

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

DISTRICT ADDRESS AND PHONE NUMBER

6th & Kipling St. (P.O. Box 25087)
Denver, CO 80225-0087
(303) 236-3000 Fax: (303) 236-3100
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

06/10/2015 - 06/18/2015*
FEI NUMBER
3005727550

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Dr. Lamar D. Jones, Pharm.D., Pharmacist in Charge (PIC)

FIRM NAME

Belmar Pharmacy

STREET ADDRESS

12860 W Cedar Dr Ste 210

CITY, STATE, ZIP CODE, COUNTRY

Lakewood, CO 80228-1971

TYPE ESTABLISHMENT INSPECTED

Producer of Sterile 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 do not include adequate validation of the sterilization process.

Specifically,

- A) Your firm's (b) (4) sterilization by (b) (4) process has not been validated ((b) (4)), bioburden studies, and (b) (4)) for the following sterile drug pellet formulations: Anastrozole, Testosterone/Anastrozole, Progesterone, Pregnenolone and DHEA.
- B) There is no environmental microbial monitoring program of the clean room suites to include the powder room, the compression room, the packaging room and the ante room to assure the process, environment, personnel activities do not negatively impact upon the sterilization process of the compounded drug pellets.
- C) There is a gap in documentation of pressure differential data from April 13, 2015 to May 30, 2015 from the Ante room to the unclassified lab space.

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OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Zachery L. Miller, Investigator
Erika V. Butler, Investigator



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OBSERVATION 2

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

Specifically,

- A) Your firm is not conducting routine sterility and/or endotoxin testing for each batch of sterile drug pellets prior to releasing them for dispensing. Furthermore, your firm lacks sterility and/or endotoxin method suitability for all pellets.
- B) Your Sterilization, Testing and Validation Policy and Procedure (P&P 10.090, Rev. 1, Effective 3/16/15) is not followed as it pertains to (b) (4) (potency, identification, endotoxins, and sterility) and (b) (4) (potency, identification, endotoxins, and sterility) pellet sampling and testing.

OBSERVATION 3

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically,

Currently, not every compounded lot of sterile drug pellets is tested for identification and/or potency. Furthermore, your firm lacks potency method suitability for all pellets. Additionally, there is no extended release testing for the potency rate of release for any of the pellet drug products.

OBSERVATION 4

The written stability program for drug products does not include reliable, meaningful, and specific test methods.

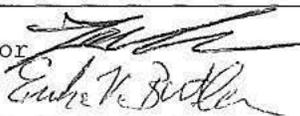
Specifically,

Stability analytical methods used for potency and sterility analyses of all compounded drugs are not

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validated for the following: estradiol, testosterone, testosterone/anastrozole, anastrozole, progesterone, DHEA, and pregnenolone. For example, the accuracy, sensitivity, specificity, and reproducibility of the potency test methods have not been established. In addition, the Certificate of Analysis (CofA) from the contract lab reads the sterility method "Does not meet all the requirements for sampling and/or method suitability specified in USP 71" This was specified on the CofA for Testosterone 12.5 mg pellet, Estradiol 6 mg pellet, Testosterone 200 mg pellet and Estradiol 75 mg pellet.

OBSERVATION 5

The building lacks adequate space for the orderly placement of equipment and materials to prevent mix-ups between drug products and to prevent contamination.

Specifically,

There is no spatial separation or dividers to prevent mix-ups during the (b) (4) operations. On 6/15/2015 we observed Testosterone 100 mg pellets lot20150612@2 and Testosterone/Anastrozole 200mg/6mg pellets lot 20150615@11 being (b) (4) in the same suite without any spatial separation or dividers to prevent mix-ups.

OBSERVATION 6

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,

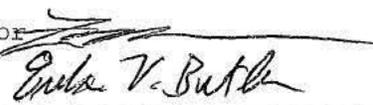
A) During the (b) (4) operation of the compounded drug pellets, your firm is not documenting the weights of the pressed pellets. The weights of the compressed pellets determine the dosage amount. In addition, your firm is performing a hardness test and there are no specifications or limits on the hardness of the compressed pellets. There are no established written procedures or batch instructions for documenting the weights or hardness of the compounded pellets.

B) There are no established written procedures to qualify technicians to perform a visual inspection on

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all types of drug products prior to distribution.

*** DATES OF INSPECTION:**

06/10/2015(Wed), 06/11/2015(Thu), 06/15/2015(Mon), 06/18/2015(Thu)

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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."