "For maximum sensitivity, incubate at room temperature at [(b) (4)]", and "Record all observations for [(b) (4)] in the USP 797 Test Log Book". The media for in-house direct inoculation sterility tests are incubated at uncontrolled room temperature observed during the inspection to range from 58-74F (14.4-23.3C). It was stated by firm personnel that drug products can be shipped after passing results have been obtained for the [(b) (4)] observation. Additionally, the [(b)] day observations for eight finished drug product lots were recorded in the sterility test log before [(b)] days had passed, for example, Testosterone Cypionate lot 07012013@5.
   b. Growth promotion studies for the sterility test media are not performed.
   c. Method suitability studies using the required organisms in the presence of product have not been performed.
   d. Negative controls are not utilized.

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e. Sterility testing is not performed with media suitable to detect the presence of anaerobic bacteria in finished drug products, for example, fluid thioglycollate media.
f. The sample size for the sterility test is not based on batch size. SOP 9.050, *General Sterility Testing Procedures of Sterile Compounds*, states that [redacted] (b) (4) tested from a batch.
g. Sterility testing of Cyanocobalamin lot 06272013@2 was observed on 7/1/13 to occur in laminar flow hood #4 and not under sterile conditions. However, the sterility test log states "sterile" for the hood number.

iii. Most lots of sterile injectable drug products are not tested for endotoxins. Since 6/1/12, only four lots have been tested for endotoxins, although approximately [redacted] (b) (4) injectable drug product lots were produced in 4/2013 alone. Examples of finished sterile injectable drug product lots that did not receive endotoxin testing include, Testosterone 100mg pellet lot 04042013@18, Ascorbic Acid 500 mg/mL injectable lot 04052013@2, and Cyanocobalamin 1000 mcg/mL lot 03122013@21.

OBSERVATION 5

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design and suitably located to facilitate operations for its intended use.

Specifically,

The aseptic processing [redacted] (b) (4), used to process all sterile injectable drug products:
i. Is located within an unclassified laboratory environment.
ii. Is constructed with several openings between the interior of the [redacted] (b) (4) and the external, unclassified environment including:
   a. an approximately 3 inch diameter hole on the right wall of the aseptic processing area.
   b. an approximately 4 inch diameter hole on the right wall of the aseptic processing area to which a black garbage bag is attached on the exterior; used to dispose of packaging materials inside the [redacted] (b) (4).
   c. an approximately 4 inch by 5 inch rectangular hole located underneath the ante-chamber of the [redacted] (b) (4).
   d. an approximately 1/2 inch by 5 inch hole located underneath the aseptic processing area of the [redacted] (b) (4)
iii. Contains an electrical cord that hangs in the back right of the aseptic processing area, but is not used during processing according to firm management. In situ air pattern analysis has not been performed to ensure the cord does not obstruct airflow or affect unidirectional airflow, and additionally, the cord is not a smooth, hard surface that can be easily cleaned.
iv. Non-sterile [redacted] (b) (4) are attached to the [redacted] (b) (4) and used inside the aseptic processing [redacted] (b) (4).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
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OBSERVATION 6

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

Specifically,

A testing program to determine appropriate storage conditions and expiration dating has not been established, rather, beyond use dates (BUD) are assigned to drug products based upon external literature and reference material. No data was provided to support that any drug products produced by the firm will conform to specifications such as potency, sterility, or endotoxin levels at the end of the labeled shelf life, for example:
Ascorbic Acid 500 mg/mL lot 04052013@2 was given a BUD of 10/2/13 (6 months)
Cyanocobalamine 1000 mcg/mL lot 03122013@21 was given a BUD of 9/12/13 (6 months)
Testosterone 100 mg pellets lot 04042013@18 was given a BUD of 10/1/13 (6 months)
Levothyroxine/Liothyronine 15/14 mcg capsule lot 04182013@17 was given a BUD of 4/18/14 (1 year)

OBSERVATION 7

Drug product containers and closures were not sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

Specifically,

Documentation was not provided to support that cleaning and sterilization processes utilized for finished drug product containers and closures are adequate to render such materials sterile and non-pyrogenic.

i. No data was provided to support that the [redacted] (b) (4) and the [redacted] (b) (4) used to [redacted] (b) (4) sterilize stoppers are adequately qualified and validated. Documentation provided did not address temperature mapping of the [redacted] (b) (4) calibration of temperature sensors, load configuration evaluations, and validation of [redacted] (b) (4) [redacted] (b) (4) using appropriate biological indicators. Additionally, no data was provided to support that the cleaning process for stoppers, which includes a rinse with [redacted] (b) (4), is adequate to remove pyrogens.

ii. No data was provided to support that the [redacted] (b) (4) used to depyrogenate glass vials is adequately qualified and validated for its intended use, including temperature mapping, calibration of temperature sensors, load configuration evaluations, and validation of [redacted] (b) (4) using appropriate endotoxin challenges. Additionally, prior to depyrogenation, vials are prepared in an unclassified environment where they are washed with soap and water, soaked in a [redacted] (b) (4), wrapped in a [redacted] (b) (4), and placed in the [redacted] (b) (4). After the depyrogenation cycle has completed, the [redacted] (b) (4) wrapped vials are removed from the [redacted] (b) (4) into the unclassified laboratory where they are cooled and stored, for approximately [redacted] (b) (4), until use in the aseptic processing [redacted] (b) (4).

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This observation applies to all glass vials and stoppers used as the primary containers and closures for all sterile injectable drug products, for example, Ascorbic Acid 500mg/ml lot 04052013@2 and Cyanocobalamine 1000mcg/ml lot 03122013@21.

OBSERVATION 8

Each lot of components, drug product containers, and closures is not withheld from use until the lot has been sampled, tested, examined, and released by the quality control unit.

Specifically,

i. Incoming drug product components are not tested to confirm the identity of such before use. Additionally, the microbial content of incoming drug product components, containers and closures is not tested, and appropriate acceptance limits for bioburden and endotoxin levels of such have not been established. Non-sterile drug components are utilized for all sterile drugs formulated at the firm, for example, Ascorbic Acid 500 mg/ml lot 04052013@2 and Cyanocobalamine 1000 mcg/ml lot 03122013@21.

ii. Container closure integrity testing has not been performed to assure the packaging of sterile drug products provides adequate protection against external factors during storage that may cause contamination or deterioration, including the penetration of microorganisms. Additionally, acceptance criteria have not been established and examinations are not performed for containers and closures received prior to use. For example, Ascorbic Acid 500 mg/ml lot 04052013@2 and Cyanocobalamin 1000 mcg/ml lot 03122013@21.

OBSERVATION 9

Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

Specifically,

Time limits and storage conditions for non-sterile bulk solution prior to [redacted] (b) (4) into finished product vials have not been established or evaluated, and no record is maintained which includes the date(s) that finished product vials are filled from bulk solution. A beaker of Dual Testosterone lot 06282013@10, consisting of [redacted] (b) (4) formulated on 6/28/13, was observed on 7/1/13 to be sitting on the laboratory counter in the unclassified area and covered in parafilm. A portion of this lot was later [redacted] (b) (4) into 2 mL vials. Additionally, on 7/2/13, HCG lot 06242013@21 (formulated on 6/24/13) was observed to be [redacted] (b) (4) into vials and bulk liquid from this lot was also observed in the refridgerator.

Time limits are not established for in-process drug products stored in a freezer after filling and prior to lyophilization, for example, Sermorelin Acetate lot 06082013@3 was formulated on 6/8/13, and lyophilization of this batch concluded on 7/1/13. No documentation was provided to support the stability of this drug product for any length of time prior to

lyophilization.

OBSERVATION 10

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

No written procedure was provided which describes the handling of Out of Specification laboratory results relating to finished product testing of your drug products.

Investigation into an apparent positive environmental monitoring result from testing the surface of aseptic processing [redacted] (b) (4) on 7/3/13 was not performed. SOP 5.005, *Environmental Testing for Laminar Flow Hood - EnviroTest*, states "Should growth occur, the unit being tested will not be used until causative agent is identified and removed", then, "Perform another test and only upon completion of a satisfactory test may the hood be used". On 7/10/13 apparent growth was observed on the media sample. The sample was thrown away without investigation. Two vials of Magnesium Chloride 20% lot 07032013@7 were filled after EM testing performed on 7/3/13.

OBSERVATION 11

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,

Most lots of finished drug products are not tested for potency. For example:

Testosterone 100 mg implantable pellet lot 04042013@18
Ascorbic Acid 500 mg/mL injectable lot 04052013@2
Cyanocobalamin 1000 mcg/mL lot 03122013@21
Methylprednisolone Acetate 40 mg/mL lot 03192013@22
Levothyroxine/Liothyronine 15/14 mcg capsule lot 04182013@17

OBSERVATION 12

The establishment of specifications, sampling plans, test procedures, and laboratory control mechanisms including any changes thereto, are not drafted by the appropriate organizational unit and reviewed and approved by the quality control unit.

Specifically,

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Written specifications and test procedures for finished drug product quality attributes have not been established and no testing has been performed for the following:

i. For all drug products, there are no specifications or testing for impurities. Examples include Testosterone 100 mg implantable pellet lot 04042013@18, Ascorbic Acid 500 mg/mL injectable lot 04052013@2, and Cyanocobalamin 1000 mcg/mL lot 03122013@21.
ii. For all liquid and lyophilized injectable drug products, there are no specifications or testing for pH or subvisible particulates. Examples include Ascorbic Acid 500 mg/mL injectable lot 04052013@2, and Cyanocobalamin 1000 mcg/mL lot 03122013@21.
iii. For solid oral drug products, there are no specifications or testing for content uniformity. For example, Levothyroxine/Liothyronine 15/14 mcg capsule lot 04182013@17.
iv. For "sustained release" drug products, there are no specifications or testing for dissolution. For example, Liothyronine (T3) SR 5mcg capsule lot 04112013@9.

OBSERVATION 13

The batch production and control records are deficient in that they do not include documentation of the accomplishment of each significant step in processing.

Specifically,

Batch records do not include documentation of [redacted] (b) (4) and filling of vials from bulk solution, including the dates that such occurred. For example, Ascorbic Acid 500mg/ml lot 04052013@2 was formulated on 4/5/13 and Cyanocobalamine 1000mcg/ml lot 03122013@21 was formulated on 3/12/13, however, a record of the number of vials produced from each bulk solution and the dates on which the bulk solution was [redacted] (b) (4) into finished product vials was not provided.

*** DATES OF INSPECTION:**
07/01/2013(Mon), 07/02/2013(Tue), 07/03/2013(Wed), 07/10/2013(Wed), 07/11/2013(Thu), 07/15/2013(Mon), 07/17/2013(Wed), 07/19/2013(Fri)

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