DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Dr., Suite 205 Lenexa, KS 66214 (913) 495-5100	6/12/2017 - 9/19/2017* FEI NUMBER 3006572203

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Wade A. Siefert, Vice President

FIRM NAME	STREET ADDRESS
Central Illinois Compounding, Inc. dba Preckshot Professional Pharmacy	5832 N. Knoxville, Ave., Suite E
CITY, STATE, ZIP CODE, COUNTRY Peoria, IL 61614	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drugs

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 OBSERVED:

We observed sterile processing activities performed by your Pharmacy Technician on 6/12/2017. He produced at least Testosterone Cypionate (Sesame oil) 200mg/mL, lot 06122017@44 and Sermorelin Acetate 1000mcg/mL, lot 06122017@33 in your LAFH area. Observations listed below may include issues observed during these activities or documentation supporting objectionable conditions since approximately 04/2015.

OBSERVATION 1

Your firm released drug product in which the strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

Specifically,

You processed 4 lots of Tacrolimus 0.02% Oil Opthalmic Solution and 1 lot of Cyclosporine 0.1% Oil Opthalmic Solution using apparent food grade (b) (4) and apparent food grade (b) (4) respectively, as follows:

- Finished Tacrolimus lots include 08232016@2, 10312016@26, 01112017@16 and 04102017@14 made using (b) (4) lot (b) (4) manufactured by (b) (4) and purchased from (b) (4).
- Finished Cyclosporine lot 03022017@18 made using (b) (4) which was manufactured by (b) (4) and is identified by lot # (b) (4).

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OBSERVATION 2

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

Specifically,

We observed sterile processing of at least Testosterone Cypionate (sesame oil) 200mg/mL oil inj solution and Sermorelin Acetate 1000mcg/mL injectable conducted by your Pharmacy Technician in your laminar air flow hood on 6/12/2017. During sterile processing, we observed the above inadequate aseptic operations employed or/and verified them via document review.

A. Cleaning of at least two individual vials with the same side of the sterile (b) (4) .
B. You have not performed a media fill for your Pharmacy Technician since 9/13/2016.
C. Media fills for your pharmacy technician were initially conducted on 12/30/2015 at this site. You initially released sterile processed product at this site on 10/28/2015.

OBSERVATION 3

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

Specifically,

We observed sterile processing of at least Testosterone Cypionate (sesame oil) 200mg/mL oil inj solution and Sermorelin Acetate 1000mcg/mL injectable conducted by your Pharmacy Technician in your laminar air flow hood on 6/12/2017. During sterile processing, we observed the above inadequate aseptic operations employed or/and verified them via document review.

A. Your ISO 7 gowning/anteroom failed ISO certification testing (failed integrity/seal integrity test) on

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or about 11/4/2015. However, sterile product continued to be prepared and exposed to the ambient air in this area.

B. (b) (4) professional (b) (4) brand (b) (4) used to clean the LAFH are non-sterile.

C. Your Pharmacy Technician did not clean the walls or ceiling of the LAFH immediately before processing on 6/12/2017.

OBSERVATION 4

Procedures for the cleaning and maintenance of equipment are deficient regarding the protection of clean equipment from contamination prior to use.

Specifically,

We observed sterile processing of at least Testosterone Cypionate (sesame oil) 200mg/mL oil inj solution and Sermorelin Acetate 1000mcg/mL injectable conducted by your Pharmacy Technician in your laminar air flow hood on 6/12/2017. During sterile processing, we observed the above inadequate aseptic operations employed or/and verified them via document review.

We observed depyrogenated equipment (glass beakers) used in aseptic processing on 6/12/2017 left unprotected prior to use.

OBSERVATION 5

The ISO-classified areas have difficult to clean, particle-generating, or visibly dirty equipment or surfaces.

Specifically,
We observed your LAFH with approximately three hard to clean and discolored areas consisting of approximately 1/4" x 1", each.