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	1/8/2018-1/17/2018* FEI NUMBER 1000117234

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Jerry S. Gillick, President/Chief Executive Officer

FIRM NAME	STREET ADDRESS
College Pharmacy, Inc.	3505 Austin Bluffs Parkway, Suite 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

You did not make adequate product evaluation and take remedial action where actionable microbial contamination was found to be present in the ISO 5 classified aseptic processing area during aseptic production.

Specifically,

a.) Actionable microbial contamination was discovered inside the ISO 5 aseptic processing environment on two occasions via viable air samples; however, no evaluation of product impact was made. For example:

i. On 07/12/17, a viable air sample was collected from the ISO 5 (b) (4) Hood (ID (b) (4) which resulted in an actionable environmental excursion of one colony forming unit identified as *Bacillus megaterium*. The firm did not evaluate any products filled in the ISO 5 Hoods on 07/12/17 for product impact, to include: Cellulite Pres. 10ml Homeopathic Injection, lot 07122017@50; Muscle/Skeletal Pres. 10ml Homeopathic Injection, lot 07122017@49; Papaverine Hydrochloride/Phentolamine Mesylate with Prostaglandin E1 30mg/1mg/ml Injection, lot 07122017@21; L-Tryptophan PF 10mg/ml Injection, lot 07122017@7; N-acetylcysteine PF 100mg/ml Injection, lot 07122017@3; Hydroxyprogesterone Caproate in Sesame Oil 250mg/ml Injection, lot 07122017@2; and Glycero Phospho Choline Pres. 500mg/ml Injection, lot 07122017@1.

ii. On 08/23/17, a viable air sample was collected from the ISO 5 (b) (4) Hood (ID (b) (4) which

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Marcus F Yambot, Investigator Haroon Vohra, Investigator	X Marcus F Yambot Investigator Signed By: Marcus F. Yambot -S Date Signed: 01-17-2018 10:15:38	1/17/2018

resulted in an actionable environmental excursion of one colony forming unit identified as *Paecilomyces puntonii*. The firm did not evaluate any products filled in the ISO 5 Hoods on 08/23/17 for product impact, to include: Hydroxycobalamin PF 1000mcg/ml Injection, lot 08232017:83@1, and Collagen Pres. 10ml Homeopathic Injection, lot 08232017:50@41.

b.) Two sterile injectable drug products failed sterility testing with actionable microbial contamination; however, no evaluation of product impact was made on products filled before and after these batches. For example:

i. On 07/13/17, Methylcobalamin PF 25mg/ml Injection, lot 07132017@2, was aseptically filled in one of the ISO 5 hoods in the buffer room, and failed sterility testing on 07/17/17. The growth was identified as *Bacillus pumilus*. The batch was discarded and not dispensed; however, the firm did not evaluate product impact of other batches aseptically filled on 07/13/17, to include: Glutathione PF 100mg/ml Injection, lot 07132017@33; Chronic Illness PF (13ml Vial) Injection, lot 07132017@20; Ammonium Glycyrrhizinate Pres. 8.33mg/ml Injection, lot 07132017@3; and Methylcobalamin Pres. 10mg/ml Injection, lot 07132017@1.

ii. On 07/20/17, Glutathione Pres. 100mg/ml Injection, lot 07202017@3, was aseptically filled in one of the ISO 5 hoods in the buffer room, and failed sterility testing on 07/24/17. The growth was identified as *Bacillus firmus*. The batch was discarded and not dispensed; however, the firm did not evaluate product impact of other batches aseptically filled on 07/20/17, to include: Vitamin D3 Pres. 50,000IU/ml Injection, lot 07202017@5; Methylcobalamin PF 10mg/ml Injection, lot 07202017@2; and Folic Acid Pres. 10mg/ml Injection, lot 07202017@1.

OBSERVATION 2

You produced highly potent drugs without providing adequate cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.

Specifically, the firm uses (b) (4) and (b) (4) to clean the shared hoods and equipment used to manufacture different sterile hormonal implantable pellets, to include estradiol,

progesterone, pregnenolone, testosterone, and dehydroepiandrosterone (DHEA). There is no assurance that the cleaning materials used prevent cross-contamination between these products.

OBSERVATION 3

Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

Specifically, on 01/08/18 and 01/09/18, we observed the Pharmacy Technician/Aseptic Operator touch the outside surface of the sterile gown arms and sterile hood with bare hands while gowning in the ISO 7 Ante Room. Moreover, the legs of the sterile gown touched the floor during gowning. The Pharmacy Technician/Aseptic Operator proceeded to conduct aseptic filling operations and was observed inserting his arms into the ISO 5 hood to aseptically fill sterile drug products and leaning into the ISO 5 hood, head included, to observe the fill level of vials. The following products were observed being filled these two days: DPN/NAD+ PF 100mg/ml Injection, lot 01082018:15@7; Dimethyl Sulfoxide Modified Pres. 6.25% Ophthalmic, lot 01082018:41@6; Vitamin D3 PF 50,000IU/ml Injection, lot 01082018:00@9; Ammonium Glycyrrhizinate Pres. 8.33mg/ml Injection, lot 01092018:46@1; and B Complex 100 PF Injection, lot 01092018:38@4.

Additionally, bare hands are placed inside the ISO 5 hoods to don sterile gloves.

OBSERVATION 4

Disinfecting agents and cleaning wipes used in the ISO 5 classified aseptic processing areas were not sterile.

Specifically, non-sterile (b) (4) Disinfectant Cleaner, lot (b) (4) is the disinfectant currently in use for (b) (4) cleaning of ISO 5 hoods and surfaces used in the production of sterile injectable and ophthalmic drug products.

OBSERVATION 5

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The ISO 5 classified aseptic processing areas had difficult to clean and particle-generating equipment or surface.

Specifically, not all the materials brought into the ISO 5 hood are easily cleanable or non-particle shedding. For example:

a.) On 01/09/18, we observed the aseptic filling of Ammonium Glycyrrhizinate Pres. 8.33mg/ml Injection, lot 01092018:46@1, in ISO 5 (b) (4) Hood ID: (b) (4), which involved the filling of 5ml vials in the vial supplier's original paperboard-like packaging container, which is particle shedding.
b.) On 01/10/18, we observed the set-up and aseptic filling of Ascorbic Acid PF ((b) (4) Source) 500mg/ml Injection, lot 01102018:48@2, in ISO 5 (b) (4) Hood ID: (b) (4) which involved the use of clear prescription label tape to affix a plastic container on the back of the repeater pump to prevent spillage, and yellow label tape to keep the lid of the repeater pump closed. Both tapes are not easily cleanable and not designed for use in an ISO 5 aseptic production environment.

OBSERVATION 6

You produced hazardous drugs without providing adequate cleaning of utensils to prevent cross-contamination.

Specifically, you do not adequately clean the glassware and utensils used to produce sterile drug products to prevent cross-contamination. There is no sterilization or depyrogenation activities performed on these materials prior to use in compounding sterile drug products. For example:

a.) Glassware, spatulas, and mixing bars are washed in a dishwasher using (b) (4) dishwasher detergent.
b.) Plastic graduated cylinders are washed in the sink using (b) (4) dishwashing liquid.

***DATES OF INSPECTION**

1/08/2018(Mon), 1/09/2018(Tue), 1/10/2018(Wed), 1/11/2018(Thu), 1/12/2018(Fri), 1/16/2018(Tue), 1/17/2018(Wed)

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X Haroon Vohra
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