DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
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	05/11/2015 - 05/28/2015* FEI NUMBER 1000117234

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Jerry S. Gillick, President and CEO

FIRM NAME	STREET ADDRESS
College Pharmacy Incorporated	3505 Austin Bluffs Pkwy Ste 101
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Colorado Springs, CO 80918-5754	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

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

Regardless of the number of cfu detected during environmental monitoring of the pharmacy, identification of microorganisms recovered is not always conducted in order to assess whether corrective/preventative actions should be undertaken should pathogenic microorganisms be found. For example, gloved fingers sampled on 3/11/2015 found 2 cfu but the microorganisms were not identified. Gloved fingers sampled on 8/27/2014 found 1 cfu but the microorganisms were not identified.

Also, although smoke studies are reported to have occurred under dynamic conditions, there are no established procedures for conducting documented smoke studies (e.g., review/conclusion whether acceptable) in order to show proper design and control in preventing turbulence and stagnant air in aseptic processing areas. For example, there is no documented visual study with smoke in the lyophilization area, and although smoke studies are reported as passing for the (b) (4) ISO 5 (b) (4) laminar flow clean benches, there is no visual record for review by your firm in order to conclude whether conditions are acceptable concerning lack of turbulence and stagnent air.

Environmental monitoring is not always conducted during (b) (4) aseptic filling operations in order to give continuous information on the quality of the aseptic processing environment:

a) dynamic particulate monitoring is conducted every (b) (4)

b) dynamic surface sampling (personnel and equipment surfaces) is conducted (b) (4)

c) dynamic viable air sampling is performed (b) (4) (b) (4)

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Media Fill (Process Simulation) is not complete. Media Fill to simulate products aseptically filled for lyophilization is not

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performed. Similarly, Media Fill to simulate the aseptic filling of eye drops is not conducted. There are (b) (4) of sterile filling (b) (4) (b) (4) This method has a Media Fill program to simulate. (b) (4) This method for simulating sterile filling (of lyophilized Glutathione, HCG, and DPN Inj) does not have a Media Fill performed, nor does the sterile filling of eye drops, such as Glutathione/Vitamin C/DMSO Ophthalmic Soln.

The lyophilization process is not adequate to protect product, as it is partly performed in ISO 7 classified air. Specifically, compounded drugs (such as Glutathione, HCG, and DPN) are (b) (4) lyophilization process. (b) (4)

Except for compounded drug pellets, there is no bioburden testing of product formulations (e.g.,such as Glutathione/Vitamin C/DMSO Ophthalmic Soln.) intended to be sterilized, nor have limits for bioburden been established to ensure that (b) (4) used to produce finished drug products are adequate.

OBSERVATION 3

Test procedures relative to appropriate laboratory testing for sterility are not written.

When conducting sterility testing of injectable products compounded at your pharmacy using your in-house laboratory:

a) growth promotion tests of aerobes, anaerobes and fungi of each lot of ready-prepared media is not conducted at receipt to ensure that it will encourage growth, i.e., the media selected is not demonstrated at your facility to support growth of gram-negative & gram-positive bacteria, yeast and mold.

b) method suitability testing of this sterility test method was only conducted on two of your compounded products.

c) should a compounded drug be found not to comply with this test for sterility, your firm has no Out-of-Specification procedures to ensure proper evaluation of results that fall outside of specifications.

d) your firm does not have written and approved procedures for performing sterility testing.

You have been doing sterility testing at your in-house laboratory since about 2011. Some products tested recently at your facility laboratory for sterility include:
-Low Dose Allergen Food Additives (b) (4) Solution Liquid containing ingredients such as (b) (4)
-Glutathione, HCG, and DPN Injections.
-Testosterone Inj.

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-Glutathione/Vitamin C/DMSO Ophthalmic Soln.

OBSERVATION 4

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the equipment to produce aseptic conditions.

Specifically, although sterilized (b) (4) is used to sanitize surfaces of the ISO 5 LAFWs, the wipes used in unison with the (b) (4) to sanitize ISO 5 LAFWs are not sterile.

OBSERVATION 5

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.

Analytical methods used for assay analyses of drugs are not always validated (i.e., the accuracy, sensitivity, specificity, and reproducibility of test methods have not been established). For example, assays run by contracted laboratories for HCG, Glutathione, Testosterone and Pyridoxine were tested with analytical methods not validated. For example, a Certificate of Analysis report from (b) (4) concerning amino acid assay testing [Amino Acid (Recover Eaze) IV Formula PF Inj] conducted for your firm states, in part, "The method(s) used for testing are not validated."

There is not complete testing of drug pellets containing testosterone, estradiol, and other hormones, compounded for subcutaneous insertion. These drugs are intended for 3 month release but there is no data to support that these drugs are released into the body in a safe, controlled, regulated and effective manner.

OBSERVATION 6

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

Allergenic Extracts used for compounding are not always obtained from FDA-licensed distributers/manufacturers (such as (b) (4)

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OBSERVATION 7

Clothing of personnel engaged in the processing and packing of drug products is not appropriate for the duties they perform.

Sterile gloves are used, but other sterile gowning components (such as sterile suits, sterile face masks, sterile hoods, and goggles) are not utilized by personnel when aseptically filling compounded products in your clean (buffer) room.

Clean room personnel are donning non-sterile suits, face masks, and hoods for operations in the clean room and ISO 5 (b) (4) laminar flow clean benches, performing aseptic manipulations of finished drug product vials. There are no procedural requirements for comprehensive sterile gowning (other than just gloves) to prevent contamination during aseptic manipulations.

Gowning (e.g., suits, face masks, gloves and hoods) that is employed (observed on 5/11/2015) does not completely cover skin, leaving areas of the face exposed (goggles are not used).

*** DATES OF INSPECTION:**
05/11/2015(Mon), 05/12/2015(Tue), 05/13/2015(Wed), 05/14/2015(Thu), 05/18/2015(Mon), 05/27/2015(Wed), 05/28/2015(Thu)

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